Mood Disorders Society of Canada
La Société Pour **Les Troubles de L'Humeur** du Canada

Improving Access to Medications in Canada
and
Strengthening the Patient Voice in CADTH
Brief
January 2017

The **Mood Disorders Society of Canada** has grown out of the vision and drive of a number of mental health consumer leaders from across Canada who in 1995 saw the need for a broad-based structure to bring consumers of mental health services together and who believe that consumers have a key role to play with regard to education and advocacy at the national level. It was formally launched and incorporated in 2001 with the overall objective of providing people with mood disorders with a strong, cohesive voice at the national level to improve access to treatment, inform research, and shape program development and government policies with the goal of improving the quality of life for people affected by mood disorders. Collaboration is an MDSC operational principle. The Society fulfills its mandate through an active partnership approach that engages like-minded organizations in the public, private and voluntary sectors. The MDSC is engaged on an ongoing basis in a wide range of projects and initiatives designed to support the inclusion of persons with disabling mental illnesses in Canadian society and has taken a lead proactive role in public policy and program development in many capacities on the national stage.

Key Messages

Access

MDSC recommends a national pharmacare program in order to:

- Cover all Canadians' medication needs, in particular the newest and most effective medications as they are discovered and approved,
- Take the worry out of life's transition points that threaten medication continuity, and
- Ensure the consistent availability of medications across the country

Strengthening the patient voice

MDSC recommends:

- An audit of the Canadian Agency for Drug Technologies in Health (CADTH)'s patient involvement mechanisms. We also recommend a much more robust communications strategy for how patient feedback is utilized,
- Funding patient groups so that they are compensated for research costs, the time it takes to prepare submissions and travel costs for face-to-face meetings,
- Including the patient voice in substantial numbers, and that of psychiatrists, not just as consultants but as decision-makers through full membership on CADTH, itself, and its various committees and adjudication bodies.

Context

The focus of this brief is patient access to medication, an important and pressing concern for people with mental illness, their families and caregivers.

However, people with mental illness have ongoing and over-arching trouble with access to ***all*** mental health treatments and services - despite dire need - no matter where in the country they live.

> Example: Cloe White's story is unusual only because her family had the money to purchase treatment in the United States. Cloe's addiction problems masked an underlying mental illness. After trying everything they could and every door they could find, her family gave up on the Canadian health care system in order to save her life. When she left the country for treatment, the Canadian wait time was 14 – 16 months long with 200 people in front of her. They knew that if they waited that long, she would die.[1]

The Mental Health Commission of Canada reports that 1.2 million Canadian children are in need of mental health treatment but only one in four finds access.[2]

Cloe's story illustrates the fact that Canada has a two-tiered mental health system despite protestations to the contrary. People, tired of waiting and, if they can afford to, buy their services on the private market.[3]

Canada's mental health system remains chronically under-funded.[4] Lack of funding means long wait times in Emergency Rooms.[5] Access to psychiatrists is slow, especially in rural and remote

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[1] Metro Morning broadcast (Aug. 29, 2016). Available at: http://www.cbc.ca/news/canada/toronto/programs/metromorning/youth-mental-health-1.3739506

[2] Picard, A. The Globe and Mail (Oct. 13, 2013). Exposing Canada's ugly mental health secret. Available at: http://www.theglobeandmail.com/life/health-and-fitness/health/exposing-canadas-ugly-mental-health-secret/article14828590/

[3] ibid

[4] MacLean's (Aug. 2016). Advocates: Canada's mental health system needs funding: Chronically underfunded: Canada's mental health system now lags behind most other OECD countries.
Available at: http://www.macleans.ca/news/canada/advocates-canadas-mental-health-system-needs-funding/

[5] Janus, A. (June 2014). Canada has made "no progress" on psychiatric care wait time, report finds. CTV. Available at: http://www.ctvnews.ca/health/canada-has-made-no-progress-on-psychiatric-care-wait-times-report-finds-1.1850794

areas where there are currently too few and those that are practicing are retiring – with no replacements in sight.[6]

First Nations and Inuit peoples are particularly ill served[7] with a suicide rate of 126 /100,000 as opposed to 26/100,000 for the rest of Canada's population. Aboriginal youth are notably at risk with children as young as 10 taking their own lives by suicide.

Access to basics such as diagnosis and inpatient and outpatient treatment are limited with valued services such as counselling and psychotherapy completely un-funded. People are left on their own to pay for them – or, a much more common result, do without.[8]

The Conference Board of Canada estimates that mental illness in the Canadian workforce costs $20.7 B per year and this figure is expected to rise to $29.1 B by 2020.[9] The Mental Health Commission places the overall cost to Canada's productivity at $51 B per year.[10]

These short-comings have been documented again and again. Presently, federal Minister of Health, Jane Philpott, has acknowledged that Canada is not investing in its citizens' mental health care as much as other developed countries in the world.[11]

The Canadian Alliance of Mental Illness and Mental Health (CAMHMI) reports that spending on mental health in Canada is 7.2% of total health funding and calls for it to be increased to a *minimum* of 9%.[12]

While the specific messages of this brief revolve around access to medication, MDSC's analysis and messages must be seen within the context of the wider problems that plague Canada's mental health system.

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[6] CBC News (Aug. 22, 2016). Time for psychiatrists to improve access to mental health care. Available at: http://www.cbc.ca/beta/news/health/psychiatrists-ices-1.3730640

[7] Kestler-D'Amours, J. (March 22nd, 2016). Canada and the Aboriginal mental health crisis. Available at: http://interactive.aljazeera.com/aje/2015/mentalhealth/index.html

[8] CBC News (Aug. 22, 2016). Time for psychiatrists to improve access to mental health care. Available at: http://www.cbc.ca/beta/news/health/psychiatrists-ices-1.3730640

[9] Mental health issues in the labour force: Reducing the economic impact on Canada. Report for sale: $195.00. Very brief summary available at: http://www.conferenceboard.ca/e-library/abstract.aspx?did=4957

[10] Mental Health Commission of Canada (2016). Advancing the mental health strategy for Canada: A framework for action (2017 – 2022). Available at: http://www.mentalhealthcommission.ca/sites/default/files/2016-08/advancing_the_mental_health_strategy_for_canada_a_framework_for_action.pdf

[11] MacLean's (Aug. 2016). Advocates: Canada's mental health system needs funding: Chronically underfunded: Canada's mental health system now lags behind most other OECD countries. Available at: http://www.macleans.ca/news/canada/advocates-canadas-mental-health-system-needs-funding/

[12] Canadian Alliance of mental Health and Mental Illness (CAMIMH) (Sept, 2016). Mental health now! Advancing the mental health of Canadians: The federal role. Available at: http://www.camimh.ca/wp-content/uploads/2016/09/CAMIMH_MHN_EN_Final_small.pdf

On a hopeful note, the Honourable Jane Philpott stated that, “It is not too late the build systems where mental health services are widely available and supportive regardless of whether you are living in downtown Ottawa or Northern Canada.”[13]

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[13] Remarks from the Honourable Jane Philpott, Minister of Health, to the Canada 2020 Health Summit: A new health accord for all Canadians. (Sept 29, 2016).

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Improving Access to Medications in Canada

and

Strengthening the Patient Voice in CADTH

1. Introduction

How medications are assessed and approved in Canada is complicated and an important subject that has caught the attention of patient groups.

Patients want their perspectives to be acknowledged and included in approvals processes. There are a number of avenues where they are invited to offer feedback but barriers persist. This brief discusses the many issues that affect meaningful patient participation and makes suggestions for improvement. The patient voice is needed to advocate for continued and improved access to medication in Canada.

2. Depression: Getting a handle on what's wrong

I'm afraid I have a problem

People who've experienced depression describe a complicated process that starts with worrying symptoms that they do their best to prevent from spiraling out of control. Given the stigma that surrounds mental illness, it is a hard decision to reach out for help. Some deny that anything is wrong for a long time.[14]And they secretly say to themselves. "This can't be me. I won't let it be me."

Thus begins a journey that involves seeking help, getting a diagnosis, trying and then embracing treatment and, for some, eventually finding wellness.[15] The first hurdle is just acknowledging something is very wrong.

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[14] 2015 pan Canadian survey raises warning signs on mental health services. Available at: https://mdsc.ca/research/2015-mental-health-care-system-survey-results/

[15] Mood Disorders Society of Canada (January 2012). What better feels like. Available at: https://mdsc.ca/documents/Better/What_Better_Feels_Like_Answers_to_Questions_Jan2012.pdf

> Nancy: “I was severely isolated, not answering the phone, or the door. It was summer, and I love summer and what I was doing was not like me at all. I started to put card board over my windows at home to block out any light from getting in my room. I mean I could barely move but I was going downstairs to search out cardboard boxes and duct tape so I could block what little light was left in my life.” (pg. 9) [16]
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> David: “I was depressed for so long, I thought it was just normal. I never understood the difference between depression as an emotion and depression as an illness. People say, ‘I’m feeling depressed,’ and they mean they are sad and it will go away. But depression, the illness, is a chemical imbalance in the brain that colours everything. The sadness and the hopelessness do not lift all by themselves. When my psychiatrist finally convinced me to take medication and I actually tried it, I began to feel better. I realized that it wasn’t normal to feel sadness and hopelessness all the time. It had been such a part of my life. It made me realize that there is a different way of being and I had been missing it for all these years” (pg. 10). [17]

Once the problem has a name - a diagnosis – people begin system navigation

When people have hit the wall, as they often describe it, they then have to find an access point to a complex health care system where mental health remains undervalued and underfunded.[18] The first point of contact is often a family doctor. Even with a referral, it can take a long time to get an appointment with a psychiatrist [19]and, should a crisis arise in the interim, wait times in Emergency Rooms are also long.[20] Emergency Rooms are sub-optimal environment for people dealing with a psychiatric crisis.

If, after navigating these barriers, people get a diagnosis, they must confront more wait times along with complicated acceptance criteria for treatment programs, and a narrow choice of helping options (for, example psychological counselling is rarely publicly funded).[21]

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[16] Mood Disorders Society of Canada (January 2012). What better feels like. Available at: https://mdsc.ca/documents/Better/What_Better_Feels_Like_Answers_to_Questions_Jan2012.pdf

[17] ibid

[18] MacLean’s (Aug. 2016). Advocates: Canada’s mental health system needs funding: Chronically underfunded: Canada’s mental health system now lags behind most other OECD countries. Available at: http://www.macleans.ca/news/canada/advocates-canadas-mental-health-system-needs-funding/

[19] Janus, A. (June 2014). Canada has made “no progress” on psychiatric care wait time, report finds. CTV. Available at: http://www.ctvnews.ca/health/canada-has-made-no-progress-on-psychiatric-care-wait-times-report-finds-1.1850794

[20] CBC News (June 3, 2014). Medical wait times three times longer in Canada. Available at: http://www.cbc.ca/news/health/medical-wait-times-up-to-3-times-longer-in-canada-1.2663013

[21] Mental Health Commission of Canada (2016). Advancing the mental health strategy for Canada: A framework for action (2017 – 2022). Available at: http://www.mentalhealthcommission.ca/sites/default/files/2016-08/advancing_the_mental_health_strategy_for_canada_a_framework_for_action.pdf

Along the way, there is the complicated question of medication. Depression is a multi-faceted illness where current thinking speculates that it may be composed of a number of subtly different disorders that medical research has yet to differentiate. [22] In addition, people come with their own individual biology and there are issues of gender, age and even size. In this mix, a medication that works well for one person may not work at all for another. [23]

Getting the right medication can entail trying and trying again. To add to the frustration, most anti-depressants take time to achieve optimum therapeutic levels, so people have to wait from two to four weeks[24] to see if the first medication prescribed is working. If not, another medication is tried and they wait another two to four weeks before they and their physician know if this next one is working.

Getting to the right medication is difficult. However, *keeping* it may be just as difficult.

3. Medication availability and affordability

"The availability of a wide choice of medications is essential to provide the best treatment possible for the individual patient's response and tolerability to medications." (pg. 2)[25]

Public plans

People have a number of avenues for coverage for their medications. If they are on social service benefits, a disability pension or are a senior, most drugs are paid for by the province or territory and are listed on what are called formularies.

The federal bodies that assess new medications for listing on formularies are covered in more detail in Appendix 1.

The first step in the approval process is for Health Canada to evaluate the drug[26] and, if approved, the next step is to answer the question: Will it be eligible for public reimbursement?

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[22] ibid

[23] Prescription for holistic care: Improving access to medication through Ontario's mental health and addictions strategy. Available at: http://www.schizophrenia.on.ca/getattachment/Policy-and-Advocacy/Papers,-Submissions-Letters/Prescription-for-Holistic-Care_SSO_June-2015-(5).pdf.aspx

[24] Lam, R. Kennedy, S. Parikh, S. MacQueen, G. Roumen, M. & Ravendran, A. (2016). Canadian Network for Mood and Anxiety Treatments (CANMAT). Clinical guidelines for the management of adults with major depressive disorders. The Canadian Journal of Psychiatry, Vol 61(9). Pg 506 – 603.

[25] Rajamannar, R. (2011). Access to newer medications: A position paper developed by the Canadian Psychiatric Association's Standing Committee on Scientific Affairs and research. Available at: http://www.cpa-apc.org/wp-content/uploads/Access_to_Newer_Medications-2011-web-FIN-EN.pdf

The Canadian Agency for Drug Technologies in Health (CADTH), a non-profit and independent body, hosts the Common Drug Review that conducts evaluations of the evidence available on the drug in question and uses its findings to support its recommendation (or not) for reimbursement through federal,[27] provincial and territorial formularies (with the exception of Quebec).[28]

Next comes the Canadian Drug Expert Committee (CDEC) asking questions such as is the medication effective but more specifically, is it *more* effective than those already available? This Committee is also concerned with cost. CDEC's approach is evidence based and its advice reflects medical and scientific knowledge, current clinical practice, economic and ethical considerations, along with estimates of patient and public impact (it is of importance to note that the Committee does not have representation from the mental health research community, psychiatric community or the mental health patient community). So, in brief, the test is; does the new medication work more effectively than those already listed on formularies and can it be had for a reasonable cost?

This is not the end of the evaluation process. Each provincial and territorial formulary, itself, reviews the CDR and CDEC recommendations and may or may not follow them – leading to substantial variation in availability (access) across Canada.[29]

Private plans

People who are employed and their dependents - that is the majority of Canadians, can be covered for medications under their employer's health benefits plans (if the employer has them).[30] Twenty-four million Canadians obtain their medications (as well as other health benefits) through these types of plans. [31]

How drugs are approved, by what methodology and who is involved in the decision making process is not publicly shared. However, the minimum standard is that private plans cover at

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[26] Note that these reviews are not only for new drugs, but also for already approved drugs where it is proposed that they be used in new ways.

[27] The federal government covers medication for the Canadian Forces, the RCMP, federal employees, federal prisoners and Aboriginal peoples living on reserves.

[28] CADTG Common Drug review synopsis. Available at: https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr

[29] Please see Appendix 1 for a description of the pan Canadian Pharmaceutical Alliance (formed in 2010), an important "bulk buy" negotiating body but tangential to the present discussion.

[30] One-third of paid employees in Ontario do not have benefit plans. Wellesley Institute (2015). Low wages, no benefits. Expanding access to health benefits for low income Ontarians. Available at: http://www.wellesleyinstitute.com/publications/low-wages-no-benefits/

[31] Canadian Life and Health Insurance Association (CLHIA) Annual Report 2015 – 2016 Available at: http://clhia.uberflip.com/i/684558-clhia-2015-16-annual-report

least the same medications as listed on public plans,[32] noting that there may be a delay in private plans covering newer drugs even though the formularies have adopted them.[33]

Some private plans have requirements whereby patients must try one or two less expensive medications first before anything else can be considered.[34] Some also insist that patients only deal with an approved network of pharmacies. And most only cover a portion of the cost of medications (85% is a common co-pay rate although employers in many instances impose their own co-pay rate).   This effectively ensures that the employee is in fact engaged in the cost sharing for access to necessary medications as he or she is responsible to pay the difference between the co-pay rate and the cost of the medications.

Despite the existence of these public and private plans, a recent survey found that 50% of respondents judged their coverage to be inadequate and, of course, many people are employed in situations where there is no plan at all. [35]

4. Medication continuity during life transitions

Finding the right anti-depressant can be a long and hard journey for patients. Threats to continued access to this medication can also be a source of worry and stress. The results of discontinuity in one's medication regime are not inconsequential. People may have to be re-admitted to hospital. They may have psychotic episodes that have serious consequences including interactions with the legal system, emergency departments and EMS. They may lose a job or a valued relationship. These are real dangers to health and to lives.

Growing up: Children and young adults are covered by their parents' employer's health benefits (should they have them) but eventually they must transition to a plan of their own or pay the cost of medications themselves. Children in foster care "age out" at different times, depending on the province or territory they are in. There are services and medication plans to help them transition to adult programs. However, young adults may not know about these programs and, if known, they may be unsure how to access them.

Changing jobs: Losing access to an effective medication is also a possibility when changing jobs and thus, health benefits plans. There is absolutely no guarantee that the new employer's plan will match the old one.

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[32] Private communication

[33] The CDR evaluates medications *only* with public plans in mind. It does not take private plans into account.

[34] To choose anything other than the least expensive medication requires a prior authorization form that must be completed by a physician – a process which can be time consuming and burdensome. Sometimes, only a portion of this "less preferred" medication is covered (50% - 85% is common) along with the requisite co-pay.

[35] 2015 pan Canadian survey raises warning signs on mental health services. Available at: https://mdsc.ca/research/2015-mental-health-care-system-survey-results/

Moving to another province or territory: Because of the way that medications make their way onto provincial and territorial formularies, there are variations in availability across the country. A medication available in one jurisdiction may not be covered in another.

Moving from hospital to community: For those who've been hospitalized for their depression, discharge entails a short-term supply of medication and a referral to a community program and possibly to a physician. Sometimes, discharge doesn't even include these basics. Patients may be left on their own to navigate this transition. The same dilemma is faced by people who are exiting the corrections system. The cost to the individual and his or her health is one factor but leaving people on their own at this critical juncture can also cost the public system through re-hospitalization, another episode of involvement with the law or perhaps homelessness.[36]

4. The emphasis on generics as a cost savings measure

When a medication's patent protection expires,[37] generic versions come to market. Generic medications must demonstrate that they are therapeutically equivalent to the brand name drug they are now competing with in order to be approved by Health Canada. However, an anxiety remains among patients. Fear of relapse can make them wary of switching to a generic – yet that is what public formularies and private plans demand pharmacists do - substitute the cheaper generic for the brand name drug. The only exception is where a physician accompanies the prescription with a note that specifically forbids substitution for medical reasons.

5. A different perspective: How patients evaluate medications [38]

Medication effectiveness and cost, which are the main focus of the approvals process, are important to patients too. However, they have additional factors which they feel require attention. Patients' experiences of taking medications and living with them – sometimes for the rest of their lives - has value and should be considered in the research, approval and marketing process.

When a medication is released to market, patients are the new "subject pool" and they number not in multiples of hundreds as in clinical trials, but in the tens of thousands. Patients just living their lives introduces into the medication equation any number of variables that simply cannot

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[36] Prescription for holistic care: Improving access to medication through Ontario's mental health and addictions strategy. Available at: http://www.schizophrenia.on.ca/getattachment/Policy-and-Advocacy/Papers,-Submissions-Letters/Prescription-for-Holistic-Care_SSO_June-2015-(5).pdf.aspx

[37] Canada provides 20 years of patent protection to pharmaceutical companies for new drugs but this period is a constant bone of contention for the industry.

[38] Note that, while this brief speaks specifically about people with depression, these concerns could apply equally to all patients, no matter the illness or disease they are living with.

be anticipated through study in highly controlled research. What effect do these variables have on the effectiveness of the prescribed medication and on patients? Patients would ask questions on the following subjects:

Quality of life:[39] How does the medication alter people's lives? Does it affect patients' ability to concentrate, slow their thinking, make them sleepy or inattentive? Can they drive safely? Do they cause nausea, diarrhea or constipation? Must they avoid certain foods? Do they put them at long-term risk of developing other health problems? Do they tax organ function (liver and/or kidneys for example)? Do they affect sexual health? In other words, do the medications solve one problem but create an array of others? Information such as this would ensure that patients' decisions are truly informed.

Patients' voices in the research, approval and marketing process would ensure such quality of life questions are raised.

Side effects: Side effects of medications can have a significant negative impact on a patient's quality of life. There is an abundance of published material on possible side effects both provided by the pharmaceutical company with the medication as well as found on the internet. Notwithstanding that this information is available, patients continue to have trouble determining what side effects of the medication which they are taking might be relevant to their particular situation. Patients continue to ask for information that is simply stated and appropriately communicated*.* While it is acknowledged that regulations exist in Canada that require the inclusion of plain language descriptions of potential side effects, observations and complaints continue to be received from patients who tell us that they have not been adequately informed and that are surprised by the impact of side effects. It is not the purpose of this paper to delve more deeply into this particular issue it is, nevertheless, an issue that needs to be considered by all healthcare providers including the physicians who prescribe the medications and the pharmacists who fill the prescriptions and deliver them directly to the patient.

Interactions: Depression has been shown to co-occur frequently with other health problems such a cancer, stroke, Parkinson's disease, epilepsy and many more illnesses which have their own medication regimes. What will be the effect of putting all these medications into one body? Add over-the-counter preparations, herbal drinks, vitamins, or naturopathic/homeopathic remedies and things have become complicated indeed, but it is the patients themselves who have to live with the results. While it is acknowledged that comprehensive information on interactions is gathered during the clinical trial phase and that this information is included in an application for approval for market, patient engagement in this process would provide comfort to the community that all interactions have been

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[39] Prescription for holistic care: Improving access to medication through Ontario's mental health and addictions strategy. Available at: http://www.schizophrenia.on.ca/getattachment/Policy-and-Advocacy/Papers,-Submissions-Letters/Prescription-for-Holistic-Care_SSO_June-2015-(5).pdf.aspx

considered and that the information is conveyed in plain language to facilitate its understanding by the broad patient community.

Severe adverse drugs reactions: Severe adverse drug reactions are not side effects but rather dangerous events traced to the medication in question; allergic reactions, the onset of cancer due to an unrecognized carcinogen pre-market, heart attacks, strokes, birth defects, as a few examples only. Severe adverse drug reactions can expose patients to potentially life threatening danger – dangers they knew nothing about until they are in the throes of fighting them off – or fighting for their lives. In the event this seems overly dramatic, research has shown that, in Canada, the total cost to hospitals of preventable drug-related reactions is $2.6 B per year. In addition, 20% of patients discharged experience some sort of adverse problem and of those, 66% are drug related.[40]

Health Canada was criticized in a Toronto Star investigation[41] in 2013 for its inattention to adverse reaction reporting. Health Canada was also shown to have failed to alert the public when reactions were known.[42] There has been movement to improve their recording and reporting in the wake of public criticism but the Best Medicines Coalition estimates that only 1 – 10% of adverse reactions are reported.[43] As a counter-balance to formal government reporting, a group of medication professionals founded Rxisk.org, a website that gathers and reports information on adverse reactions.[44]

Choice: Given the multi-faceted expression of depression, a broad choice of medications is especially important to patients. Yet, there are, as discussed above, a number of barriers that inhibit choice in Canada. First, generic substitution is now the norm for public and private plans. Second, it is often a condition of coverage that less expensive medication must be tried before a patient can move onto another selection, potentially lengthening the trial and error period - and the suffering of people with depression. Third, and of salient importance, since its inception in 2003, CDR, has not recommended even one anti-depressant for listing on federal, provincial and territorial formularies, despite the fact that four out of six new medications for treatment of depression have been reviewed. These decisions greatly narrow potential choice for patients – and negatively affect access across the country in both public

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[40] Accreditation Canada, the Canadian Institute for Health Information, the Canadian Patient Safety Institute, and the Institute for Safe Medication Practices Canada. (2012). Medication Reconciliation in Canada: Raising The Bar – Progress to date and the course ahead. Ottawa, ON: Accreditation Canada. Available at: https://www.cihi.ca/en/med_reconcil_en.pdf

[41] McLean, J. & Bruser, D. (Feb, 4 2013). Star gets action: Health Canada announces new standard for reporting side effects. Available at: https://www.thestar.com/news/investigations/2013/02/04/star_gets_action_health_canada_announces_new_standard_for_reporting_side_effects.html

[42] Note that pharmaceutical companies are required by regulation to report known adverse reactions to Health Canada.

[43] Best Medicines Coalition http://bestmedicines.ca/

[44] Rxisk.org is a website hosted by Data Based Medicine Americas Ltd. It was founded in 2012. It lists medications alphabetically along with reported adverse reactions. The medical professionals involved are listed at: http://rxisk.org/about/team/

and private plans. [45] Patients would ask why these decisions have been made, and insist on an answer.

After-market research: What attention is paid to a new medication once it hits the market and is available, not to a narrow group of research subjects, but to the general population? Recent revelations of serious flaws in medications released broadly to the market (think Vioxx and Hormone Replacement Therapy)[46] have had wide publicity and have alerted patients to the possibility that they could be real life science experiments and, unwittingly, risk serious consequences to their health. Independent foundations and government research dollars tend to favour unique and new avenues of investigation and show little interest in funding after-market research for medications. Pharmaceutical companies keep a sharp eye on sales figures but are in no way required to continue research into after-market results. Patients would like to ask, who (if anyone) is monitoring medications once they are released to the general population? While acknowledging the existence of Vanessa's Law and Health Canada's safety reporting mechanisms as examples of ongoing monitoring efforts there clearly needs to be further action in this regard.

6. Where is the patient voice?

Promising signs of change

Patient involvement in the development and approval of new medications has historically been only as research subjects. They are happy to have the opportunity to contribute. However, patients are asking for a more prominent role in the decisions that define all care, including medication approval.

The Canadian Agency for Drug and Technologies in Health (CADTH) was created in a time when the "patient voice" in its approvals process wasn't even considered relevant.

Today, there are clear signs of efforts to engage patients in multiple aspects of the organization. For example, CADTH has a Patient Engagement Officer. It also sponsors a Patient Community Liaison Forum,[47] established in 2013. Membership is comprised of CADTH representatives and designated members of patient umbrella organizations – meaning that disease specific patient groups (of which there are many) are not eligible to participate. Presently, there is also a pilot project to invite individual patients to provide feedback but is has yet to evolve into a widespread call for input.

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[45] CDR decisions for all products could be found at that link: https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports

[46] While these instances are rare, they are nonetheless salient. The public knows about these failures and, justified or not, worry that others, as yet undiscovered, may exist.

[47] The Patient Community Liaison Forum's Terms of reference are available at: https://www.cadth.ca/sites/default/files/corporate/corp_committees/TOR-CADTH-PCLF.pdf

Patient representatives for CADTH patient liaison consultations are selected for their capacity to understand the issues and, it is implied, understand CADTH (which is a complicated organization with multi-level roles and, in the way of these things, communicates in a barrage of acronyms when describing its many functions and committees).[48] In addition, patient representatives are mostly responsible for their own accommodation and travel expenses – a considerable burden for patient organizations which are typically not generously funded.

In the most recent published summary of the Patient Liaison Forum (December 2015) there is mention of new guidelines that will define how patient input is used by CADTH committees. Members are invited to help with the development of these guidelines and provide feedback on subsequent drafts.

In addition, CADTH's sub-committee especially devoted to issues and medications for cancer (pCODR) includes in its four operating tenets a commitment to aligning its work with patient values. [49]

But barriers persist

As patient involvement in all aspects of the health care system has evolved over what are now decades, patients have historically encountered barriers to their participation that had to be named and addressed. Once identified, experience has showed that it can take a considerable period of time to achieve barrier minimization but patients are persistent.

CADTH has clearly embraced the idea of patient participation and has set up initial structures. But there is certainly room for improvement.

Some unacknowledged barriers.

1. ***Nice people trying to do the right thing:*** In the early days of patient participation, many professional groups actively resisted involving patients and didn't feel the need to disguise their annoyance. Today, a somewhat paradoxical barrier to meaningful patient participation (given its history) is sincere professionals doing their best – but retaining significant blind spots. Patients can self-inhibit their advocacy and fail to speak up because they don't want to hurt feelings, so real and troublesome barriers to participation may remain unaddressed.

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[48] Note that nowhere on CADTH's website is the acronym "CADTH" explained and, if it is somewhere, it is deeply buried.

[49] pCODR has also developed a Patient Engagement Guide (2015) specific to its needs available at: https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/pcodr-patient-engagement-guide.pdf

2. ***An unrecognized steep learning curve for patient participants***: People who earn their living employed in the medical and pharmaceutical industries and in CADTH itself, tend to forget what complicated structures they navigate daily. Acronyms, insider language and scientific and medical terms, are only a few examples of what patients must learn in order to carry on the most basic of conversations. The learning curve is steep and often unrecognized by their regulatory, industry and CADTH partners. In the case of CADTH, simply getting to the patient input template is not an easy task. There can be no doubt of CADTH's sincerity in requesting patient input, but it has not yet embraced a plain language approach to its materials or website.

3. ***Patients have day jobs***: Patients are studying these complicated matters on their own time. Meeting schedules (for the Patient Liaison Committee, for example) assume that it easy for them to take time off work and it may not be at all. Providing thoughtful feedback entails a period of considerable study (on their own time), formulating their ideas in a manner that conforms to CADTH's specification (on their own time), and attending conferences or consultations (on their own time and at their own expense).

4. ***Submission times for input are short:*** Underlying data (such as member input or research) must be produced quickly and without paid resources. [50] Calls for patient input and the deadlines to answer these calls are posted on the CADTH website (Open Calls for Patient Input) 20 days before an application from a pharmaceutical company is received. A total of 35 business days is allotted to patient groups to develop and submit their background research, comments and conclusions regarding the submission. Participation guidelines are often slightly disguised admonitions for patients to keep it short and get to the point. For example, CADTH's patient input template asks that submissions be "clear and concise and no more than six pages" – followed by a stern statement that anything more than that will not be considered. Patient groups try to meet these requirements but it is a tall order: Do your own research, get quickly to the point (anything more will be ignored despite your effort or its value) and submit your feedback within short time frames. All of this in the context for most mental health patient groups of significant financial constraints.

5. ***What is done with the feedback?*** If patient groups clear the above hurdles, they are often unsure what effect they've had. CADTH describes where their feedback goes but is silent on how it is considered or whether or not it is acted upon. After all the effort patients made to get their voices to the table, they want evidence of a knowable, seeable, and measurable impact.

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[50] Prescription for holistic care: Improving access to medication through Ontario's mental health and addictions strategy. Available at: http://www.schizophrenia.on.ca/getattachment/Policy-and-Advocacy/Papers,-Submissions-Letters/Prescription-for-Holistic-Care_SSO_June-2015-(5).pdf.aspx

6. **Consultation only - no involvement in actual decision-making:** Patients can provide their views but they are not part of the actual decisions CADTH makes. While being invited to provide experience and opinion is part of the participation equation, the role that patients can and should occupy is as part of the team that rules on approval and listing recommendations. Patient involvement at this level signals equality of influence.[51]

7. Conclusions

With a particular emphasis on medications, this brief tries to bring the reader along on the journey that people with depression must take in order to obtain and maintain a treatment regimen that works for them. It illuminates two areas where improvement is needed:

1. Access

Many Canadians are not covered at all by a drug plan. Of those that are, national survey results report that 50% assess their coverage as coming up short. The various transition points in people's lives (just growing up, changing jobs, moving within Canada and discharge from hospital) imperil the continuity of their medications – risking relapse and the many serious consequences associated with it.

MDSC recommends a national pharmacare program in order to:

- Cover all Canadians' medication needs,
- Take the worry out of life's transition points that threaten medication continuity, and
- Ensure the consistent and timely availability of the best medications as determined by the patient's personal physician across the country.

As a caveat, MDSC acknowledges that people are nervous about the increase emphasis on generics and a national pharmacare plan would only solidify this direction. However, universal coverage is greatly desired and the trade-off is acceptable with the proviso that, should a patient and his or her physician deem that only a patent brand has been experienced to be effective, that it is made available as an exception and at basic pharmacare costs.

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[51] Personal communication: It is important to note that *no* psychiatric expertise (physicians or psychiatrists) is sought by the Canadian Drug Expert Committee (CDEC).

2. Strengthening the patient voice

Patient involvement has become a much more prominent feature of all aspects of health care in Canada. CADTH and its many committees have recognized patient involvement as an adjunct to their decision-making processes. Patients bring a different, needed and valuable perspective to the medication assessment process. So far, CADTH has invited patients to participate as consultants to their various processes. MDSC recommends:

- An audit of the Canadian Agency for Drug Technologies in Health (CADTH)'s patient involvement mechanisms. We also recommend a much more robust communications strategy for how patient feedback is utilized,
- Funding patient groups so that they are compensated for research costs, the time it takes to prepare submissions and travel costs for face-to-face meetings,
- Including the patient voice, in substantial numbers, not just as consultants but as decision-makers through full membership on CADTH, itself, and its various committees and adjudication bodies.

Access to *all* mental health services in Canada is problematic. This brief discusses only one aspect of access; medication.

APPENDIX 1

Most people want the medication they need to be, first, prescribed by their physician and then, available at their pharmacy. They want it to work and they also want it to be affordable; covered by public or private employer health plans ideally.

How medicines are approved in Canada and subsequently get to market and in the hands of patients is a complex topic. Understanding the process is generally not for the lay person – nor are communications regarding that process geared towards the lay person. The following is a primer that summarizes how drugs are approved in Canada. In the interests of simplicity, many interim steps have been left out or summarized – but this is how things, more or less, go.

The **Canadian Agency for Drug Technologies in Health (CADTH)** was established in 1989. It is an independent not for profit body that reviews drugs intended for the Canadian market (as well as prospective diagnostic tests and medical, dental and surgical devices). It has a target of 180 days to make its recommendations which are then passed along to the Common Drug Review.

The **Common Drug Review (CDR**) was established in 2003. CDR was intended to replace the individual provincial, territorial and federal drug review bodies charged with the responsibility of evaluating drugs for potential listing on their respective public formularies (after approval by CADTH). CDR was designed to speed up the drug review process and recommendations to formularies. Some critics say that it has not accomplished this goal

The **Canadian Drug Expert Committee (CDEC)** is another body of CADTH. Its job is to evaluate the effectiveness of a proposed drug compared with older drugs already on the market and assess advantages against what the new drug is expected to cost. This is the question of value for money which is an ever present concern for the Canadian health care system and is not incidental to patient concerns either. Its recommendations to the provinces and territories can be one of the following: reimburse; reimburse but with prescribing conditions; reimburse but not at the price that it is projected to cost (it will have to be lower); don’t reimburse at all.

The **pan Canadian Oncology Drug Review (pCODR)** advises specifically on all matters relating to cancer. Its deliberative Framework has four tenants: Overall clinical benefit, alignment with patient values, cost effectiveness and feasibility of adoption to the health system. Its terms of reference are available at: https://www.cadth.ca/sites/default/files/pcodr/CADTH%20pCODR%20Advisory%20Committee/pcodr-pac-terms-reference.pdf

The **CADTH Patient Community Liaison Forum** was established in September 2013. It is comprised of patient umbrella organizations, meaning that patients and families from any number of illness/disease group are represented with no one disorder predominating. It also has members from CADTH itself. It meets three times per year via teleconference with one additional face-to-face forum. It publishes reports from its meeting with the last one dated December 2015 – none since seem to be available. Its terms of reference are at: https://www.cadth.ca/sites/default/files/corporate/corp_committees/TOR-CADTH-PCLF.pdf

Conflict of interest

In the complex world of medication approval, there is more than a possibility that participants may occupy dual roles. For example, they may consult or perform research for a pharmaceutical company and, as well, been invited to sit on one of CADTH's committees because of their professional expertise. Conflict of interest is most commonly defined as a duality of roles, each of which may call on the individual's loyalty. The "conflict" resides in the question, to which does the individual owe fealty?

There is no doubt that CADTH is well aware of the potential for conflict of interest. If CADTH has an organization-wide conflict of interest policy, it is not published on its website. However, a number of its advisory groups have their own policies

A video that explains it all for you

To bring this complex process to life, Amgen Canada through it Policy Matters Canada arm, has developed a clear and entertaining video available at: https://www.youtube.com/watch?v=d5mrlj7Cyg8 Just note that Amgen is a for-profit biomedical company that develops, among other medical products, medications. The video concludes with its advocacy position. That said, it has a contribution to make towards an everyday understanding of the drug approval process in Canada.

Other important groups

The **pan Canadian Pharmaceutical Alliance (pCPA)** was formed in 2010. It is hosted by the Council of the Federation, Premiers' Council. Its aim is to negotiate better prices with pharmaceutical and medical companies on behalf of provincial and territorial formularies – a bulk-buy discount so to speak. The subject of negotiations is confined to medications that have been recommended by the Common Drug Review and the pan Canadian Oncology Drug Review. Its aims are:

- To lower medication costs
- To improve access
- And to improve the consistency of coverage across the country.

A description is available at: http://www.canadaspremiers.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance

Negotiations are proceeding drug by drug. An example of published completed negotiations (July 31st, 2016) is available at: http://www.canadaspremiers.ca/phocadownload/pcpa/2016/pcpa_completed_negotiations_july31_2016.pdf

The **Patent Medicines Prices Review Board** was established by Parliament in 1987 and is a under the Patent Act. It is an independent body (operating at arms' length from the Minister of Health) with two mandates:

Regulatory – to ensure that patent medicines are priced reasonably, Reporting – on trends in pharmaceuticals and pharmaceutical companies along with tracking research and development investment.

Generic medications are not under its mandate.

Patients Canada

Patients Canada is a national, independent organization that champions the patient voice in all aspects of healthcare. It goals are to:

- Improve healthcare
- Act as equal partners
- Improved the patient experience, and achieve better health outcomes

It involves itself through:

- Continuous and attentive listening
- Collaborative partnerships
- Education and training
- Monitoring and involving itself in the full cycle of change
- Maintaining a pan Canadian lens

Website available at: http://www.patientscanada.ca/