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Viewpoint

The Medical Cannabis Standards Engagement Evaluation and Dissemination (SEED) project: A community-based research approach to self-regulating medical cannabis dispensaries in Canada



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Medical cannabis dispensaries in Canada have served tens of thousands of patients during more than 20 years of operation. Operating outside of the federal legal framework for access to cannabis for therapeutic purposes (CTP), illegal dispensaries were tolerated in several municipalities and were a well-utilized point of access to CTP. In this Viewpoint we present a case report of the Medical Cannabis Standards, Engagement, Evaluation and Dissemination (SEED) project, which engaged academic researchers, CTP patients, dispensary operators, health care providers and other stakeholders to develop a self-regulatory process for CTP dispensaries. We also include the resulting standards developed for medical cannabis dispensaries (Appendix 1). We hope that the standards produced through the SEED project - combined with an overview of the context from which they emerged, obstacles in development and implementation, and an evaluation of the consequences of the project - may inform future efforts to develop systems to provide access to CTP.

Context

The first medical cannabis dispensary in Canada opened in 1997, predating the 2001 initiation of a federally regulated program to provide legal access to CTP. Although Canadian courts acknowledged that dispensaries helped address constitutionally protected rights of Canadians by addressing barriers to CTP access, successive iterations of federal CTP regulations have not included dispensaries, relegating them to a largely unregulated legal "gray zone" requiring informally tolerated but nonetheless illegal acts of civil disobedience from providers and patients (Belle-Isle et al., 2014). A study of Canadian CTP users found use of dispensaries was more widespread than the use of legal sources of CTP (Capler et al., 2017). Estimates prior to the legalization of cannabis for non-medical use suggest that over 25% of patients registered in the federal medical cannabis program (Lucas and Walsh, 2017) and 28% of CTP users in the general population (Government of

Canada, 2018) accessed cannabis via these community-based outlets.

Despite exclusion from federal CTP regulations, dispensaries have operated continuously in several municipalities in Canada since 1997, expanding from fewer than 10 nationwide in the early 2000s which focused strictly on the provision of CTP, to over 175 storefront dispensaries by 2015, many of them focused on non-medical use (Hager, 2015). In 2011, in response to accelerating increases in numbers of dispensaries - primarily in the large metropolitan areas of BC and the greater Toronto area - several medically-focused dispensaries from across Canada collaborated to incorporate the Canadian Association of Medical Cannabis Dispensaries (CAMCD¹, 2014) to organize for collective advocacy and to develop self-regulatory standards. The standards and certification program developed by CAMCD was designed to highlight and support best practices among dispensaries, increase awareness and acceptance of dispensaries among regulators and other community stakeholders, and help provide a framework through which dispensary clients and operators might engage with federal, provincial, and municipal governments to inform the development of a national CTP strategy.

The Medical Cannabis Standards, Engagement, Evaluation and Dissemination (SEED) project

In 2012, the Medical Cannabis Standards, Engagement, Evaluation and Dissemination (SEED) project brought together dispensary operators, academic researchers, medical cannabis patients, health care providers and other stakeholders to engage in a formal effort to support CAMCD's efforts to develop standards for medical cannabis dispensaries. The first stage of SEED involved consultations among dispensary operators, medical cannabis patients, and representatives from the medical community, municipal and provincial governments, and the criminal justice system. Two full-day stakeholder consultation meetings initiated an iterative feedback process on central

¹ CAMCD changed its name to ACCRES Association of Canadian Cannabis Retailers in 2018.

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I. PATIENT ELIGIBILITY II. PATIENT INTAKE III. PRODUCTS AND SERVICES IV. DISPENSING SERVICES 1. Age of Patient 1. Applications 1. Access 1. Operational Requirements 2. Medical Conditions and Symptoms 2. Registration 2. Cannabis Strains and Products 2. Restrictions 3. Documentation 3. Patient Education and Individual Plans 3. Support and Monitoring 3. Dispensing Practices 4. Ineligible Applications 4. Ancillary Services 4. Accuracy and	CAMCD Standards: key operational areas and compliance points (see Appendix 1 for complete and detailed standards).			
1. Applications 1. Access ions and Symptoms 2. Registration 2. Cannabis Strains and Products 2. Cannabis Strains and Products 3. Patient Education and Individual Plans 3. Support and Monitoring Actions 1. Access 4. Ancillary Services	IV. DISPENSING	V. SUPPLY	VI. SAFETY, SECURITY AND PRIVACY	VII. EFFECTIVE ORGANIZATION
 Cannabis Strains and Products Support and Monitoring Ancillary Services 	 Operational Requirements 	1. Product Quality	1. Healthy Environment	1. Governance and Management
 Patient Education and Support and Monitoring Individual Plans Ancillary Services 	2. Restrictions	2. Inventory Management 2. Safe Conduct	2. Safe Conduct	2. Legal and Regulatory Compliance
4. Ancillary Services		3. Supply Accountability	3. Security and Privacy Measures	3. Accountability to Patients
				 Personnel and Employment Practices Community Contributions and Relations

Table

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considerations for certification standards. Meetings focused on 7 key operational areas: Patient Eligibility; Patient Intake; Products and Services; Dispensing; Supply; Safety, Security and Privacy; and Effective Organization. Input from these consultations was integrated into the final certification standards which consisted of 74 distinct compliance targets (Table 1; see Appendix 1 for a detailed list of targets).

The second step of SEED was the presentation of standards and certification processes to dispensary operators at symposia in Vancouver and Toronto, which were the two cities with the greatest number of dispensaries. Finally, a pilot program was initiated with 9 dispensaries that assessed impacts of certification on patients and dispensaries. The assessment process was developed with academic partners and included a survey of dispensaries before and after engagement with the program and a medical cannabis patient satisfaction questionnaire to assess perceived quality of care and services provided to dispensary patients.

Outcomes

In general, SEED met its goals of supporting the development of CAMCD's standards and certification program. Based on reports of workshop facilitators and on a survey of stakeholders who participated in the consultations, understanding of issues and practices related to CTP dispensaries was enhanced by the participation in the consultation process and the accompanying in-depth discussions about the standards. Tracking of pilot dispensaries through the certification process, including a survey of baseline practices and patient questionnaire, also indicated that participation in the pilot program may have positively impacted practices among these dispensaries. However, our conclusions regarding the impact of the program on practices among pilot dispensaries are limited by the lack of comparative assessments of dispensaries and patients where the program was not implemented. Indeed, given the substantial changes in attitudes and awareness of CTP during the assessment period it is possible that observed changes may be attributable to less formal dissemination of best practices.

Federal and municipal regulatory activity related to medical cannabis amplified the impact of SEED. Specifically, the certification standards were considered as evidence in the development of subsequent iterations of federal CTP regulations. The standards were also reviewed by federal and provincial governments to inform their efforts to regulate cannabis retail as part of the 2018 legalization of nonmedical cannabis, with CAMCD/SEED representatives engaged in diverse governmental consultations on this topic. Factors that may have attenuated the influence of SEED included concurrent amendments to the federal medical cannabis regulatory framework, which resulted in a period of great flux among dispensaries including those involved in the SEED pilot program, limiting their participation. Regulatory changes at the municipal level also impacted the implementation of the certification program. Specifically, during the proposed pilot period, the city of Vancouver began officially licensing cannabis dispensaries at the municipal level, with reduced fees for dispensaries that engaged in CAMCD's certification program. This recognition increased demand for the program without commensurate increase in the oversight capacity of CAMCD, resulting in the program being abridged to a subset of required organizational practices (ROPs) with self-attested compliance, while the full standards and certification program remained aspirational. These ROP's, excepting those related directly to patient eligibility, were also applied to membership in CAMCD's non-medical stream that was later implemented in anticipation of legalization of cannabis for non-medical use.

Conclusions

The SEED project successfully supported the development of a set of standards for medical cannabis dispensaries that informed policy development and encouraged best practices. In general, the case study of the SEED project suggests that self-regulation may be a viable approach to improve the capacity of dispensaries to provide CTP, particularly in contexts where engagement with more formal regulatory bodies is complicated by complex legal issues. Self-regulation may also have a role to play in legalized context for non-medical cannabis retail to promote and develop best practices.

This project demonstrates a potentially useful model for the role of academic/community partnerships in the transition from illegal to legal cannabis retail. The impact of the SEED project also speaks to the potential for partnerships between dispensaries and academic researchers to facilitate knowledge translation from people with lived experience to inform policy development. To the extent that the development of CTP policy in other jurisdictions follows the tortuous path evinced by Canada and the United States of America, such partnerships might be helpful in providing safe access to CTP in the gaps left in the wake of evolving policies. To be successful, such projects must anticipate community partner's capacity for implementation, and identify opportunities and challenges within a dynamic policy context.

Declaration of Interests

Rielle Capler sits on the advisory board of ACCRES, however receives no compensation for that role.

Philippe Lucas is Vice-President, Global Patient Research and Access for Tilray, a federally authorized medical cannabis company. However, he was not employed by Tilray during his involvement with the SEED study, and his current compensation is not tied in any way to the outcomes of this study.

Zach Walsh sits on the advisory board of ACCRES, and has received research support from Tilray and DOJA licensed producers of cannabis. He has not received any financial compensation for his work in these capacities. He is also a Medical Advisor to the Indigenous Bloom corporation which seeks to establish opportunities to engage Canadian Indigenous communities in the cannabis industry. He has shares in Indigenous Bloom to compensate for his contributions and this compensation is not tied in any way to the outcomes of this study.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.drugpo.2020.102708.

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