Opioid Overdose and Naloxone: Collaboration for Policy Innovation

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Ambulance Paramedics
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The opinions in this report, and any errors, are those of the authors, and do not necessarily reflect the views of the APBC.

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Foreword

Ambulance Paramedics of British Columbia (APBC) represents the 3,900+ paramedics and emergency dispatchers of the province of British Columbia, working in one of the largest ambulance services in the world. Our members provide pre-hospital medical care to 4.5 million people across a land mass over 944,000 square kilometers in size—larger than California, Oregon, and Washington combined. We respond by air, land, and sea to over 500,000 annual 911 calls throughout the province.

APBC's aim is to collaborate with other health care providers and agencies, the Ministry of Health, community partners and other stakeholders to improve policy-making so as to benefit patient care and patient safety. For example, in the last few years, we have been actively collaborating to help introduce community paramedic programs in BC. The first program was launched in 2015. Such programs benefit BC's residents by providing high quality health care services in the home and in the community as an alternative to expensive hospital care or no care at all.

Opioids and opioid overdose are a recent health care and public safety issue in North America. In Canada, BC is particularly affected. Making good policy to address opioid overdose is challenging, because the issue is so complex. As this report calls it, it is a "wicked issue", where even to define the problem is difficult. In such cases, no single agency or health care provider has the answers. Instead, such complex issues need to be approached through collaboration and innovative policy-making by networks of stakeholders.

As part of APBC's contribution to such collaborative policy-making, we are pleased to offer the following report to stakeholders and all of BC's residents, to encourage dialogue about the issue and, we hope, to inspire creative approaches to resolving it.

Bronwyn Barter
President
Ambulance Paramedics of British Columbia

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Summary

> With appropriate intervention many opioid overdose deaths may be preventable. Naloxone is a life-saving overdose reversal drug that rapidly counteracts the effects of opioids. It has been used in emergency medicine in hospitals and by ambulance personnel since the 1970s to reverse the respiratory depression caused by opioid overdose, and it is included in the World Health Organization's list of essential medicines.[1]

There is no dispute that naloxone is an effective and safe medication for reversing opioid overdoses, and nothing in this discussion paper should be taken to suggest otherwise. As the above quotation from the EMCDDA report on take-home naloxone indicates, paramedics themselves have been administering this drug for decades. And in the absence of any other means to treat an opioid overdose, naloxone is essential.

In the last few years, there have been an increasing number of opioid-related overdose deaths in North America. There are a number of factors that have contributed to this increase, including widespread prescribing of opioid analgesics for pain control. Since 2015, there has also been considerable media coverage of overdoses suspected to be related to illicit fentanyl, a particularly potent synthetic opioid. Opioid overdose is a serious problem, but also a complex one, because of the range of causes and the wide demographic it affects.

However, policy decisions that have consequences for patient and provider safety from both clinical and regulatory perspectives need to be made carefully, taking into account the relevant contextual factors and stakeholder concerns. Such policy decisions concern what have been called wicked problems or wicked issues – "wicked", because there is disagreement and uncertainty about what the problem is, and because attempts to address the problem have wide-reaching consequences, often unintended.

This report examines the policy-making process around a recent decision to authorize a change in the scope of practice for BC's first responders (FRs) and emergency medical responders (EMRs) that allows them to dispense naloxone and administer it by intramuscular (IM) injection in cases of suspected opioid overdose. This decision might appear to be a straightforward response to the increasing number of opioid-related overdose fatalities that have been recorded in BC since 2014. Such an increase is a serious problem, and the BC Ministry of Health and its associated agencies are right to look at means to mitigate the harm from opioid use. However, it is also important that responses to such

[1] Strang and McDonald, 2016, 5.

issues are not simply driven by political urgency, but also take into account as much of the available evidence as possible. For that reason, we look at this policy-making process as an attempt to "tame" a wicked issue. The aim of our analysis is to contribute to discussion of this issue by explicating the contexts that need to be considered in order for policy-making to be better informed. To do so, we look at this particular policy decision by taking the widest possible view of the issue, to include not just the mechanics of IM injection or the safety of naloxone, but also the underlying factors behind opioid use and opioid overdose.

This report is one attempt to assemble available evidence, and to do so in a wide-ranging fashion, by first looking at various dimensions of this specific issue. These show that it is a far more complex issue than might at first be assumed, since it involves aspects of health care, public safety and, at the intersection of both, drug policy, each of which is a complex domain in its own right. The argument throughout this report is that opioids and their use need to be understood contextually, in order to gain a better understanding of how policy-making can be enhanced to address this issue in a more effective way. When faced with wicked issues such as this, authoritative policy-making is less likely to lead to optimal policy decisions.

So how best to understand and approach an issue like opioid overdose? With a wicked issue such as this, where not only is there disagreement about possible resolutions but also about the problem or issue itself, a different type of approach is required, one that involves stakeholders not just presenting their perspectives, but actively engaging in collaborative definition and understanding of the problem. Ideally, such approaches are managed through networks of stakeholders, who join together to effect outcomes that are beyond any individual stakeholder. However, such ventures are fraught, as they rely on particular dynamics that allow for proper collaboration. The danger is always that, in the interests of "getting something done", particular stakeholders end up in positions of control, and thereby are able to push their own concerns to the forefront.

In Chapter 1, we look at the nature of wicked issues, to argue that they are beyond the capacity of any one agency to resolve, whether government, non-government or private sector,. The reason for this is that such issues are different from those that can be dealt with by authoritative action, in which stakeholder engagement is managed in a hierarchical fashion. In fact, it is part of the nature of such issues that they defy such approaches. The literature on wicked issues emphasizes characteristics such as the fact that defining the problem is part of the problem, i.e., they are not amenable to linear decision-making that starts with a problem definition, followed by research to determine the most

effective solution, and then implements or operationalizes that solution. Instead, as stakeholders engage in a collaborative effort to understand the issue, based on different and conflicting values and perspectives, they change the way it is perceived. The problem context is dynamic and constantly changing, both in terms of conditions and constraints, on the one hand, and conceptions, on the other.

For this reason, there is in fact no definitive "solution" to a wicked issue, only better and worse resolutions, which means that they are essentially open-ended. Furthermore, each such resolution is a "one-shot" operation, since putting it into effect has wide-ranging consequences, some unforeseen, that cannot be easily undone. For this reason, they cannot be implemented in a trial-and-error fashion. And resolving a wicked issue gives rise to other wicked issues, just as the original wicked issue was a symptom of others. This is evident, for example, in the case of opioid overdose, which has become a prevalent problem in North America because of changes in the medical approach to the treatment of pain. Untreated chronic, non-cancer pain came to be understood as a serious medical issue, which pain medicine physicians advocated could be solved by increasing the prescription of analgesics, particularly opioid analgesics. The unforeseen consequences of this solution include a marked increase in addiction and overdose.

Wicked issues are prevalent in areas of social concern. Drug policy is particularly wicked, not only because of conflicting values about drug use, but also because it lies at the intersection of two other wicked issue domains, namely health care and public safety. In the context of the recent regulatory change in BC that has authorized the administration of naloxone, the opioid antagonist that is remarkably effective in reversing opioid overdose, this report looks at contentious aspects of drug policy, such as how drugs are conceived, and how use and users are characterized. Conflicting values are evident for each of these, such as the fluid distinction between "substances", "drugs" and "medications", or between "patients", "users" and "misusers". Further value conflicts are evident in types of policy response, such as the law enforcement approach of supply interdiction and punitive measures for users, compared to the medicalized harm reduction approach.

To discuss wicked issues in public (or community) safety relevant to opioid overdose, we examine emergency response in terms of the three main agencies responsible, namely fire, paramedic and police services. The structure and responsibilities of these services have evolved over the last 50 years due to social, technical and professional changes, as have inter-service relations. Here, we focus in particular on first responders in emergency medical services, as this is an area of some contention between fire services, which face a declining

number of fire calls and an increasing number of emergency medical calls, and paramedic services, which are playing an increasing role in health care delivery. The question in this regard has to do with safe and beneficial types of intervention by individuals who may have limited training. Available evidence suggests that, in many cases, advanced life support interventions in the prehospital environment are of little benefit, but determining when such interventions are warranted depends on clinical judgement, which itself requires training and experience.

Finally, attempts to "solve" wicked issues by addressing them as if they were simple or even complex problems, i.e., by attempting to "tame" the problem, has policy consequences, and can often lead to disjointed policy. As this report argues throughout, that appears to be the case with recent regulatory changes to the scopes of practice of BC's EMAs.

In Chapter 2, we look at opioids from historical, pharmacological and demographic perspectives. Opioids have a long history, but their modern prominence began in the 19th century, with the isolation of morphine and, later, other active components. Morphine was used extensively as an analgesic in the American Civil War, which also made evident its propensity to lead to dependence. In the 20th century, a variety of synthetic and semi-synthetic opioids were developed and marketed, but with the introduction of the international drug control regime in the 20th century, most opioids came to be classified as controlled drugs. Naloxone, itself an opioid, was synthesized in 1960.

Opioids act by binding to receptors in the central nervous system, which affects cellular processes involved in the response to pain or injury. However, these receptors are also involved in the regulation of respiration, which is why opioid overdose leads to respiratory depression and, if left untreated, can result in cardiac arrest and death. There are differences in the rate at which opioids are metabolised, which partly depends on how they are ingested. This has implications in the treatment of overdose with naloxone, since it is metabolised relatively quickly. When used to reverse an overdose from a longer-lasting opioid, repeated administrations may be necessary.

The global prevalence of opioids is highly uneven, the highest levels of use being found in North America. Data from 2011 show that Canada had the highest level of consumption on a per capita basis, with the U.S. a close second. These levels were around twice as high as those found in the next group of countries, such as Australia and Germany. Prescription opioids constitute a significant component of these levels of use. However, data on *misuse* of prescription opioids showed that the U.S. had a much higher level (over 5 percent) than Canada (1 percent). Unfortunately, national level data on drug use in Canada is difficult to assemble, due to incompatibilities between

provincial data systems. However, a dataset on the number of publicly-funded prescriptions for opioids shows that the highest level in 2013 was in BC.

In Chapter 3, we look at the issue of opioid overdose, which in recent years has been represented in the media, academic journals, and official documents and statements as an "epidemic" and a "public health crisis". There is no question that the recent increase in opioid overdose fatalities is a serious issue. However, such representations can be counterproductive, as they can give rise to moral panic that, in turn, puts pressure on politicians and public health authorities to act rapidly. As we argue throughout, in the face of a wicked issue, policy-making done in haste can lead to suboptimal policy decisions. We first briefly discuss the concepts of overdose and toxicity, to point out how these are relative concepts, and how exposure to a substance can change its propensity for toxicity. In the case of opioids, for example, habitual users can develop tolerance, which allows them to ingest greater amounts or stronger types of opioids than those who are opioid-naïve. We then look at the representations of prescription opioids in the media, and contrast this with the case of benzodiazepines, another type of drug used for anti-anxiety and sedation. These drugs can also have harmful effects, particularly when taken in combination with other substances and, in the U.S., fatalities resulting from benzodiazepine overdose have increased at a greater rate over the past 15 years than those from opioid pain relievers. Yet these drugs have not been the subject of media (and other) representations of an "epidemic". The point here is not to downplay the risks of opioid use or the seriousness of the prevalence of opioid overdose, but rather to suggest that such representations support demands for urgent action, which can forestall the collaborative policy-making needed to address the wicked issue of opioid overdose.

The final sections of this chapter look at the prevalence of opioid overdose, factors that have contributed to its increase in North America, and the manner in which fatal overdoses are attributed to opioids, all of which are important aspects of the issue. Data from BC show that opioid-overdose fatalities have been increasing in the last few years, particularly those in which fentanyl has been detected.

In Chapter 4 we examine the use of naloxone for reversal of opioid overdose. Although this drug has been used clinically for many years, in the last decade a number of jurisdictions have taken steps to make it more widely available. Two approaches stand out. The first is *take home naloxone*, in which naloxone kits and overdose education are provided to opioid users and/or their families and friends. This is a harm reduction approach that seeks to provide bystanders who witness an opioid overdose with a relatively safe means to reverse it. This is justified by the fact that such bystanders are unlikely to have medical or

first aid training, and therefore would be unable to provide an opioid overdose victim with supportive care (e.g., rescue breathing) while waiting for emergency medical response. As well, in cases of illicit use, bystanders may be inhibited from calling emergency services out of fear of criminal sanctions. The available evidence on such programs has shown them to be generally effective in reducing overdose fatalities.

A second approach, found particularly in jurisdictions in the U.S., but also starting to be seen in Canada, is to equip first responders such as firefighters and police with naloxone. This has been effected through regulatory changes to allow these first responders to administer naloxone in cases of suspected opioid overdose. To date, however, there is little evidence available as to the outcomes associated with such programs. Anecdotal evidence suggests that they have had a positive impact, particularly in regions where paramedic availability is low.

To contribute to the discussion, we examine some of the issues that need to be considered in making such regulatory changes, particularly in terms of patient and provider safety. One such issue has to do with the safety of different routes of administration of naloxone. One common route is through intramuscular injection, but there are risks associated with this, such as infection and tissue trauma. As well, the use of syringes poses a risk to providers, who may suffer needle stick injury and exposure to blood-borne pathogens. A safer approach is to administer naloxone intranasally, which has shown to be nearly as efficacious as other routes. Regardless of the route of administration, however, naloxone can have adverse effects, such as acute hypertension and pulmonary edema. These adverse effects are rare, but can be potentially life-threatening. More important, perhaps, is the reaction of the patient to opioid withdrawal. For patients who are opioid-dependent, this can trigger combativeness and agitation, which can pose a risk to both patient and provider.

We conclude this chapter by discussing the use of supportive care in treating opioid overdose, particularly airway support and ventilation. Because the danger in this situation comes from respiratory depression, such supportive care is an effective way to manage it. In BC, FRs and EMRs are trained in such interventions, and it is therefore arguable that providing such supportive care is more important than having naloxone on hand. However, bystanders, who are unlikely to have such training, have a much greater need for naloxone.

In Chapter 5, we look at the legislative and regulatory context for emergency medical assistants (EMAs) in BC. Regulatory authority for EMAs is the responsibility of the Emergency Medical Assistants Licensing Board, which sets license terms such as educational standards, scopes of practice, continuing competence requirements, and examinations, and is also responsible for complaints. The process that resulted in the change to the scope of practice of

FRs and EMRs, however, involved assignment of some regulatory authority to BC Emergency Health Services. This was also the case with a previous regulatory change in relation to community paramedic programs. The risk with this approach is that it blurs regulatory authority and accountability, which has the potential to reduce oversight. To illustrate this, we look at issues of training and education, continuing competence, and sustainability in relation to FR/EMR administration of naloxone.

In Chapter 6, we turn to the idea of collaborative policy-making and network governance, to suggest that such approaches to policy-making are essential when dealing with wicked issues, because in order to understand them more fully, the disparate and conflicting ways they are seen need to be taken into account. In such cases, understanding the problem is part of the problem. Attempts to define the problem in advance in order to pursue policy-making in a linear way are bound to fail. To illustrate the analysis, we evaluate the processes behind the two recent regulatory changes for EMAs in terms of collaboration and network governance. Our conclusion is that these processes ultimately failed to be properly collaborative, and therefore it is not unexpected that they resulted in suboptimal policy-making.

In light of the evidence presented in this report, and in the interests of better policy and better policy-making, we offer the following suggestions:

- **That, in light of the regulatory concerns outlined here, the decision to empower BCEHS to require EMALB to endorse EMAs for procedures beyond their current scope of practice be reviewed;**
- **That, in light of the patient and provider safety concerns outlined here, the decision to endorse FRs/EMRs to administer naloxone be reviewed;**
- **That, in the interests of better policy-making regarding complex health-care, drug policy and other issues, the Minister of Health consider championing a collaborative policy network involving all stakeholders, to help resolve policies about wicked issues.**

Introduction

> Death in opioid-overdose can be averted by emergency basic life support resuscitation and/or the timely administration of an opioid antagonist such as naloxone.[2]

This report looks at a case of "disjointed" policy-making that recently occurred with respect to the scope of practice of first responders (FRs) and Emergency Medical Responders (EMRs) in British Columbia, and suggests that this resulted from an attempt to "tame" a wicked issue. The "politics of urgency"[3] (in this case, the need to be seen to responding to a recent increase in fatal opioid overdoses) worked in tandem with the interests of certain stakeholders to result in a policy response that presented the issue at hand as straightforward, or as a "tame" problem.

Regulatory Change For FRs And EMRs

A recent Ministerial Order (MO) granted BC Emergency Health Services ("the corporation") the authority to require that BC's Emergency Medical Assistants Licensing Board (EMALB), the body charged with overseeing BC's Emergency Medical Assistants (EMAs), allow FRs and EMRs, the two lowest tiers of Emergency Medical Assistants licensed by the EMALB, "to dispense and administer narcotic antagonistic drugs".[4] This establishes an authority for BCEHS that lies outside the EMALB's remit.[5] In fact, it goes further, since it establishes the authority whereby the corporation can require the EMALB to license FRs and EMRs to perform controlled or restricted acts that were until recently only within the scope of practice of paramedics with a significantly greater amount of education and training. However, if this were not sufficient to raise questions, the MO also allows the corporation to insist that the EMALB endorse FRs and EMRs to *dispense* narcotic antagonists. As far as we are aware, no paramedic in BC has ever been endorsed for dispensing any kind of substance. By way of contrast, in responding to criticisms that the nurses registered by Health Canada (HC) are not able to provide naloxone, the federal Minster of Health issued a statement to clarify that HC nurses have been able to administer naloxone for several years, but that none of them were currently

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2 World Health Organization (WHO), 2014, 2.

3 Wexler, 2009, 538.

4 British Columbia, January 8, 2016.

5 A previous Ministerial Order regarding community paramedic services involved a similar transfer or displacement of authority (British Columbia, November 15, 2015). This MO will be discussed further below.

licensed to dispense these drugs.[6]

On January 28, 2016, the British Columbia Ministry of Health (BCMoH) announced this change to the endorsements for EMAs to allow both FRs and EMRs to "carry and administer...naloxone for patients suffering opioid drug overdoses".[7] The rationale that BCMoH provided for this was that "[a]n overdose can happen to anyone...with the increasing number of overdoses we're seeing, we have to make sure the people on the front lines responding to emergency calls have the right treatment available to save lives".[8]

In a departure from standards that have been in place for more than a decade, which graduate the types of procedures that BC's EMAs are permitted to administer based on their level of training and their licensing by the EMALB, both FRs and EMRs will now be permitted to conduct an invasive procedure – intramuscular injection of naloxone – that was previously reserved for BC's paramedics (i.e., those EMAs "holding a licence in the category PCP" or above).[9]

This change was a "result of collaboration between the Ministry of Health, Provincial Health Services Authority (PHSA), BC Emergency Health Services (BCEHS), BC Centre for Disease Control (BCCDC), Fraser Health and municipal authorities to respond to the rising number of drug overdose cases in B.C."[10] It is notable that no other Health Authorities are referenced in this press release, nor are any of the many other organizations involved with this issue, particularly BC's paramedics, as represented by the Ambulance Paramedics of British Columbia. This suggests that the MO was produced through a process that did not include engagement with many of the stakeholders involved in dealing with the very issue it aims to address.

This recent change in the scope of practice of BC's EMAs that this MO has effected raises a number of issues, ranging from the specific (e.g, the implications for patient safety of having minimally trained FRs administer needle injections) to the most general (e.g., how should BC's health care system and public safety organizations address drug issues in the province). It may well appear that the use of naloxone to reverse opioid overdoses is a straightforward matter, as its pharmacology is well understood, the risk of harm of naloxone itself appears to be minimal, and it is being employed by FRs in various jurisdictions in the United States. Nevertheless, without a proper understanding of the context

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6 Health Canada, March 2, 2016.

7 British Columbia (BC) Government News, January 28, 2016.

8 *Ibid*.

9 B.C. Reg. 210/2010. It should be noted here that the term "paramedic" is not actually defined in the Act.

10 BC Government News, January 28, 2016.

of such interventions and their potential implications, changes to the delivery of emergency health care services done by fiat rather than by stakeholder collaboration are likely to result in unforeseen consequences that do not support the goal of improving the provision of health care services to BC's residents.

However, the phenomenon of drug overdose does not occur in a vacuum. Rather, it is just one node in a complex network of problems. Such problems have been characterized as 'wicked problems' or 'wicked issues', in the sense that they are complex, involve multiple stakeholders, multiple contestations about what the problem is, and therefore, no clear way of defining a solution. Drug policy, health care policy, and public safety policy all involve such 'wicked problems', which authoritative processes are ill-equipped to deal with for the very reason that there is no clear understanding or agreement about what the problem really is.

Although we analyze in detail here the various aspects of this particular example of disjointed policy-making, our objective is in fact broader. We use this case to exemplify the pitfalls of *non-collaborative* policy-making where wicked problems are concerned, and to argue that this kind of approach is prone to result in contradictory or disjointed policy, in this case, health care regulation.

Fatal overdoses from prescription medicines have become more common in North America over the past decade and a half. But because drugs – both licit and illicit – and drug policy are highly contentious, we feel it is important to state from the outset that nothing in this paper should be interpreted as disagreement with, or criticism of, the idea that wider availability of naloxone to reverse opioid overdoses saves lives and reduces harm.

In British Columbia, however, the issues of (i) *who* should be able to administer this substance, (ii) *how* they should be able to administer it, and (iii) how to best arrive at a *coherent policy* that balances patient safety with the urgent need for overdose reversal have not yet been properly examined. This document draws together evidence on the matter, to argue that such decisions involve a wider array of stakeholders than has been recognized, and failure to draw on their insights results in suboptimal policy decisions, not only for policy-makers, but more importantly, for the residents of British Columbia, who rightly expect the highest quality of health care delivery at all times and in all places.

A Note on Figures and Statistics

Throughout this report, we draw upon various sources of quantitative data to present statistics of relevance to the drug policy context and the issue of opioid overdose. Due to limitations in country-wide data for Canada, in several instances we have drawn upon US data. However, as there are significant differences between the two countries with respect to health care and controlled substances policies, these figures should be taken as indicative, not as determinative.

Wicked Issues[11] and Disjointed Policies

> 'Wicked problems'...go beyond the scope of any one agency, and unaligned interventions by any one agency can have perverse knock-on effects.[12]

What are 'wicked issues'?

Wicked issues are issues that, because of their complexity, are not amenable to simple solutions nor, more importantly, to simple linear processes to determine solutions. The concept was formulated by Rittel and Webber in the 1970s in relation to social planning.[13] These authors argued that unlike scientific or engineering problems, social problems are "inherently wicked" because they are "ill-defined" (160), not because of any failure to do so, but because "[t]he information needed to *understand* the problem depends upon one's idea for *solving* it...To find the problem is thus the same thing as finding the solution; the problem can't be defined until the solution has been found" (161). In other words, formulating what the problem is actually involves formulating the solution; they are not separable or sequential.[14] This has consequences for policy-making.

With 'tame' problems, not only is the problem well-defined, but also it is clear what would constitute a solution to the problem. Such problems are amenable to "an orderly and linear process, working from problem to solution",[15] and decisions can be made through a form of authoritative leadership or strategy, i.e., by "giv[ing] the problem to some group (or an individual), who take on the problem-solving process while others agree to abide by its decisions".[16] This may include some form of public engagement, typically in the form of consultation, where policy-makers share ideas and information, and perhaps also gather input and advice. However, it may be conducted as more of a deliberative process, in which the public and stakeholders "must go another step to engage

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11 We use the terms "wicked problems" and "wicked issues" interchangeably through this report, depending on the context, as we agree with the authors of the Demos report *Connecting the dots*, who state "We are also doing our best to avoid referring to wicked issues as wicked problems – the literature does not make this distinction consistently. The reason for the distinction is that there is a strong association between 'problems' and 'solutions' – and…the wicked, messy, end of the spectrum of issues defies 'solutions'." (Chapman et al., 2009, 13).

12 Ferlie et al., 2011, 308.

13 Rittel and Webber, 1973.

14 *Ibid.*, 161.

15 Australian Public Service Commission (APSC), 2012.

16 *Ibid.*; see also Alford and Head, 2015.

one another in a dialogue where they work through the issues together".[17] In both cases, however, power to decide on a course of action is reserved for the policy-makers themselves.

Clearly, these kinds of approaches are problematic for wicked issues which, because of their inherent complexity, "have many interdependencies and are often multi-causal" and may also have "internally conflicting goals or objectives within the broader wicked problem".[18] With drug policy, for instance, there may be "tension between the goal of minimising harm to existing drug users... and the goal of sending a clear message that illicit drug use is illegal".[19] These interdependencies also mean that such problems "are inescapably connected to other problems",[20] and therefore "go beyond the scope of one agency".[21] As Weber and Khademian point out

> the wicked problem space comprises multiple, overlapping, interconnected policy domains and levels of government. Wicked problems, in other words, cut across hierarchy and authority structures within and between organizations and across policy domains, political and administrative jurisdictions, and political "group" interests.[22]

Such inherent complexity can be seen in the domain of public or community safety, in which there are conflicting objectives between security and freedom, multiple agencies involved, and overlapping jurisdictions (in Canada, municipal, provincial/territorial, and federal, for example).

However, not only are wicked issues inherently complex, they are also *dynamically* complex.[23] One reason for this is that the understanding of the problem changes in the process of attempting to address it. Another reason is that "constraints, such as resources and political ramifications, are constantly changing",[24] as are the stakeholders involved. Such dynamic complexity is evident in health care, for example, in the interaction of demographic change, technological and scientific development, and changing conceptions of what 'health' means.

A further feature of wicked issues is that attempts to address or resolve them[25] have consequences and repercussions, often unforeseen and often

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17 Lenihan, 2009.

18 APSC, 2012

19 *Ibid.*

20 Weber and Khademian, 2008, 336.

21 Ferlie et al., *op. cit.*

22 Weber and Khademian, *op. cit.*

23 *Ibid.*

24 Roberts, 2000, 1.

25 Rittel and Webber argue that "[s]ocial problems are never solved. At best they are only re-solved – over and over again" (*op. cit.*, 160).

undesirable.[26] For example, McGuffog points out that one unintended consequence of "the international system of drug control" has been "the creation of a highly profitable and violent illicit drug market", and that "pressure on the market for one particular substance can, inadvertently, promote the use of an alternate drug".[27] An example of the latter may be seen with the rise in the extra-medical use of fentanyl (a synthetic opioid pain medication some 80–100 times more potent than morphine) in Canada over the last four years after OxyContin, a pain medication containing oxycodone (a semi-synthetic opioid 1.5–2 times stronger than morphine) was banned from sale in the country.[28]

Such consequences and repercussions "spread rapidly to have an impact with other issue areas". As a result, "wicked problems are relentless", because they "are not going to be solved once and for all despite all the best intentions and resources directed at the problem".[29]

Yet another challenging feature of wicked issues is that their solutions are essentially "one-shot operations".[30] That is, they are not trial-and-error experiments that can be run repeatedly. Rittel and Webber argue that

> [w]ith wicked planning problems...*every* implemented solution is consequential. It leaves "traces" that cannot be undone...Whenever actions are effectively irreversible and whenever the half-lives of the consequences are long, *every trial counts*. And every attempt to reverse a decision or to correct for the undesired consequences poses another set of wicked problems, which are in turn subject to the same dilemmas.[31]

All of these features are evident in drug policy.[32] For example, Alford and Head argue that "formulating and implementing policy to control illicit drugs...rests on three factors that...make it a wicked problem". These factors are addiction, criminality, and "the multifarious nature of drug production and distribution".[33] But drug policy overall is about more than just the control of illicit drugs; it also involves disposition towards *licit drugs* or *medications*, such

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26 *Ibid*., 163; APSC, *op. cit.*

27 McGuffog, 2012, 19.

28 Our use of the term "extra-medical" here will be further explained below. One dimension of opioid substances is that in many cases they are licit, similar to benzodiazepines, but unlike some other controlled substances such as cocaine. This makes the terminology referring to use problematic. For example, an individual with a prescription for an opioid pain medication who takes them in a way that is not prescribed (e.g., double-dosing or mixing with another substance) is not behaving illicitly. Nor is it clear that such use constitutes "abuse" of the substance. Tupper examines the language of psychoactive substances using a critical discourse analytical approach (Tupper, 2012).

29 Weber and Khademian, *op. cit.*, 336-337.

30 Rittel and Webber, *op. cit.*, 163.

31 *Ibid.*

32 "[T]he global illicit drug problem is arguably the archetypal 'wicked problem' of the twenty-first century" (Seddon, 2013, 50).

33 Alford and Head, *op. cit.*, 16.

as opioid analgesics and benzodiazepine sedatives/anxiolytics,[34] which involves yet another dimension in terms of both health care and public safety, and thus further compounds the wickedness of the drug policy problem.

For example, despite the pharmacological dangers of many opioids, it is also widely recognized that they have beneficial application in pain alleviation, so much so that international organizations concerned with drug control have expressed concern at the *un*availability of such products to the vast majority of the world's population. In 2011 the United Nations Office on Drugs and Crime (UNODC), "a global leader in the fight against illicit drugs and international crime",[35] produced a discussion paper stating that

> The rational use of controlled medicines – i.e. medicines controlled under the international drug treaties – is essential to health. Their rational prescription and administration are essential aspects of good medical practice for pain treatment and other clinical interventions.[36]

In 2016, the UN International Narcotics Control Board (INCB), "the independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions",[37] produced a report stating that

> Around 5.5 billion people still have limited or no access to medicines containing narcotic drugs, such as codeine or morphine, leaving 75 percent of the world population without access to proper pain relief treatment... Inadequate access contradicts the notion of article 25 of the Universal Declaration of Human Rights, including the right to medical care, which also encompasses palliative care.[38]

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34 Terminology in drug policy is ambiguous, and often either conflates or elides characteristics of different substances in order to classify them in a certain way. Tupper distinguishes three different meanings of "drug": (i) legal psychoactive substances, e.g. alcohol, caffeine and nicotine ("non-drugs"); (ii) regulated psychoactive substances ("medicines"); and (iii) illegal psychoactive substances, "deemed inherently bad or dangerous", e.g. coca, opium and cannabis ("drugs") (*op. cit.*, 469). As illuminating as this distinction is, it still fails to capture the complex status of substances or products such as opioid analgesics, whose classification can shift from "medicine" to "drug" (in Tupper's sense), or "licit" to "illicit", depending on the circumstances and context of use, i.e., whether they are used "as prescribed" or not.

35 UNODC website, "About UNODC".

36 United Nations Office on Drugs and Crime (UNODC), 2011, 2, referencing a 2011 report by the World Health Organization (WHO), *Ensuring balance in national policies on controlled substances* (WHO 2011a). It is interesting to note that in its report, the WHO claims that "[t]he universal adoption of the treaties and their implementation continue to be *highly effective* in preventing the diversion of drugs from licit to illicit markets in international trade and *in protecting society from the consequences of dependence*" (1, emphasis added), which even at the time would have been somewhat at odds with the situation of opioid analgesics in North America, at least as represented by some of the agencies on the ground.

37 INCB website, "Mandate and Functions".

38 UN International Narcotics Control Board (INBC), 2016, iii. This report was an update of a 2010 INBC report.

As both of these reports suggest, there is a "difficult balance between 'remedy' and 'poison'",[39] a central aspect of the wicked issue of drug policy.[40]

Addressing wicked issues

As has been mentioned above, the inherent complexity of wicked issues makes them hard to resolve and, in particular, means that they are ill-suited to linear problem-solving approaches (i.e., those in which the problem is first defined, information is gathered and analyzed, a range of possible solutions is developed, and the most optimal solution is chosen – the "systems-approach"[41]). Rather, because problem *definition* is part of the problem itself, resolving wicked issues requires approaches that incorporate from the outset problem definition as part of the process leading towards problem resolution, that is,

> a model of planning as an argumentative process in the course of which an image of the problem and of the solution emerges gradually among the participants, as a product of incessant judgment, subjected to critical argument.[42]

In other words, they require *collaborative strategies* in which stakeholders discuss, deliberate and define the problem itself, in the course of determining viable solutions. As the APSC puts it,

> a linear, traditional approach to policy formulation is an inadequate way to work with wicked policy problems...because part of the wickedness of an issue lies in the interactions between causal factors, conflicting policy objectives and disagreement over the appropriate solution. Linear thinking is inadequate to encompass such interactivity and uncertainty...a true understanding of the problem generally requires the perspective of multiple organisations and stakeholders, and...any package of measures identified as a possible solution usually requires the involvement, commitment and coordination of multiple organisations and stakeholders to be delivered effectively.[43]

In this sense, wicked issues connect to and align with what has been termed the "holistic turn" in policy-making, i.e., the idea that issues in one domain may be influenced by factors from a number of other domains, "closely connected to it in all kinds of complex and unexpected ways".[44] Such complexity and interconnectedness challenges any attempt to formulate issues too narrowly, too linearly, or, we might say, too 'tamely', and then expect policy success. As the

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39 *Ibid.*, 1.

40 See also Degenhardt et al., 2007, vi.

41 Rittel and Webber, *op. cit.*, 161-162.

42 *Ibid.*, 162.

43 APSC, *op. cit.*

44 Lenihan, *op. cit.*, 12.

ASPC points out, "locking down the problem definition" by "addressing a sub-problem that can be solved" is one way to try and tame a wicked problem. And this approach has the advantage that "the problem can appear solved at least in the short-term". [45] However, because it only addresses one element of a much more complex problem, the solution is most probably illusory and, worse, may exacerbate the problem through unforeseen and unintended consequences.

> Unintended consequences tend to occur even more frequently if the problem has been artificially tamed, that is, it has been too narrowly addressed and the multiple causes and interconnections not fully explored prior to measures being introduced.[46]

In a previous report on community paramedic programs in BC, the APBC focused on this holistic dimension of health care policy, and argued there that effective policy transformation "requires an appropriately resourced, collaborative approach that brings health care professionals together in a way that places the patient at the centre".[47] Just as with drug policy, health care is a wicked problem, particularly in terms of how best to distribute finite health care resources equitably and effectively, which cannot be "solved" by approaches that construe it as a tame problem.

The opioid overdose issue that this report addresses, as an aspect of drug policy in general, lies at the intersection of two broad domains of wicked issues, public safety and health care. Resolving this issue requires input from, and collaboration between, a range of stakeholders. Paramedics, whose professional role straddles public safety and health care, are in a unique position to engage in such collaborative policy making, and are able to bring a wealth of experiential evidence to the discussion.

Health Care as a Wicked Issue

> Health is an exemplar of the interconnected policy-making required in the 21st century, not only because of the need to address the health determinants but also because it is clearly a so-called 'wicked problem'.[48]

> These wicked problems are exemplified by the crises facing health systems worldwide, in both the developed and developing world. In the developed world the predominant focus of the health system is in treating ill health, where the escalating costs associated with technological advances, community expectations and an ageing population are putting unsustainable

45 ASPC, *op. cit.*

46 *Ibid.*

47 Evashkevich and Fitzgerald, 2014, 58.

48 Kickbusch, 2010, 13.

> pressure on the health system – dealing with illness or 'illth' rather than health.[49]

We have discussed health care systems and BC's health care challenges at length in a previous report.[50] Here we simply point out that health care is complex, involving a wide range of stakeholders, including governments, health care providers, funders, patients, and patient support organizations, among others. It also involves a wide range of systems or sub-systems, such as service delivery, the health workforce, health information systems, the pharmaceutical system, and so on.[51] The services themselves are multifarious, including primary care, secondary care, emergency care, etc. All of these exist in a context of demographic and technological change, meaning that health care is characterized by dynamic complexity. And the challenges facing the provision of health care make it clear that it is a wicked issue domain.

Use as Directed: Drug Policy as a Wicked Issue

> ...drug policy is a complex and often controversial policy domain, frequently characterised by the notion of 'wicked problems'[52]

Drug policy[53] is a wicked issue, because it involves different and conflicting values and objectives. In fact, there is debate and disagreement as to what the problem actually is (a characteristic of wicked problems, as we discuss below). On the one hand, there are those who argue that drug use should be minimized, if not eliminated altogether (what could be termed a "prohibitionist" view), whereas another view accepts that some level of drug use has always existed in human societies, [54] but that it requires regulation.[55] Such views are often defended by appeal to a need to protect the public or to reduce harm, thereby connecting drug policy with the domains of public safety and health care policy, each of which is itself a wicked problem context.

A significant aspect of the drug policy problem has to do with how drugs are understood and represented, i.e., whether they are considered therapeutic

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49 Kickbusch and. Buckett, 2010, 3.

50 Evashkevich and Fitzgerald, *op. cit.*, 8-41.

51 Hoffman et al., 2012, 6.

52 Lancaster et al., 2014, 147.

53 Here we use the term 'drug policy' as shorthand for policies that address the various social dimensions of drugs, including production, distribution, and consumption on the one hand, and also definition, classification and social construction on the other. On the latter, see for example Tupper, *op. cit.*

54 Mosher and Akins, 2007, x.

55 A view typified by the "harm reduction" approach: "'Harm Reduction' refers to policies, programmes and practices that aim primarily to reduce the adverse health, social and economic consequences of the use of legal and illegal psychoactive drugs without necessarily reducing drug consumption" (Harm Reduction International website, "What is harm reduction?").

medications, licit but (somewhat) innocuous substances, or illicit and/or harmful "drugs".[56] Such representations are anything but stable, as they are social constructions that depend on policy imperatives and perceived social problems as much as from advances in scientific knowledge. Since the late 19th century, various substances have crossed the boundary from the category of therapeutic to that of illicit and harmful (e.g., marijuana, cocaine, MDMA), others have crossed from licit but innocuous to the illicit and harmful, still others have crossed from licit but innocuous to harmful (but still licit) (e.g., tobacco, alcohol). It seems that fewer substances have been able to make the reverse journey (although recent changes in the way marijuana is represented and understood suggest that it is in the process of crossing back to the therapeutic).[57]

As this brief discussion already shows, even the categories of substances are problematic, since the legal status of a substance does not necessarily correspond to the level of risk associated with it. In the present context, this is evident with prescription opioids (licit but high-risk) as compared to, say, marijuana (illicit but lower risk). Adding further complexity is the different categorization afforded to members of the same family or class of substances, as is the case with heroin (illicit, highly harmful) and morphine (therapeutic medication). Furthermore, as the previous example suggests, both legal status and degree of harm can be represented as intrinsic to a substance or as attendant upon context and nature of use. Prescription medications have been represented as having a low risk of harm if "used as directed" (i.e., with a prescription, following a doctor's orders, etc.), although this has often turned out not to be the case. It should also be noted that the qualification "prescription" is ambiguous since, depending on context, it may either refer to a specific substance (i.e., one that is generally unavailable except in a formulation for prescription), or to pharmaceutical origin of a substance in a particular form, such as fentanyl for injection, that is also available from non-pharmaceutical origins (e.g., clandestine laboratories) or in other forms.[58]

Such categorizations or classifications involve value judgements, attaching to roles played in the understanding of such substances and the devising of policies about them. Rogers et al. put this succinctly:

> Given that all psychotropic agents (prescribed or recreational, legal or illicit) expose their recipients to biological, psychological and social risks, value judgements are made and applied, by those with the power to do so, to divide 'right' from 'wrong' drugs…The social-cognitive reallocation of a

[56] Tupper, *op. cit.*

[57] Indeed, Carter et al. argue that "[c]annabis and its active ingredients, cannabinoids, are a much safer therapeutic option" than "prescription opioids" (Carter et al., 2015, 13). For an overview of "political, legislative, commercial and social developments relating to cannabis" (x), see European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), 2008.

[58] Once again, the case of "medical" marijuana blurs all of these distinctions.

> psychotropic agent from one category to another disrupts existing norms and so creates a risk to norm maintenance.[59]

Yet another problematic dimension of drug policy is how to categorize types of *use*. Disagreement and confusion exists about categories such as misuse, extra-medical use, non-adherent use, recreational use, abuse (a term which seems to be falling somewhat out of favour, at least in some medical circles), and even use *per se*.[60] In some cases, this is associated with the reason or motivation for use. For example, taking prescription opioids for pain is considered acceptable, whereas taking them for their euphoric properties is not, although taking anxiolytics or anti-depressants to alter mood is considered medically (and socially) acceptable.[61] Along with use go different and labile categorizations of *user*, ranging from the neutral to the highly judgemental: user, misuser, non-medical user, recreational user, abuser, problem drug user (PDU), substance abuser, person who injects drugs (PWID), drug addict, drug fiend.[62] Representations of both context of and motivation for use, particularly non-medical types of use, can range along a continuum of what might be called "moralized" to "medicalized", i.e., viewing such use as some combination of individual choice, social determinants, or of physiological origin.[63]

A further layer of complexity comes from the difference in the profiles of various types of users, combined with the prevalence of different types of medications or substances available in different jurisdictions. With opioids, for example, amongst "licit users" are those who take prescription opioids for pain associated with cancer, those who take them for chronic non-cancer pain, and those who take them episodically for minor pain or other conditions (including non-prescription codeine for fever or cough). Amongst these "licit users" there may be those who are taking other medications under a prescription, such as benzodiazepines. In a slightly different category but licit users nevertheless, are those who are prescribed opioids for opioid substitution therapy (OST) (also called opioid maintenance therapy (OMT) and methadone maintenance therapy (MMT)), i.e., to control the physiological dependence on opioids that has arisen from prior use (licit or illicit) of opioids (licit or illicit). Amongst the "illicit users" are those who take prescription opioids outside of a doctor's orders (i.e., without a prescription or not as directed), but for their (licit) therapeutic purpose (i.e., analgesia) (sometimes termed "extra-medical" users). Then there

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59 Rogers et al., 2007, 194.

60 See for instance Larance et al., 2011, 236-245.

61 Mosher and Akin, *op. cit.*

62 See, for example, Seddon, 2011. Even the term "user" is problematic, since in much of the literature it already connotes non-medical or illicit use, as opposed to "patients" who take such medications under a doctor's prescription (and as directed).

63 See, for example, Seddon, 2010, which traces the relationship between conceptions of freedom and addiction in the evolution of Western liberalism from the 18th century onwards.

are "non-medical users", who may use both prescription and non-prescription (i.e., illicit) opioids for non-therapeutic reasons (i.e., for their euphoric effects). Which particular substances are involved is highly dependent on drug policy regime and geographic location.

Such distinctions – substances, use, users – are anything but theoretical, as their consequences can be significant. For example, the distinction between cocaine and crack cocaine, introduced into US legislation as a response to the apparent crack "epidemic", involved much harsher penalties for possession of the latter, including mandatory minimum sentences, and at a different quantity (a 100:1 ratio by weight of cocaine to crack).[64] And classification of an individual "appearing in an English magistrates' court" as a PDU could mean "that the usual presumption in favour of bail is reversed".[65]

The notion of harm is yet another contested area in the drug policy (and public health) domain, since there is disagreement as to what constitutes harm. It is relatively straightforward to categorize fatal overdose as harm, but longer-term effects may be harder to categorize. As well, there is also the issue of balance between different harms, such as between the physiological dependence that can result from long-term prescription opioid use and control of cancer-related pain. The prevalence of harm resulting from medications, substances and drugs is another area that is also often socially constructed, with regular appearances of "epidemic" and "crisis" being related to the increased occurrence (or increased awareness) of adverse events, particularly overdose and treatment-seeking.

The final aspect to be mentioned here is the disagreement over how drug policy should best respond to these issues, ranging from punitive, prohibitionist approaches to medicalized, harm reduction approaches, and including combinations thereof, such as Vancouver's Four-Pillar Approach.[66] Because of the complexities already mentioned, and the political urgencies to which they sometimes give rise, drug policies can often end up as contradictory, if not incoherent.

Thus, drug policy is intractable because, as a complex issue, it fails to be amenable to simple solutions. Not only are there disagreements as to how best to address the issue (i.e., the 'solutions'), there are disagreements as to what exactly the 'problem' is (i.e., protecting the public, minimizing risk, reducing harm, etc.). As with many social issues, this makes drug policy a 'wicked problem'.[67] Its status as such is exacerbated, or magnified, by the fact that it lies at the nexus

64 Ahrens, 2013, 403.

65 Seddon, 2011, 339.

66 MacPherson, 2001.

67 APSC, *op. cit.*; McGuffog, *op. cit.*, 19-20; Alford and Head, *op. cit.*

of two different areas of social concern, namely health care and public safety, both of which are domains of wicked problems themselves.[68]

What's the Nature of Your Emergency? Public Safety as a Wicked Issue

> Among public safety agencies...EMS is often regarded as a secondary service, with police and fire taking more prominent roles; within medicine, EMS personnel often lack the respect accorded other professionals, such as physicians and nurses.[69]

How is public safety a wicked issue? The concept of public safety is broad, encompassing a range of situations that pose risks to human security, whether at the local, regional or national level. For example, the mandate of Public Safety Canada, the federal department responsible for public safety, "is to keep Canadians safe from a range of risks such as natural disasters, crime and terrorism".[70] In this regard, the department works with agencies such as the Canada Border Services Agency, the Canadian Security Intelligence Service, and the Royal Canadian Mounted Police (RCMP). However, as its website states, it "also work[s] with other levels of government, first responders, community groups, the private sector and other nations".[71] First responders "such as medical professionals and hospitals, fire departments, the police and municipalities" (and, we would add, emergency medical services) are centrally involved in emergency management "at the local level".[72]

A similar concept at the local level is that of 'community safety'. Although this is sometimes viewed in a narrower sense as concerned primarily with prevention or mitigation of, and protection from, crime and other kinds of disorder, it can also be understood in a broader sense. For example, along with Correctional and Policing Services, the responsibilities of Ontario's Ministry of Community Safety and Correctional Services include Public Safety and Security, whereby the Ministry "maintains the physical and economic security of Ontario, by coordinating public safety initiatives among municipal, fire and emergency services organizations" and "delivers programs and fosters partnerships to minimize or eliminate hazards to persons or property".[73]

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68 "Public safety activities, such as anti-terrorism, law enforcement, fire control and emergency medical, are ill-defined and unsolvable 'wicked problems'...", Tomasino, 2011, 1350; see also Ferlie et al., 2013, 30.

69 Committee on the Future of Emergency Care in the United States Health System, 2007, 4.

70 Public Safety Canada website, "About Public Safety Canada".

71 *Ibid.*

72 Public Safety Canada website, "Emergency Management".

73 Ontario Ministry of Community Safety and Correctional Services website, "Ministry Information".

Because of the broad range and complexity of the issues that public or community safety encompasses, the different types of information involved, the diversity of agents it engages, and the different values and perspectives these agents bring to the range of issues, there is ongoing disagreement about public safety,[74] e.g., whether certain issues properly belong within its domain, such as mental health or homelessness, the extent to which it requires limiting certain individual freedoms or civil rights (and, correlative to this, the extent of the powers public safety official and agencies should be granted), and the degree to which public safety organizations should be oriented towards exceptional events such as natural disasters or terrorist attacks.[75] These aspects, we would argue, suggest that public safety qualifies as a wicked issue. For this reason, as Tomasino points out, networks of public safety agencies "tend to re-solve their problems by restructuring based on reactions to critical safety events or the exertions of member agencies with the greatest power".[76]

Here we wish to narrow our focus to the three primary emergency response services involved in community safety – police, fire, and EMS – to look at the current challenges these agencies face as a result of social, institutional and technical changes over the last few decades, and the policy responses and professional changes that have resulted. An in-depth discussion of these challenges is beyond the scope of this paper. Our aim, rather, is to look at some of the key points at issue for these different services, and to argue that the challenges they face, particularly in the context of the wicked issue of public or community safety, highlight the need for better collaboration, both at the operational level and at the policy-making level. As one study of these three agencies put it,

> To build an effective response to the increasing complexity, the literature recognizes that multi-agency collaboration is a critical ingredient of overall community resilience, and that collaborative partnerships now serve as a new standard for addressing community problems...Furthermore, existing literature advocates that the effectiveness of responder institutions to solve community problems is a direct consequence of the inter-organizational relationships and arrangements within a multi-organizational domain...[77]

First, however, it is important to recognize that, although paramedics and EMS in North America have evolved over the past half-century to become more aligned with health services, they are still a key component of public or community safety.[78] As the Committee on the Future of Emergency Care in the United States Health System stated in 2007, "EMS has one foot in the

74 Tomasino, *op. cit.*, 1353.

75 Head and Alford, 2015, 715.

76 *Ibid.*

77 Murray, 2015, 2.

78 Evashkevich and Fitzgerald, *op. cit.*, 44.

public safety realm and one foot in medical care".[79] Indeed, it could be argued that this hybrid identity itself is a factor in the wickedness of the issue of public safety, insofar as it concerns emergency response services, since it serves to obscure the differences between the three services, particular between fire and EMS.[80] Of course, the hybridity of paramedics' professional identity is a result of just those social changes and policy responses referred to above.

Of particular interest here is how fire departments and, to a lesser extent, police departments, are facing challenges to what could be taken to be their "core mission", in terms of the amount of time they spend on various types of response. Most significant is the reduction in fire call outs, i.e., the percentage of emergency calls received by (or dispatched to) fire departments that are actually fire-related. Police departments are facing a similar, though less pronounced, shift in call outs from crime-related to other types, particularly mental health-related. These shifts present a challenge both to departments and individual practitioners, who may find themselves routinely engaged in providing services for which they are not well trained, and which they do not view as appropriate or desirable activities.

Fire and EMS

> Fire-based systems across the United States are in transition. The number of fires is decreasing while the number of EMS calls is increasing, raising questions about system design and resource allocation.[81]

Of the three emergency response services, North American fire departments have seen the most significant shift in the type of emergency calls to which they respond. National data are unavailable for Canada, but are collected in the U.S. by the National Fire Protection Association (NFPA) through a survey of approximately 10 percent of the country's fire departments. The NFPA's survey for 2014 showed an increase of 4.7 percent in the total number of fire incidents over the previous year,[82] but this was a slight uptick in what has essentially been an ongoing decrease in such incidents since 1977. Over that period, total fire incidents have decreased 60 percent.[83]

There are no publicly available national level data for Canada on fire incidents and emergency calls to fire departments. Some data on fire incidents

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79 Committee on the Future of Emergency Care in the United States Health System, *op. cit.*, xvii.

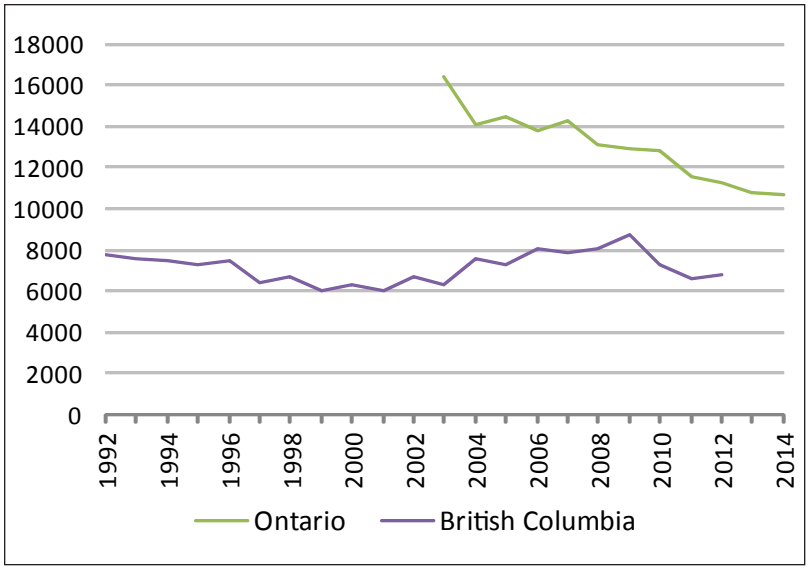
80 The origins of North American EMS systems in fire departments, as an enhancement of their rescue capabilities, also contributes to a lack of distinction between the services on the part of the public.

81 Committee on the Future of Emergency Care in the United States Health System, *op. cit.*, 2.

82 Haynes, 2015, 8.

83 *Ibid.*, 11.

are available at the provincial level. Figure 1 shows the number of loss fire incidents[84] in BC (1992–2012) and Ontario (2003–2014). Interestingly, whereas over an 11-year period such incidents declined by 34.8 percent in Ontario (a greater decrease than in the US over the same period, which was 18.1 percent), they have remained virtually flat in BC over a 21-year period.[85] A study done in 2014 reported that the incidence of fires in BC had decreased from 1.34 per 1000 residents in 2004 to 0.91 in 2013, or 32.1 percent.[86] These decreases in the number of fire incidents are likely due to regulatory changes pertaining to fire safety standards, such as building codes, sprinkler systems, and smoke alarm installation, as well as fire prevention and education efforts on the part of fire departments and officials.[87]



Source: Office of the Fire Marshal, Ontario; Office of the Fire Commissioner, British Columbia

Figure 1. Loss Fires in Ontario and British Columbia

In terms of the services that fire departments provide, and the different types of calls they respond to, data from the U.S. Fire Administration's National Fire Department Census show that, of the "27,198 fire departments registered" (which amounts to "91 percent of all U.S. fire departments"), 15,759 or 58 percent provide Basic Life Support services, 10,342 or 38 percent provide EMS without transport, 5,588 or 20.6 percent provide EMS with ambulance transport and 5,593 or 20.6 percent provide Advanced Life Support. [88] In the

84 "A loss fire is a fire with an injury, fatality or estimated $ loss." Ontario Ministry of Community Safety and Correctional Services website, "Ontario Fire Incident Summary".

85 This may be due to wildfires, which are more frequent in BC than in Ontario.

86 Dow, September 2014, 4.

87 Performance Concepts Consulting, 2011, 2. However, it should be pointed out that other changes in the building industry, such as residential layout and type of materials used, have reduced the time in which structure fires spread. (Pomax, 2013, 9.)

88 U.S. Fire Administration website, "National Fire Department Census quick facts".

US, many EMS systems are in fact fire-based (around 40 percent), whereas such joint or integrated services are relatively rare in Canada, the cities of Lethbridge and Red Deer in Alberta, and Brandon, Thompson and Winnipeg in Manitoba being some of the exceptions.[89] In recent years various fire organizations (unions, associations and fire departments) have expressed a desire to be endorsed for a wider range of medical interventions, for a number of reasons, including the declining percentage of fire call outs, the high workload faced by EMS systems, and changes to the EMS dispatch system. We look at each of these in turn. However, a 2013 study of the Toronto Fire and EMS systems was "unable to find literature that provides evidence of a fire-EMS model being financially, operationally or organizationally superior to the model Toronto currently enjoys [i.e., separate services]".[90]

According to the NFPA, in 2014 "[f]ires accounted for only four percent of the 31,644,500 total calls...64 percent of the calls were for aid such as EMS".[91] *EMS at the Crossroads* puts this number (in 2007) even higher: "an estimated 80 percent of fire service calls are now EMS related".[92] A recent study of Ontario EMS/Fire tiered response noted that "the Fire Marshall has recently reported that 41% of all urban fire department calls in Ontario are medical tiered responses – the single largest component of total fire department call volumes",[93] although a report on the Toronto Fire Services indicated that for this municipality medical calls amounted to 58 percent of all calls in 2011 based on outcome, whereas false alarms and fires amounted to 14 percent and 1.4 percent, respectively.[94] Other non-fire emergency calls include incidents such as floods, gas leaks, hazardous materials, rescue and electrical emergencies, for which fire departments are the first point of call, and in which they have training and expertise.[95]

Despite the fact that EMS-related calls constitute a large (and growing) proportion of fire departments' call volumes, such calls are only a small proportion of total EMS calls. As one study stated, in Ontario (as of 2011) "EMS call volumes are always significantly higher than Fire call volumes, and Fire call volumes are composed of a growing proportion of emergency medical calls and a declining proportion of actual structure fires".[96]

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89 See Braedley, 2015.

90 Pomax, *op. cit.*, 109.

91 *Ibid.*, Abstract.

92 Committee on the Future of Emergency Care in the United States Health System, *op. cit.*, 2.

93 Performance Concepts Consulting, *op. cit.*, iii.

94 Pomax, *op. cit.*, 25, 242.

95 *Ibid.*, 17, 20.

96 Performance Concepts Consulting, *op. cit.*, 3.

Fire First Responder System

> The original intention of the first responder system was for TFS [Toronto Fire Services] to provide needed time-critical interventions for the few additional minutes that it might take TEMS [Toronto EMS] to arrive. It is an appropriate supplement to EMS response of time-critical emergencies.[97]

It is also of interest to look at the *types* of EMS-related calls to which fire departments respond, particularly because this has recently changed in some jurisdictions (e.g., Toronto in 2012, BC in 2013[98]), and is one of the root causes of present disagreement between fire and EMS services.

Unlike EMS, fire department emergency response is predominantly if not exclusively station-based. Because of fire response requirements (discussion of which is beyond the scope of this paper), fire departments tend to have capacity available for EMS response:

> ...fire services are often available for calls; stations aren't constantly active or responding to incidents which means that the capacity available, while waiting for a core fire incident to occur, can be used to respond to medical emergencies.[99]

EMS agencies, on the other hand, are more likely to use "fluid deployment", in which ambulances respond from hospitals or mobile locations rather than ambulance stations.[100] As a result, the response times to medical emergency calls by fire and EMS services are rather different. For example, in Toronto

> The TFS arrives at Echo and Delta events [the highest tier or most urgent] before TEMS 67 percent of the time (although EMS reaches the scene within 2 minutes of the fire service in just over 60% of the cases when fire arrives first).[101]

Response times for fire and EMS services differ, partly due to the nature of their deployment, and partly due to the way they are dispatched. The 2014 Ontario Municipal CAO's Benchmarking Initiative report indicates that median response time for fire services across nine municipalities was 6:45 min for urban response and 14:02 min for rural response, whereas the median percentage for ambulance crews arriving on scene within 8 minutes was 76 percent for patients categorized as CTAS 1.[102] These figures are not easily

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97 Pomax, *op. cit.*, 121.

98 *Ibid.*, 21.

99 *Ibid.*, 18.

100 *Ibid.*, 78.

101 *Ibid.*, 120.

102 Ontario Municipal CAO's Benchmarking Initiative, 2016, 44, 57. CTAS 1 is the Canadian Triage and Acuity Scale categorization for those patients with more severe presenting signs and symptoms.

comparable, nor are response times in general for the two services, since they use different metrics. Nevertheless, they do suggest that fire first responders may well be on scene before EMS, even in CTAS 1 calls.

A 1999 study of the Vancouver Fire and Rescue Service (VFRS) indicated that "fire department first responders...were dispatched code 3 (lights and sirens) in 54% of cases" of EMS-related calls,[103] whereas in a study for the Surrey Fire Service, 2013-14 data for twelve municipalities in Metro Vancouver indicate that medical calls involving first responders amounted to between 28.0 and 66.6 percent of all calls, depending on the particular municipality, for an average of 52 percent.[104] Prior to the BCEHS Resource Allocation Plan (RAP) changes in 2013, which downgraded 74 incident calls from Code 3 (lights and sirens) to Code 2 (routine),[105] the average FR response time for all medical calls in eight Metro Vancouver municipalities was 5:40 minutes, whereas the ambulance response time was 10:50 minutes, resulting in an average wait time by FRs of 5:10 minutes. Subsequent changes in emergency medical dispatch lengthened the average ambulance response time somewhat, resulting in an average FR wait time of 6:32 minutes. [106] However, these data do not distinguish between types of calls. Data specific to the Surrey Fire Department show that the FR wait time for the remaining Code 3 calls was reduced by 33 seconds on average and 1:05 minutes at the 90th percentile, but increased by 5:43 and 11:48 for the downgraded calls, respectively.[107]

It is of note that several municipalities in BC have objected to the implementation of the BCEHS RAP, particularly regarding the process whereby this was effected. Two resolutions (B50 and C2) in the Union of BC Municipalities (UBCM) 2014 Resolution Book explicitly refer to the "unilateral decision" on the part of the Provincial Health Services Authority (PHSA)[108] or BCAS, taken "without consultation with local government".[109] Both resolutions expressed concern about the impact of the changes to first responder protocols on local community needs. Resolution C2 was referred to B50, which was endorsed at the conference.[110]

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103 Berringer et al., 1999, 94.

104 Dow, *op. cit.*, 6.

105 *Ibid.*, 1; Dow, April 2014.

106 Dow, September 2014, 7.

107 Dow, April 2014, 2. These averages appear to hold across the province, according the Ministry of Health's response to the 2014 UBCM resolution B50 (see below) (British Columbia Ministry of Community, Sport and Cultural Development, 2015, 63.

108 Union of BC Municipalities (UBCM), 2014, 126.

109 *Ibid.*, 193.

110 UBCM, n.d.

A further aspect of this changing role, and one that is particularly relevant to the specific problem of opioid overdose, is that fire first responders are often the first on scene for EMS calls, with varying wait times until the arrival of paramedics, yet there is evidence that the care they provide is not highly effective. This is a concern in patient conditions where timely intervention is of the essence:

> For patients who cannot breathe, are in hemorrhagic shock, or are in cardiac arrest, the decisions made and actions taken by EMS personnel may determine the outcome as much as the subsequent hospital-based care – and may mean the difference between life and death.[111]

However, as pointed out in a review of the BCEHS RAP,

> ...short EMS response times, including the extensive use of first responders to shorten that time, were previously considered universally beneficial to patients. There is now a formal consensus among EMS physicians that short response times alter patient outcome in only cardiac arrest, respiratory arrest and total airway obstruction, conditions found in less than 1% of all EMS responses.[112]

Further on, this same review states that

> Dispatching first responders (fire apparatus, police or others) is most beneficial where the specific time-sensitive interventions available from these responders (CPR, automated defibrillation, and bag-mask ventilation) are most likely to be needed. At present, there is limited scientific evidence of outcome benefit from first response beyond these most urgent incidents.[113]

There have been few studies of fire first responder outcomes and effectiveness. The 1999 study of VFRS examined the Code 3 calls for which VFRS first responders were first on the scene during the study period, and found that "first responders performed primary critical interventions...during only 133 (37%) of 362 calls when they arrived first on scene, or 18% of the 743 code 3 calls studied".[114] Because first responder interventions were so limited, and wait times between fire and EMS arrival were relatively brief, the study authors concluded that "it seems an unnecessary and potentially dangerous duplication of services to routinely dispatch both a fire apparatus and an ambulance code 3".[115] More significant than the low frequency, however, was the fact that the

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111 Committee on the Future of Emergency Care in the United States Health System, *op. cit.*, 1.

112 Craig, 2014, 5.

113 *Ibid.*, 16.

114 Berringer et al., *op. cit.*, 95-96. Interestingly, because "the busiest two fire halls in [the] study were in close proximity to the downtown east side of Vancouver", overdose, collapse and seizure constituted 49 percent of all calls (97).

115 *Ibid.*, 97.

fire first responder intervention that was performed the most frequently (oxygen administration), was performed inappropriately 33-35 percent of the time.[116]

A modeling study of the Toronto EMS dispatch system in 2008 estimated that "[f]irefighter first response was warranted in 3,067 (1.4%) of the 220,358 incidents".[117] More recently, a retrospective study conducted on "electronic patient care records from a single ambulance service and two municipal fire departments that partner to provide emergency response in two suburbs of Minneapolis, Minnesota" over a 2.5 year time period showed that "EMRFs arrived first in 9,001 calls (88%) with an average lead time of 4.5 minutes".[118] These firefighters had received "advanced clinical training beyond the standard EMR level and are dispatched to all medical calls regardless of acuity".[119] Their training included "six advanced skills...intravenous line placement, administration of oral nitroglycerin and aspirin for chest pain, placement of supraglottic airways...administration of albuterol via nebulizer, injection of intramuscular glucagon, and injection of epinephrine".[120] However, although these EMRFs "used at least one of the six advanced clinical skills in 7.6% of patient encounters", they performed "traditional EMR skills known to be time-sensitive and critical for survival – namely chest compressions, defibrillation with an AED, basic airway management, and bleeding control – in 1.7% of encounters".[121] From this data, the study authors concluded that

> EMRF training should focus on ensuring that BLS resuscitation interventions are applied fervently and consistently in all cardiac arrest patients before progressing to advanced skills whose clinical significance in the hands of EMRs has not been demonstrated.[122]

Finally, the OPALS study in Ontario, "a large, multicenter, controlled clinical trial conducted in a prehospital setting",[123] looked at advanced life support interventions in cases of cardiac arrest, respiratory distress and major trauma.[124] The findings from the various aspects of this study were that, in the case of cardiac arrest,

> the systematic introduction of full advanced-life-support programs to an emergency-medical-services system that had previously optimized its rapid-

116 *Ibid.*

117 Craig et al., 2010, 112.

118 Boland et al., 2015, 96.

119 *Ibid.*, 97.

120 *Ibid.*

121 *Ibid.*, 100.

122 *Ibid.*, 101.

123 Stiell, Wells et al., 2004, 648.

124 Such interventions "include advanced airway management (endotracheal intubation) and intravenous fluid therapy", as opposed to basic emergency medical care, in which providers "administer oxygen, ventilate with a bag valve mask, and provide immobilization and dressings" (Stiell et al., 2008, 1141).

> defibrillation program did not decrease mortality or morbidity associated with cardiac arrest...In order to save lives, and to do so efficiently, public health planners should make CPR by bystanders and a rapid defibrillation response major priorities for the allocation of resources.[125]

Similarly, in the case of major trauma, "the systemwide implementation of prehospital advanced life-support did not decrease mortality or morbidity among major trauma victims".[126] However, for respiratory distress, the OPALS study did show "that the introduction of an EMS advanced-life-support program and interventions for symptom relief significantly reduced mortality",[127] although it was unclear what the specific mechanisms were that led to this outcome.

In summary, the best available evidence indicates that prehospital interventions beyond basic emergency medical care do not lead to improved clinical outcomes in most situations, whereas consistent application of basic emergency medical care interventions does, particularly with CPR, defibrillation and rescue breathing. Furthermore, determining whether interventions beyond BLS are warranted in the prehospital situation itself requires advanced life support training and experience. However, as the TFS/TEMS study cited above points out, "[e]xperience shows that the ALS *intervention* with the largest impact on patient care is appropriate critical clinical decision making."[128]

This same study reported on an "unpublished trial involving qualified fire first responders at the Surrey Fire Department in British Columbia...and the BC Emergency and Health Services Commission", the goal of which

> was to determine whether a fire department response – without a concurrent EMS response to some motor vehicle accidents, and firefighter determination as to whether an ambulance was in fact required – would be clinically safe.[129]

The trial was discontinued for patient safety reasons, as it was determined that firefighters at both the FR and EMR levels "did not possess the clinical interpretive skills required to consistently and safely determine that patient medical care was not required".[130]

In terms of firefighters themselves, a study of firefighters' perceptions of their contemporary role found that one of the "most resounding themes is that the work of the fire service has changed radically in recent years", because "[t]he fire service is...engaged in activities far beyond fire prevention and control,

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125 *Ibid.*, 655.

126 Stiell, Nesbitt et al., 2008, 1148.

127 Stiell, Spaite et al., 2007, 2164.

128 Pomax, *op. cit.*, 65.

129 *Ibid.*, 114.

130 *Ibid.*

performing social and medical functions that are key to supporting the public's health." Despite the fact that "the fire service has become an important out-of-hospital source of emergency medical care", the firefighters surveyed reported "high occupational stress, low morale, and desensitization to community needs" because departmental protocols require them to treat each call as an emergency, but there is a "high volume of low-acuity calls". Study participants expressed dissatisfaction with not being able to use their specialized skills, and in some cases even resentment towards frequent 9-1-1 non-emergent callers, although many did recognize that "community residents rely on emergency departments for primary care and on the 9-1-1 system for "free" ambulance transport to the hospital. Firefighters often acknowledged that poverty was a root cause of the community challenges they respond to daily." [131]

The decline in the number of fire incidents combined with the ratio of fire-related calls to EMS calls to which fire departments respond suggests that fire departments, as key organizations involved in community safety, are facing an ongoing transformation in the relevance of their service delivery and, therefore, the role they play in community safety. In such a situation, where the overarching issue of community safety is ill-defined and roles are becoming more fluid, a collaborative approach to emergency response would seem warranted and professionally prudent. However, in BC, jurisdictional differences complicate this, since EMS is provided at the provincial level, whereas fire departments are the responsibility of municipalities. This is further compounded by the variety of policing services in the province, to which we now turn.

Police and EMS

Compared to fire-EMS interaction, there is much less information available on police-EMS interaction, possibly because there is much less overlap between the responsibilities of these two agencies. The contemporary configuration of the police as an organization devoted to fighting crime[132] means that its public or community safety role is much narrower than that of fire, with correlatively fewer areas of interaction with EMS, particularly in the role of first responders.[133]

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131 Cannuscio et al., 2015.

132 Braithwaite, 2008, 12.

133 One interesting exception to this is the role of the tactical paramedic, a paramedic with specialized training for tactical response situations who functions as an integral member of a police tactical response team. In BC, such paramedics work in the Integrated Tactical Support Unit (APBC website, "Integrated Tactical Support Unit").

The structure of policing in BC is different from those of fire and EMS. Whereas fire is a municipal responsibility, and EMS a provincial responsibility delivered on a province-wide level, police services are a shared responsibility between the federal, provincial and municipal governments. Under the *Police Act*, any municipality with a population of 5,000 and above is responsible for providing police services. At present, there are 75 such municipalities, 12 of which have their own police departments and 63 which "contract with the province for RCMP municipal police services".[134] First Nations policing is effected through Community Tripartite Agreements with the federal and provincial government; one First Nation administers its own police service, the Stl'atl'imx Tribal Police Service.[135] Other municipal and provincial policing is done by the RCMP (E-Division) through the *Provincial Police Service Agreement*. Federal policing is also done by the RCMP.[136]

Although police are less centrally involved in emergency medical response, the de-institutionalization of mental health patients has created an environment in which an increasing number of police calls involve individuals with mental health issues.[137] As a Parliamentary Committee report put it,

> Law enforcement agencies have become the social and mental health services of first resort. The Committee heard that 70% to 80% of the calls police now receive are not related to crime.[138]

In testimony to this Committee, the Chief Constable of the Vancouver Police Department "explained that city-wide, up to 30% of calls are related to mental health and in certain areas of the city having more persons addicted to drugs, they constituted up to half of the calls".[139]

In the context of this paper, the crime prevention and law enforcement functions of the police create an obstacle to emergency calls for drug overdoses. In cases where such overdoses are due to illicit use of drugs, there is evidence that bystanders are reluctant to call 911 out of fear of criminal sanctions if police respond to the call.[140] Such reluctance has been one of the motivating factors in the spread of take-home naloxone programs. Another mitigating strategy has been the enactment of specific "Good Samaritan" laws that shield 911 callers from criminal prosecution for drug possession and sometimes other

134 Government of British Columbia website, "Municipal Policing".

135 Government of British Columbia website, "Structure of Police Services in First Nation Communities".

136 Government of British Columbia website, "Municipal Policing".

137 Mazowita and Greenland, 2015, 4.

138 Canada. Parliament. House of Commons. Standing Committee on Public Safety and National Security, May 2014, 15. See also Council of Canadian Academies, 2014, 31-33.

139 Canada. Parliament, *op. cit.*, 15-16.

140 Darke, 2014, 111-112.

minor infractions. For example, as of September 2015, 35 states in the U.S. had passed such laws.[141]

Is FR/EMR Administration of Naloxone a Wicked Problem?

> I suppose it is tempting, if the only tool you have is a hammer, to treat everything as if it were a nail.[142]

Given our discussion, the question arises whether the administration of naloxone by first responders is really a wicked issue. As will be discussed below, naloxone is considered to be very safe, with few if any effects on a non-opioid user and, except in relatively rare cases, few life-threatening or injurious effects on opioid users. Combined with its effective reversal of opioid overdose, then, it might appear that this is actually an example of a *tame* problem, not a wicked one.

However, as this report aims to show, the apparent tameness of this issue is a result of viewing it from a narrow physiological or pharmacological perspective, one that takes into account only the physiological condition of the suspected opioid overdose patient and the pharmacological action of naloxone administration, and ignores or overlooks the *context* in which such administrations occur. But context is integral to the wickedness of issues or problems. As Rittel and Webber pointed out, "[o]ne cannot understand the problem without knowing about its context".[143] Thus, it makes a difference whether the suspected opioid-overdose patient is an injecting drug user or an elderly cancer patient, whether she is found in the back room at a party or in her bed at home, whether she had any prior exposure to opioids, whether she is on any other medication, etc.

Furthermore, it makes a significant difference whether the individual responding to the emergency has the training and clinical skills such that she can distinguish between opioid overdose, diabetic coma, or other condition and the equipment and medications at hand to provide prehospital treatment for a wide range of conditions, including those that might result from the administration of various forms of treatment, or has only one medication in her toolkit. The danger being, of course, that if the only medication you have is naloxone, it is tempting to treat everything as if it were an opioid overdose, with the further danger that in concentrating on naloxone, FRs and EMRs may well pay less attention to ventilation and airway support, basic life support measures that are effective in *all* forms of induced respiratory depression, not just those that are opioid-induced.

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141 The Network for Public Health Law, 2015, 2.

142 Maslow, 2002, 15.

143 Rittel and Webber, *op. cit.*, 162.

Opioids

This chapter provides an overview of the history of the use and discovery of opioids, their pharmacology, and statistics on their global and regional prevalence and use.

A Brief History of Opioids

> Opioids play a unique role in society. They are widely feared compounds, which are associated with abuse, addiction and the dire consequences of diversion; they are also essential medications, the most effective drugs for the relief of pain and suffering.[144]

Knowledge about the analgesic and euphoric properties of the opium poppy, *Papaver sominferum*, goes back to at least 3400 BCE, when it was cultivated by the Sumerians in Mesopotamia,[145] although there is archeological evidence that it may have been familiar to *homo neanderthalensis* as far back as 30,000 years.[146] Sumerian written records describe the harvesting of poppy juice and the production of opium.[147] Subsequently, use of opium spread throughout Mesopotamia and to Egypt, and is mentioned in the writings of Hippocrates (4th-5th century BCE) in ancient Greece.[148] It was also available in the Roman Empire. Widespread in the Arab Empire from the 7th century CE onwards, Arab traders brought knowledge of the medicinal uses of the opium poppy to the Chinese,[149] although evidence suggests it had already been cultivated and used in India for centuries.[150]

Europe was reintroduced to opium through the work of the Swiss philosopher-physician Paracelsus (also considered to be the founder of modern chemistry and toxicology[151]) in the 16th century CE, who discovered (or possibly encountered during his travels) that opium dissolved better in alcohol than in water, and developed a tincture of opium he called "laudanum".[152] An English

144 Rosenblum et al., 2008, 405

145 Trescot, 2015, 99. The Sumerians called it *hul gil*, the "joy plant". See also Brownstein, 1993, 5391.

146 Mann, 2004, 139.

147 Schiff, Jr.., 2002, 186.

148 *Ibid.*

149 *Ibid.*, 187.

150 Brownstein, *op. cit.*

151 Borzelleca, 2000, 2.

152 Schiff, Jr., *op. cit.*, 187; Stannard et al., 2013, 1.

physician, Thomas Sydenham, introduced laudanum into Britain as a remedy for a variety of conditions, including pain, insomnia and diarrhea.[153]

The modern history of substances derived from opium started at the beginning 19th century CE, when a German pharmacist, Friedrich Wilhelm Adam Sertürner, isolated one of the key active components (now called "alkaloids") in opium, a substance he named *morphium*.[154] Although other opium alkaloids were also isolated in the 19th century (e.g., noscapine/narcotine in 1827, codeine in 1833, papaverine in 1848[155]), these were either weaker analgesics than morphine (as it came to be called), or had no evident analgesic effect. Morphine was therefore the dominant analgesic throughout the 19th century. It was first commercially manufactured in 1827, by E. Merck & Co. of Darmstadt, Germany, and figured prominently in the treatment of injured soldiers in the American Civil War (1861-65) and the Franco-Prussian War (1870-71). Morphine was used to such an extent in the former that it resulted in widespread addiction or dependence among soldiers, which came to be called "soldiers' disease".[156]

The development of new opioids[157] accelerated towards the end of the 19th century, as pharmacological research became more intensive. One of the most significant discoveries was the acetylization of morphine in 1874, resulting in a compound called diacetylmorphine or diamorphine, later produced by the Bayer pharmaceutical company under the name "Heroin". Originally marketed as an analgesic less addictive than morphine (although stronger), as its use became widespread, it became evident that it was just as addictive, if not more so.[158] However, by the time Bayer withdrew heroin from the market and ceased

153 Schiff, Jr., *op. cit.*; Stannard et al., *op. cit.*

154 Schiff, Jr., *op. cit.*, 189; Brownstein, *op. cit.*

155 Schiff, Jr., *op. cit.*, 192-193.

156 *Ibid.*, 189.

157 The WHO defines "opioid" as "[t]he generic term applied to alkaloids from the opium poppy (*Papaver somniferum*), their synthetic analogues, and compounds synthesized in the body, which interact with the same specific receptors in the brain, have the capacity to relieve pain, and produce a sense of well-being (euphoria)" (WHO, 1994, 49) (although there are opioids such as naloxone that neither relieve pain nor induce euphoria). Originally, "opiates" referred to alkaloids contained in *Papaver somniferum* and the compounds synthesized from them, whereas "opioids" referred to entirely synthetic compounds (such as methadone and fentanyl) that have properties similar to opiates ("opiate analogues") and later also to chemicals produced by the body itself such as endorphins and enkephalins ("endogenous opioids") (OED Online, 2016). With respect to human physiology, both opiates and opioids bind to the same proteins in the central nervous system (CNS), which are called "opioid receptors". For this reason, "opiate" and "opioid" are often used interchangeably, although the latter has become the term conventionally used to refer to all such substances that have an effect on the opioid receptors regardless of origin (Trescot, *op. cit.*; Degenhardt et al., *op. cit.*, 4). We follow that convention in this report. Opioids produced for therapeutic purposes may be referred to as "pharmaceutical opioids", although this term does not distinguish between opiates and opioids (Degenhardt et al., *op. cit.*, viii).

158 Again, a terminological caveat is in order here. The connotation of the term "addiction" has undergone changes over the last century, and there is now a consensus that it should be distinguished from "dependence", which refers to the *physiological* impacts of exposure to psychoactive or metabolic substances, and is contrasted with *psychological* or *behavioural* impacts of such exposure. That is, a person who takes opioid pain medicine, for example, may develop a physiological dependence

production, the damage had been done. Since the production of heroin from morphine is not technically difficult (it was initially accomplished just by boiling a morphine solution), and given its greater potency (about which, see below) combined with efforts to interdict and disrupt the supply of both opium and heroin, the latter became a more popular illicit drug to import. That is, in terms of the value-per-weight ratio and the risk involved, importation of heroin into jurisdictions such as the US, which had banned both opium and heroin, was preferred on a cost-benefit basis.[159]

The last era that warrants attention in this rather brief historical discussion of opioids is one that can be thought of as the "pain management" era. As will be discussed below, prescription opioids are highly over-represented in the drug-consumption profile of the US and Canada, both relative to other countries and in absolute terms.[160] Since the same profile is not evident in other high-income countries (e.g., in Western Europe), this high rate of consumption cannot be solely attributed to the high income levels in the US and Canada. Rather, the difference seems to be more closely connected with the advent of "pain medicine" or "pain management" as a new medical subspecialty. Whatever the reasons, US and Canadian residents are prescribed and consume *prescription* opioids at a level unparalleled anywhere else. One of the factors in this situation is the availability of semi-synthetic and synthetic opioids that are more potent (often startlingly so) than morphine.[161] These began to appear during and after World War I, and include substances such as oxymorphone (1914), oxycodone (1917), hydrocodone (1920), hydromorphone (1926), methadone (1937-39), pethidine (1939), etorphin (1960) and fentanyl (1960). Part of the motivation for the development of such opioids was the desire to find substances with analgesic effects similar to morphine, but without the side-effects (particularly dependence and respiratory depression). However, this search has been unsuccessful to date.

Most opioids, particularly the synthetic opioids such as fentanyl, are listed on Schedule I of the UN Single Convention on Narcotic Drugs of 1961. A few weak opioids such as codeine are on the less restrictive Schedules II and III, whereas many of the analogues of fentanyl (e.g., α-methylfentanyl and β-

whereby ceasing to take such medicine results in withdrawal symptoms, but doesn't display any "addictive behaviour", i.e., what is in essence socially sanctioned behaviour related to consumption of such medicine, such as criminal activity.

159 This remains the case today. Data from the Canada Border Services Agency, Pacific region's Drug Seizure Report show that, in 2013, 48.6kg of heroin was seized, with an estimated value of $19.5 million, or $400/gm, whereas 3.4kg of opium was seized, with an estimated value of $204,000, or $60/gm (Tanner et al., 2014, 101).

160 Which is itself a matter of concern for those agencies such as the WHO (but also interestingly the UNODC and INCB, as discussed above), that are concerned with the social determinants of health and with health equity.

161 For example, when compared to morphine administration by the same route (e.g, IV), fentanyl can be anywhere from 40-100 times more potent. Etorphine is 1,000-3,000 times more potent.

hydroxyfentanyl) and other potent opioids such as etorphine are on the highly restrictive Schedule IV.[162]

In terms of the specific history of North America, it would be fair to say that the *licit* consumption of prescription opioids in general outweighs both the *illicit* consumption of such opioids and the consumption of non-prescription *illicit* opioids.[163] We return to this issue below, after a brief discussion about how opioid analgesics work (their *pharmacodynamics*), and how they are metabolised in the body (their *pharmacokinetics*).

Naloxone Hydrochloride

The final event on the opioid timeline that needs to be discussed is the synthesis of naloxone from oxymorphone, a semi-synthetic opioid derived from thebaine. This was accomplished by a US scientist, Jack Fishman, in 1960. Fishman's aim was to synthesize an opioid antagonist with better therapeutic properties than nalorphine, which was derived from morphine. Although nalorphine is an effective antagonist for opioid overdose, it has undesirable side-effects such as causing hallucinations and reduced respiration. After Fishman successfully synthesized naloxone, a second US scientist, Harold Blumberg, researched its biological properties and determined that it was a potent opioid antagonist. Subsequent research showed it to be an effective antagonist against a wide range of opioids, including even other opioid antagonists such as nalorphine. Aside from its therapeutic properties, naloxone was also central to the scientific work on endogenous opioids.[164]

Opioid Pharmacodynamics and Pharmacokinetics

Demonstration of the existence of an endogenous opioid system in the 1970s has transformed the understanding of the mechanisms of opioid activity.[165] Opioids act on a set of proteins called "opioid receptors" found in various parts of the central nervous system (CNS) and the peripheral nervous system, and mimic or reproduce the effects of the endogenous opioids, the endorphins, enkephalins and dynorphins, which are produced by the body itself.[166] Three opioid receptors, the μ-, δ- and κ-receptors, are primarily involved in opioid activity, in which opioid molecules bind to one or more of these receptors,

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162 United Nations, 2015.

163 Although it is, of course, inherently difficult to ascertain illicit use with a high degree of precision.

164 Garfield, 1983.

165 Pasternak, 2014, 198.

166 Gutstein and Akil, 2006, 547-548; Trescot, *op. cit.*, 99.

thereby producing analgesia and a range of other effects, including euphoria, nausea, drowsiness, constipation and respiratory depression. All three receptors seem to be associated with the analgesic effects of opioid agonists, whereas most other opioid effects are specific to one or two of them. Animal models indicate that the effect on respiratory function is associated with the μ-receptor alone. Morphine is selective for this receptor, as are most other clinically used opioids. [167]

The motivational (reward/aversion) effects of opioids, and hence their addictiveness, results from their activity in a region of the brain called the nucleus accumbens, and is related to the differential effects that activation of each of the three receptors has on the release of the neurotransmitter dopamine.[168] However, the details of these effects at the molecular level are beyond the scope of the present discussion.

In pharmacodynamic terms, activation of an opioid receptor results in the release of a protein that then affects other cellular processes, which can inhibit the activity of neurotransmitters such as the release of acetylcholine, norepinephrine and serotonin, resulting in analgesic and other effects. One of these effects is to increase the release of dopamine, which results in heightened pleasure sensations.[169] However, such effects are known to vary from person to person (and from opioid to opioid for the same person), due to genetic variability.[170] These effects may also vary depending on the physiological status of the person to whom they are administered. In particular, for individuals who are pain-free, the non-analgesic effects can be pronounced.[171] For individuals who have developed tolerance for opioids (e.g., through long-term administration due to chronic pain), the activation response may be much lower compared to an opioid-naive patient at the same dose level.

Opioids also differ pharmacokinetically, as some are metabolised at a much slower rate than others. For example, levorphanol can take up to 6 times longer than morphine to be metabolised, and methadone can take up to 12 times longer.[172]

There are a number of factors in the degree of opioid effect. Some of the most important are: (i) how strongly the opioid binds to the receptor; (ii) *bioavailability*, which depends on route of administration, and the *lipophilicity* of the opioid, which determines how easily it crosses the blood-brain barrier; and (iii) the dose.

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167 Gutstein and Akil, *op. cit.*, 551, 556.

168 *Ibid.*, 559.

169 Trescot, *op. cit.*, 100.

170 *Ibid.*, 99-100.

171 Gutstein and Akil, *op. cit.*, 557; O'Brien, 2006, 617.

172 Inturrisi, 2002, S4.

In cases of sufficiently high doses, some opioids that are relatively selective for a receptor (typically the μ-receptor) may also interact with other receptors.[173] The issue of bioavailability and routes of administration is of particular concern with the extra-medical use of opioids, as this often involves the use of an opioid formulation intended for a particular route being administered by another route. For example, oral syrup methadone may be injected, or an oral tablet formulation may be crushed and intranasally administered or injected. Such alternative routes can then result in a more immediate or higher potency effect than that indicated by the manufacturer.[174]

Interestingly, when naloxone is orally ingested, it is quickly and almost completely metabolised in the liver, resulting in negligible bioavailability. This property has been used to create at least one formulation of an opioid analgesic, pentazocine (marketed as Talwin), by adding naloxone to the tablets (marketed as Talwin Nx). When orally ingested, the analgesic property of the pentazocine is unaffected, but if crushed and administered intranasally or by injection, the naloxone counteracts the effect of the pentazocine.[175] It has also been used in combination with buprenorphine, a partial μ-receptor agonist, to create sublingual preparations to treat opioid dependence.

Opioids are further classified in terms of their action upon opioid receptors in the CNS, primarily as *agonists* (i.e., those that activate the receptors) and *antagonists* (i.e., those that bind to the receptors but do not activate them). Competitive antagonists have a higher affinity than agonists, and can therefore displace the agonists at the site of the receptors, thereby reversing the agonist effect. Naloxone and naltrexone are examples of competitive opioid antagonists. However, such reversal effects are dependent upon the relative rates at which the agonist and antagonist are metabolised and lose their pharmacologic activity. Naloxone in particular is metabolised quickly, whereas some opioid agonists such as methadone are metabolised at a much slower rate, meaning that the reversal effect may itself be reversed. In cases of overdose reversal, then, additional administrations of an opioid antagonist may be required over time. Table 1 shows the approximate half lives of some common opioids.

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173 *Ibid.*

174 For an overview of this issue, combined with a study of one population of extra-medical opioid users, see Butler et al., 2011. The most high-profile case of this in recent years was that of Purdue Pharma's OxyContin, a medication containing oxycodone, which was designed and marketed in an extended release (ER) tablet formulation for oral administration. Extra-medical users soon discovered that crushing the tablet and snorting the resulting powder allowed the entire dose of oxycodone to be delivered to the body immediately. See O'Brien, *op. cit.*, 617; Griffin III and Spillane, 2012.

175 Lahmeyer and Craig, 1987.

Drug	Approximate half-life
Heroin	6 minutes
Morphine	120 minutes
Hydromorphone	150 minutes
Codeine	180 minutes
Fentanyl	220 minutes
Methadone	24 hours
Buprenorphine	37 hours
Naloxone	**30-80 minutes**

Table 1. Comparison of durations of opioids[176]

Statistics on Opioid Prevalence and Use

In order to understand the extent of the problem of opioid overdose and opioid overdose fatalities, it is important to have an idea of the prevalence and availability of licit and illicit opioids. However, determining these figures can be a challenge, due to incomplete data, variations in definition, incompatible time series or baselines, and methodological changes in data collection, not to mention the inherent difficulty of determining the prevalence of illicit substances in general. For example, the United Nations Office of Drugs and Crime (UNODC) reports on the illicit *use* of drugs, using the definitions in the United Nations conventions on drug control, e.g., the 1961 Single Convention on Narcotic Drugs.[177] Although this is useful in making comparisons between regions and types of drugs, it is less so in terms of understanding patterns of use pertaining to opioids in general. As well, the categorizations of *licit* and *illicit* are in some cases used to refer to the substances themselves, the status of which can vary from one jurisdiction to another. For example, diacetylmorphine or diamorphine (i.e., heroin) is a schedule I controlled substance in the United States, and is not legal for prescription, whereas in the U.K. it can be prescribed. Furthermore, the UNODC only began to include reporting on opioids other than opium and heroin in a significant way in the *World Drug Report 2011*,[178] possibly as a result of the studies that both the UNODC and the INCB had done on the adequacy of availability of opioids for medical and scientific purposes.

176 Adapted from Tas and Day, 2016, 17.

177 UNODC website, "Information about drugs".

178 E.g., UNODC, 2012, 24.

Thus, it is difficult to gain a clear picture of the prevalence of opioids, partly because this category of drugs (or substances) can include both prescription and non-prescription opioids, depending on the way these are categorized by different countries or jurisdictions. As well, there are differences in how the use and misuse of these drugs is reported, since in some cases misuse includes both extra-medical use (e.g., for recreational purposes) and dosing error or non-adherent use (e.g., inadvertently failing to follow prescription directions).

In this section, then, we draw upon various sources to provide some comparative statistics regarding opioid use, with the caveat that different data sources may be incompatible.

Prevalence of Illicit Drug use – UNODC World Drug Report 2015

According to the UNODC's *World Drug Report 2015*, as of 2013 (the latest year for which data is available) there had been "little change in the overall global situation regarding the production, use and health consequences of illicit drugs".[179] The estimate for 2013 is a global prevalence for illicit drug use of 5.2 percent, the same level as in 2011 and 2012.[180] By far the largest proportion of this is cannabis use (see Figure 2), although the UNODC considers the use of opiates to be "the most problematic form of drug use globally", due to "the relationship between the use of opiates and injecting drug use, HIV, AIDS and overdose deaths".[181]

The report indicates that "global prevalence of the use of opioids...has remained stable", at 0.7 percent of the world's adult population (32.4 million users), although this is based on "limited information". The situation is similar for opiates as a subcategory of opioids, with global use at 0.4 percent (16.5 million users). [182] However, opium poppy cultivation has increased markedly, and in 2014 "reached the highest level since the late 1930s", while opium production, at 7,554 tons, reached the second highest level, an increase in supply that "has not yet been reflected in an increase in heroin supply in most regions".[183]

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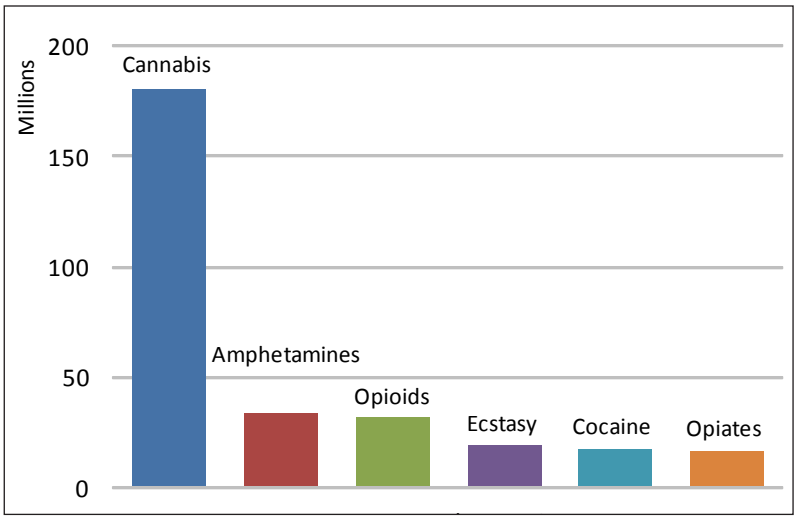
179 UNODC, 2015, ix. Although not defined in the report itself, the UNODC website states that "[t]he United Nations drug control conventions do not recognize a distinction between licit and illicit drug, they describe only use to be licit or illicit. Here, the term illicit drugs is used to describe drugs which are under international control (and which may or may not have licit medical purposes) but which are produced, trafficked and/or consumed illicitly" (UNODC website, "Information about drugs").

180 UNODC, 2015, 1.

181 *Ibid.*, xi.

182 *Ibid.*, xii, 41.

183 *Ibid.*, xiii.



Source: UNODC *World Drug Report 2015*

Figure 2. Prevalence of Illicit Drug Use by Type of Drug – Global, 2013

Also unchanged from the previous year is the global prevalence of people who inject drugs (PWID), although there are significant regional differences. In North America, it was estimated that 2.07 million people injected drugs, "representing 17 percent of the global total number of PWID", [184] a far higher proportion than North America's share of the global population, which was around 5 percent.[185] This is of particular note in the context of the discussion here, as drug injection is associated with a high risk of overdose.[186]

In North America, "[t]he prevalence of [illicit] opioid use remains high...in relation to the global average", at 3.8 percent.[187] As Figure 3 shows, this was much higher than the prevalence for any other type of drug, save for cannabis, and was significantly higher than amphetamine use. In the US, however, the UNODC notes

> indications of a partial shift in the use of opioids towards heroin use, attributable in part to changes in the formulation of OxyContin...as well as an increase in the availability of heroin and a decrease in its price in some parts of the country.[188]

Source of Opioids

The UNODC's global map of the trafficking flow of heroin usefully illustrates some of the differences at regional and country-specific levels that have an

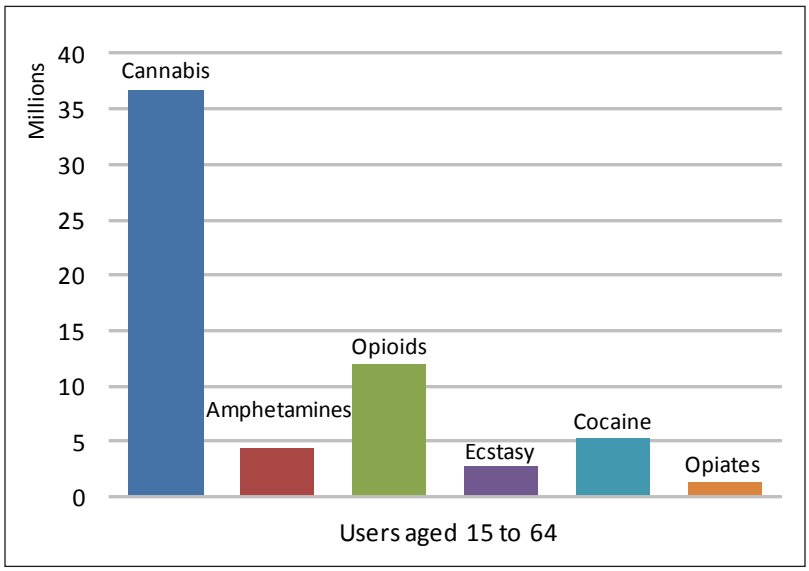
184 *Ibid.*, 5.

185 Population Reference Bureau, 2013.

186 UNODC, 2015, 8.

187 *Ibid.*, xiii.

188 *Ibid.*



Source: UNODC *World Drug Report 2015*

Figure 3. Prevalence of Illicit Drug Use by Type of Drug – North America, 2013

impact on opiate vs opioid use (in the UNODC's sense of "opioid").[189] Three primary sources of heroin are shown: Afghanistan, Myanmar/Lao People's Democratic Republic (LPDR), and Mexico/Colombia. Whereas heroin from Afghanistan is trafficked throughout the world save for South America, Myanmar/LPDR heroin flows predominantly to China, Southeast Asia and Oceania. Mexico/Colombia heroin essentially fills in the gaps, flowing to South America and constituting a large part of the flow of heroin to the United States. In contrast, the primary source of heroin in Canada is Afghanistan,[190] although the proportion of this route of traffic is small compared with the flows from Afghanistan to Europe, Africa, Asia, and Oceania, and with flows from Mexico/Colombia to the US, [191] likely because of transportation challenges. Such supply differences help explain differences in opioid use, particularly for pharmaceutical opioids, between countries. For example, the WDR 2015 points out that

> Levels of opioid use in Australia and New Zealand remain high (2.9 percent), mainly because of high levels of misuse of prescription opioids. According to a recent survey in Australia, there has been an increase in the misuse of

189 *Ibid.*, xiv.

190 "Unlike all the other countries in the Americas, Canada is not supplied to a large extent by Latin American heroin" (*ibid.*, 46).

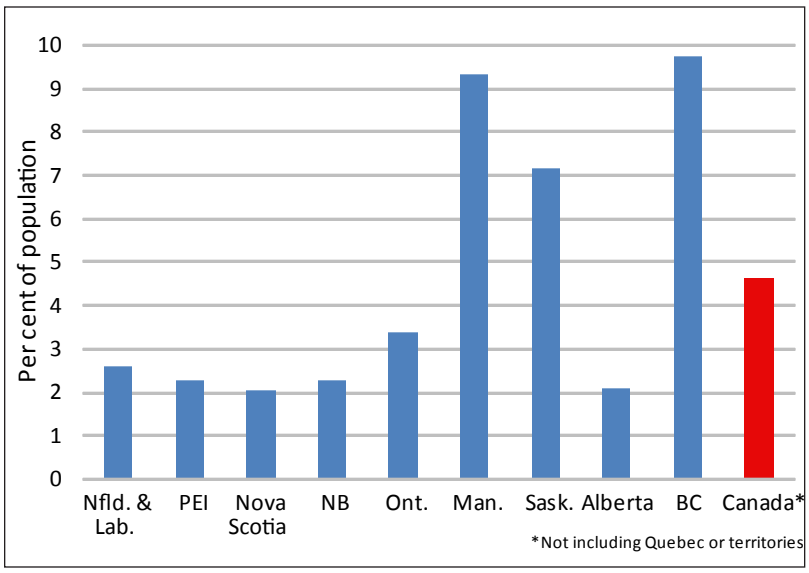
191 *Ibid.*, 44. It is important to note that because of the very nature of such drug traffic, it is difficult to obtain reliable data. The UNODC warns that "[t]he trafficking routes represented on this map should be considered broadly indicative and based on data analyses rather than definitive route outlines. Such analyses are based on data related to official drug seizures along the trafficking route as well as official country reports and responses to annual report questionnaires" (*ibid.*).

prescription opioids (from 3.0 percent in 2010 to 3.3 percent in 2013), while the prevalence of heroin use has declined from 0.2 to 0.1 percent.[192]

Unfortunately, although WDR 2015 does report data on the prevalence of synthetic drugs, these are limited to amphetamine-type stimulants and "new psychoactive substances", and do not include prescription opioids (or their illicit analogues).

Prevalence of Opioid Use in the United States and Canada

To understand the scope of the problems that arise with prevalent opioid use in a particular country or sub-national region, it is important to have good data. In North America, the majority of the data comes from the US. However, due to significant differences in the supply of both illicit opioids such as heroin and licit opioids (due to factors such as different prescribing regulations, healthcare coverage, and payment systems), these data are not reflective of the situation in Canada, and even less so for particular provinces, such as BC. Although there are various sources of data on country-wide opioid use in the United States, such as the Centers for Disease Control and Prevention (CDC), the National Institute on Drug Abuse (NIDA) and the Drug Enforcement Administration (DEA), there are no similar sources for Canada, partly because health care is a provincial jurisdiction, and therefore monitoring and reporting is done at the provincial level, often using incompatible data systems. For this reason, the data presented here are, at best, suggestive of trends.

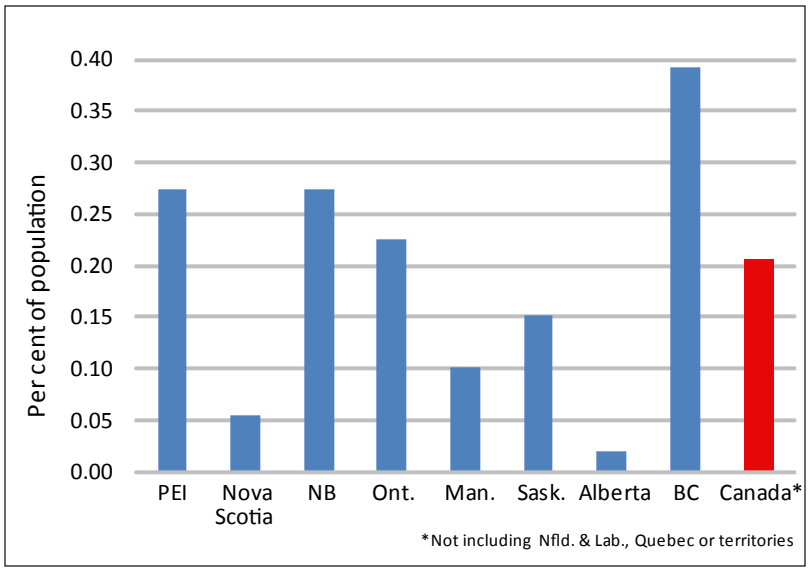


Source: CIHI, Statistics Canada

Figure 4. Active Beneficiaries Prescribed Opium Alkaloids in Canada, by province (2013)

[192] *Ibid.*, 46.

One comprehensive dataset that covers every province except Quebec comes from the Canadian Institute for Health Information (CIHI) on publicly-funded rates of prescription drug use in Canada's provinces.[193] Using 2013 population estimates from Statistics Canada, these data show that the number of active beneficiaries of natural opium alkaloid prescriptions is approximately 4.6%. However, there is significant variation between provinces, the lowest being Nova Scotia and Alberta at 2.1 percent of the population, and the highest being Manitoba and British Columbia, at 9.4 and 9.8 percent, respectively. Ontario, the province with the highest population, had a rate of 3.4 percent (Figure 4).



Source: CIHI, Statistics Canada

Figure 5. Active beneficiaries prescribed drugs used in opioid dependence in Canada, by province (2013)

The CIHI dataset also includes prescriptions for opioid dependence (i.e., for opioid maintenance therapy, typically involving prescriptions for methadone and buprenorphine) separately. In Canada (again, excluding Quebec), the number of active beneficiaries of such prescriptions was 0.21 percent, but the provincial rates differed from those for natural opium alkaloids, with BC again being the highest, at 0.39 percent, and Alberta the lowest, at 0.02 percent (Figure 5).[194]

These datasets provide information about the number of opioid *prescriptions* in each province, but provide no information about length or strength, i.e., the number of days and the dosage levels prescribed, which also have an influence on opioid prevalence, since prescriptions for longer courses of treatment or

[193] Public funding thus would not include those whose prescription drug coverage is "under federal jurisdiction (military veterans, registered First Nations people and Inuit, and federal penitentiary inmates…)", Smolina et al., 2016.

[194] No data were available from Newfoundland and Labrador.

stronger opioids (e.g., fentanyl rather than oxycodone) mean that a greater amount of opioid efficacy (as measured in milligrams of morphine equivalent, MME) is in circulation, and thus available for accident, misuse or diversion. As a number of studies in Canada, the US and Australia have shown, opioid overdose is correlated with prescription levels.[195] However, there are no national data available for Canada that include length and strength of prescriptions, due to inconsistent data collection systems between provinces. In fact, only a few jurisdictions in North America have robust data in this regard, BC being one of them.[196]

Another source of data for drug use in Canada is the Canadian Centre on Substance Abuse (CCSA), which has published fact sheets for a number of drugs from two primary sources, using data from the 2008 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) and the 2013 Canadian Tobacco, Alcohol and Drugs Survey (CTADS), both of which estimated general population use of the drugs concerned. CCSA notes, however, that methodological differences between the two data sources make straightforward comparisons problematic,[197] so we provide this information only due to the absence of more robust data.

In contrast to the UNODC data, which only report illicit use, these figures refer to both licit and illicit use (where applicable). Hence, the percentage of the population reported to have used prescription opioids is higher in both years than those reported to have used cannabis, and significantly higher than for any of the other substances (see Figure 6). Interestingly, the percentage of population using prescription opioids is reported to have decreased by more than a quarter from 2008 to 2013 (from 21.6 to 14.9), a time during which OxyContin was banned from sale in Canada. In contrast, the percentage of the population using prescription sedatives is unchanged at 10.4 (although both of these may be an artifact of the methodological differences between the two surveys).

Unfortunately, no data seem to be available for trends in heroin use, therefore it cannot be determined whether the decrease in the use of prescription opioids was a secular decline, or instead was accompanied by an increase in heroin use (i.e., heroin use being substituted for prescription opioid use). Since data suggest that this type of substitution has taken place in the United States, a country

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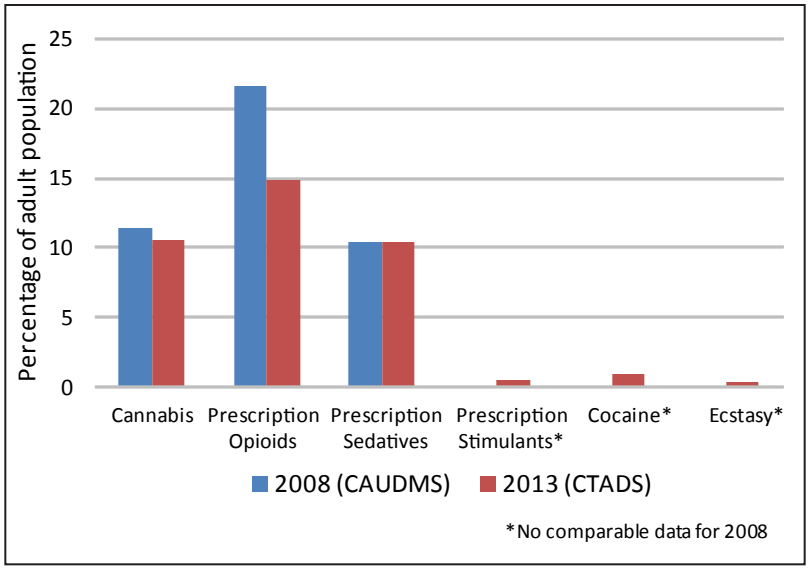
195 See for example Bohnert et al., 2011; Fischer et al., 2013; Fischer et al., 2014; Modarai et al., 2013. However, data from another study of overdose deaths in North Carolina (Hirsch et al., 2014) that also looked at formulations suggested "that dose strength or formulation type alone cannot independently predict which these products will be most likely involved in overdose deaths" (1192), although it did show "general increasing linear trends between dispensed prescriptions and subsequent overdose deaths among individuals" (1194).

196 Smolina et al., *op. cit.*

197 See for example, Canadian Centre on Substance Abuse (CCSA), 2015, 2.



Source: Canadian Centre for Substance Abuse

Figure 6. Drug use trends in Canada, 2008 & 2011)

which has a similarly high rate of prescription opioid use, it is plausible that the same might have occurred in Canada. On the other hand, differences in the availability and cost of heroin in the two countries could mean that such substitution did not occur in Canada.

The final set of data that is informative for understanding opioid drug prevalence comes from the International Narcotics Control Board's (INCB) 2015 report on the availability of internationally controlled drugs for medical purposes.[198] The purpose of this report was to examine the extent to which opioid pain medications are available to the world population for pain relief and opioid dependency treatment. It showed that 75 percent do not have adequate access although these medications are widely available. In effect, they are primarily utilized by those living in Western countries in North America, Europe, and Oceania. For example, the INCB reports that "92 percent of morphine used worldwide is consumed in countries in which only 17 percent of the world population lives".[199] Further specification can be found in a guidance document published by the WHO in 2011, which provides a breakdown of the INCB's 2009 global morphine consumption figures, and shows that in the United States and Canada the percentage of global consumption was ten times greater than the percentage of world population (at 55.9% vs. 5.5% and 6.2% vs. 0.6%, respectively).[200]

198 International Narcotics Control Board, 2016.

199 *Ibid.*, iii.

200 WHO, 2011a, 15.

The data the INCB was able to collect through a variety of means[201] allowed it to develop a synoptic overview of the current state of global opioid medication availability and consumption, using "defined daily dosages for statistical purposes" (S-DDD) as an approximate measure to rank consumption, expressed in terms of S-DDD per million inhabitants per day.[202] For all opiates, the INCB determined that stocks and production levels were sufficient to cover global demand.[203] However, the distribution on the consumption side is highly uneven. Over the past two decades, opioid consumption has increased approximately six-fold, but "has been driven mainly by North America, but also by Europe and Oceania".[204] Although the INCB raw data has not been made publicly available, the data graphically presented in the report shows a more than two-fold increase in consumption for each of these regions between 2001-2003 and 2011-2013, whereas for all other regions the trend was minimal.

On a per capita basis, according to the INCB, in 2011 Canada had the highest level of consumption of opioid analgesics, at over 800 milligrams morphine equivalent (MME), with the United States a close second at approximately 750 MME. These levels were around twice the level of consumption in the next group of countries that included Australia, Switzerland, Germany and New Zealand.[205] However, this pattern was not reflected in the prevalence of misuse of prescription opioids. Here the United States had the highest level, at over 5 percent, whereas the rate for Canada was only 1 percent.[206]

Prevalence of Opioid Use in British Columbia

The 2013 CIHI data discussed above show that, for publicly funded drug programs in British Columbia, there were 447,596 active beneficiaries for "natural opium alkaloids" and 18,020 for drugs used in opioid dependence (9.7 and 0.4 percent of the overall population, respectively).[207] The first figure is roughly in accord with a recent study on prescription opioid use in BC between 2005 and 2013, which indicated that "[i]n each year of the study period, approximately 12% of BC residents were dispensed at least one opioid prescription".[208]

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201 *Ibid.*, 6-7.

202 *Ibid.*, 6.

203 *Ibid.*, 9-10.

204 *Ibid.*, 14.

205 *Ibid.*, 20.

206 *Ibid.*, 21.

207 Canadian Institute for Health Information, 2015. "Active beneficiary" is defined as "[a]n individual with at least 1 claim accepted by a public drug program" (29).

208 Smolina et al., *op. cit.*

The most comprehensive data available on opioid use in British Columbia comes from the BC Centre for Disease Control's Drug Overdose and Alert Partnership (DOAP), a "multi-sectoral committee...established to prevent and reduce the harms associated with substance use".[209] DOAP collects and correlates data from a variety of sources

> including monthly illicit drug overdose deaths and weekly data: ambulance calls for poisonings, Vancouver hospital emergency room attendance for overdose, overdoses at InSite, and Drug and Poison Information Centre calls related to drugs.[210]

However, these types of data do not provide an overview of opioid use *per se*. The most recent DOAP report available is from 2014, and only captures data up to 2013. In addition, because the report draws upon data gathered through surveys of specific populations, e.g., "people who use illicit drugs in Vancouver",[211] "street-involved youth who use illicit drugs in Vancouver",[212] it only provides a partial overview of illicit opioid use, particularly regarding the division between heroin, prescription opioid, and non-prescription pharmaceutical opioid use. Among the populations just mentioned, illicit prescription opioid use was fairly stable between 2009 and 2013, whereas heroin use was more variable.

Unfortunately, the focus of the DOAP report is on *illicit* substance use, and therefore does not report on the level of licit prescription opioid use in BC. Yet studies in Canada, the US and Australia have indicated that the incidence of opioid overdose is correlated with the level of opioid analgesic prescribing. A 2014 systematic review found a number of studies that provided such evidence, as well as evidence of the association of higher dosage opioid prescription with increased opioid-related mortality.[213]

Opioid Substitution Therapy (OST)

Opioid substitution therapy (OST), also referred to as opioid maintenance therapy (OMT) or methadone maintenance therapy (MMT), is a treatment, based on harm reduction principles, for individuals who have developed a dependence on opioids. This approach views opioid dependence as a health issue, and seeks to address it by providing these patients with a prescription opioid that alleviates the effects of their dependency without producing euphoric effects, with a view to either weaning them off opioids entirely or, if this is not possible or is not desired, then assisting them to manage the dependency.

209 BCCDC website, "BC Drug Overdose & Alert Partnership [DOAP]".

210 Tanner et al, *op. cit.*, 9.

211 *Ibid*, 19.

212 *Ibid.*, 29.

213 King et al., 2014, e33.

The two most common opioids used for this purpose are methadone and buprenorphine, the latter commonly combined with naloxone in a sublingual formula to discourage alternative routes of administration.[214] Although OST has the benefit of helping opioid-dependent patients to avoid more risky opioids such as heroin, it comes with risks of its own. In particular, unlike most other opioids, methadone has a particularly long half-life (on average, around 24 hours), which means that reversal of overdose or polydrug toxicity incidents using naloxone may only be temporary, as the half-life of the latter is only 60-90 minutes. Furthermore, certain formulations of methadone are provided to patients in a highly concentrated form, to be diluted for ingestion, which can pose a risk to others in a household.[215]

[214] Wiegand and Bettendorf, 2016.

[215] Tanner et al., *op. cit.*, 87.

Opioid Overdose: Serious Problem or 'Epidemic'?

> ...while most opioid users have suffered overdoses (and survived)...overdose death is a statistically rare event...[216]

This chapter looks at the issue of labelling episodes of high use of, and/or high morbidity or mortality from, psychotropic substances as "epidemics" or "crises", a phenomenon that has occurred with a noticeable regularity, approximately once a decade. First, we provide a brief overview of overdose and toxicity. We then turn to the specific case of prescription opioids, and examine some of the significant ways in which these psychotropic substances differ from those that featured in previous "epidemics". As well, we discuss the issue of the prevalence of opioid overdose, first in terms of reported statistics, and second in terms of how fatal overdoses get attributed to opioids.

Overdose and Toxicity

> ...what is there that is not poison, all things are poison and nothing (is) without poison. Solely the dose determines that a thing is not a poison.[217]

The notion of overdose may seem fairly straightforward, in the sense of being an amount of some substance that is more than one's body can metabolize. This notion is connected to that of toxicity through the idea of harm: "The concept of toxicity is an important one: it involves a damaging, noxious, or deleterious effect on the whole or part of a living system, which may or may not be reversible".[218] Toxicity and overdose start to appear more complex when the various factors that affect the metabolism of the substance in question are taken into account. The most important point is that there is no straightforward demarcation between a non-toxic and a toxic amount of any particular substance (i.e., a "dose" vs. an "overdose"):

> It has been said that there are "no harmless drugs only harmless ways of using them." It could equally be said, "There are no harmless substances, only harmless ways of using them," which underscores the concept of toxicity as a *relative* phenomenon. It depends on the dose and type of

[216] McDonald and Strang, 2016, 82.

[217] Paracelsus, 1986, 210.

[218] Timbrell, 2009, 3.

> substance, the frequency of exposure, and the organism in question. There is no absolute value for toxicity...[219]

For this reason, toxicity is measured in two different ways, in terms of graded effects and "all or nothing" effects. Graded effects show an increase in severity, whereas "all or nothing" effects are either present or absent, death being one such effect.[220] As well, "some effects may be reversible, whereas others are irreversible",[221] death, of course, being one of the latter.

In relation to opioid overdose, the significant issues from a toxicological standpoint are the type of harm, or "deleterious effect", that the opioid has, and the mechanism whereby this is effected. As has been mentioned previously, opioids bind to receptors in the CNS, interrupting the release and uptake of particular biochemicals, thereby providing analgesic and also euphoric effects. These effects are not harmful in themselves, but effects that accompany them can well become so. On the one hand, one set of receptors that opioids bind to are also associated with respiration, and if the concentration of the opioid becomes too great, respiration is negatively affected, leading to respiratory failure, which in turn leads to cardiac arrest and, ultimately, death. On the other hand, repeated exposure to opioids inhibits the normal functioning of the system involving these receptors, leading to withdrawal symptoms in the absence of opioids. In other words, a high frequency of exposure can have a deleterious, although not necessarily lethal, effect.

A further complication with the toxicity of opioids is that repeated exposure can result in *tolerance* or reduced responsiveness,[222] such that the amount that would cause respiratory depression in an "opioid-naive" person is well tolerated by someone who is a regular user. This is of particular concern for certain populations, such as regular opioid users who are incarcerated and unable to obtain opioids. Upon release, such individuals may return to opioid use and believe it is safe to ingest the same amount as just prior to their incarceration. However, because of the period of non-use, their tolerance has diminished, and what was once a safe quantity turns out to be an overdose.

Another factor in toxicity is the route of ingestion or administration and its effects on the *rate* of dose, as can be seen with certain pharmaceutical opioids that are prescribed in "extended-release" formulations, such as OxyContin and fentanyl patches. When these formulations are defeated, for example, by crushing OxyContin pills to snort or inject them, or by extracting the fentanyl gel from the patch for injection, the full dose contained in the pill or patch

219 *Ibid.*

220 *Ibid.*, 9.

221 *Ibid.*

222 *Ibid.*, 15.

becomes immediately bioavailable rather than being extended over time. In other words, although the amount of the opioid is the same, the difference is now the rate at which it is being ingested.

Yet another complicating factor is that there is no such thing as a "dose". Although prescription medications are "dosed", i.e., are prescribed in certain formulations with directions as to frequency of ingestion, these are in effect suggestions (hopefully cautious ones). That is, the amount prescribed may not in fact have the analgesic effect intended, or it may be the case that a lower amount would have resulted in the desired effect, because the response depends on the individual in question.

Another factor in toxicity is substance interaction, whereby the presence of one substance changes the impact of another, whether in an additive, synergistic, or potentiative manner.[223] For example, when opioids are combined with alcohol or other drugs, such as benzodiazepines, their inhibitory effect on respiration is increased, leading to the phenomenon known as "polydrug toxicity".

Finally, alongside these technical or scientific complexities of the notion of overdose, there is a conceptual difficulty, pertaining to the meaning of "dose" when opioids are used for non-medical or recreational purposes. This has to do with the *intent* of substance use. If that intent is to alleviate pain, then the idea that there is a particular amount of an opioid, route of ingestion, and rate at which it is administered that results in the alleviation of the pain in question is fairly straightforward, although the details may be in question. However, if the intent is to produce a euphoric effect, then it is less clear that "dose" has a specific meaning, which also problematizes the meaning of "overdose". This reiterates the point made above, i.e., that there are no harmless substances, only harmless ways of using them.

The Prescription Opioid Situation

The opioid overdose situation is undoubtedly a serious problem that needs to be addressed in innovative ways. However, it is questionable whether the language of "epidemic" or public health "crisis" or "emergency", as used frequently by the media, scientific journals, official agencies, and politicians, is helpful in addressing this problem. Although such language may be politically efficacious, in that it focuses political attention on the issue, and politically useful, for example, by enabling the invocation of emergency measures, as has happened recently in Alberta and BC,[224] in its tendency to lead to moral panic, it may be

[223] *Ibid.*, 14.

[224] In Alberta, the Minister of Health declared the increasing number of overdoses due to fentanyl a "public health emergency", and issued two ministerial orders on December 10, 2015, MO 41/2015

responsible for pressure on politicians that leads to rapid policy decisions that can, in fact, be counter-productive.

Such rhetoric has appeared with increasing frequency in the media and also in scholarly publications over the past decade, as some titles illustrate:

- "Addressing the overdose epidemic requires timely access to data to guide interventions" (*Drug and Alcohol Review*, 2015)
- "Avoiding abuse, achieving a balance: Tackling the opioid public health crisis" (CPSO, 2010)
- "Prescription opioids, abuse and public health in Canada: is fentanyl the new centre of the opioid crisis?" (*Pharmacoepidemiology and Drug Safety*, 2015)
- "Addressing the opioid epidemic" (*JAMA*, 2015)
- "CDC Grand Rounds: Prescription drug overdoses – a U.S. epidemic" (CDC, *MMWR*, 2012)
- "Non-medical prescription opioid use among youth: Gaining perspective from decades of previous drug use epidemics" (*International Journal of Drug Policy*, 2016)
- "The prescription drug epidemic in the United States: A perfect storm" (*Drug and Alcohol Review*, 2011)
- "The prescription opioid and heroin crisis: A public health approach to an epidemic of addiction" (*Ann. Rev. Public Health*, 2015)
- "The Epidemic of Prescription Opioid Abuse, the Subsequent Rising Prevalence of Heroin Use, and the Federal Response" (*Journal of Pain & Palliative Care Pharmacotherapy*, 2015)
- The prescription opioid epidemic: An evidence-based approach" (Johns Hopkins Bloomberg School of Public Health, November 2015)

Recent Canadian media headlines also show this usage:

- "A prescription for curing Canada's opioid epidemic" (*iPolitics*, Nov 20, 2015)
- "Opioid addiction epidemic has many factors" (*Telegraph-Journal*, February 23, 2016)

and MO 42/2015, relating to the prescription, dispensing and administration of naloxone. Both MOs were issued under s. 3.1 of Schedule 7.1 of the *Government Organization Act*, which permits the Minister to authorize the performance of restricted activities "[f]or the purposes of preventing, combating or alleviating a public health emergency". In BC, the Provincial Health Officer declared a public health emergency in order to authorize the collection of information related to drug overdoses (BC Government News, April 14, 2016).

- "Canada's new opioid crisis" (*Calgary Herald*, February 4, 2016)
- "Ontario drug strategy leaders urge province to take action against opioid epidemic" (*Peterborough This Week*, December 10, 2015)
- "This deadly prescription opioid epidemic must be stopped" (*Waterloo Region Record*, December 7, 2015)
- "National tracking system urged for epidemic of opioid-related deaths" (*The Globe and Mail*, December 1, 2015)
- "Addressing the prescription opioid epidemic" (*Winnipeg Free Press*, November 26, 2015)
- "Mac study reveals new face of opioid addiction" (*The Spectator*, November 10, 2015)
- "We now face a public health crisis" (*Alaska Highway News*, August 22, 2014)
- "Canada slow to respond to opioid addiction crisis" (*The Guelph Mercury*, August 21, 2014)
- "Opioid addiction epidemic; Doctors need more education to mitigate the risks associated with these drugs" (*The Vancouver Sun*, March 3, 2014)
- "Addicted at birth: Ontario drug epidemic means more babies than ever face withdrawal" (*Toronto Star*, June 23, 2012)

Recent U.S. media headlines are similar:

- "Our heroin, opioid epidemic is a national emergency, Washington needs to treat it like one" (*Fox News*, February 11, 2016)
- "Opioid epidemic in state skyrockets" (*The Times-Tribune*, February 4, 2016)
- "Endgame for an opioid epidemic" (*The Christian Science Monitor*, February 22, 2016)
- "Big Pharma is partly to blame for America's opioid epidemic" (*Time*, February 10, 2016)
- "Crooked doctors are not fuelling the opioid epidemic" (*New York Times*, February 17, 2016)
- "Cutting off the opioid epidemic at the root" (*The Boston Globe*, February 14, 2016)
- "Drug-induced bipartisanship on need for fixes to opioid crisis" (*The Seattle Times*, February 24, 2016)"
- "The legal drug epidemic" (*The Washington Post*, March 11, 2015)

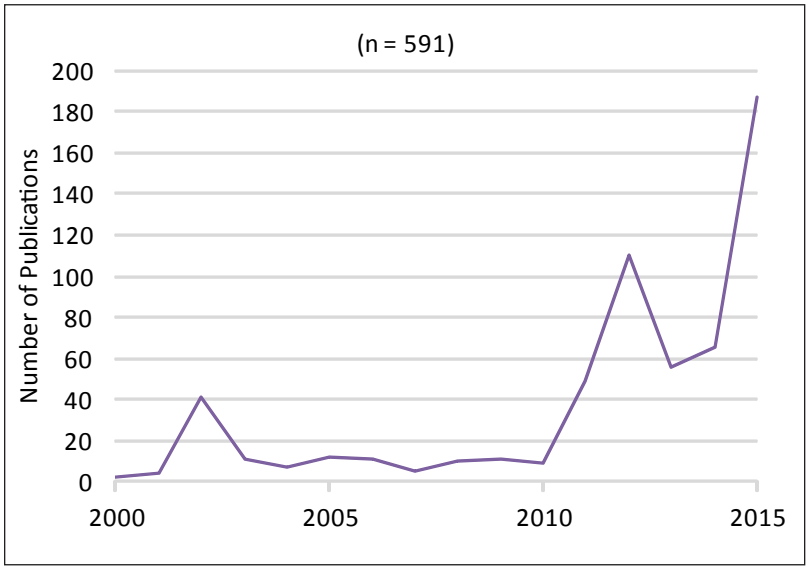


Figure 7. Canadian Newsstand Complete Search 1 – March 3, 2016

To determine the pattern of such language use over time, searches were conducted on the Canadian Newsstand Complete database (with source type limited to newspapers and magazines) and on the National Center for Biotechnology Information's PubMed database[225] using the search string "(opioid OR oxycodone OR fentanyl OR hydrocodone OR oxycontin OR hydromorphone) AND (epidemic OR crisis)" in any field. As Figures 7 and 8 show, since 2010 there has been a significant increase in the attribution of

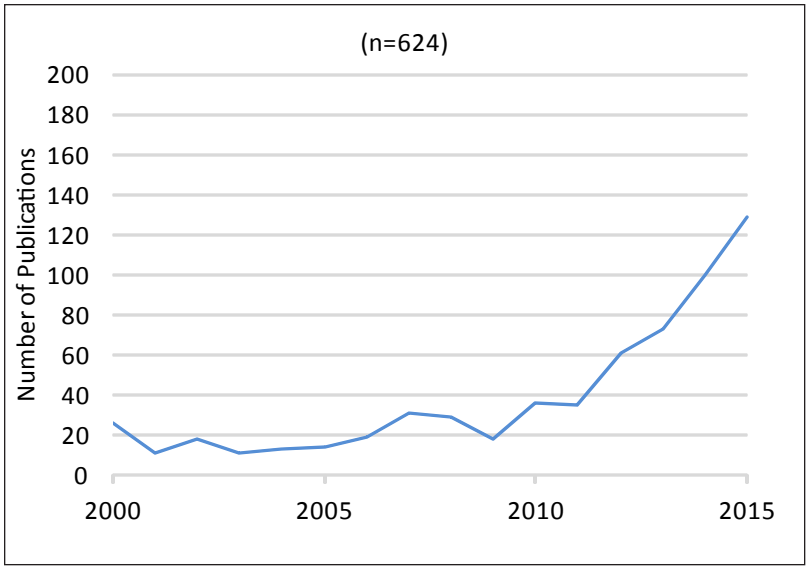


Figure 8. PubMed Search – March 3, 2016

[225] National Center for Biotechnology Information website.

either "epidemic" or "crisis" to the situation of opioids, both in media and scholarly reports.

Interestingly, a search of Canadian newspapers and magazines on the string " "prescription drug" AND (epidemic OR crisis)" showed a somewhat different pattern over the same time period (Figure 9).

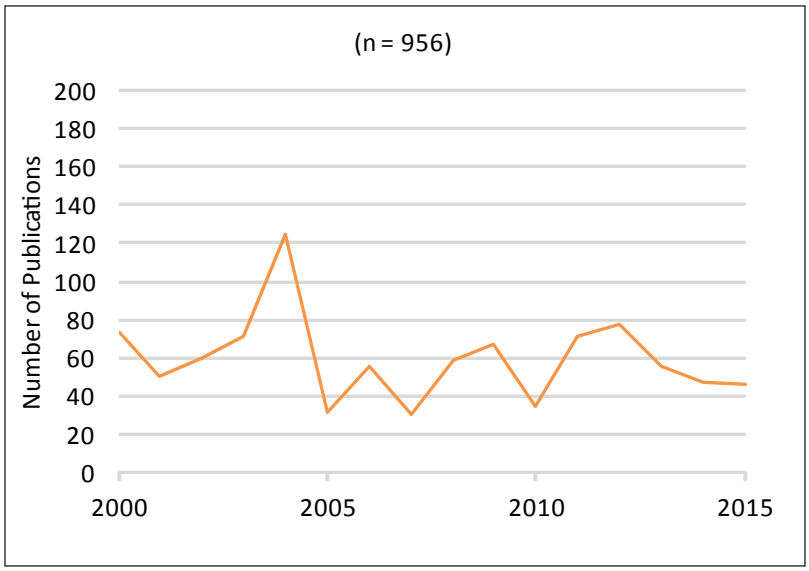


Figure 9. Canadian Newsstand Complete Search 2 – March 3, 2016

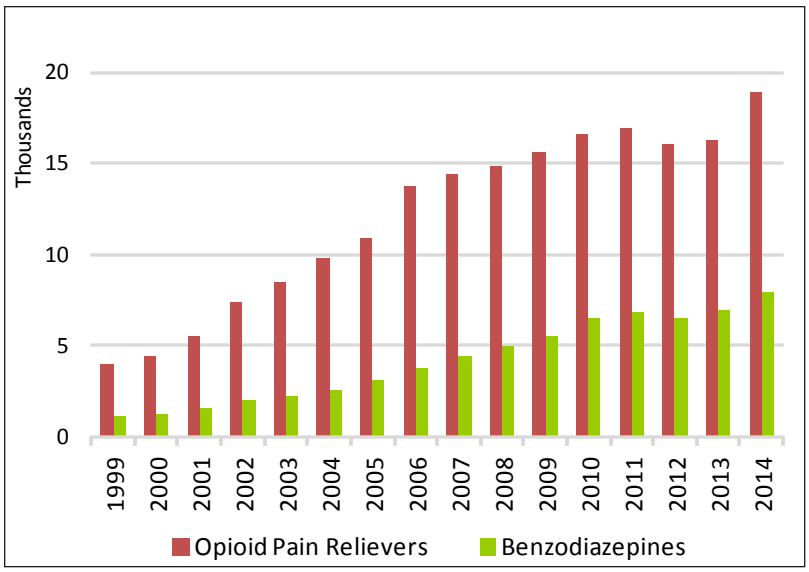
The Contrasting Case of Benzodiazepines

These data are interesting when compared to similar reporting on benzodiazepines, drugs used for sedation and anti-anxiety that are widely prescribed in the US and Canada, and also significantly associated with overdose fatalities. A Google search on ("benziodiazepine epidemic" OR "benzodiazepine crisis") on March 5, 2016 produced 64 results, compared to 410,000 for ("opioid crisis OR "opioid epidemic"). A search on Google Scholar on the same date produced 9 results for the former, compared to 4,370 for the latter. A PubMed search on ("benziodiazepine epidemic" OR "benzodiazepine crisis") produced no results, as did a Canadian Newsstand database search. The headline of one of the few articles on this topic simply states "CDC: Benzodiazepine overdose cases on the rise" (Morning News USA, March 1, 2016), whereas the online CDC report it links to contains the following headings: "Deaths from prescription opioid overdose", "Prescription opioid painkillers and the epidemic of drug abuse and overdose" and "Costs of prescription opioid overdose".[226] This is despite a large increase in the number of benzodiazepine-related mortalities. A recently published article examined the relation between increasing benzodiazepine

[226] CDC website, "Prescription drug overdose data".

prescriptions and overdose mortality in the US between 1996-2013, and found that "overdose mortality involving benzodiazepines rose at a faster rate than did the percentage of individuals filling prescriptions and the quantity filled", possibly due to higher daily doses, more days of treatment, diversion, or polydrug toxicity. [227]

The US National Institute on Drug Abuse, using data from the National Center on Health Statistics and the CDC's Wide-ranging Online Data for Epidemiological Research (WONDER) system, reports that in the US, overall prescription medication-related mortality increased 242 percent between 1999 and 2014. Of this, the increase in mortalities related to prescription opioids was 369 percent, whereas that related to benzodiazepines was 600 percent, although starting from a much lower level (Figure 10).



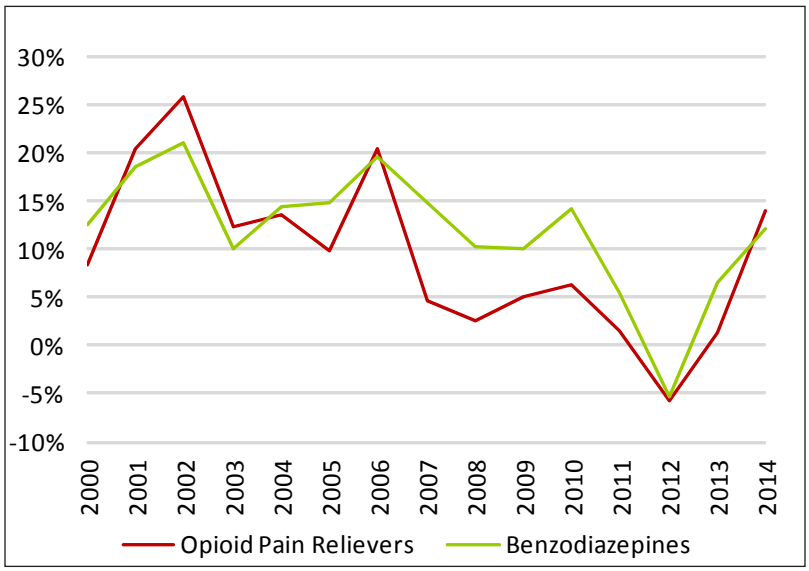
Source: NCHS/CDC WONDER

Figure 10. Prescription drug overdoses in the U.S., 1999-2014

In nine of the fifteen years, the increase in benzodiazepine-related mortalities was higher than that of prescription opioids, often significantly so (see Figure 11).[228]

227 Bachhuber et al., 2016, 687. Just as with figures on opioid-related deaths, the data used in this study are subject to limitations, as the authors recognize (688).

228 National Institute on Drug Abuse website, "Overdose Death Rates". It is possible that the figures for benzodiazepines understate their prevalence, as polydrug-related deaths involving both opioids and benzodiazepines are typically to be attributed to the former, according to the WHO's ICD guidelines.



Source: NCHS/CDC WONDER

Figure 11. Year-over-year increases in prescription drug overdoses in the U.S., 1999-2014

However, benzodiazepines have not been the subject of media (or medical) "sensationalism". This may in part be due to the fact that, taken by themselves, they are far less toxic than prescription opioids.[229] Another reason may be that these drugs lack a criminal analogue such as heroin, and thus are not subject to same kind of associations as are prescription opioids. A third reason may be that benzodiazepines are not associated with stereotypes of a particular social group in the way that prescription opioids (particularly OxyContin) in the US have been associated with Appalachian residents, particularly those of Kentucky.[230] Taken together, the data presented here suggest that media coverage of prescription *opioid* misuse (as opposed to overall prescription drug misuse) may be following a pattern seen with previous substances, such as (in recent years) crack cocaine, methamphetamine and Ecstasy: "Prescription drug abuse...is once again the fastest growing drug problem facing our nation and described in the disease language of epidemic".[231]

The point of this analysis is not to downplay the risks of opioid use, nor in any way to suggest that the prevalence of opioid overdose is not a serious

[229] A systematic review of available research on benzodiazepine-related mortality (Charlson et al., 2009) found "some evidence of increased mortality in regular benzodiazepine users and among 'drug misusers'" (100), but that overall there was insufficient research to draw any definite conclusions. One population-based registry study "found that benzodiazepines caused 3.8% of all deaths caused by poisoning from a single drug" (95).

[230] See, for example, Tunnell, 2004. This stereotype also formed the basis for the television series *Justified*. Such stereotypical associations have typified many of the drug panics over the last century or more.

[231] Ahrens, *op. cit.*, 416. In this article, Ahrens provides the results of a search of Westlaw's US newspaper database for articles about prescription drug abuse, which show that "the intensity of coverage demonstrably has grown in the past several years".

issue. Opioids are potent substances, and "[o]f all commonly used drugs...have by far the highest mortality risk".[232] Rather, the intent is to better understand the factors that may influence policy-making in a way that fails to adequately address a wicked problem such as this. The use of the alarmist language of "epidemic" and "crisis" makes it harder to collaborate around resolving the issue, as it provokes a desire for an immediate "solution", i.e., the politics of urgency, and thus encourages the tendency to present the problem as a tame one, rather than the wicked problem it actually is.

Prevalence of Opioid Overdose

The UNODC's *World Drug Report 2015* points out that "[n]ot all drug overdoses are fatal; different studies have estimated that only 1 out of 20-25 overdose cases is fatal"; this ratio could well be lower, however, since "[n]on-fatal overdoses are underreported".[233] In 2013, according to UNODC estimates, there were 187,100 drug-related deaths with overdose being the "primary cause" and opioids "the main drug type implicated".[234] The percentage of the global number of drug-related deaths in North America was estimated to be 23 percent, with the United States reporting "one of the highest drug-related mortality rates", accounting for "approximately one in five drug-related deaths globally".[235] One factor in this high rate is the increase in the number of fatal heroin overdoses, which "nearly tripled...between 2010 and 2013". The rate of opioid painkiller-related deaths was stable over this period, although at a high level.[236]

Etiology of the Increase in Opioid Overdose

There is a confluence of factors that has led to the increase in opioid overdoses in the last decade in North America. One major factor has been the steep increase in the prescription of opioid analgesics, which is closely associated with the prominence of the discipline of pain medicine. Prior to the 1990s, opioid analgesics were most frequently prescribed to patients with cancer-related pain. However, as pain medicine developed, with the advocacy of pain as a "fifth vital sign", it became more acceptable and more commonplace for physicians to prescribe opioid analgesics for non-cancer related pain, such as chronic pain.

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232 Darke, 2014, 109.

233 UNODC, 2015, xii.

234 "Drug-related deaths" can include "fatal drug overdoses; deaths due to HIV acquired through injecting drug use; suicide; and unintentional deaths and trauma due to illicit drug use", depending on the Member State reporting. *Ibid.*, 11.

235 *Ibid.* However, the UNODC points out that "[t]he high mortality rate in North America in part reflects better monitoring and reporting of drug-related deaths than in most other regions".

236 *Ibid.*, 12.

The prevalence of opioids in North America is evidence of this increase in prescribing.

The dependency associated with opioid use, combined with problematic prescribing practices such as high-volume prescribing and high-dose prescribing, particularly to opioid-naïve patients,[237] has led to a situation in which a significant proportion of the North American population is using opioid analgesics, often in unsafe ways (e.g., in combination with a variety of other prescription medications, with alcohol, or with other recreational drug use). Aggressive marketing of OxyContin by Purdue Pharma as a safe analgesic also contributed to the sharp increase in opioid dependency and consequent overuse.

Although recent media reports might suggest that the spike in opioid-related deaths is due to illicit pharmaceuticals, particularly fentanyl, being imported from countries such as China and distributed in ways that disguise the potency of this particular opioid, this is only one of the causes of opioid overdose mortality and morbidity. OxyContin, prior to it being banned in Canada, had been responsible for another spike in overdose fatalities, but in that case was due to diversion and non-medical use of a licit prescription drug. Medication error is yet another cause of opioid overdose.[238]

In short, there are a number of factors involved in the prevalence of opioid overdose, not all of which are illicit. These can be summarized as follows:

1. Misprescription, i.e., the prescription of overly strong opioid analgesics (particularly fentanyl) to patients who are opioid-naive and therefore have insufficient tolerance for the strength of this drug;

2. Unsafe administration, i.e., in-hospital administration of a stronger opioid or higher dose than clinically warranted;

3. Medication error, i.e., the administration of the wrong medication to hospital or nursing home patients;[239]

4. Non-adherent use, i.e., use that is not as directed by the prescriber, such as inadvertent or intentional over-consumption;

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237 See, for example, King et al, *op. cit.*, e33-e36; Gomes et al., 2014; Friesen et al., 2016.

238 Maxwell, 2011; King, 2014; Whelan and Ashbridge, 2013; Hallinan et al., 2011. See Carter and Graham, *op. cit.*, 4-5 for an overview of opioid overdose factors.

239 Institute for Safe Medication Practices Canada, Deaths associated with medication incidents: Learning from collaborative work with provincial offices of the Chief Coroner and Chief Medical Examiner, *ISMP Canada Safety Bulletin*, 13(8), August 28, 2013.

5. Diversion or substitution, i.e., the intentional or unintentional use of a prescribed medication by others to whom it was not prescribed, either for extra-medical or non-medical purposes;

6. Illicit use, i.e., the use of illicit opioid substances such as heroin or fentanyl, for recreational purposes;

7. Opioid intolerance, i.e., the reversion to use of opioids by habitual users who have either been inadvertently deprived (e.g., through incarceration) or have been attempting to detoxify.

It is evident from this list that the range of potential overdose victims is not only broad, but is also not confined to any one segment of society (e.g., intravenous drug users). As will be discussed below, however, coroners' and medical examiners' reports on causes of death are somewhat indiscriminate.

Polydrug Toxicity

As has been mentioned above, a significant factor in the increase in opioid-related mortality is the use of opioid drugs in combination with other drugs and substances, particularly alcohol. Such events are termed "polydrug" or "polysubstance" events. [240] Reviewing some of the prominent myths related to opioid overdose, Darke points out that

> If the preceding decades of research have proven anything, it is that polydrug toxicity is *the* major factor in opioid overdose. In retrospect, it would have been extraordinary if the concomitant use of other central nervous system (CNS) depressants did not increase the risk of overdose.[241]

In particular, the combination of opioids with alcohol, benzodiazepines or both synergistically increases the depressant effective of *each* substance on the central nervous system (CNS), such that "the overwhelming majority of opioid overdoses, both fatal and non-fatal, involve multiple CNS depressants, most notably alcohol and benzodiazepines".[242] In a discussion of the factors responsible for the rise in problematic opioid use in the US, Maxwell argues that "[p]rescribing practices by untrained physicians contributed to increases in adverse events". One of these practices was "not considering interactions with

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240 The World Health Organization (WHO) defines polydrug use (which it references to "multiple drug use") as the "use of more than one drug or type of drug by and individual, often at the same time or sequentially, and usually with the intention of enhancing, potentiating, or counteracting the effects of another drug. The term is also used more loosely, to include the unconnected use of two or more drugs by the same person. It carries the connotation of illicit use..." (WHO, 1994, 46).

241 Darke, *op. cit.*, 110.

242 *Ibid.*

other prescribed drugs".[243] Finally, in a systematic review of 47 articles on opioid-related mortality, King et al. found 14 that provided evidence "that polydrug toxicity may have played a role in increased opioid-related mortality. Evidence suggests that increased opioid-related mortality might be characterized as part of an epidemic of polydrug mortality."[244]

Attributing Fatal Overdoses to Opioids

The prevalence of polydrug events is thus a significant problem in determining the role of opioids in overdose events. In such cases, attributing overdose causality to one single substance is therefore problematic.[245] "What [are] termed 'opioid' overdoses are, in reality, multiple drug toxicity deaths".[246] In an overview of the literature on prescription opioid misuse since 2006, Brady et al. make the same claim:

> Concomitant use of multiple prescribed and illicit substances is implicated in the majority of overdose deaths. Of note, concomitant use of benzodiazepines is the most common factor in prescription opioid-related overdose deaths.[247]

Dineen points out the limitations listed in the Centers for Disease Control and Prevention's (CDC) 2007 *Morbidity & Mortality Weekly Report* (MMWR), Unintentional Poisoning Deaths: "mortality coding assigns the underlying cause of death to broad categories rather than to specific drugs", "death certificates do not reveal the circumstances of drug use" and "determining the intent of a person who took a drug is often difficult for a coroner or medical examiner".[248] A later *MMWR* concerning drug poisoning involving opioid analgesics states that the figures "include all intents" and identify such deaths "using the *International Classification of Diseases, Tenth Revision*" [ICD10], for which "[d]rug poisoning deaths involving opioid analgesics are the subset of drug poisoning deaths with a multiple case of death code of T40.2-T40.4".[249] However, one year later, an article entitled "Increases in drug and opioid overdose deaths – United States, 2000-2014" once again provides caveats regarding the classification of deaths as opioid-related, pointing out that "substances tested for and circumstances under which the tests are performed vary by jurisdiction". As well, more overdose deaths had drug types specified in 2014 than in 2013, which "might have

243 Maxwell, *op. cit.*, 265.

244 King et al. *op. cit.*, e37.

245 See, for example, Dineen, 2016, 18-19.

246 Darke, *op. cit.*

247 Brady et al., 2016, 19.

248 Dineen, *op. cit.*, 3.

249 Centers for Disease Control (CDC), 2015, 32. See also Degenhardt et al., *op. cit.*, 25.

contributed to some of the observed increases in drug overdose death rates involving different types of opioids from 2013 to 2014" (a reported increase of 7.9%).[250]

In their study of the association of news media reporting with opioid-related deaths, Dasgupta et al. make a similar point: "Medical examiners and coroners in the United States do not have standardized assessment and attribution procedures for suspected drug poisoning deaths. In addition, acute poisonings due to patients' medication dosing errors with potent opioids would be classified the same as...fatal opioid poisonings from drug abuse under ICD-10 coding".[251] This study compared monthly counts of opioid-related deaths in the US from 1999 to 2005 to monthly counts of news articles mentioning opioids over the same time period, which showed that "[n]ews reports preceded poisoning deaths with peak correlation at 2-6 months prior to mortality, accounting for 88% of the variability",[252] which might be a result of "diagnostic suspicion bias", i.e., "that medical examiners more carefully screened for opioid poisonings in deaths of uncertain cause, after they themselves were exposed [to] the media reports about overdose, or concerns expressed in the medical literature".[253]

It is notable that many jurisdictions use the terms "opioid-related" or "opioid-involved" to refer polydrug overdoses where opioids are detected through toxicology or suspected from on-scene evidence. Even in cases where only opioids are detected or suspected, it is not always clear what role they may have played.[254] In cases of fatal overdose, the statistics may be unreliable. In the U.S., for example, it has been argued that

> there are (1) no standardized definitions for post mortem toxicology, (2) no standard qualifications or training for individuals who complete death certificates, (3) overlapping and confusing ICD-10 categories for death, and (4) no standard definition for "opioid related death".[255]

250 Rudd et al., 2016, 1381.

251 Dasgupta et al., 2009, 6

252 *Ibid.*, 3.

253 *Ibid.*, 6.

254 Dineen, *op. cit.*, 9.

255 *Ibid.*, 19. The World Health Organization's (WHO) Guidelines to the ICD10 advises that in cases of "multiple drug deaths" (i.e., those involving more than one drug) "it is of the utmost importance that the *most dangerous drug* is identifiable in addition to the underlying cause" and that if "no appropriate combination category is available", the "main injury code" should be selected using a priority list at the top of which is opioids (WHO, 2011b, 113, emphasis added). Globally, the definition of "drug-related death" is even more variable, as it can include "fatal drug overdoses; deaths due to HIV acquired through injecting drug use; suicide; and unintentional deaths and trauma due to illicit drug use", depending on the country (UNODC, 2015, 11).

Opioid Overdose in Canada

In Canada, the national statistical picture of opioid overdose fatalities is further complicated by the fact that determination of cause of death by coroners and medical examiners is the jurisdiction of the provinces and territories, which has given rise to incompatible definitions, procedures, and data collection.[256] For example, unlike other jurisdictions, Alberta does not classify overdose deaths according to whether they are accidental or undetermined; as well, it includes deaths caused by long-term effects of drug use.[257] As a recent article states, unlike in the US, "[i]nformation related to prescription opioid-related harms in Canada is incomplete. These indicators are not systematically reported or monitored at national or provincial levels".[258]

Statistics on overall overdoses are made all the more complex because the sources of data, such as hospital ER presentations and coroner's or medical examiner's reports, only capture those overdoses that come before them. Unreported overdoses lie outside these sources.[259] Finally, as mentioned above, causal attribution is problematic, even where toxicology screens are conducted.

Even without the statistical complications mentioned above, it is difficult to determined the level of opioid overdose in Canada. As the Canadian Drug Policy Coalition notes,

> With only a few provinces actively reporting overdose fatalities, it is difficult to gauge the extent of opioid related overdose deaths and injuries across Canada. Nor does data exist to allow us to compare between jurisdictions or to assess the extent or impact of non-fatal overdose injuries...[260]

Opioid Overdose in BC

The 2014 DOAP report discussed above states that between 2002 and 2011, the rate of hospitalizations "attributable to illicit drugs did not significantly change", and in 2011 was significantly less than those attributable to either tobacco or alcohol (which were more than six times greater and five times greater, respectively).[261] The rate of hospitalization for injury or overdose as a result of illicit drugs was, however, much greater than that as a result of

256 CCSA, August 2015, 7.

257 *Ibid.*, 4, 10.

258 Gladstone et al., 2016, E67.

259 UNODC, 2015, xii.

260 Carter and Graham, 2013, 5.

261 Tanner et al., *op. cit.*, 30.

tobacco (for obvious reasons).[262] These data are not broken down further into categories of illicit drug use. As well, overall mortality rates related to these three categories were significantly lower for illicit drugs (7 per 100,000) than for either alcohol (23 per 100,000) and tobacco (87 per 100,000).[263] More recent publicly available data comes from the University of Victoria's Centre for Additions Research of BC, which estimated 2013 hospitalization rates per 100,000 population of 539 for tobacco, 496 for alcohol, and 115 for illicit drugs, indicating a slight increase in the relative rate of those for illicit drugs. Overall mortality rates per 100,000 were 85 for tobacco, 29 for alcohol, and 7 for illicit drugs. In absolute terms, there were 4,868 mortalities attributed to tobacco, 1,281 to alcohol, and 336 to illicit drugs.[264]

Another source of data reported on by DOAP comes from the BC Ambulance Service (BCAS, now incorporated into BC EHS), on weekly ambulance calls due to ingested poisoning (a category that includes, but is not limited to, prescription and street drugs). In almost all weeks of 2013, these were significantly lower than the historical average for the province as a whole, which was also true for three of the five health regions.[265]

Naloxone Events in British Columbia

The DOAP 2014 report provides BCAS data for naloxone events in BC's regions and sub-regions from 2009 to 2013. During that period, "[a]mbulance administered naloxone events in BC peaked in 2011...with 2,242 events, and decreased subsequently reaching 2,011 in 2013".[266] In regional terms, these data show shifting patterns of prevalence; for example, the Vancouver Central Health region had the second lowest rate of naloxone administrations per 100,000 population in 2009, but the highest in 2013. At the sub-regional level, Vancouver had the highest rate in 2013, followed by the Okanagan. [267] Unfortunately these data do not indicate any of the factors involved in such shifts, nor is there any breakdown as to the different opioids involved in these administrations.

More importantly, it is difficult to obtain data as to the *disposition* of these naloxone events. That is, no data are publicly available as to the number of

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262 *Ibid.*, 32.

263 *Ibid.*, 63.

264 University of Victoria Centre for Addictions Research of BC, "Substance-related Hospitalizations and Deaths".

265 *Ibid.*, 39. However, it should be noted that such poisoning counts include a variety of toxic substances, not just prescription medications and street drugs.

266 Tanner et al., *op. cit.*, 42.

267 *Ibid.*, 43-44.

events in which naloxone was indicated, to the outcome of these events (e.g., treat and release, transport to hospital, recurrence of overdose, mortality, etc.), nor the number of overdose fatalities occurred due to a delay in administering naloxone, all of which are necessary to begin to grasp the scope of the problem. A further data gap exists regarding response times from 911 dispatch to naloxone administration.[268]

Opioid Overdose Fatalities in BC

The most prominently and frequently reported figures relating to opioid overdose are those pertaining to fatalities, and it is these figures that are cited when opioid overdose is characterized as an 'epidemic' or 'public health crisis'. Using data from the BC Vital Statistics Agency, DOPA 2014 reported that "drug-induced deaths" accounted for 371 (1.7 percent) of total deaths in 2011. Of these, 71.2 percent were "attributed to accidental poisoning by drugs". These data include all drugs – "illicit drugs,...prescription and over-the-counter drugs". The majority of the remaining drug-induced deaths (22.1 percent) were classified as suicide by drugs.[269] In 2011, multiple narcotics and other mixed drugs were by far the most common cause of illicit drug fatalities, each accounting for 32 percent, with heroin/morphine accounting for another 18 percent.[270]

Deaths due to fentanyl have been on an upward trend since 2012.[271] The BC Coroners Service reported 474 "apparent illicit drug overdose deaths in 2015, a 30% increase from 2014", with fentanyl "detected" in 31 percent of cases. In January 2016, 76 such deaths were reported, "the largest number of deaths in a single month for the examined period".[272]

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[268] As this report was being finalized, BC's Provincial Health Officer declared a public health emergency, exercising emergency powers under the *Public Health Act* for the first time. The declaration empowers the collection of more data related to overdoses. The press release regarding this declaration states that "[i]nformation regarding the circumstances of any overdose in the province where emergency personnel or health care workers respond or provide care will be reported as quickly as possible to the regional health authorities' medical officers. This is expected to include location, the drugs used and how they were taken. The information will be reported for both fatal overdoses and overdoses where the person recovers." (BC Gov News, April 14, 2016). Notably lacking here is any reference to data collection regarding treatment initiated by first responders in such cases.

[269] Tanner et al., *op. cit.*, 60.

[270] *Ibid.*, 69.

[271] *Ibid.*, 68.

[272] British Columbia Coroners Service, 2016, 1.

Naloxone and Opioid Overdose Reversal

This chapter discusses the distribution and use of naloxone by bystanders (i.e., Take-home naloxone (THN) programs) and FRs, and the regulatory and patient safety considerations the latter raises, particularly in relation to the situation in British Columbia. To do so, we first revisit the notion of wicked problems, to ask whether decisions about who can administer naloxone to reverse an opioid overdose is really a wicked problem.

However, it should be noted that although media and agency reports indicate that there are a number of jurisdictions in the US which have made regulatory changes to allow various first responders (including law enforcement officials, firefighters and EMTs - a lower-tier designation common in US Emergency Services) to administer naloxone, we were unable to find any studies that reported on the outcomes of these regulatory changes. Such documentary evidence as is available (for the most part, media articles and agency reports) suggests that such regulatory changes have enabled FRs to reverse opioid overdose and, potentially, save lives in a number of cases. But this evidence is anecdotal. The most that can be said is that in jurisdictions such as Quincy, Massachussetts, with only two ambulance stations to serve a population of 92,000, training law enforcement officials on overdose recognition and naloxone administration is likely to have had positive outcomes.[273]

Naloxone in General

As discussed above, naloxone itself is an opioid that binds with opioid receptors in the central nervous system. However, unlike opioid *agonists* such as morphine, fentanyl and methadone that activate opioid receptors, naloxone is an opioid *antagonist* that fails to activate the receptors it binds to. Because it is a strong competitor, it is able to displace an opioid agonist and bind to the receptors in its place. In the case of opioid overdose, this alleviates the effects of the opioid agonist, particularly respiratory depression, which allows the patient's breathing to return to a more normal rate and avoid the often fatal consequences that would otherwise result. Given this effect, it would seem obvious that every case of suspected opioid overdose should be administered naloxone without delay, so as to prevent fatalities.

[273] Davis et al., 2014, e8.

In biomedical terms, this seems to make sense. A substance has been administered that causes a potentially life-threatening condition which another substance can reverse, therefore administration of the latter is all that matters. However, treating the problem of opioid overdose as just a pharmacological issue overlooks the *context* in which the overdose occurs and, more importantly, in which treatment needs to be provided. For example, an unconscious patient in respiratory depression may not in fact be experiencing an opioid overdose. And even if she is, it may be important to manage the reversal carefully, for example, if the purpose of the opioid administration was to manage acute pain, or if the overdose is occurring because of polydrug toxicity. In the latter case, "[u]se of naloxone may also 'unmask' the toxicity of coingestants, such as TCAs, and concurrently abused substances".[274] Another issue is that the environment in which the patient is found may not be conducive to rapid reversal, which has been known to lead to disorientation and combativeness.

Admittedly, these would be minor considerations if the only alternative to administering naloxone were that the patient would die. But in terms of providing professional assistance, this is rarely, if ever, the case. In fact, as is evident from the literature on the administration of naloxone, ensuring airway patency and adequate ventilation is far more important.[275] We look at these issues in more detail below. The point here is that the pharmacological approach is an attempt to tame the wicked problem, i.e., to see it simply as a problem that has already been defined, and then finding a way to solve the problem.

Take-Home Naloxone

> Historically, the use of naloxone had been limited to ambulance workers and medical staff at hospitals. The new guidelines constitute a paradigm shift in the pre-hospital management of opioid overdose, by identifying the responsibility of non-medical (and medical) bystanders to intervene in an overdose emergency and administer naloxone.[276]

In response to the problem of increasing occurrence of opioid overdose, many jurisdictions have taken an approach of providing a take-home naloxone (THN) kit (usually consisting of one or more ampoules of naloxone, a delivery mechanism such as a syringe, and ancillary supplies such as alcohol swabs, latex gloves and a rescue breathing mask[277]) to opioid substance users and/or

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274 Betten et al., 2006, 260.

275 For non-professional "bystanders" who lack the knowledge and ability needed to ensure airway patency and perform rescue breathing, the situation is different, and the argument can be made that in such cases immediate administration of naloxone is essential. But this merely reinforces the point being made, i.e., that the *context* of the overdose is crucial.

276 McDonald and Strang, *op. cit.*, 79.

277 For details of the THN kit available through a pilot program in BC, see BCCDC Harm Reduction Program, "Take Home Naloxone: Overdose Prevention Training and Kits".

their families or other individuals who know such users. The process involved in providing THN kits varies, depending on the status of naloxone in the jurisdiction (e.g., whether it requires a prescription). In BC, for example, until recently a prescription was required, and a THN kit could only be supplied to those who had such a prescription, after they had completed an overdose prevention and response training course.[278] The BC kit contains safety syringes, and is designed for IM injection of naloxone in the case of opioid overdose. As of March 24, 2016 naloxone has become available over-the-counter, i.e., without a prescription.[279] This was made possible by Health Canada's revision to its listing of naloxone on the Prescription Drug List on March 22, 2016.[280]

Such programs have been in existence for over a decade,[281] and are now implemented in a number of countries.[282] However, only Scotland has done so at the national level. In other countries they are implemented at municipal or state/province levels.[283] In Canada, besides BC, Alberta began a province-wide THN program in January, 2016, with distribution of THN kits through pharmacies to prescription-holders, and Ontario has a provincial program, the Ontario Harm Reduction Distribution Program, that distributes THN kits to eligible organizations for redistribution to opioid users.[284] A 2014 survey by the Harm Reduction Coalition in the US reported "644 local opioid overdose prevention sites that provide naloxone kits, located in 30 states and the District of Columbia".[285] Of the 136 organizations that responded to this survey, 69 provided only injectable naloxone, 51 provided only intranasal naloxone, and 16 provided both.[286] Finally, in Europe seven countries have THN programs operating at either municipal or regional levels, although this initiative is being considered by a number of other countries.[287]

Studies of THN programs have generally shown them to be effective in reducing overdose fatalities, and also to be cost-effective (in that they reduce health care costs associated with post-overdose follow-up and treatment). A

278 BCCDC Harm Reduction Program, "Take Home Naloxone: Frequently Asked Questions".

279 BC Pharmacists website, "Naloxone now available in BC without a prescription".

280 Health Canada website, Drugs and Health Products, "Notice: Prescription Drug List (PDL): Naloxone". The revised listing reads "Except when indicated for emergency use for opioid overdose outside hospital settings". Canada has now joined the few countries in which naloxone is available without a prescription: "Naloxone is a prescription medicine in almost all countries", although "at least one country [Italy] has made naloxone available in pharmacies without a prescription" (WHO, 2014, 2). A second country, Australia, re-scheduled naloxone to allow it to be sold over-the-counter, and some states in the US also permit this (Lenton et al., 2016, 146).

281 Dettmer et al., 2001.

282 UNODC, 2013, 14.

283 Lenton et al, *op. cit.*, 146.

284 Ontario Harm Reduction Distribution Program website, "Opioid overdose prevention".

285 Wheeler et al., 2015, 631.

286 *Ibid.*, 633.

287 Strang and McDonald, *op. cit.*, 5

systematic review by the EMCDDA in 2015 examined 21 studies, and concluded that they "showed that naloxone provision among drug users and their peers may be an effective strategy to reduce fatal overdoses".[288] These studies also demonstrated that the "risk of opioid-related fatalities was significantly lower in communities providing naloxone distribution and overdose management education than in communities without programme implementation".[289] And although the WHO's systematic review found only weak evidence in support of these programs, it nevertheless "judged the risk-benefit profile to be strongly in favour of naloxone distribution, due to its clear potential for saving lives and apparent low risk of significant adverse effects."[290]

Since bystander administration of naloxone, including IM administration, has been shown to be effective in reducing overdose fatalities, it would seem to suggest that extending the administration of this medication to FRs and EMRs would be beneficial. However, there are some important differences between the two cases. Under s. 1 of BC's *Good Samaritan Act*, someone who renders emergency medical aid to another person "at the immediate scene of an accident or emergency" is not liable for an adverse outcome, "unless that person is grossly negligent".[291] However, under s. 2, this does not apply "if the person rendering the medical services or aid (a) is employed expressly for that purpose...".[292] That is, different standards of care apply to professionals acting in the course of their duties, which is justified since there is an expectation that professionals are properly trained so as to reduce the risk of harm from their actions. In the case of naloxone administration by injection, it is arguable that a higher level of training is needed than has been put into effect, particularly for FRs who only have 40 hours of basic life support training and have limited skills in clinical decision-making.

The issue of training points to a further difference between the bystander and the professional, which is that bystanders are unlikely to have any experience of and ability with airway management and ventilation, whereas this is a central component of basic life support training. As will be argued further below, airway management and ventilation are perhaps a higher priority than naloxone administration in the case of opioid overdose (and other drug overdoses, such as benzodiazepines). It is only when these are absent, as with the untrained bystander, that naloxone becomes vital.

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288 EMCDDA, 2015, 8.

289 *Ibid.*, 11.

290 WHO, 2014, *op. cit.*, 8.

291 British Columbia, Good Samaritan Act [RSBC 1996] Chapter 172.

292 *Ibid.*

Safety of FR/EMR Administration of Naloxone

The administration of any medication requires a route into the body, such as through an intravenous line (IV), by intramuscular injection (IM) or subcutaneous injection (SQ), by nebulisation (atomized to be inhaled), by intranasal (IN) administration, and so on. Many medications require different formulations for different routes of administration (e.g., a formulation for IV may be less concentrated than one for IM or SQ, since it is likely to take effect far more rapidly), and some health care professions may be regulated such that they can only administer a certain medication by a particular route (e.g., only by IM).

There are a number of routes of naloxone administration currently available to medical personnel. In some jurisdictions, for particular provider professions, naloxone is approved to be administered only through a single route, while in other jurisdictions it can be administered through multiple routes. For example, on November 13, 2015, Manitoba's Emergency Medical Services Branch added "nasal naloxone" (i.e., IN naloxone) as a delegated medication to the scope of practice (Basic) of Tech-EMRs (equivalent to BC's EMRs), [293] whereas paramedics (PCPs and above) in many jurisdictions, including BC, are endorsed for "administration of the following intravenous, oral, sublingual, subcutaneous, inhaled, intra-muscular or nebulized medications: (i) narcotic antagonist...".[294] Currently, Health Canada has only approved naloxone formulations for injection (i.e., for IV, IM and SQ administration).[295] As health is a provincial matter, however, there are differences between the provinces as to which providers (e.g., physicians, nurses, midwives, paramedics) and first responders (such as fire and police) can administer naloxone by which routes.[296]

Safety of FR/EMR Administration by Intramuscular (IM) Injection: Risk to the Patient

Needle routes of medication administration increase the risk of complications to patients. For example, IM injections have been associated with "local infectious complications, such as abscesses, skin necrosis or intra-articular infections, and can rarely progress to generalized sepsis and multi-organ failure".[297] Although IM injection is clinically considered to be "a minor procedure...Recent studies

293 Manitoba Health, Healthy Living and Seniors, 2015, 3.

294 B.C. Reg. 210/2010, Emergency Medical Assistants Regulation – Schedule 1, s. 3(b).

295 Health Canada, Drug Product Database.

296 There may also be differences as to which health care providers can prescribe and dispense naloxone, but since prescription and dispensing are outside the scope of practice for paramedics, let alone first responders, we have not addressed this issue here.

297 Velissaris et al., 2009, 7365.

have highlighted the importance of correct IM drug administration, in order to minimize the risk of potentially serious complications".[298] As these authors further point out,

> Injection safety is a complex problem, and unsafe practices can place patients at increased risk of infection. However, even when properly administered, IM injections can result in severe tissue trauma, by creating a local entry point for bacteria.[299]

Safety of FR/EMR Administration by Intramuscular (IM) Injection: Risk to the Provider (Needlestick Injury)

The WHO considers a safe injection of one that 1) does not harm the recipient, 2) does not expose the provider to any avoidable risk and 3) does not result in any waste that is dangerous for other people. Needle routes, such as IV, IM and SQ, of naloxone administration delivered by FRs could expose the provider to an avoidable risk. When comparing the various routes, safety must be considered first and foremost in the development of policy about such administration. In this regard, IN administration of naloxone has many advantages. As one organization advocating for IN naloxone argues, "intranasal naloxone delivery eliminates the risk of a contaminated needle stick...An especially high-risk patient population for first responders is the IVDU [intravenous drug user]. These patients have HIV, HBV and Hepatitis C (HBC) seroprevalence rates that are far higher than the baseline population".[300] Yet another consideration is the environment in which FRs and EMRs work, which are often less than clinically ideal. Factors such as poor lighting, unfavorable weather conditions, uncontrolled scene circumstances and combative patients and bystanders increase the risk of a needlestick injury.[301] This issue has been adverted to for a community fire department in the US, with respect to "[f]irefighters who are inadequately trained". For such first responders, "when rescue efforts are conducted in confined areas with poor lighting, an increased risk of exposure to blood and other body fluids exists".[302]

The issue of needlestick injury and risk of exposure to blood-borne pathogens is, of course, an occupational hazard for those engaged in out-of-hospital emergency health care delivery. Even highly trained paramedics are susceptible to this type of injury. A 2002-2003 survey of paramedics in the US

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298 *Ibid.*, 7367.

299 *Ibid.*, 7368.

300 Therapeutic Intranasal Drug Delivery website, "Intranasal Naloxone for acute opioid overdose: Reducing needle stick risk, improving time to medication delivery".

301 *Ibid.*

302 Scarborough and Doell, 2006, E69.

on blood exposure indicated that "paramedics have percutaneous exposures at least as high as, and possibly substantially higher than, most hospital-based healthcare workers".[303] This is unsurprising, given the environments in which paramedics deliver out-of-hospital emergency care. It does suggest, however, that decisions to expand the administration of medications by FRs and EMRs should take into account the risk of harm to both patient and provider.

Although a systematic review indicated some evidence that use of "safety engineered injection devices" (e.g., safety syringes and auto-injectors) reduces the risk of needlestick injury,[304] other studies have been unable to find clear evidence that the rate of injury was reduced.[305] However, this review was unable to identify studies that addressed the effect of these devices on reducing the risk of infection by blood-borne viruses.[306]

To summarize, then, any administration of naloxone involving a needle (i.e., IV, IM and SQ) places both the patient and the practitioner at greater risk than IN administration. The World Health Organization reported that 37.6% of Hepatitis B, 39% of Hepatitis C and 4.4% of HIV/AIDS in Health-Care Workers around the world are due to needlestick injuries.[307] In addition, first responders such as police, fire or EMRs, who are less well trained for such routes of administration than paramedics, and who have less clinical training in dealing with environmental factors such as uncontrolled scene issues, poor lighting and combative patients, are likely to be at much greater risk for a needlestick injury. In terms of the effectiveness of the various routes of administration, the evidence (however limited) suggests that IN naloxone is as effective as IV/IM/SQ and, therefore, the added risk of administration through a needle versus IN should be carefully evaluated before any policy is crafted, especially when evaluating the introduction of a medication for first responders with little or no clinical training and whose primary activities and responsibilities lie outside of the medical field.

Patient Safety in Post-administration Care

Although naloxone is generally considered a safe medication that has little or no effect unless there are opioids in the patient's system,[308] a number of studies have shown that it can result in adverse reactions. For example, one

303 Boal et al., 2010, 198.

304 Harb et al., 2015, 78

305 *Ibid.*, 80.

306 *Ibid.*, 78.

307 WHO website, "Needlestick Injuries".

308 Wermeling, 2015, 21.

article reported several cases of cardiovascular complications resulting from postoperative naloxone administration,[309] and pointed out that "[w]hen an excess dose of naloxone is used in the treatment of an acute narcotic overdose in an opioid-dependent patient, it can acutely precipitate Abstinence Syndrome. Signs and symptoms of Abstinence Syndrome range from anxiety and irritability to potential life-threatening tachycardia and hypertension".[310] In such cases, the provider must be prepared to treat life threatening conditions such as hypertension and the loss of the airway. Naloxone may also be associated with adverse cardiovascular effects such as acute hypertension, ventricular tachycardia and fibrillation, pulmonary edema and sudden death in patients who are not opioid dependent following administration of naloxone for reversal of opioid effect.

A review of 10 studies that contained evidence of complications with naloxone found reports of "episodes of severe hypertensive reactions" that followed "administration of naloxone to patients with pre-existing simple hypertension",[311] whereas a report on policy changes in Massachusetts to provide naloxone to first responders noted that "significant negative effects from administration, while rare, do occur. Chief among these is precipitated withdrawal, which can occur in opioid-dependent individuals. Such withdrawal can cause individuals to become agitated or combative".[312] A case study and literature review found a number of reports of ventricular tachycardia resulting from administration of naloxone, which suggest that "[p]atients who are multi-drug users or receive opiates in high doses may be prone to VT/VF due to acute (iatrogenic) opiate withdrawal or reduction of sympathetic suppression and therefore overstimulation".[313]

Evidence for the Efficacy of IN Naloxone

There are advantages and disadvantages to each route of administration of naloxone, and also different risks of harm to the patient. Although naloxone is generally considered to be a safe medication, in a small number of cases there is evidence of adverse reaction. As well, because the rate of onset of overdose reversal varies with the route of administration, abrupt cessation of analgesic effects can result in sudden onset of a high level of pain. The different routes of administration also have different risks of harm to the provider. This section reviews recent literature on the various routes of administration of naloxone,

309 Burke and Dunwoody, 1990, 44-46.

310 *Ibid.*, 45.

311 Clarke et al., 2005, 612.

312 Davis et al., *op. cit.*, e8.

313 Lameijer et al., 2014, 4.

which suggests that IN administration is as effective in reversing opioid overdose as IV or IM administration but has a lower risk of harm, and therefore is more suitable for first responders with limited or no medical training.

A retrospective review of EMS and hospital records compared IN and IV routes of administration, and concluded that although "time from dose administration to clinical response...was longer for the IN route...the overall time from patient contact to response was the same". [314] These findings suggested that IN naloxone is a "potentially safer alternative" to the IV route, "[g]iven the difficulty and potential hazards in obtaining IV access in many patients with narcotic overdose".[315] A randomized clinical trial study in 2011 of administration of naloxone to opioid overdose patients presenting at an ED concluded that "[i]ntranasal naloxone is as effective as IV naloxone in reversing both respiratory depression and depressive effects on the central nervous system caused by opioid overdose".[316]

A short-cut review that screened 596 papers concluded that, from the eight that presented the best evidence, the evidence was weak, and "there are conflicting results regarding the efficacy of intranasal compared to intravenous and intramuscular routes of Naloxone administration",[317] but nevertheless concluded that "[t]he clinical bottom line is that it is likely that intranasal Naloxone is a safe and effective first line prehospital intervention in reversing the effects of an Opioid overdose and helping to reduce the risk of needle stick injury".[318]

Another study on the safety and efficacy of a variety of intranasally administered medications in the emergency department and prehospital settings, among them naloxone, concluded that the published literature indicates that "intranasal administration of …..naloxone….may be a safe, effective, and well-tolerated alternative to intramuscular or intravenous administration in the prehospital and ED settings".[319]

A More Important FR/EMR Practice? Basic Emergency Medical Care Ventilation/Airway Support

Writing about the management of opioid overdose, although recognizing the efficacy of naloxone, medical toxicologist Edward D. Boyer states that

[314] Robertson et al., 2009, 512.

[315] *Ibid.*

[316] Sabzghabaee et al., 2014, 309.

[317] Ashton and Hassan, 2006, 223.

[318] *Ibid.*, 221.

[319] Corrigan et al., 2015, 1552-1553.

> Patients with apnea [suspension of external breathing] need a pharmacologic or mechanical stimulus in order to breathe. For patients with stupor who have respiratory rates of 12 breaths per minute or less, ventilation should be provided with a bag-valve mask...providing adequate ventilation is a simple response that offers the certain benefits of restoring oxygenation...[320]

Referencing Boyer, Sivilotti reiterates this point:

> ...irrespective of the availability of naloxone and during its titration, non-pharmacological approaches to treating respiratory depression take precedence. Rescuers should not simply rely on the antidote in patients with severe respiratory depression without first performing basic measures including clearing the airway and assisting ventilation. Ventilation and oxygenation by bag-mask-valve has the highest priority...[321]

He also cautions that, although "the safety and efficacy of naloxone are well established", "[a]n excessive dose of naloxone in an opioid-dependent patient induces immediate opioid withdrawal, which...can cause a behavioural emergency with some risk to rescue personnel".[322] Erickson et al. describe a "two-pronged" approach to "the diagnosis and management of the poisoned patient"; on the management side, this involves "basic emergency medical care – the ABCs (airway, breathing, circulation)", followed by "DONT...dextrose, oxygen, naloxone, thiamine".[323]

For the prehospital approach to the patient with an unknown overdose, these authors suggest that

> Apart from basic stabilization measures (such as oxygen administration, cardiac monitoring, and venous access establishment), emergency medical system (EMS) personnel need to do little in the field with the overdosed patient, especially when the transport time to the nearest hospital is short... Small doses of naloxone may be required if opioids are highly suspected and the patient is hypoxic or suffering from airway compromise.[324]

As regards treatment, they further suggest that "[t]he management of any clinically significant poisoning should begin with basic supportive measures. *Most poisoned patients do well with supportive care alone*...The first priority is to stabilize the ABCs and manage life-threatening complications".[325] Although they endorse the use of naloxone, which "may have therapeutic and diagnostic value", they also advise caution in administration:

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320 Boyer, 2012, 149.

321 Sivilotti, 2015, 431.

322 *Ibid.*

323 Erickson et al., 2007, 251.

324 *Ibid.*

325 *Ibid.*, 267, emphasis added.

> Naloxone can precipitate acute opiate withdrawal in the opioid-dependent patient. Caution should be exercised because acute withdrawal can be accompanied by belligerence and violence.[326]

Discussing diagnosis, these authors also point to the difficulty encountered with polydrug toxicity:

> When multiple drugs have been ingested, conflicting clinical effects may be present or may negate each other and cloud the clinical picture. In addition, the clinical onset of a specific toxic agent may be delayed when multiple substances have been ingested concomitantly.[327]

Finally, Snyder et al. advise EMS providers that

> Respiratory depression is the primary morbidity and cause of almost all the mortality associated with opioid toxicity and overdose. Therefore, opening the airway, keeping the airway open, correcting inadequate ventilation and reversing hypoxia is the most important treatment for the patient with opiate toxicity or overdose. [328]

These authors also warn that "[w]hile miosis [constriction of the pupils] is considered a classic finding associated with opioid overdose, there are factors that can prevent it from occurring. Not all opioids will produce miosis...".[329]

Although naloxone has been shown to be safe and highly effective at reversing opioid overdose, as all of these authors argue, it is not the priority in attending to a case of suspected opioid overdose. Opioids affect respiration, which in the case of overdose leads to respiratory depression or failure, which can lead to cardiac arrest and, ultimately, death. However, even if the overdose is non-fatal, resulting respiratory depression can result in brain damage. For this reason, the WHO's recommendation is that in such cases "ventilation is a priority", and that "first responders should focus on airway management, assisting ventilation and administering naloxone".[330] A joint UNODC/WHO discussion paper makes the same point: "In managing opioid overdose, the primary focus should be to address respiration and oxygenation, including assisted ventilation with rescue breathing or bag and mask with supplemental

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326 *Ibid.*, 269.

327 *Ibid.*, 266-267.

328 Snyder et al., 2013, 60.

329 *Ibid.*, 59. These authors mention meperidine (e.g., Demerol), pentazocine (e.g., Talwin) and propoxyphene (e.g., Darvon). Boyer also mentions tramadol (Ralivia) (*op. cit.*, 148). Smolina et al. note that "[t]ramadol was introduced to the Canadian market in 2005" and, in BC at least, had shown a significant increase in use by 2013 as a consequence of "the uptake of this new opioid" (*op. cit.*).

330 WHO, 2014, *op. cit.*, 14. Other guidelines cited in this report "recommend that airway maintenance and assisted ventilation commence prior to the administration of naloxone for individuals in respiratory depression but not in cardiac arrest" (36).

oxygen, if possible",[331] a point which is reinforced in the case of overdose events where naloxone is not available.[332]

In its discussion of the first responder system, the 2013 study of Toronto Fire and EMS systems points out that for the time-critical medical emergencies of cardiac arrest and respiratory failure (the two medical emergencies related to opioid overdose)

> The TFS already has the tools to deal with these problems – for example CPR and automatic external defibrillators for cardiac arrest, and bag and mask ventilation for respiratory failure...Other time urgent problems requiring advanced life support care...are not critical over an additional 2- to 5-minute span while waiting for EMS.[333]

331 UNODC, 2013, 7.

332 *Ibid.*, 8. It should be noted, though, that the EMCDDA argues that "failing to use [naloxone] at the earliest opportunity in cases of opioid overdose may result in the death of the overdose victim" (Reed, 2016, 29)

333 Pomax, *op. cit.*, 121.

British Columbia Legislative and Regulatory Context

> The abatement or control of risks to society, a key purpose of *regulation*, has emerged as central to health regulation.[334]

The nature and purpose of health care regulation stems from the fundamental concern to minimize the risk of harm to patients and to the population in general. Issues concerning life and health, most people would agree, are those that require oversight, and the growing awareness that medical errors are not uncommon has led to increasing attention to regulation in the health care field. In BC the two key pieces of legislation that regulate Emergency Medical Assistants are the Emergency Health Services Act (EHSA) and the Emergency Medical Assistants Regulation (EMAR). The EHSA establishes the Emergency Medical Assistants Licensing Board (EMALB), which is responsible for examining, registering and licensing all emergency medical assistants in BC, including First Responders (FRs) and Emergency Medical Responders (EMRs). Under the authority of the EHSA, EMALB sets license terms and conditions and investigates complaints and conducts hearings where necessary.[335]

The Emergency Medical Assistants Licensing Branch provides support to the EMALB by:

- Reviewing training programs;
- Administering examinations;
- Issuing and renewing licences;
- Ensuring continuing competence requirement are met; and
- Managing complaint files.[336]

EMALB licenses six categories of EMAs in BC:

- Emergency Medical Assistant First Responder (EMA FR)
- Emergency Medical Responder (EMR)
- Primary Care Paramedic (PCP)
- Advanced Care Paramedic (ACP)

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334 Braithwaite et al., 2005, vi.

335 British Columbia Government website, "Emergency Medical Assistants Licensing Board".

336 British Columbia Government website, "Emergency Medical Assistants Licensing Branch".

- Critical Care Paramedic (CCP)
- Infant Transport Team (ITT)

Policy Process leading towards Recent Regulatory Changes

Recently, two Ministerial Orders were issued that appear to take the legal authority for certain aspects of the regulation of EMAs out of the hands of the EMALB and place it in the hands of the corporation (BCEHS). As discussed below, there is a concern that this action has the potential to reduce the ability of the EMALB to control the risks to society.

Prior to the most recent Ministerial Order, an EMA could provide only the services specified in Schedule 1 and 2 of the EMA Regulation for the category in which he or she was licensed (see Appendix I). In the case of administration of a narcotic antagonist, this could only be performed by PCPs, ACPs, CCPs, and ITTs once they had completed the endorsement education or a course of study that includes narcotic antagonist training. It was not within the scope of practice for an EMA FR or an EMR.

The typical process for expanding the scope of practice of an EMA by adding an endorsement to the Regulation is as follows:

- The corporation or another stakeholder makes a recommendation to add an endorsement to an EMA license
- The Ministry of Health reviews the request and makes a decision
- If approved, the endorsement is added to Schedule 2 of the Regulation
- The corporation or other training agencies develops a training program and submits it to the EMALB for recognition
- If recognized, the training is offered
- Once an EMA completes the training, proof of completion is submitted to the EMALB and the specific endorsement is added to the EMA's license

The January 8, 2016, EMAR was amended through a Ministerial Order as follows:

> "Section 10 of the Emergency Medical Assistants Regulation, B.C. Reg. 210/2010, is amended by adding the following subsections:
>
> (4) If the corporation determines that it is necessary or appropriate in the circumstances for the protection of public health or safety, the corporation may request that the licensing board endorse the licence of a

person who holds a licence in the category EMA FR or EMR to permit the person to dispense and administer narcotic antagonist drugs.

(5) If the corporation makes a request under subsection (4), despite subsection (1), the licensing board must endorse the licence as requested.

(6) An endorsement under subsection (5) is subject to the condition that a narcotic antagonist drug must not be dispensed or administered to an individual except in accordance with the direction of a medical practitioner who is an employee or agent of the corporation.

(7) Despite section 2 (3) of the Drug Schedules Regulation, a narcotic antagonist drug listed in Schedule I of that regulation may be provided to the public by a person whose licence is endorsed under subsection (5) of this section."

Disjointed Policy 1: FR/EMR Administration/Dispensation of Naloxone

This amendment raises a number of issues. First of all, unlike all other endorsements, the legal authority for this endorsement has been blurred and appears to have been taken out of the hands of the EMALB and placed in the hands of the corporation. This has the potential to reduce oversight by the EMALB. A second impact of this Ministerial Order is that it appears that the corporation is not required to submit the IM naloxone education program to EMALB for approval. However, education is a key regulatory function, one that now appears to be under the legal authority of the corporation for this endorsement rather than the EMALB. Thirdly, the Ministerial Order presents regulatory inconsistencies. For example, for PCPs, ACPs, CCPs and ITTs the legal authority for the naloxone endorsement lies with the EMALB, whereas for EMA FRs and EMRs, the legal authority lies with the corporation. This has the potential to result in differences in educational and examination standards for the same skill within the same profession, and to potentially lead to conflicts of procedure in the field.

It bears mentioning that many health professions in BC (as in other provinces) have their standards of professional practice codified under a single provincial umbrella Act, the *Health Professions Act*. In BC there are currently 26 health professions regulated under this Act, including physicians, nurses, midwives, massage therapists, chiropractors, dentists, dental hygienists and

pharmacists; 25 are self-regulating professions governed by 22 regulatory colleges.[337]

The situation is further complicated with respect to FRs and EMRs, because the legal authority for the majority of EMRs within the province lies with BCEHS, but EMA FRs work for municipal fire departments. This has the potential to blur lines of accountability and responsibility (of which oversight is just one element). For example, BCEHS, as part of the Ministry of Health, is responsible for the provision of EMS throughout the province, whereas municipalities are individually responsible for the provision of fire services. This raises the question as to who is ultimately responsible for making the decision as to whether a municipal fire department should administer naloxone. Another question left unanswered relates to the situation of EMR who work for industry. Their practice is under the same regulation as the practitioner working for BCEHS. If an industry employer of such EMRs want them to be able to deliver naloxone, who is responsible for their training and oversight? We note that is perhaps unlikely that an industry employer would seek this endorsement for their EMRs, but the point here is that the MO is silent about this category of EMRs, thus adding to the regulatory confusion.

Training and Education

Another consideration in terms of risk of harm associated with this policy change has to do with the level of training of EMA FRs and EMRs, and whether this is sufficient to enable them to deliver this new procedure safely.

EMALB determines the training program requirements for all EMAs in BC and recognizes training programs that qualify, with different levels of training for the different EMA licence levels. For example, the training program for an EMA FR at the Justice Institute in BC consists of approximately 4 hours of pre-reading and 42 hours of classroom study. The EMR training program at the same institute consists of approximately 14 hours of pre-reading and 105 hours of classroom study, whereas the full-time PCP training program requires an EMR licence, and is 8 months long, and consists of a one-month online instructor-facilitated anatomy and physiology course, a classroom component of five days a week for four months and three months of clinical training through hospital (32 hours) and ambulance (168 hours) placements. Prior to the MO, administration of narcotic antagonist drugs was only within the scope of practice of EMAs at the PCP level and above, as was the IM injection of any other medication. Given the significant difference in the levels and types of training, there is a legitimate concern that EMA FRs and EMRs may not

[337] British Columbia Government website, "Professional Regulation".

have sufficient skills (e.g., in patient assessment and clinical procedure) to safely deliver the new procedures for which they are being endorsed.

Until recently, the only health care professionals in the province of BC that had needle injections (IM and/or SQ) within their scope of practice were physicians, nurses, midwives, respiratory therapists, paramedics and, more recently, pharmacists, who in 2009 were endorsed for this procedure in order to provide immunizations.[338] It is instructive to compare the training that pharmacists are required to complete in order to be certified for this procedure with that required by the corporation for EMA FRs and EMRs. In order to be certified to administer injections, pharmacists must be registered with the BC College of Pharmacists, which itself requires completion of a degree program in pharmacy studies and successful completion of the jurisprudence examination and the Pharmacy Examining Board of Canada Qualifying Exams. They must then complete the 'Administration of Injections Certificate Program for Pharmacists', a program consisting of a 10 hour online pre-study component (which as of December 3, 2015 also includes an IN administration module) and a 7-hour practical workshop. First aid and CPR training certificates are also required.[339].

Another baseline of comparison can be found in the scope of practice for BC's registered nurses (RNs), who have educational and professional examination entry-to-practice requirements similar to those for BC pharmacists. RNs are endorsed to compound, dispense and administer "by any method" (i.e., including IM administration) medications specified in Schedule II of the Drug Schedules Regulation, and certain medications specified in Schedule I of the Drug Schedules Regulation, among which is naloxone. However, in order to administer naloxone, RNs "must successfully complete additional education".[340]

In comparison, the BCEHS training module for IM administration of naloxone for EMA FRs and EMRs is a four-hour course, covering "the theory and practice for suspected opioid overdose identification and management, intramuscular injection principles and the administration of naloxone".[341] However, the MO that enabled EMA FRs and EMRs to be endorsed for the administration and dispensing of naloxone makes no stipulation whatsoever as to the level of training required for this endorsement. This amendment to the EMA Regulation seems to mean that there is no required training other than that determined by the corporation. This is another symptom of the disjointed

338 British Columbia Pharmacy Association website, "Administration of Injections".

339 *Ibid.*

340 College of Registered Nurses of British Columbia (CRNBC), 2016, 26.

341 BCEHS, March 8, 2016.

policy that has arisen due to lack of collaborative policy-making: EMALB has been required by the corporation to endorse EMA FRs and EMRs for a skill, but has no role in reviewing and/or recognizing training requirements.

Of greater concern perhaps is that the recent MO has also authorized EMA FRs and EMRs, the two lowest tiers of EMAs, to *dispense* narcotic antagonist drugs, which represents a significant departure from the hitherto existing scopes of practice of any EMA level of licence. Furthermore, it would appear that the upper tiers, i.e., PCPs, ACPs, CCPs and ITTs, do not have this endorsement under the current regulation. Again, it is instructive to compare this with the conditions placed on RNs, who do have medication dispensing within their scope of practice, on dispensing naloxone. For RNs, the CRNBC requires that they "possess the competencies established by the B.C. Centre for Disease Control (BCDDC) and follow decision support tools established by BCCDC".[342] These competencies include, among others, skill in "[o]btaining relevant health history...[s]creening for risk of opioid overdose...[p]roviding appropriate participant education" and "[a]ssessing the need for referral to other health care providers",[343] knowledge of opioid overdose factors, signs and symptoms, and response and knowledge of the pharmacology of naloxone,[344] and assessing the client's "understanding of opioid overdose prevention, recognition, and response".[345] However, naloxone is only to be dispensed to opioid users who have undergone training. RNs are required to conduct a clinical assessment as to opioid and other substance use or misuse and a physical assessment.[346] Client education about opioid overdose and naloxone administration is also required.[347] It is unlikely that FRs and EMRs have developed such competencies, and it is unclear in which circumstances such dispensing of naloxone would take place.

Continuing Competence

Aside from the issue of sufficient *initial* training, there is also a question about *continuing* competence requirements. On this issue, the MO is silent, which may point to another policy disjunction. It would be reasonable to expect that administration of naloxone is a skill requiring ongoing competence in order to maintain the endorsement. This may be achieved through patient contact,

342 CRNBC, *op. cit.*, 26.

343 BCCDC, 2015a, 1. We note that given the recent revision to the listing of naloxone, requirements for RN dispensing may well be reviewed.

344 *Ibid.*

345 BCCDC, 2015b, 1.

346 *Ibid.*, 2.

347 *Ibid.*, 4.

but for those EMAs lacking such contact, a continuing education refresher course might be warranted. Although EMRs, in order to maintain their licence, must participate in the continuing competency program outlined in the EMA Regulation, there is no requirement for FRs to either have a minimum number of patient contact hours or to complete continuing education requirements. This could be problematic for EMALB, as it is now required by the corporation to endorse this skill for FRs, but has no mechanism for ensuring that whatever competency has been acquired through the corporation's training session is in fact maintained. Arguably, this increases risk of harm to patients, and is not in the interest of the "protection of public health or safety", as stated in the MO.

Sustainability

One further consideration is worth noting. Because fire departments are the responsibility of municipalities, the costs associated with administering and dispensing naloxone will be borne by municipalities, rather than the province. Such costs include not only the need to stock naloxone administration kits, and to replace them upon expiry (between 18 and 24 months for the IM formulation), but also the training involved and, quite possibly, retraining, depending upon BCEHS determination.

Yet there has been little study done on whether this is either sustainable or cost-efficient. BC's municipalities are already concerned about the financial impact of the BCEHS Resource Allocation Plan, and it is unclear to what extent BCEHS held discussions with the municipalities about the regulatory change effected by the Ministerial Order regarding administration and dispensation of naloxone by FRs and EMRs. In the absence of such collaboration, it is possible that uptake of this initiative will be low. At least one municipality, Langley City, has indicated that it does not intend to equip its FRs with naloxone, as wait times between FR response and ambulance arrival do not warrant this step.[348]

Disjointed Policy 2: The Community Paramedicine Ministerial Order

Some of the concerns outlined above are similar to those raised by a previous Ministerial Order regarding Community Paramedicine, which also involved shifts in legal authority and oversight for the paramedics working in this capacity.

[348] Ferguson, 2016.

For a number of years, the APBC's strategic priority has been to collaboratively work towards the implementation of CP programs in BC. In May 2014, APBC released its report, *A Framework for Implementing Community Paramedic (CP) Programs in British Columbia*, in response to the lack of accessible and timely acute and chronic health care in rural and urban BC. To cultivate this idea in the health care community, APBC consulted with a number of stakeholders in BC and across the country, and engaged consultants to research and craft the foundation document. Subsequent to the release of APBC's report, BCEHS moved to implement a phased roll out of CP programs across the province, starting with northern BC in May 2015.

On November 15, 2015, the Emergency Health Services Act was amended by a Ministerial Order as follows:

> "Pursuant to section 5.1 (2) and section 5.1 (1)(1) of the Act, the following service is hereby designated and included within the purposes of the corporation:
>
> 1. The name of the service is the "Community Paramedicine Program".
>
> 2. The nature of the service is:
>
> a) the selection, training and examination of employees who may provide community paramedic services;
>
> b) the maintenance of a registry of community paramedics;
>
> c) the establishment of standards of practice, guidelines or protocols respecting the delivery of community paramedic services by community paramedics;
>
> d) the establishment of continuing competency requirements and the monitoring of compliance by community paramedics with those requirements; and
>
> e) the administration of a process to receive, investigate, make determinations and take away any necessary action in response to complaints about community paramedicine.

The above amendment to the EHSA appears to place the legal authority for many aspects of Community Paramedicine in the hands of the corporation, such as the approval of education programs, examination, the establishment of continuing competency requirements, and the monitoring of compliance. A second concern is that the Administrative Tribunals Act applies to the EMALB when addressing a compliance concern, but it is not clear as to

whether the employer (BCEHS) is legally obligated to follow this Act regarding competency concerns for a Community Paramedic. If this interpretation is correct, this change results in inconsistencies in regulation and substantially reduces EMALB's oversight and involvement and raises concerns regarding the processes and procedures for addressing issues related to competency concerns, including investigation processes, appeal procedures, etc.

Network Governance and Collaborative Policy-making

> …no organization of government possess sufficient authority, resources, and knowledge to effect the enactment and achievement of policy intentions. Instead, policies require the concerted efforts of multiple actors, all possessing significant capabilities but each dependent on multiple others to solidify policy intention and convert it into action.[349]

Our examination of various aspects of the recent FR/EMR naloxone endorsement make it evident that this is a wicked issue, in the contexts of the domains of community safety/emergency response, health care, and drug policy. In this chapter we discuss approaches to resolving wicked issues, and contrast them with the policy-making processes (i.e., the whole sequence of interactions) that led to our two case studies, the FR/EMR naloxone MO and the Community Paramedicine Programs MO. We suggest that in both cases, a network governance approach based on collaborative policy-making is likely to have been more effective. The FR/EMR naloxone MO process appears to have been a typically authoritative or hierarchical approach to policy-making. In contrast, the CP program MO process did start out collaboratively, and showed promise of forging new ground in collaborative policy-making. However, with the recent CP program MO itself, there was a reversion to an authoritative approach that appears to have undercut the collaborative groundwork that preceded it.

First, we review some approaches to resolving wicked issues suggested in the literature on network governance and collaborative policy-making, and how this contrasts with approaches more suited to tame problems, particularly the hierarchical or authoritative approach often found in public policy making. We then outline the processes that led to the two MOs, as far as can be determined from available documentation, to show that in both cases the end result was authoritative rather than collaborative, and thus ill-suited to resolving the wicked issues at hand.

Network Governance and Collaborative Policy-making

> Collaboration…is seldom an efficient endeavour…[350]

[349] Bressers et al., 1995, 4 (cited in Imperial, 2005, 282).

[350] Provan and Kenis, 2007, 242.

The literature on network governance and collaborative policy-making is extensive, and a thorough review would be beyond the scope of this paper. Here we draw on a few studies that indicate the components and considerations involved in these approaches to policy-making, and how they are more applicable when dealing with wicked issues.

To briefly recap, wicked issues are those kinds of issues or problems where the problem itself is part of the problem, i.e., "there is broad disagreement on what 'the problem' is".[351] Different stakeholders have different values and judgements they bring to the issue, and see it in different ways, from different perspectives. And "the paradox of wicked problems is that strategies for solving such problems are informed by the way one looks at them".[352] For that reason, there is no definitive "solution", only a better or worse *resolution*, and one that has lasting consequences. As Roberts points out, they are also dynamic, in that "constraints...are constantly changing" in part because of the variety of stakeholders involved and the fact that they come and go,[353] in part because working to resolve such issues changes the understanding of them along the way. Such "dynamic complexity…defies the confines of established 'stovepiped' systems of problem definition, administration, and resolution".[354]

With this kind of complexity, it could seem that wicked issues are inherently intractable. However, the challenge lies not so much with the issues themselves as with the predominant forms of policy-making. In particular,

> top-down centered models of public governance that leave policy making and policy innovation in the hands of politicians and executive managers can result in policy execution problems: The policies fail to produce the desired outcomes because decision makers rarely acknowledge the full complexity of the problems they seek to solve, the limitations of existing policies and the potential of new and emerging policy ideas.[355]

Under such conditions, what is required is policy innovation, "the formulation, realization and diffusion of new problem understandings, new political visions and strategies for solving them".[356] Yet all too often, collaboration is viewed from the perspective of service delivery, "while little attention is given to the question of how collaborative forms of governance can contribute to promoting policy innovation".[357] Collaborative policy-making has great potential in addressing wicked problems, because it allows for the development of new,

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351 Roberts, *op. cit.*, 1.

352 Termeer et al., 2015, 681.

353 *Ibid.*

354 Weber and Khademian, *op. cit.*, 336.

355 Sørensen and Waldorff, 2014, 3.

356 *Ibid.*

357 *Ibid.*, 2.

shared understandings of the issue at hand by bringing together disparate perspectives, each of which informs such understanding. Policy formulated on the basis of such shared understandings thus is likely to encourage a higher level of commitment on the part of stakeholders, as well as a higher degree of trust among them.

> [P]olicy execution problems are overcome through mobilization of the knowledge, ideas, entrepreneurship of the public employees and other relevant stakeholders not only in the implementation phase but also when new policies are being developed and tested.[358]

However, collaborative policy-making faces barriers, some of which arise from "the traditional institutional set up of policy making in representative democracy", others because

> the traditional perception of politicians as sovereign legislators and strong visionary political leaders in their own right…leaves limited or no space to collaborative policy innovation with other actors than other politicians or leading public administrators.[359]

Finally, policy-making is often viewed as an "in-house activity", for which the input from stakeholders who are not politicians or public administrators is either in the form of lobbying or response to proposals (as with the practice of "public consultation"). "[T]here are few political arenas that accommodate policy innovation between politicians and relevant and affected stakeholders".[360]

Despite such barriers, network governance theorists argue that networks have the potential to foster such collaboration, depending on how their governance is understood and conducted. Networks can be understood as "the enduring exchange relations established between organizations, individuals, and groups",[361] and as "structures of interdependence, involving multiple organizations, that exhibit some degree of structural stability but that include both formal and informal linkages or relationships".[362] In other words, they are organizations of organizations that are linked or interrelated, typically around some common purpose or issue. What makes them *networks* is their interdependence, i.e., that in order to achieve their aims, they need to rely on one another, not only because each organization has limited resources, but more importantly because each one only has a partial understanding of the wicked issue with which they are dealing. That is, their interdependence is not simply operational; it is, in some sense, constitutive of their mission or policy objectives as the organizations they aim to be.

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358 *Ibid.*, 3.

359 *Ibid.*, 5.

360 *Ibid.*

361 Weber and Khademian, *op. cit.*, 334.

362 Imperial, 2005, 287.

Keast et al. suggest that network structures go beyond networks as other theorists understand them. They argue that "wicked issues require new ways of working and thinking, beyond the traditional approaches that have been found to be inadequate and inappropriate".[363] However, these new ways of working and thinking are difficult for decision makers, who "expect outcomes and processes that are consistent with the traditional, comfortable forms of working".[364] The "network structure" is one such new way of working and thinking, which goes beyond simple networks that "occur when links among a number of organizations or individuals become formalized" but each organization or individual operates independently. "[I]n a network structure people must actively work together to accomplish what they recognize as a problem or issue of mutual concern". What is particularly challenging for policy makers is that, in network structures, "there is no one 'in charge'...the typical forms of power and authority do not work".[365] In the absence of authoritative leadership, mutual trust is a key element, but "[t]he reality is that in the political arena, this trust may not be easy to build".[366] However, recognition of mutual interdependence and developing a holistic perspective can facilitate building trust.

Keast et al. summarize this kind of arrangement as follows:

> A network structure is composed of representatives of many diverse entities. It may include representatives of government, business, the voluntary sector, and community members. Each member, however, is perceived as an equal partner in the endeavour. Actions are based, not on top-down authority, but on horizontal partnerships. Hierarchical control will not lead to results.[367]

However, when no one is in charge, *governance*, "the means for achieving direction, control, and coordination of individuals and organizations with varying degrees of autonomy to advance joint objectives",[368] becomes a concern. How are more or less autonomous organizations to ensure that they can work together in a coherent way, if there is no central directing agency? It is tempting to see this as a *meta*-wicked issue, in the sense that addressing the wicked issue around which the network is forming would seem to first require resolving this governance issue. But this is an analytical mistake. The governance issue occurs at the same level as the wicked issue the network is forming around and, arguably, is a constituent component of the effort to resolve that wicked issue. This is not to say that governance need not be considered. Rather, we

363 Keast et al., 2004, 363.

364 *Ibid.*, 364.

365 *Ibid.*

366 *Ibid.*, 365.

367 *Ibid.*, 369.

368 Imperial, *op. cit.*, 282.

suggest that the demand for a governance structure or the uneasiness with no one being in charge is a response that arises from the perspective of traditional policy-making, which serves to forestall the ability of a network to actually engage with the wicked issue at hand.

In this regard, it is useful to look at the ways that different governance models can be characterized. Roberts, for example, contrasts "three generic coping strategies: authoritative, competitive, and collaborative",[369] which she relates to the degree to which power is concentrated among stakeholders. When power is concentrated, authoritative strategies can be used, which put "problem solving into the hands of a few stakeholders who have the authority to define a problem and come up with a solution".[370] These kinds of strategies work by "taming" the problem, in that they forestall any conflict over it. Although they have the advantage of being able to get things done, they have the disadvantage that what is done may be the wrong thing, since "authorities and experts can be wrong – wrong about the problem and wrong about the solution".[371]

Competitive strategies, also called market strategies, come into play when power is dispersed but contested, and are characteristically zero-sum games. That is, winning the right to define the problem means that the opponents lose:

> Central to the pursuit of competitive strategies to deal with wicked problems is the search for power. To the extent a competitor can build a power base larger than his opponents…he can increase his chances to win and define the problem and solutions in a way he sees fit.[372]

The advantages here are that such strategies can encourage new ideas, and also "Challenge the institutionalization of power".[373] The disadvantages are that they can exacerbate conflict, and "consume resources that could be spent on problem solving". That is, the struggle for power can become an end in itself, and in cases where "stakeholders have enough power to block one another but not enough power to get something done", leads to "stalemates and gridlock".[374]

Finally, collaborative strategies come into play where power is dispersed but *not* contested, and are "premised on the principle that by joining forces parties can accomplish more as a collective than they can achieve by acting

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369 Roberts, *op. cit.*, 2. Imperial terms these hierarchical, market and collaborative control mechanisms (*op. cit.*, 286), as do Weber and Khademian (*op. cit.*, 334).

370 Roberts, *op. cit.*, 4.

371 *Ibid.*

372 *Ibid.*, 5.

373 *Ibid.*, 6.

374 *Ibid.*

as independent agents".[375] The advantages are that costs and benefits can be shared. The disadvantages are the increased 'transaction costs' that come from having to negotiate with a larger number of stakeholders, and the need for collaborative skills, which are often lacking. In the worst case, collaboration breaks down entirely.[376]

Head and Alford make a similar point about collaboration, which they argue "is important but requires other measures", namely

> broader ways of thinking about variables, options, and linkages; and new models of leadership that better appreciate the distributed nature of information, interests, and power.[377]

Central to collaboration, these scholars argue, are

> some degree of shared understanding, agreed purposes, mutual trust, and usually an element of interdependence...which usually require time, effort, and skill to bring about.[378]

The advantages that accrue to functioning collaborative networks are that they foster shared understanding of the problems, finding provisional solutions, and implementing solutions.[379] One particular advantage is that they can "tap into a wider body of specific knowledge and skills than can unilateral decision makers", including "expert knowledge" and "situational knowledge", the latter which refers to the knowledge participants in the network have due to their "social or institutional location".[380] In other words, collaboration doesn't just expand the range of professional and technical knowledge available to the network, it also expands the range of social and institutional knowledge available, e.g., the relationships between different actors the network may encounter. And these become beneficial when combined with two other important characteristics of collaborative networks: regular communication and "a degree of trust and mutual commitment".[381]

This is not to say that collaboration does not involve control mechanisms, but rather that network governance has to correspond to the kind of interaction that occasions the formation of networks themselves. In some cases, networks are mandated by some decision-making authority, rather than forming in a more spontaneous way.[382] In such cases, "no choice of form is even possible",

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375 *Ibid.*

376 *Ibid.*, 7.

377 Head and Alford, *op. cit.*, 722. We return to the issue of leadership below.

378 *Ibid.*, 725.

379 *Ibid.*, 725-726.

380 *Ibid.*, 727.

381 *Ibid.*

382 See, for example, Provan and Kenis, *op. cit.*

but even so, "decisions about network governance do not simply emerge out of thin air...they are determined by decision makers, like government policy officials..."[383]

Provan and Kenis discuss an approach that views networks *as* "a form of governance" or "a mechanism of coordination",[384] with particular attention to what they call "goal-directed networks", i.e., "those set up with a specific purpose".[385] These authors see two dimensions to network governance: (i) the continuum between "highly decentralized" and "highly centralized" (which these authors refer to as "brokering"); and (ii) internal versus external governance, i.e., governance done by one or more of the network participants as opposed to an external organization:

> Externally governed networks are governed by a unique network administrative organization…which may be either voluntarily established by network members or mandated as part of the network formation process.[386]

These two dimensions can be used in tandem to understand typical forms of network governance. Provan and Kenis focus on three of these: participant-governed (decentralized and internal), lead organization-governed (centralized and internal), and network administration organization (NAO)-governed (somewhat centralized and external). Each form has "its own particular strengths and weaknesses".[387] In particular, they argue, there are "three basic tensions…inherent in network governance", and the way these are managed is critical to a network's success.[388] These tensions are between inclusiveness and efficiency, internal versus external legitimacy, and flexibility versus stability.

For example, highly decentralized "shared participant governance" networks are more inclusive, but less efficient, as network members must be involved in decision-making, whereas lead-organization governed networks are "far more efficient, but the trade-off may be a reduction in the commitment of participants and a focus on the needs of the lead organization, thereby potentially reducing overall network effectiveness".[389] Interestingly, Provan and Kenis see both of these forms commonly occurring in health and human services: "shared-governance networks are common, in part because networks are often considered to be an important way of building 'community capacity'". However, lead-organization-governed networks occur when "one organization

383 *Ibid.*, 237.

384 *Ibid.*, 232.

385 *Ibid.*, 231.

386 *Ibid.*, 234.

387 *Ibid.*

388 *Ibid.*, 242.

389 *Ibid.*

has sufficient resources and legitimacy to play a lead role", such as "a core provider agency that assumes the role of network leader because of its central position in the flow of clients and key resources".[390] Examples of such core provider agencies are hospitals, mental health clinics, and the local health department.[391]

The NAO form of governance can be seen as a compromise between inclusiveness and efficiency, although "any increase in administrative efficiency may be viewed by participants as being bureaucratic and, thus, inconsistent with network goals of collaboration".[392]

The tension between internal and external legitimacy arises in network governance because participants may have limited experience of interacting with a variety of other organizations, or may be used to competing. One of the key roles of network governance, then, is "to develop and encourage interaction, making it commonplace and accepted", such that the network has legitimacy for its participants.[393] Failing to do so can result in participants simply acting more or less independently.

> If participants do not see interactions and coordinated efforts as being a legitimate way of conducting business, with potential benefits from these interactions…then the network is likely to exist in name only with little real commitment by participants to network-level goals and outcomes.[394]

On the other hand, external legitimacy is required in order to be able to respond to external expectations, and so that "[o]utside groups can see that the network is an entity in its own right, and not simply a group of organizations that occasionally get together to discuss common concerns".[395] The absence of such legitimacy can make it difficult for outsiders to view the actions of individual participants "as representing the full network".[396]

Establishing such external legitimacy can also strengthen participants' commitment to the network. However, doing so can come in conflict with internal legitimacy, since it "often involves actions and activities that may benefit the overall network, but not necessarily many of the individual participants or the internal needs of the network itself, such as building interactions".[397] Shared-governance networks are more conducive to internal legitimacy,

390 *Ibid.*, 234-235.

391 *Ibid.*, 235.

392 *Ibid.*, 242-243.

393 *Ibid.*, 243.

394 *Ibid.*

395 *Ibid.*

396 *Ibid.*

397 *Ibid.*, 244.

whereas lead organization-governed networks are more conducive to external legitimacy, but also more prone to be seen as acting to the benefit of the lead organization itself. Again, the "NAO form attempts to strike a balance between these two forms", but often sequentially rather than simultaneously and "only following a legitimacy crisis stemming from lack of attention to one side of the tension".[398]

Finally, flexibility and stability are in tension, particularly because one of the advantages of networks is that they can respond quickly to changing circumstances compared to hierarchies, "which can be cumbersome and bureaucratic".[399] But stability is also required for a network to be sustainable, and for maintaining legitimacy:

> Essentially, flexibility is important for ensuring rapid network responses in ways that meet changing stakeholder needs and demands. But stability is important for developing consistent responses to stakeholders and for efficient network management over time.[400]

As might be expected, networks with more formal and structured forms of governance, either through a lead organization or an NAO, are more stability-oriented, whereas shared-governance networks have the advantage of greater flexibility.

The final dimension related to network effectiveness we discuss here pertains to "the challenge associated with knowledge sharing among diverse participants".[401] Weber and Khademian argue that "[k]nowledge sharing and integration are key to building collaborative capacity", but achieving this can be difficult "for networks built around wicked problems, where the differences between participants are deep and the barriers to knowledge transfer, receipt, and integration are distinct".[402] In such contexts, the diversity of the participants may well result in different interpretations of information because of their different perspectives: "the information flowing through the network is likely to have different meanings, different uses, and different values for the individuals and groups receiving it and using it".[403] Because one of the advantages of networks in addressing wicked problems is the sharing of knowledge and information, mitigating such barriers is another important aspect of network governance.

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398 *Ibid.*

399 *Ibid.*

400 *Ibid.*, 245.

401 Weber and Khademian, *op. cit.*, 335.

402 *Ibid.*

403 *Ibid.*, 337.

Weber and Khademian distinguish knowledge and information, arguing that knowledge "is socially mediated information" that "cannot be separated from the application, use, and development of information".[404] Even more fundamental, knowledge in this sense is not some kind of object or asset that can be transmitted to other participants. Rather, it is a form of practice, whereby "participants *know* the problem and perceive possible solutions through their engagement with the problem".[405] In this sense, knowledge is viewed as a form of practice, which is situated or "local" to "a geographic setting, a particular point in time, or within a particular set of relationships", and "intricately connects the knowledge that people and organizations have to the practices or activities of both".[406]

Managing network knowledge sharing thus requires particular skills and competencies that takes the situatedness of knowledge into account, in order to "integrate network knowledge into the kind of unified, practical and useful knowledge base necessary for achieving effective collaborative problem-solving capacity for wicked problems".[407] Among these, Weber and Khademian suggest, is a "commitment to govern with the rules yet think creatively", and a "commitment to networks as mutual-aid partnerships with society".[408] The first recognizes that

> a heavy rules-oriented approach is unlikely to create the kinds of relationship among stakeholder that are required for the sending, receiving, and integration of knowledge needed for long-term problem-solving capacity.[409]

The second recognizes that participants and potential participants in the network "face legitimate constraints on collective action", including

> the fear that government authorities will not listen to, much less incorporate and allow, innovative solutions produced by those outside the agency that has formal jurisdiction over the problem.[410]

In such conditions, the management role needs to be facilitative, rather than "the blunt, coercive use of formal authority", which "risks breeding resistance and alienating the very people necessary for successfully managing a particular wicked problem".[411]

404 *Ibid.*, 338.

405 *Ibid.*

406 *Ibid.*, 339.

407 *Ibid.*

408 *Ibid.*, 342.

409 *Ibid.*

410 *Ibid.*

411 *Ibid.*

To summarize, then, collaborative, network-based approaches are a valuable way of working to address a wicked issue, that avoid the pitfalls and policy failures that come from top-down or authoritative approaches that attempt to tame the issue. In particular, they present a viable way to achieve policy innovation. However, the success of these approaches is highly dependent on how the inherent conflicts and tensions that arise when diverse participants seek to work together are managed. Again, research suggests that top-down or authoritative approaches may be the least appropriate.

The Recent Ministerial Orders from the Network Governance and Collaborative Policy-making Perspective

We are now in a position to analyze the processes that led these two recent MOs as instances of policy-making that addresses wicked issues in terms of the collaborative and network dimensions just discussed. Our contention is that both of these processes are indeed network approaches, but because of the kind of hierarchical approach to managing the network involved, they fall short as attempts to resolve those wicked issues.

The FR/EMR Naloxone MO Process

> Naloxone access is not a magic bullet. The initiatives outlined above must be undertaken in the context of a broad, nationwide effort to reduce inappropriate opioid prescribing, increase access to evidence-based treatment, and modify punitive, counterproductive criminal justice approaches to addiction.[412]

As previously discussed, the FR/EMR naloxone MO amending the *Emergency Health Services Act* was issued on January 8, 2016, specifically empowering BCEHS ("the corporation") to order the EMALB to endorse FRs and EMRs to dispense and administer narcotic antagonist drugs. According to the BC government's press release announcing this regulatory change,

> The new program is the result of collaboration between the Ministry of Health, Provincial Health Services Authority (PHSA), BC Emergency Health Services (BCEHS), BC Centre for Disease Control (BCCDC), Fraser Health and municipal authorities…[413]

Here there is a clear reference to collaboration, and the list of stakeholders presented suggests that they are functioning as some kind of network.[414] In

[412] Davis and Carr, 2015, 119.

[413] British Columbia Government News. January 28, 2016.

[414] However, it should be noted that two of the participating agencies (BCEHS and BCCDC) are actually part of a third, the PHSA.

terms of governance structure, a quote in the press release from Linda Lupini, executive vice president, PHSA and BCEHS seems to suggest that BCEHS was the lead organization for this initiative: "We're very pleased that BC Emergency Health Services is in a position to oversee this program..."[415]

Arguably, then, this is a case of a network formed to address the wicked issue of access to naloxone in the case of opioid overdose. But rather than grapple with the wicked issue, the MO as the outcome of the process represents a top-down attempt to tame it that resulted in suboptimal policy-making.

One indication of the failure to address the wicked issue is immediately evident from the list of stakeholders involved, as apart from the unspecified municipal authorities it only comprises government institutions. And even in that regard, it seems deficient, as there are five other regional Health Authorities that perhaps ought to have been involved. Nor is it clear how many of BC's 161 municipal authorities were actually involved. The most that can be determined from the press release is that there were at least two.

However, it is the absence of other stakeholders that stands out with this process. Given the scope of the issue and the impact of measures to address it, one could have expected involvement from all of the following: (i) non-governmental organizations, (ii) health professionals,[416] (iii) health profession colleges and associations, (iii) community safety organizations,[417] (iv) hospital representatives, (v) representatives of people who use drugs, such as the Vancouver Area Network of Drug Users (VANDU), (vi) BC Patient Safety & Quality Council, (vii) the EMALB, and (viii) the APBC.[418]

It would appear, then, that the policy-making approach to this issue was not as collaborative as the press release tries to suggest, and was in fact a more traditional, hierarchical or top-down approach, effected by the BCEHS as the lead organization. As such, it is unsurprising that this policy decision has resulted in disjointed regulation and may, in fact, serve to compromise patient and provider safety.

It is unclear why such an approach was taken, rather than a properly collaborative approach. According to a recent newspaper article, BCEHS had

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415 British Columbia Government News. January 28, 2016

416 We note that a Qs & As document attached to a January 28, 2016 memorandum to all BCEHS staff from Linda Lupini, Executive Vice-President, PHSA and BCEHS and Jodi Jensen, Chief Operating Officer, BCEHS states that "Numerous medical professionals such as ER physicians, intensivists and public health officers have voiced their support for this program". However, no additional information is provided about who these individuals are, or how and when they were consulted.

417 Although the press release does quote Surrey fire chief Len Garis.

418 The January 28 memorandum to all BCEHS staff, as well as an earlier on January 14, indicate that there was little if any discussion about this initiative with the APBC prior to the MO being signed.

met with the APBC in June 2015 "to discuss firefighters using naloxone",[419] so presumably had begun to consider the issue beforehand. Seven months would have been enough time for BCEHS to collaborate with a wider network. It is possible, then, that this process was driven by the "politics of urgency", as a result of increasing media attention to the issue of opioid overdose.

The CP Program MO Process

> So a collaborative partnership is not about giving away authority. It is about exercising it differently. It is about learning how to make decisions together with others, rather than trying to command and control them.[420]

In contrast with the FMR/EMR naloxone MO process, the CP program MO process seems to have been more genuinely collaborative, as indicated in a variety of documents. For example, the first BCEHS press release about this initiative (released May 25, 2015) states that "BCEHS has been coordinating the implementation of community paramedicine in BC with Ministry of Health, the province's health authorities, and the Ambulance Paramedics of BC".[421] A later brochure issued by BCEHS expands the list of partners to include "the First Nations Health Authority and others".[422] However, work had been underway on this initiative for several years. As the APBC's 2014 report, *A Framework for Implementing Community Paramedic Programs in British Columbia*, states, "[f]or a number of years, APBC's strategic priority has been the implementation of CP programs in BC".[423] Two brochures produced by the APBC in 2013 are evidence of this.[424] Furthermore, a notice dated June 24, 2014 from the Health Employers Association of BC regarding negotiations with the Facilities Bargaining Association indicated that one highlight of the agreement signed on May 12, 2014 was "[c]hanges that will allow for the implementation of a community paramedicine program".[425] Finally, the EMALB's *Annual Report 2014/15* states that "[t]he EMA Licensing board will continue our collaborative relationship with BCEHS to support the training, examination and licensure of community paramedics as required for the successful implementation of the program".[426]

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419 Howell, 2016

420 Lenihan, *op. cit.*, 41.

421 BCEHS website, "Community paramedicine program launches in Northern BC". This statement was repeated in subsequent press releases as the community paramedicine program was rolled out in the BC interior and coast, on August 6, 2015 and December 2, 2015, respectively.

422 BCEHS, January 2016.

423 Evashkevich and Fitzgerald, *op. cit.*, iii.

424 APBC, 2013a and 2013b.

425 Health Employers Association of BC, 2014.

426 British Columbia Emergency Medical Assistants Licensing Board, n.d.

This evidence suggests that the CP program MO process was also a network approach, in this case to address the wicked issue of health care. Unlike the FR/EMR naloxone process, however, this network appears to have been more participant-governed than governed by BCEHS as a lead organization. That is, although BCEHS (as the employer) was a key participant, power seems to have been more widely dispersed, with the APBC able to provide impetus through the bargaining process, and with other organizations such as the EMALB ready to provide support from their domains of expertise.

It is surprising, then, to see that the CP program MO issued on November 15, 2015 assigns regulatory responsibility for those paramedics working as "community paramedics" entirely to BCEHS, when such assignment creates regulatory confusion. In contrast to the collaborative network approach that launched the initiative and led up to this regulatory amendment, here it seems that BCEHS has been positioned as the lead organization. As previously discussed, it is hard to see how such regulatory confusion and blurring of responsibility is in the best interests of the patients and communities this program is intended to serve. Arguably, in this case the shift from participant governance of the network to lead organization governance of the regulatory amendment also led to suboptimal policy-making.

Recommendations

In light of the evidence presented in this report, and in the interests of better policy and better policy-making, we offer the following suggestions:

- **That, in light of the regulatory concerns outlined here, the decision to empower BCEHS to require EMALB to endorse EMAs for procedures beyond their current scope of practice be reviewed;**
- **That, in light of the patient and provider safety concerns outlined here, the decision to endorse FRs/EMRs to administer naloxone be reviewed;**
- **That, in the interests of better policy-making regarding complex health-care, drug policy and other issues, the Minister of Health consider championing a collaborative policy network involving all stakeholders, to help resolve policies about wicked issues.**

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