The Ethics of Screening and Treating Persons with Hepatitis C:
A Canadian Perspective

Ramseyer Apau Bediako

Article abstract

In this article, I argue that the Canadian government's position against screening for hepatitis C virus (HCV) and publicly funding HCV treatment is ethically unjustifiable. Cost of medication and likelihood of widening existing health inequality are the government's argument for not funding HCV treatment and for also not having a screening program. I object to this position and argue in favour of a screening program and public funding of HCV treatment. I argue that these barriers are ethically unjust. Conclusively, being denied screening and early treatment is to be denied the best possible outcome.
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Keywords
Public funding, hepatitis C, screening program, vulnerable populations, resource allocation, eradication

Introduction
The World Health Organisation (WHO) estimates that about 130 to 150 million people are chronically infected with hepatitis C virus (HCV), with 1.75 million people being newly infected every year, and a whopping 350,000 die each year of hepatitis C related liver disease (1,2). Aside from increased risk of developing chronic liver disease, cirrhosis, and hepatocellular carcinoma (HCC), HCV-infected persons also serve as a reservoir for transmission to others (3). In Canada, it is estimated that about 251,000 persons in Canada have hepatitis C (4), but close to 44% of that population is unaware of their hepatitis C infection (5,6). Hepatitis C first gained public health attention in the 1980s when it was discovered that blood transfusions were a common source of infection or transmission (7). Even though the incidence rate of HCV in Canada has decreased in recent times, its prevalence has been relatively high (4).

Several studies and reports have shown that people who inject drugs (66%), inmates in federal or provincial prisons (23.3-24%), people living in nursing and long-term care homes (3%), men who have sex with men (5%), and immigrants (1.19%) are at an increased risk of HCV (1.5). A similar report by the Public Health Agency of Canada (PHAC) in 2011 suggested that using needles and other equipment by an infected person constitute an increased risk of HCV. The most common ways that people become infected were through receiving blood transfusions in Canada before 1992 and before blood was effectively screened for hepatitis C or receiving a blood transfusion in a country where procedures for screening blood are insufficient. In addition, sharing or borrowing personal items (such as razors, toothbrushes or nail clippers that contain traces of blood from a previous user), unsafe medical practices that involve reusing medical equipment that has not been properly sterilized, using tattoo or body-piercing or acupuncture equipment that has been reused without being properly sterilized, having unprotected sex, mother-infant transmission during pregnancy and delivery are also means of infection (7,8). The majority of all HCV cases are among Canadians who are 30 years or older and the highest reported rates are in the Yukon, Saskatchewan and British Columbia (7). The risk of reinfection is relatively low for the general population (1.1%), except for persons with HIV coinfection which increases the risk to about 21.7% (9).

Undoubtedly, HCV infection poses serious challenges to Canada’s public health and remains a global health issue. Subsequently, in 2016, the WHO adopted its first strategy to fight hepatitis “Global Health Strategy on Viral Hepatitis, 2016-2021”. This strategy seeks to eliminate viral hepatitis as a public health problem, and it is captured in the global target of reducing new viral hepatitis infections by 90% and reducing its associated deaths by 65% by 2030 (2). The Federal Government of Canada signed onto this strategy, but several expert commentaries (including those from hepatologists) suggest Canada is not on track to possibly meet those targets (10). Worst yet, there are no clear indications that either the federal or provincial governments are committed to or are on track towards eliminating viral hepatitis.

Interestingly, several studies have shown sustained virologic response-SVR (treatment success rates) to be between 90-100% after 4 to 12 weeks treatment (11,12,13). The improved SVR cuts across all populations (14). Notwithstanding the advances in treatment and improved SVR, HCV remains a significant medical and economic burden in Canada (4) because it requires an expensive and resource-intensive course of treatment. I argue that the Canadian (federal and provincial) government’s position against screening for hepatitis C virus (HCV) and publicly funding HCV treatment is ethically unjustifiable. The argument that the high cost of medication and the likelihood of widening existing health inequalities justify not funding HCV
treatment or screening programs is ethically untenable. To be denied screening and early treatment is to be denied the opportunity for the best possible outcome.

Arguments against treatment and screening

In recent years, the pace of HCV drug development has increased dramatically (15). Despite these advances, multiple barriers stand in the way of HCV eradication, chief among these being the cost of medication/treatment. For instance, the Canada Taskforce on Preventive Health Care (16) reported that the high cost of medication discourages provincial governments from conducting widespread hepatitis C risk-based screenings. Thus, the cost of medication hinders population-wide and even risk-based screening. Provincial governments have argued that they cannot publicly fund treatment for the many people that are likely to be identified as true positives (people who are accurately identified as having HCV) through screening because of the cost of treatment. For instance, between 2015 and 2016, Ontario spent $290 million on a new discounted hepatitis medication for 3,700 patients for a 12-week treatment course (17). However, there are doubts as to whether other provincial governments could even do the same. How could Ontario and the other provinces provide population-wide screening and fund treatment for all persons with HCV? The argument is that public funding of HCV treatment will unnecessarily drain the government’s finances or the public purse. Note, however, that other equally expensive treatments for HIV, tuberculosis, and cancer are being publicly funded.

This argument against screening follows directly from the cost-related argument, i.e., that screening has the potential to increase or widen existing health inequality since the government has no intention to publicly fund HCV treatment. Currently, it is estimated that 44% of HCV-positive persons are not aware of their HCV-positive status [6], and in the event of public access to screening, this percentage would decrease while the percentage of people who know about their HCV status would increase substantially. Further, individuals at increased risk of HCV are mostly people with lower socioeconomic status (3), will most likely be without any comprehensive private insurance plans and may also not be able to pay out of pocket. The assumption is that, given their social class (or socio-economic status), those at higher risk of HCV may not be able to afford HCV treatment. Most screen-detected HCV patients would thus not benefit, except for those very few who may have comprehensive drug insurance plans or can pay out of pocket. Further, identified but untreated HCV-infected people would suffer an obvious harm (psychological and emotional) from having a known diagnosis (i.e., information) but no access to treatment (i.e., ineligibility to act on the information).

So, the argument goes that publicly funding screening, while affordable, will increase the number of persons with known HCV but they will, for the most part, be unable to access publicly funded treatment. Thus, it is argued, screening would do more harm than good.

Arguments in favour of funding treatment and screening

Benefits of funding HCV treatment

Despite the advances in therapeutic options and understanding of current trends in treatment in recent years (15), several barriers stand in the way of HCV eradication. As I have already argued, the high cost of HCV treatment is one of several barriers (18). Nonetheless, I object to this 'cost-related argument' and instead argue that HCV patients have a justified claim to publicly funded full course treatment, just like persons with HIV/AIDS, cancer and tuberculosis.

Given the importance of pharmaceutical drugs in modern healthcare delivery, it is puzzling that largely universal health service coverage in a nation like Canada ends when a patient is handed a prescription. In fact, Canada is one of the very few developed nations with a universal public health insurance system that does not include universal coverage of prescription drugs outside the hospital setting (19). Sadly, 1 in 10 Canadians cannot afford to take their medicines as prescribed and several studies within and outside the Canadian context show that such barriers worsen health outcomes, including premature deaths and severe disabilities (19,20). And this outcome can be even worse for those who are already “worse off”, i.e., HCV patients.

The various governments positions on access to hepatitis C medication is simply a case of injustice in the allocation of health care resources. I do not in any way suggest that governments have infinite resources to fund all healthcare services, but rather that these HCV positive individuals do have claims to equal access to essential healthcare services. Therefore, the government’s position also raises concerns about moral entitlement and equity in health, especially when other out-of-hospital drugs and treatments are being publicly funded. This underscores an arbitrary system.

As already mentioned, there is evidence to suggest that “less well-off citizens” generally suffer a greater number of health-related problems throughout their lives. For instance, lower socio-economic status is associated with an increased risk of HCV infection and patients with low SES also have higher mortality (3) and disability rates. For example, Shah et al.’s study in Ontario showed that HCV causes more lost years of life and illness than any other infectious disease (21). Against this backdrop, a Rawlsian egalitarian will argue that a society like Canada has an obligation to correct already existing inequalities in resource distribution (22). As Coughlin et al. argue, this theory favours the unequal but equitable distribution of resources to favour the worst off (i.e., persons with HCV). Persons who inject drugs, prisoners, street youth and others who also have
HCV do have greater health needs. Therefore, any system that does less for these HCV patients, who are already worse off, is unjust.

The egalitarian argument is that all individuals in our society deserve equal concern and respect with regard to access to needed health care services and that the basis for determining how health care ought to be distributed justly is need, but should not be based on social worth or ability to pay (23). The egalitarian’s goal is to reduce disparities in health status among different groups in societies: including the poor, people living in rural areas, ethnic or racial minorities and others (24). Therefore, the egalitarian’s concept of justice as being fair implies the right to free and universally accessible healthcare for every citizen, including access to medication for HCV patients. Thus, the availability of free health care remains central to the egalitarian’s concept of a fair society.

Also, a common assertion central to the theory of justice is that “equals must be treated equally, and unequals must be treated unequally.” This suggests that when all circumstances for all persons are equal, everyone should be treated equally (25). Unfortunately, all persons cannot be equal. Therefore, the principle of justice requires not only fair distribution of resources but also doing more for an already vulnerable population with compounding HCV. In fact, fair distribution of healthcare resources should favour persons with HCV. Similarly, applying the rule of fair opportunity would require that disadvantaged individuals receive healthcare benefits that improve the unfortunate effects of life’s lottery. So, as these individuals cannot be held responsible for their HCV infection, the rule of fair opportunity demands they receive publicly funded treatment to help reduce the unfortunate consequences of life’s lottery (25).

There are opposing arguments suggesting that HCV patients do not have a just claim to social resources needed to restore their health because of the strong social disapproval attached to behaviours that result in HCV infection, which suggest individuals are responsible for their health status (26). There are also arguments that it is unfair to individuals who have been responsible, to be paying for the excessive health needs of those who have been irresponsible with their health (26). These victim-blaming arguments are seriously flawed. As Holland (27) argues, to focus on a person’s behaviour is to shift focus from the underlying determinants of health that are usually a multitude of environmental factors rather than personal responsibility. Providing access to healthcare to these vulnerable persons is a moral responsibility. HCV infection is curable, and early detection and intervention lead to improved overall health outcomes (21). Treatment aims to eradicate HCV viral load thereby increasing the quality of life and reducing the risk of cirrhosis and hepatocellular carcinoma (28). Victim-blaming and ignoring the medical needs of these individuals compounds existing inequality. It is also worth noting that inequalities begot inequalities, and existing inequalities compound, sustain and reproduce a multitude of deprivations, and the cycle continues (29).

**Benefits of public screening**

Hepatitis C is often touted as a silent killer because it can be asymptomatic for decades (6) until an infected person develops serious liver disease (30). Therefore, the first step toward improving health outcomes and preventing transmission is the identification of those with active HCV infection (31). Screening will reduce the harms associated with Hepatitis C by “providing presumptive identification of an unrecognized disease or defect through the application of tests, examinations or procedures which can be applied rapidly to sort out persons who probably have the disease from those who probably do not” (32). Even though the Public Health Agency of Canada (PHAC) and the College of Family Physicians recommend testing of individuals at increased risk for HCV, there are currently no screening programs across Canada (21). The lack of screening programs in Canada ought to be treated as a major public health concern, given that almost half of persons with HCV are not aware of their HCV status, and could be unknowingly exposing others to HCV or putting a whole population at risk. In fact, a population wide screening is recommended.

**Social utility benefit**

The utilitarian argument in favour of screening is that it is essential for early detection, and when the infection is treated, is linked to improved health outcomes. Essentially, screening and early treatment of HCV provide both public health and personal benefits by interrupting viral transmission or onward transmission, and by reducing associated mortality and morbidity (6,33).

There are several benefits of screening without treatment. Just knowing about one’s HCV status without treatment has a social-utility benefit, that is, it could cut down on viral transmission or onward transmission (34). For instance, Trepka et al. (34) reported that all interviewed patients in their study reported one or more positive behaviours to prevent HCV transmission to others or to protect their liver. For instance, 93.2% of persons that screened HCV-positive reported being careful not to share personal care items such as razors that could expose others to the infection, and 70.5% reported they had not donated blood, tissue, or semen since they were screened positive. Trepka et al. (34) also reported that 83.7% to 88% of HCV patients admitted cutting down alcohol use, stopping intravenous drug use (IDU), or had completed the hepatitis A or B vaccination series. The goal of vaccination against hepatitis A and B is to prevent liver failure occurring in individuals with liver affliction. Vaccination against hepatitis B also prevents potentially more severe liver damage associated with hepatitis B coinfection. These positive behaviours were adopted when people were screened and they became aware of their HCV positive status. A screening program with or without treatment stands to benefit a good number of persons who would otherwise be undiagnosed or unaware of their HCV status, and thus also the general public who are being exposed to or being placed at risk of HCV infection. Therefore, the government argument against screening, i.e., that it will increase existing health inequality and provide no clear benefit to those that will be identified as true positives, is weak and even unfounded. If anything, the government is doing more harm and placing the society at risk by not funding public screening.
Cost-effectiveness

HCV is very often asymptomatic until an infected person gets to the advanced stage. However, HCV infection is curable, and early detection and intervention lead to improved overall health outcomes (21). Thus, screening would lead to early diagnosis, which when linked to care could reduce HCV-related morbidity, mortality, and transmission (35).

Patients whose infection has been eradicated before cirrhosis develops have a life expectancy similar to that of uninfected people (36). However, in the absence of treatment, advanced stages of liver disease may present complications that may need inpatient hospital care, including liver transplantation (37), which can be very expensive. For instance, a study in the United States showed that Hepatitis C antiviral treatment averaged $10,000 to $30,000 per year, while liver transplant costs were at $203,434 for the transplantation and first year of postoperative care (38). Ultimately, if the government were to provide screening, detect persons with HCV and treat, it will be more cost-effective than waiting for an HCV patient to develop a liver complication that will require hospital in-patient treatment, which will be much more expensive. Further, the average incremental cost-effectiveness ratios for all HCV patients was US $55,400 per QALY (39). Baggaley et al.'s study (40) found that incremental cost-effectiveness ratios for screening for HIV in primary care were £22,201 per QALY gained, £372,207 per death averted, and £628,874 per HIV transmission averted. More important, the overall budget needed for HCV treatment is reasonable when compared to the treatment of other diseases like HIV (39,40). HCV is curable between 4-12 weeks, and therefore, spending on HCV would sharply decrease with time when compared to HIV treatment, which is a lifetime treatment. This direct and comparative evidence suggests that screening and early treatment of HCV would cost-effective.

The right to know or not to know

Text for this sub-section. Ensuring that HCV positive people have access to screening is a means of supporting “the right to know about a diagnosis”, a core means of respecting patient autonomy, as well as being consistent with the principles of non-maleficence and beneficence. Despite the obvious harms associated with not knowing about a diagnosis (34), not knowing can sometimes be beneficial, especially in cases where there are no treatments. For instance, knowing about a diagnosis and not having treatment can lead to serious psychological consequences (i.e., the veil of ignorance has been unveiled without treatment) (41), and so can be less harmful to the individual. This has been governments’ position against screening and treating persons with HCV. However, in the case of HCV, there are effective treatments with SVR of more than 90% (11—13). Also, as already discussed, most people with known HCV tend to take on healthier lifestyles in order to reduce risk to self and others (34).

Conclusion

The overarching goal of a publicly funded screening and treatment program for HCV is to decrease hepatitis-related morbidity, mortality, and transmission. To eradicate HCV, the government ought to have a population screening program, and publicly fund HCV treatment in order to increase treatment success rates and decrease treatment duration. Indeed, the elimination of HCV seems very possible if appropriate and timely steps are taken (40). The value of screening has been demonstrated and should be implemented and expanded beyond targeting at-risk populations. Not only is it just to screen and publicly fund treatment, but it is also cost-effective. Costs and other budgetary constraints impose difficult choices that influence the services that are provided, the patients whose drugs will be funded and the circumstances of general healthcare in Canada. However, the threat of arbitrary decision-making looms. How government decides which healthcare service to fund (which is based on medical necessity) is often described as arbitrary, which is in sharp contrast with accountability for reasonableness. Arbitrariness creates an unfair system which consequently leads to injustice in resource allocation. Going forward, these problems are likely to threaten the trust of Canadian citizens (patients) have in their healthcare system.
Les éditeurs suivent les recommandations et les procédures décrites dans le Code of Conduct and Best Practice Guidelines for Journal Editors de COPE. Plus précisément, ils travaillent pour s’assurer des plus hautes normes éthiques de la publication, y compris l’identification et la gestion des conflits d’intérêts (pour les éditeurs et pour les auteurs), la juste évaluation des manuscrits et la publication de manuscrits qui répondent aux normes d’excellence de la revue. Les éditeurs suivent les recommandations et les procédures décrites dans le Code of Conduct and Best Practice Guidelines for Journal Editors de COPE. Plus précisément, ils travaillent pour s’assurer des plus hautes normes éthiques de la publication, y compris l’identification et la gestion des conflits d’intérêts (pour les éditeurs et pour les auteurs), la juste évaluation des manuscrits et la publication de manuscrits qui répondent aux normes d’excellence de la revue.

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