

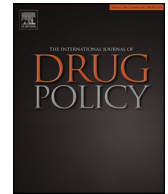


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Research paper

Beyond viral response: A prospective evaluation of a community-based, multi-disciplinary, peer-driven model of HCV treatment and support

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ABSTRACT

Background: Although the majority of new cases of hepatitis C (HCV) occur among people who inject drugs, very few receive treatment. In response, low-barrier, multidisciplinary models of HCV treatment have emerged in recent years to serve illicit drug users and have demonstrated comparable outcomes to the care delivered in tertiary care settings. However, few studies have measured comprehensive outcomes of these models.

Methods: The Toronto Community Hep C Program (TCHCP) is a community-based partnership between three primary health care centres with integrated specialist support. Program clients were interviewed using standardized questionnaires at three time points (baseline, post completion of HCV support group, and one year post group completion). The primary outcome of this study was self-reported overall health. Secondary outcomes included mental health, substance use, housing and income stability, and access to health care.

Results: TCHCP clients reported high rates of poverty, histories of trauma and incarceration. Physical and mental health co-morbidities were also very common; 78% reported having at least one chronic medical problem in addition to HCV and 41% had a lifetime history of hospitalization for mental health reasons. Participation in the program improved access to HCV care. Prior to joining the TCHCP, only 15% had been assessed by a HCV specialist. By the end of the study period this had increased significantly to 54%. Self-reported overall health did not improve during the study period. Housing status and income showed significant improvement. The proportion of participants with stable housing increased from 54% to 76% during the study period ($p=0.0017$) and the proportion of patients receiving income from provincial disability benefits also increased significantly (55% vs 75%, $p=0.0216$).

Conclusion: This study demonstrated that a multi-disciplinary, community-based model of HCV treatment improves participant's lives in ways that extend beyond hepatitis C.

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Background

Hepatitis C (HCV) is one of the world's most common chronic viral infections, infecting an estimated 170 million individuals

worldwide (World Health Organization [WHO], 1998). In Canada, estimated seroprevalence rates are 0.8%, with 4000–6000 new cases occurring each year (Remis, Hogg, Krahn, Preiksaitis, & Sherman, 1998; Zou, Tepper, & El Saadany, 2000). Although the majority of new cases of HCV occur among people who inject drugs, most illicit drug users are not treated despite the fact that effective therapies exist. Studies in both the United States and Canada have demonstrated that less than 1% of injection drug users initiate treatment (Grebely et al., 2009; Mehta et al., 2008).

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Barriers to HCV treatment for people who use drugs have been documented at a systems, provider and patient level. Systems barriers include exclusions for public funding of treatment medications and lack of access to specialists willing to treat drug users (Myles, Mugford, Zhao, Krahn, & Wang, 2011). At a provider level, concerns exist about adherence to treatment and mental health side effects, in particular where co-morbid psychiatric issues are present (McGowan & Fried, 2012). At a patient level, barriers to HCV treatment include: lack of knowledge about HCV, past negative experiences with health care providers/systems, as well as other competing health and social issues, such as unstable housing, poverty, incarceration and social isolation (Doab, Treloar, & Dore, 2005).

In an attempt to address some of these barriers, multi-disciplinary, community-based models of HCV treatment and support have emerged in recent years and have demonstrated treatment initiation and success rates comparable to HCV treatment delivered in tertiary care settings (Charlebois, Lee, Cooper, Mason, & Powis, 2012; Grebely et al., 2010; John-Baptiste et al., 2009; Sylvestre & Zweben, 2007). In addition to successfully providing HCV treatment, there is qualitative and experiential data to suggest that individuals enrolled in these programs may also experience positive outcomes beyond sustained virological response (SVR) such as housing and income stabilization, an improved sense of well-being and community-belonging (Newman et al., 2013; Woolhouse, Cooper, & Pickard, 2013).

Little prospective data, however, exists on the comprehensive outcomes of HCV care models designed to provide treatment and support to past or current drug users with potential concomitant mental health or other complex social issues. The purpose of this study was to examine health care and psychosocial outcomes in a prospective cohort of marginalized former or current drug users enrolled at a community-based HCV program.

Methods

Program model

The Toronto Community Hep C Program (TCHCP) is a partnership between three community-based primary health care centres with integrated specialist support from nearby hospitals. The aim of the program, which began in 2007, is to provide low-barrier HCV treatment and support to people who use illicit drugs and/or have mental health issues. In addition to HCV care and treatment, the program offers comprehensive social, emotional and practical supports. The program is anchored by a weekly psycho-educational support group (lasting 16–18 weeks) with up to twenty clients attending at each site. Clients may participate in multiple group cycles. In addition to providing accessible information about HCV, the group is also an important space for peer-to-peer support and knowledge sharing, as well as acting as a bridge to primary health care. As much as possible, clients receive their HCV assessment and care during the 2-h time period when the group takes place. Clients can receive both HCV-specific and general primary health care. Primary care clinicians (physician, nurse, nurse practitioner) are available during the weekly group sessions with monthly on-site support from the infectious disease specialist and psychiatrist, who also provide ongoing consultation between on-site visits. Primary care physicians have been mentored to be independently able to prescribe and manage HCV treatment medications. In addition to clinical care, clients can also access one-on-one supports including case management, peer support and mental health counselling on-site. The TCHCP is embedded within community-based agencies that are familiar with and willing to provide health care and other social services to people who actively use drugs, without

abstinence as an expectation or goal. There is no on-site opioid substitution therapy program at any of the community health centres and clients are not required to participate in addiction specific treatment programs. The program is based on the principles of harm reduction, community development and the involvement of people with lived experience of HCV in program design and delivery. The program is guided by a Patient Advisory Board and employs peer support workers. These are current or former clients of the program who provide informal counseling, group facilitation, outreach, and patient accompaniments. A schematic of the program model is represented in Fig. 1.

Study sample

Beginning in January 2011, all new clients who attended one or more group sessions at any of the three program sites were invited to participate in the study. Participants were interviewed at baseline, at the end of the first group cycle (weeks 16–18), one year post-completion of the first group cycle and then annually for four more years. For this paper, only clients who had reached the one year post-group time point were included. Individuals were excluded if they had previously attended the program or if they had a negative HCV RNA test. Research ethics approval was obtained through the University of Toronto.

Study measures

Standardized questionnaires were administered by trained staff who were not part of the clinical care teams. Chart data (genotype, cirrhosis level) was extracted by the HCV treatment nurse. All other data were self-reported.

Overall health status was measured using a question from the Canadian Community Health Survey that asks respondents to rate their general health (physical, mental and social well-being) on a 5-point scale from poor to excellent (Statistics Canada, 2003). Depression and anxiety were measured using the Patient Health Questionnaire-9 (PHQ-9) (Spitzer, Kroenke, & Williams, 1999) and the Generalized Anxiety Disorder-7 (GAD-7) (Spitzer, Kroenke, Williams, & Lowe, 2006). The PHQ-9 is a 9-item clinical tool used to measure depression. Scores range from 0 to 27. Scores of 5–9 indicate mild depression, 10–14 indicates moderate depression and more than 15 is severe. The GAD-7 is a 7-item questionnaire, which measures anxiety with scores ranging from 0 to 21. Scores of 0–4 indicated minimal anxiety, 5–9 indicate mild, 10–14 indicate moderate and scores of 15 or more are severe. Social Support was measured using the Medical Outcomes Study – Social Support Survey (MOS-SSS), a 19-item questionnaire that measures four support/assistance domains using a 5-point scale for each item (Sherbourne & Stewart, 1991). Post-traumatic stress disorder was measured using the PTSD Checklist – Civilian Version, a standardized self-report rating scale comprised of 17 items (Ruggiero, Del Ben, Scotti, & Rabalais, 2003).

Physical and mental health status and health care utilization questions are from the Addictions Severity Index, as are questions about legal status and problems due to drugs and/or alcohol (McLellan, Luborsky, Woody, & O'Brien, 1980). Using this tool, mental health problems in the past 30 days were determined by the number of days participants had experienced either self-reported depression, anxiety, violent behavior, or suicidality. Drug or alcohol problems in the past month were also derived from self-report of any days when participants experienced disturbing effects of use. Additional questions about drug use were drawn from I-Track, a national surveillance study of injection drug users across Canada (Public Health Agency of Canada [PHAC], 2006). Access to HCV care was measured by evaluating changes in self-reported HCV assessment and care procedures including: blood work, liver



Fig. 1. Program model.

biopsy/fibrotest, electrocardiogram test, and vaccination for hepatitis A/B.

Housing status was categorized as stable or unstable on the basis of participant self-report of current living situation. Stable housing included participant's own apartment or house. Unstable housing included staying in hotel/motel, rooming or boarding house, relative or friend's place, shelter/hostel, public place, transitional housing, or in an institution. Our income outcome was measured by the proportion of participants receiving disability benefits, a form of social assistance with higher benefit levels. A history of incarceration was defined as any time served in client's lifetime in either juvenile detention, provincial or federal prison.

Statistical methods

Data were analyzed using SAS version 9.4 (Cary, North Carolina). Descriptive statistics were used to describe demographic baseline data. We used generalized estimated equation models to assess whether psychosocial or health care outcomes changed over time (Zeger & Liang, 1986).

Results

A total of 84 individuals were approached to participate in the study, of which six were excluded (two due to negative HCV RNA, one due to language limitations and three who refused to participate). Data was available for 78 individuals at baseline. Post-group (week 16–18) interviews were completed with 75 (96%) participants and 58 (74%) participants at 1-year post-group. Thirty-one individuals were still receiving support from the program at this latter time period. There were three known deaths (4%) during the follow-up period (two from accidental overdose and one from a trauma-induced intracerebral hemorrhage

potentially attributed to coagulopathy secondary to HCV). Four participants withdrew from the study and thirteen were lost to follow up. These follow-up rates are comparable to other studies with marginalized populations (McKenzie et al., 1999; Veldhuizen et al., 2014). There was no difference at baseline between those lost to follow-up and study participants according to: age, gender, race, housing stability, primary income source, history of incarceration, current crack use, current IDU, emergency department use in past six months, and history of mental health hospitalization.

Participant characteristics

Socio-demographic data at baseline are presented in Table 1. Participants had a mean age of 46.9 (SD 10.45). The majority of participants (82%; $N=64$) relied on government forms of social assistance as their primary income source and almost half (46%; $N=36$) did not have stable housing. Half (49%; $N=38$) had completed only an elementary school level of education or less. The vast majority of participants (85%; $N=66$) reported a lifetime history of incarceration with a mean individual cumulative time spent in jail of 6 years (SD 7.6). Rates of lifetime histories of physical abuse (71%, $N=55$) and sexual abuse (46%; $N=36$) were also very high. Participants were asked if they needed assistance with specific basic needs: 37% ($N=28$) reported needing help with income supports (welfare, disability), 45% ($N=34$) reported needing help with housing issues and 43% ($N=33$) reported needing help with food access/security issues. Specific questions related to food insecurity revealed that 9% ($N=7$) often or always did not have enough to eat in the past six months and 31% ($N=24$) were often or always not able to eat the quality or variety of food that they wanted in the same period. Additional data pertaining to mental health status and health care utilization can be found in Table 2.

Table 1
TCHCP baseline participant demographics.

	N = 78
Gender	
Male	59 (76%)
Female	18 (23%)
Trans	1 (1%)
White/Caucasian (only)	57 (73%) ^b
Aboriginal	16 (21%) ^b
Income – monthly (CAD)	
>\$999	36 (47%)
1000–1999	34 (44%)
2000+	8 (10%)
Primary income source – past year	
Disability assistance	43 (55%)
Social assistance (welfare)	21 (27%)
Other ^a	13 (16%)
Education – highest level completed	
Elementary or less	38 (49%)
High school	33 (42%)
University/college/trade school	7 (9%)
Housing status – current	
Own apartment or house	42 (54%)
Shelter/hostel	11 (14%)
Hotel, motel, rooming or boarding house	10 (13%)
Living with friends/relatives	9 (12%)
Transitional housing (includes detox/recovery house, halfway house)	6 (8%)

^a Other sources of income included: seasonal work (1), selling drugs (3), theft (2), old age security benefits (1), shelter allowance benefits (2), trust fund (1), severance pay (1), money from family/friends (1), asking for money on the street (1).

^b Missing data, N = 1.

Health status and substance use

A total of 78% (N = 61) of participants reported having at least one chronic medical problem in addition to HCV that interfered with their life, as well as an average of 13.7 days (SD 13.09) in the past month when they had medical problems. 4% (N = 3) were co-infected with HIV. Participants also reported an average of 16.04 (SD 12.17) days when they were bothered by mental health problems in the past 30 days and nearly half of all participants (49%; N = 38) received disability income primarily or partly for mental health reasons. More than half (64%; N = 50) reported at least one head injury in their lifetime that had caused loss of consciousness with a mean reported of 5.2 (SD 5.84).

Table 2
TCHCP participants: health care utilization and mental health status (N = 78).

Health care utilization	
Had family doctor or nurse practitioner	66 (84%)
No. of hospitalizations for medical reason, lifetime	3.0 (5.0) ^b
History of hospitalization for mental health reason	31 (40%) ^c
Emergency Department visit (yes/no), past six months	29 (37%)
No. of emergency department visits, past six months	2.58 (2.26) ^a
Mental health status	
Depression, lifetime	64 (82%)
Depression, past 30 days	35 (45%)
Anxiety, lifetime	67 (86%)
Anxiety, past 30 days	45 (58%)
Suicide attempt, lifetime	31 (40%)
Suicide attempt, past 30 days	1 (1%)
Trouble controlling violent behaviour/episodes of rage, lifetime	51 (65%)
Trouble controlling violent behaviour/episodes of rage, past 30 days	11 (14%)
Prescribed medication for mental health reason, past 30 days	43 (73%)

^a Results reported as mean (standard deviation).

^b Results reported as median (IQR).

^c Missing data, N = 1.

The majority (89%; N = 69) of participants had a history of injection drug use (IDU) and the mean age of first IDU was 22.8 years (SD 9.7). Fifteen participants (19%) were on opioid substitution therapy at baseline. Of the 24 participants (34%) who reported IDU in the past six months, 11 had injected drugs in the past 30 days. The drugs most frequently injected in the past 30 days were: crack (3), cocaine (3) and heroin (2). Other than cannabis (78%; 61 participants), crack cocaine was the most commonly reported drug (non-injection) used in the past six months (50%; N = 39). The majority of participants (N = 53; 68%) reported alcohol use in same time period.

HCV treatment

The number of participants completing investigations for HCV by the end of the first group cycle (time point 1, week 16–18) and at one-year post end of first group (time point 2) are outlined in Table 3. Prior to joining the TCHCP, 85% (N = 66) had a primary health care provider but only 12 participants (15%) had been assessed by a HCV specialist. By the end of the study period access to HCV care had increased significantly with 54% (p = 0.0024) reporting access to the HCV specialist. In addition, 93% reporting a visit with one of the program's primary care HCV physicians and the entire study sample reported a visit with an HCV treatment nurse by one-year post group. HCV assessments were completed on the majority of participants. By the end of the study period blood work had been completed on 95%, 77% had received an abdominal ultrasound, 86% had been vaccinated for hepatitis A and B (or had tests indicating immunity), and 58% had a fibrosis assessment. Only 4% (N = 3) of participants had previously initiated HCV treatment prior to joining the TCHCP. By the end of the study period, 15 participants (19%) had initiated HCV treatment. Of these, 9 completed the recommended treatment course during the study period and SVR status was available for 5; 3 were non-responders and 2 had an SVR. Among those who did not initiate treatment, 10 reported the main reason for not starting treatment was the need to prioritize physical health issues other than HCV. An additional 13 participants reported the main reason for not initiating treatment was because they did not meet current public funding eligibility requirements. Other main reasons for not starting treatment included: mental health or substance use issues (5), housing instability (3), waiting for new treatments (2), fear of treatment (2) and pregnancy (1).

Psychosocial outcomes

Changes in multiple psychosocial outcomes are presented in Table 4. Our primary outcome (self-reported overall health) did not change significantly over time. At baseline 51% (N = 40) reported that their health was poor or fair and this remained stable. The proportion of participants with stable housing increased significantly from 54% to 76% during the study period (p = 0.0017). Income stability also improved with a significant increase in the proportion of patients receiving income from provincial disability benefits (55% vs 75%, p = 0.0216).

Discussion

This study demonstrated that a multidisciplinary, community-based model of HCV treatment can improve access to care for clients with multiple health and social challenges with impacts beyond HCV including significant improvements to key social determinants of health in terms of housing and income.

Participants served by the TCHCP in this study were highly marginalized. The majority of participants reported very low income and education levels, histories of trauma and incarceration. Current alcohol and/or illicit drug use was also common, as

Table 3
TCHCP participants: HCV status and health assessments.

HCV status (baseline)				
Hep C genotype				
1	50 (64%)			
2/3	28 (36%) ^a			
4	1 (1%)			
	(missing: 1)			
Fibrosis score				
F4	11 (14%)			
F3	7 (9%)			
F2	10 (13%)			
F1	13 (17%)			
F0	9 (12%)			
Not available	28 (36%)			
Health assessments	Post group (N = 78)	Missing	1 year post group (N = 58)	Missing
Clinical consultations				
TCHCP nurse/nurse practitioner	70 (97%)	1	57 (100%)	1
TCHCP primary care physician	67 (91%)	1	53 (93%)	1
TCHCP psychiatrist	37 (49%)		35 (61%)	1
TCHCP HCV specialist	28 (37%)		31 (54%)	1
Referred to another specialist (non HCV)	10 (13%)		8 (14%)	1
Investigations				
Blood work	66 (88%)		54 (95%)	1
Abdominal ultrasound	48 (64%)		44 (77%)	1
Chest X-ray	30 (54%)	1	40 (70%)	1
Electrocardiogram (ECG)	46 (61%)		45 (80%)	1
Vaccinated for Hep A and Hep B or test indicating immunity	53 (72%)	1	49 (86%)	1
Spirometry/pulmonary function test	30 (40%)		38 (67%)	1
Fibrosis assessment	26 (35%)		33 (60%)	1
Endoscopy	9 (12%)		6 (11%)	2
Paraclinical consultations				
Dentist	20 (27%)		21 (37%)	1
Eye doctor	17 (23%)		18 (32%)	1

^a Two participants had both genotypes 1 and 3 and are counted in both.

were mental health issues. Despite having HCV and other physical and mental health co-morbidities, few participants reported having accessed any HCV care or treatment at baseline. Preparing TCHCP clients for treatment often requires having to first address other serious health issues, as well as multiple social determinants of health including: helping people to find or maintain stable housing, improving income supports (helping people obtain disability benefits), and stabilizing (though not necessarily eliminating) drug or alcohol use. This study is the first to delineate the significant morbidity and complexity of the lives of individuals who make up the bulk of the HCV epidemic in many countries.

The TCHCP successfully delivered HCV treatment and care to clients with complex health and social needs, especially when compared to traditional models. Treatment initiation rates in this study (19%) are comparable to rates seen for specialist-based HCV care in tertiary settings (Myers et al., 2014). Access to specialists, vaccinations, and work up assessments was very high for study participants. Treatment outcomes were available for only a minority of study participants; however, other studies of this program have

demonstrated comparable SVR rates to clinical trials (Charlebois et al., 2012). It is likely that the program could have treated even more clients if public funding for antiviral medications was not restricted to advanced fibrosis. At least thirteen who were assessed for treatment in this study could not receive funding for HCV medications due to public funding criteria.

Longitudinal analysis of study participants suggests that the TCHCP model also has benefits beyond treatment initiation. Measures of housing stability and income level improved significantly for study participants. This is likely because both clinicians and support staff work with TCHCP clients to obtain income supports and help them to find and maintain housing. The process for obtaining disability supports in the province where this study took place can be onerous and often requires multiple medical assessments. The TCHCP program facilitates this process for clients and providers through its multidisciplinary and supportive team approach. Addressing these particular social determinants of health is a key focus of the pre-treatment period and an essential component of treatment readiness. Indeed, in a previous retrospective

Table 4
TCHCP participants: psychosocial and health care utilization outcomes.

Outcome	Baseline (N = 78)	Post group (N = 75)	1 year post group (N = 58)	p-Value
Self-reported health ^a	3.43 (1.16)	3.38 (1.26)	3.53 (1.08)	0.5192
Depression (PHQ9) ^a	10.4 (6.5)	10.0 (6.9)	10.45 (6.7)	0.8520
Anxiety (GAD7) ^a	8.7 (6.0)	8.2 (6.8)	7.9 (6.3)	0.6386
Post-traumatic stress disorder (PCL – civilian version) ^a	43.2 (15.4)	41.7 (17.0)	40.9 (15.6)	0.5844
Social support (MOS-SSS)	62.7 (20.1)	61.1 (20.0)	62.7 (20.7)	0.8290
Mental health problems – days in past month ^a	16.0 (12.2)	17.6 (11.5)	14.2 (10.9)	0.2573
Drug use problem – days in past month ^a	4.8 (8.7)	5.0 (10.2)	4.3 (9.2)	0.8924
Alcohol use problems – days in past month ^a	2.8 (7.9)	2.6 (7.7)	4.4 (9.5)	0.2194
Emergency department use – past six months (yes)	29 (37%)	Not available	16 (28%)	0.2564
Stable housing (yes)	42 (54%)	50 (67%)	43 (76%)	0.0017
Income from disability benefits (yes)	43 (55%)	43 (57%)	42 (75%)	0.0216

^a Results reported as mean (standard deviation).

study of this model, housing status was the only variable associated with initiation of HCV treatment (Charlebois et al., 2012). This finding also has implications for the long-term overall well-being of program participants as both housing and income have been shown to be highly related to a variety of improved health outcomes and health care utilization (Braveman, Cubbin, Egarter, Williams, & Pumak, 2010; Krieger & Higgins, 2002; McIntosh, Finès, Wilkins, & Wolfson, 2009; World Health Organization [WHO], 2008). Our findings demonstrate that it is possible to improve key social determinants of health, which are essential for HCV treatment and may have other positive benefits for program participants.

Although overall health scores did not improve significantly for study participants, it is possible that this and other secondary outcomes may take longer to show improvement given the multiple and profound challenges detailed at baseline for this group. That measures of mental health and well-being did not improve over time may be secondary to liver disease or to the side effects of treatment with interferon-alpha therapy (Sockalingam & Abbey, 2009). However, this study was not powered enough to look at this variable in detail. Many of the mental health scores reported in this study are less severe than what might be anticipated and suggests that participants may have normalized their ongoing life hardships and challenges. It is also possible that the standardized measures selected for this study may not be adequate to capture the complex realities of individuals who experience multiple and complex health and social issues. Qualitative data has shown that TCHCP program participants experience improvements in the areas of mental health, substance use and social support (Woolhouse et al., 2013). Even without measurable changes to mental health status or substance use, participants were still able to engage in HCV care and obtain positive outcomes through this model. Previous study of this issue within the program has demonstrated that individuals with serious psychiatric burden have similar HCV treatment outcomes compared with clients without such co-morbidity (Sockalingam et al., 2013).

Limitations

This study has some limitations. The small sample size may have limited our power to detect small but still clinically meaningful effects. Despite the sample size limitations, to our knowledge this study is the largest prospective cohort of highly marginalized HCV patients actively using drugs and being treated in a community-based model. An additional limitation is that due to the comprehensive and holistic design of the program, participants were exposed to a variety of intervention elements and this study was not designed to examine which components might be responsible for each outcome. It was also not feasible to control for other health care or social supports outside of the program model. Finally, most outcomes were determined on the basis of self-report and may therefore be subject to recall or social desirability biases. As mentioned previously, this study presents only up to one year (approximately 16 months post baseline) of follow up. Many of the outcomes being considered may require a longer follow-up period, which is currently ongoing for these participants.

Conclusions

The Toronto Community Hep C Program successfully provides HCV care and support to highly marginalized individuals who would be unlikely to receive treatment elsewhere. Our study shows that community-based, multidisciplinary, harm reduction models of HCV care driven by peer engagement and group support, can lead to improved access to HCV treatment with benefits that extend beyond HCV to key social determinants of health. Even as

treatment regimens for Hepatitis C become shorter and easier to tolerate, many individuals with HCV will continue to require multi-disciplinary, highly supportive models in order to address these significant pre-treatment health and social issues before antivirals can be safely provided. In the context of new treatments, which are costly and require strict adherence, these types of supportive models may become even more critical for people who are socially and economically marginalized.

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Conflict of interest statement

None declared.

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