

BMJ Open Effect of free medicine distribution on ability to make ends meet: post hoc quantitative subgroup analysis and qualitative thematic analysis

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ABSTRACT

Objectives Out-of-pocket medication costs can contribute to financial insecurity and many Canadians have trouble affording medicines. This study aimed to determine if the effect of eliminating out-of-pocket medication costs on individual's financial security varied by gender, racialisation, income and location.

Design In this post hoc subgroup analysis of the CLEAN Meds trial, a binary logistic regression model was fitted and a qualitative inductive thematic analysis of comments related to participant's ability to make ends meet was carried out.

Setting Primary care patients in Ontario, Canada.

Participants Adult patients (786) who reported not being able to afford medicines during the previous 12 months.

Intervention Free access to a comprehensive list of essential medicines for 24 months.

Primary outcome measure Ability to make ends meet or afford basic necessities.

Results There were no significant differences in the effect of free medicine distribution by gender (OR for male 0.82; 95% CI 0.51 to 1.33, $p=0.76$), age (older than 65 years OR 1.28; 95% CI 0.62 to 2.64, $p=0.73$), racialisation (OR 0.85; 95% CI 0.51 to 1.45, $p=0.66$), household income level (above US\$30 000 per year OR 1.08; 95% CI 0.64 to 1.80, $p=0.99$) or location (urban OR 0.47; 95% CI 0.23 to 0.96, $p=0.10$). The main theme in the qualitative analysis was insufficient income, and there were three related themes: out-of-pocket medication expenses, cost-related non-adherence and the importance of medication coverage. In the intervention group, additional themes identified included improved health, functioning and access to basic needs.

Conclusions Providing free essential medications improved financial security across subgroups in a trial population who all had trouble affording medicines. Free access to medicines could improve health directly by improving medicine adherence and indirectly by making other necessities more accessible to people who have an insufficient income.

Trial registration number NCT02744963.

INTRODUCTION

Financial security is strongly associated with better health outcomes.¹ Individuals lacking income security are less likely to access

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Combined quantitative and qualitative analysis provides richer understanding of policy impacts of free essential medication provision.
- ⇒ Improvement in ability to make ends meet was self-reported and participants were not blinded to their study arm.
- ⇒ The subgroups were not selected prior to the outset of the trial.

prescribed medications, or do so only by sacrificing other basic needs.² With 33.7% of Canadian adults living with the following treatable chronic diseases: cardiovascular disease, cancer, kidney disease, diabetes and psychiatric illnesses,³ access to medicines can be the difference between life and death. Out-of-pocket medication costs can be a barrier to access and to financial security. Patients pay about 22% of all Canadian drug prescriptions out of pocket⁴ and approximately 1 in 10 Canadians cannot afford their prescription medications.⁵ Cost-related non-adherence to prescription medication in Canada was highest in those aged 18–64 years with low income or precarious work, no drug insurance and high out-of-pocket drug costs.⁶ In 2008, 7.6% of Canadian households spent more than 3% of their after-tax income on prescription drugs.⁷

Canada is the only high-income country that provides publicly funded healthcare services, but not publicly funded medication. In Ontario, Canada prescription medication coverage is a patchwork of government coverage for specific groups (eg, social assistance recipients and seniors over 65), private coverage (eg, workplace insurance) and out-of-pocket payments. Providing free medication has been shown to improve surrogate outcomes in many diseases.^{8–11} The CLEAN Meds randomised control trial was conducted

in multiple sites across Ontario, Canada to determine the impact of providing free essential medicines.¹² This study found that after 1 year, there was a 12% absolute improvement in adherence and a 53% absolute improvement in the ability to make ends meet in the group randomised to receive free essential medicines.

The purpose of this post hoc analysis of CLEAN Meds trial results was to determine the effect of eliminating out-of-pocket medication costs on the ability to make ends meet or afford basic necessities by gender, age, racialisation, income and location. We designed this exploratory and hypothesis-generating post hoc analysis after the trial results indicate a large improvement in the ability to make ends meet. We also designed a qualitative analysis of comments related to ability to make ends meet to better understand the findings.

METHODS

Design

This was a post hoc analysis of the results of the CLEAN Meds randomised controlled trial. The CLEAN Meds trial was an individually randomised clinical trial with intention to treat analysis conducted at nine primary care sites in Ontario, Canada.¹² The study enrolled 786 patients from 2016 to 2017 who were 18 years of age or older and self-reported cost-related nonadherence. Individuals in the same household or who had joined a practice within 6 months were excluded. Participants were randomised to receive free essential medicine (n=395) or usual medicine access (n=391), baseline characteristics including age, gender, race, income level, income source and number and type of medications prescribed were balanced across groups. Study participants were not blinded but outcome assessors were blinded. Participants were followed-up with at 12 months and 24 months. The primary outcome was medicine adherence but the study also evaluated self-reported ability to make ends meet. This was based on the survey question ‘Was it easier to make ends meet at the end of the month?’ in which participants would answer ‘yes’ or ‘no’ and also had the option to leave a comment. Only those who answered this question were included in the subgroup analysis (consecutive sampling). The quantitative analysis is based on the 24-month results and the qualitative analysis on responses during both 12 and 24 months follow-up responses.

This study sought to determine whether there were differences in treatment effect between subgroups (interaction). To prevent data-driven conclusions that can occur in subgroup analysis,¹³ hypotheses were pre-established and founded in existing literature and all subgroup analyses that were tested were reported in the results section.

Based on existing data on cost-related non-adherence⁶ and the current structure of prescription coverage in Ontario, we tested the hypotheses that participants in the following groups will be more likely to have increased financial security by receiving free essential medications: female, younger than 65 years old, racialised, income less

than US\$30 000 and living in rural areas. We hypothesised that women may benefit more from the intervention with respect to the ability to make ends meet because they tend to take more prescription medications than men in Canada, this may be related to gynaecological and reproductive health needs.¹⁴ Although, men are 2.3% less likely to have drug coverage, women in Canada have been seen to have higher out of pocket drug costs.¹⁵ We also predicted that individuals younger than 65 years may benefit more from the intervention because in Ontario, many common medications are covered for individuals over 65. Canadians between 18 and 65 have been shown to have higher rates of cost-related non-adherence.⁴⁶ Racialised individuals may also have more significant improvement in ability to make ends meet. Although there is limited Canadian data, cost-related non-adherence was higher among Black and Hispanic seniors in the USA.¹⁶ In Canada, white people are more likely to have prescription coverage¹⁷ and individuals who self-identified as First Nations, Inuit or Metis had higher levels of cost-related non-adherence despite inclusion of drug coverage on the non-insured Health Benefits Programme.¹⁸ We predicted that individuals with lower income may have more improvement in financial security. Individual who are not using social assistance who have lower income jobs, precarious work or intermittent employment are more likely to have more cost-related non-adherence⁴⁶ and individuals with income between \$10 000 and \$29 999 are less likely to have prescription coverage.¹⁵ We hypothesised that individuals in rural Ontario may be more impacted, as individuals living in rural Canada are 33% less like to have medication coverage.¹⁵

Statistical analysis

To determine if there was a difference between subgroups a binary logistic regression model¹⁹ with interaction terms was fitted. The model was constructed with a term for each independent variable and an interaction term with each independent variable and the group of allocation. The null hypothesis is that there is no heterogeneity in the treatment effect (ability to make ends meet) between the subgroups (eg, women and men). Independent variables are gender (male, female), age (less than 65 years old or 65 and above), racialisation (racialised or not), income (less than \$30 000 or above) and site (rural or urban). The dependent variables were improved ability to make ends meet or no improvement. The OR of the difference in ability to make ends meet within subgroups (eg, male vs female) and 95% CIs were calculated. The statistical significance of the interaction terms were used to determine whether there were subgroup effects.¹³

Qualitative analysis

In order to better understand the importance and relevance of the characteristics included in the quantitative analysis, a qualitative analysis of optional free-text comments was carried out. The data included in the qualitative analysis were from the 12 and 24-month surveys.

Only comments related to the ability to make ends meet were included. An inductive thematic analysis was done across subgroups to determine themes related to the ability to make ends meet. This was done by reading through the comments irrespective of randomisation group and outcome initially, then again within randomisation and outcome groups. One person coded the data (MH). Themes were derived from the data and themes that were specifically related to subgroup factors were also sought out to help understand subgroup-specific effects. The comments were then reviewed again to ensure themes were representative.

Positionality statement

We offer the findings of this post hoc analysis as interpreted by a white female who is resident physician and a racialised male who is a practising family physician and scientist. Our backgrounds likely influence the interpretation of the data. Both authors made efforts to practice reflexivity and positionality throughout the study process.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination of our research.

RESULTS

Quantitative

Of the 786 participants randomised, 536 (68.2%) responded to the question about making ends meet (302 (76.5%) in the free distribution group and 234 (59.8%) in the usual access group) at 24 months. The characteristics of participants in the trial and those who answered the question about making ends meet are summarised in [table 1](#).

As previously reported,¹² there was a significant improvement in the ability to make ends meet in the intervention group (OR 17.54, 95% CI 10.59 to 29.12, $p=1.83 \times 10^{-28}$).

There was no difference in the effect of free essential medicine distribution on the ability to make ends based on gender, age, racialisation and income level ([table 2](#); [figure 1](#)). There were no statistically significant interactions between characteristics and the group of allocation. There was a non-significant trend towards a larger effect of free essential medicine distribution in rural versus urban participants (OR 2.13, 95% CI 1.04 to 4.35; $p=0.10$).

Qualitative

Of the 616 participants who reported their ability to make ends meet at 12 and 24 months, 227 (36.9%) participants made optional comments (106/328, 32.3% in the free distribution group and 121/288, 42% in the usual access group).

The main theme identified was insufficient income and there were three income-related subthemes: out-of-pocket medication expenses, cost-related non-adherence and the importance of medication coverage.

Participants commented on having insufficient income or lack of employment and the relationship with financial security.

Absolutely because my medications... its extra money, I've been struggling lately and thank goodness, I've had my meds taken care of cause I don't know that I could have otherwise, I lost my job recently

All I have is my pension so it gets rough sometimes. This helps me out a lot.

Participants commented on how their low income prevented them from some health needs such as eating 'nice or healthy food' because of the need to 'budget'.

Participants commented on high out-of-pocket medication expenses.

It has become harder to make ends meet. The price of my meds have gone up and my income remains the same.

Table 1 The number of participants in each subgroup category

Subgroup		Free distribution group (n=395)	Usual access group (n=391)	Free distribution group, answered ability to make ends meet question (n=302)	Usual access group, answered ability to make ends meet question (n=234)
Gender	Male	175 (44.3%)	172 (44%)	138 (45.7%)	109 (46.6%)
	Female	220 (55.7%)	219 (56%)	164 (54.3%)	125 (53.4%)
Age	<65 years	324 (82%)	327 (83.6%)	247 (81.8%)	194 (82.9%)
	≥65 years	71 (18%)	64 (16.4%)	55 (18.2%)	40 (17.1%)
Race	Racialised	138 (34.9%)	124 (31.7%)	110 (36.4%)	77 (32.9%)
	Non-racialised	256 (64.8%)	260 (66.5%)	192 (63.6%)	157 (67.1%)
Household income	<\$30 000	205 (51.9%)	182 (46.5%)	169 (56%)	124 (53%)
	≥\$30 000	113 (28.6%)	121 (30.9%)	101 (33.4%)	85 (36.3%)
Site	Urban	269 (68.1%)	267 (68.3%)	204 (67.5%)	160 (68.4%)
	Rural	126 (31.9%)	124 (31.7%)	98 (32.5%)	74 (31.6%)

Table 2 OR comparing ability to make ends meet within subgroups

Subgroup	OR (95% CI, p value)	Interaction p value
Overall (free medicine vs usual access)	17.54 (10.59 to 29.12, p=1.83×10 ⁻²⁸)	
Gender		
Male	0.82 (0.51 to 1.33)	0.76
Female	1.22 (0.77 to 1.96)	
Age		
≥65 years	1.28 (0.62 to 2.64)	0.73
<65 years	0.78 (0.38 to 1.61)	
Race		
Non-racialised	1.17 (0.69 to 1.98)	0.66
Racialised	0.85 (0.51 to 1.45)	
Household income		
≥\$30 000	1.08 (0.64 to 1.80)	0.99
<\$30 000	0.93 (0.55 to 1.56)	
Site		
Urban	0.47 (0.23 to 0.96)	0.10
Rural	2.13 (1.04 to 4.35)	

I do not have a job. Medicines cost [more than] \$300 a month.

Relatedly, participants commented on how high medication costs create the need to incur debt including the need to 'put them on my credit card'.

Participants also commented on their ability to continue their medications. In the intervention group, some people had improved adherence and reported that they 'Would not be able to take some medications' without being in the study.

Could not afford meds if I wasn't on CLEAN Meds. [I'm] on disability [making] \$700 per month

I wouldn't be able to afford them otherwise- even with the over 65 plan

Alternatively, in the control group, individuals described cost-related non-adherence and that medications were 'too expensive to take'.

Harder [to make ends meet], I ended up discontinuing meds because they were too expensive

Participants commented on the benefits of having drug coverage as well as the limitations of some coverage programmes that are 'not great at all' and the impact on their financial security.

Since kids [are] covered now through OHIP+ [public prescription drug coverage for children and youth] I can afford this medication. Many of my medications are very expensive.

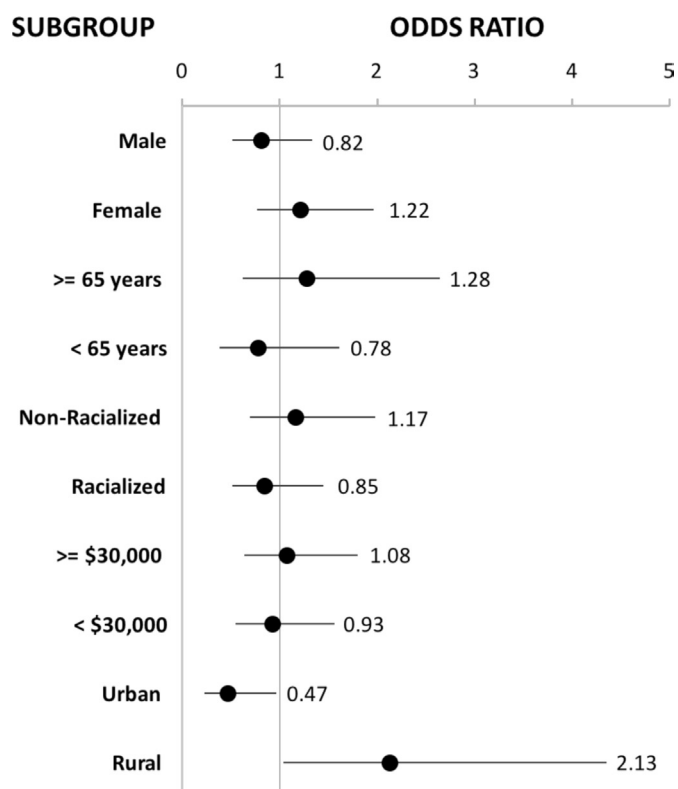
Only because I was able to go back to my job, I was off sick when the study started so I didn't have coverage but now I have coverage again

Individuals in the control group who did not have an improved ability to make ends meet commented that medications were so costly that medication expenses impacted their financial security and that things get 'harder every day', that they had to discontinue medications, that they experienced loss of income during the study, or that they had no medication coverage or were paying a deductible.

I am off work for the last four years and get little income from my farm

The medicines are expensive and I can't afford the meds if they are not covered as I only have pension

Participants in the intervention group who did not have an improved ability to make ends meet commented on

**Figure 1** OR comparing ability to make ends meet within subgroups.

having low income or that some of their medications were not part of the free essential medication list.

I still had to pay for [an antidepressant] and a medication the heart specialist prescribed

I spent a lot of money on purchasing [one medication]

In the group that did have an improved ability to make ends meet the themes were different in the control and intervention groups. Those in the control group commented on already having medication coverage.

Most of drugs covered by ODB [Ontario Drug Benefit Program that provides prescription drug coverage to social assistance recipients]

It is still hard but she has benefits

In the intervention group, three other themes emerged which were the ability to maintain basic needs, improved functioning, and improved health. The following comments were made regarding change in ability to address basic needs:

This study has meant that I don't have to give up food for a few days each month in order to buy my [prescriptions].

I did not have to choose between rent, groceries or life saving meds!

Participants commented on improvement in their functioning and improved ability to work.

Besides getting the meds for free, it helped me function better so I could go to work and make money and go to school as well.

Easier to function, I get migraines at work

Participants also described improvements to their health.

The number one benefit was feeling less stress and anxiety because of the study, reduced rationing of medications, more financial freedom and saves time

This program helped me in my efforts to get sober and maintain my sobriety.

DISCUSSION

The improvement in the ability to make ends meet caused by free essential medicine distribution did not differ substantially between subgroups. Comments indicated that the factors related the ability to make ends meet were insufficient income, high out-of-pocket medication expenses, and lack of and insufficient medication coverage. Skipping medicines was discussed as a necessary strategy to maintain basic needs and, conversely, those provided free medicines described improved adherence and ability to meet basic needs. An insufficient income seems to link together all of these findings.

Income level was the only characteristic included in the quantitative analysis that we identified in the qualitative

analysis. Yet having an income of less than US\$30 000 was not associated with the impact on ability to make ends meet in the quantitative analysis. The qualitative findings and quantitative findings could both be explained by most or all participants in the study having an insufficient income regardless of whether their income was above US\$30 000. Among trial participants, few (5.5%) had a household income above US\$70 000. Among individuals with an insufficient income, characteristics such as age, gender and racialisation may be relatively unimportant. Individuals with low income are more likely to experience cost-related non-adherence⁴⁶ and less likely to have prescription coverage.¹⁵ In addition, individuals with low income are more likely to borrow money to pay for prescription medications.²⁰ Borrowing money for medication was highlighted in the qualitative responses, for example, a respondent in the control group mentioned having to purchase medication using credit.

The trend towards a larger effect of free medicine distribution on the ability to make ends meet in people living in a rural community is, if true, supported by data that suggests rural Canadians experience lower baseline income (individuals in major cities earn on average 25% more),²¹ tend to have a higher burden of chronic diseases,²² and are less likely to have medication coverage.¹⁵ If expenses are lower for individuals living rurally (due to lower housing costs, self-sufficient food production), the free medicine distribution could be more likely to mean the difference between being able to make ends meet or not.

Strengths and limitations

This was a secondary analysis of a rare trial of a change in health policy. The results of this study are not generally applicable because only people who had trouble affording medicines were included in the trial. In this post hoc subgroup analysis of clinical trial results, the subgroups were not selected prior to the outset of the RCT, and the randomisation was not stratified for these subgroups other than site location. Some of the results could have been false negative results due to underpowered subgroups although the sample size was likely sufficient to detect effects in the regression model. There was a substantial amount of missing data, and participants in the free distribution group were more likely to provide responses. The ability to make ends meet was self-reported.

CONCLUSION

Distributing free essential medications improves individual financial security across subgroups in people who cannot afford medicines. Our qualitative data suggests income, medication costs, drug coverage models and medication adherence are all factors that impact financial security. Policy changes to provide universal free essential medication would directly impact health by improving medication adherence but could also impact



financial security, an important social determinant of health. Studies of urban versus rural populations should be done to determine if there would be a greater benefit of essential medication access for people living in rural communities. Future studies could focus on the effect of interventions such as medicine access on the ability to make ends meet as the primary outcome.

Contributors MH contributed to the study design, data analysis, visualisation, writing original draft and reviewing and editing. NP contributed to the study design, visualisation and the reviewing and editing of the manuscript. RW contributed to the formal analysis using regression model. AW and HW contributed to the acquisition of qualitative data and reviewing and editing of the manuscript. NP is the guarantor who accepts full responsibility for the work and the conduct of the study, had access to the data, and controlled the decision to publish.

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Disclaimer Funders played no role in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The CLEAN Meds trial received ethics approval from the St. Michael's Hospital Research Ethics Board (15-114).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Deidentified participant data are available on reasonable request from the corresponding author.

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