



Case Management may Reduce Emergency Department Frequent use in a Universal Health Coverage System: a Randomized Controlled Trial

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BACKGROUND: Frequent emergency department (ED) users account for a disproportionately high number of ED visits. Studies on case management (CM) interventions to reduce frequent ED use have shown mixed results, and few studies have been conducted within a universal health coverage system.

OBJECTIVE: To determine whether a CM intervention—compared to standard emergency care—reduces ED attendance.

DESIGN: Randomized controlled trial.

PARTICIPANTS: Two hundred fifty frequent ED users (5 or more visits in the prior 12 months) who visited a public urban ED at the Lausanne University Hospital between May 2012 and July 2013 were allocated to either an intervention ($n = 125$) or control ($n = 125$) group, and monitored for 12 months.

INTERVENTIONS: An individualized CM intervention consisting of concrete assistance in obtaining income entitlements, referral to primary or specialty medical care, access to mental health care or substance abuse treatment, and counseling on at-risk behaviors and health care utilization (in addition to standard care) at baseline and 1, 3, and 5 months.

MAIN MEASURES: We used a generalized linear model for count data (negative binomial distribution) to compare the number of ED visits during the 12-month follow-up between CM and usual care, from an intention-to-treat perspective.

KEY RESULTS: At 12 months, there were 2.71 (± 0.23) ED visits in the intervention group versus 3.35 (± 0.32) visits among controls (ratio = 0.81, 95 % CI = 0.63; 1.02). In the multivariate model, the effect of the CM intervention on the number of ED visits approached statistical significance ($b = -0.219$, $p = 0.075$). The presence of poor social determinants of health was a significant predictor of ED use in the multivariate model ($b = 0.280$, $p = 0.048$). **CONCLUSIONS:** CM may reduce ED use by frequent users through an improved orientation to the health care system. Poor social determinants of health significantly increase use of the ED by frequent users.

KEY WORDS: case management; vulnerable populations; utilization; clinical trials.

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INTRODUCTION

Frequent emergency department (ED) users account for 3 to 8 % of all patients and 12 to 28 % of all ED visits,^{1,2} contributing to overcrowding.³ Common reasons for such frequent use include pain, chronic physical and mental illness, and substance abuse.^{1,2,4,5} Frequent ED users are mainly men, are between 40 and 50 years of age, are sicker and have higher rates of mortality than occasional ED users.^{1,2,6} As such, they merit focused attention, and research on interventions to meet their needs is needed.⁶

Case management (CM) is an intervention designed to assist frequent ED users in reducing their ED utilization.^{7,8} CM aims to meet patients' individual needs and to optimize resource allocation for the frequent user and payer.^{9,10} To our knowledge, only

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three randomized controlled trials (RCTs) have examined the impact of CM on ED use.^{11–13} Two RCTs^{12,13} found that CM reduced the number of ED visits among frequent users, while the third¹¹ found no significant impact. A randomized information-sharing intervention did not result in a significant reduction in ED use.¹⁴ Health care system characteristics and insurance coverage are factors that influence ED use,¹⁵ and may explain discrepancies among these studies.

According to a study conducted in Switzerland,¹⁶ frequent ED users accounted for 4.4 % of all ED patients and 12.1 % of all ED visits at the Lausanne University Hospital in 2008–2009. Like the majority of developed countries (91 % of OECD member nations),¹⁷ Switzerland has universal health coverage, established in 1994. The system relies on mandatory individual health insurance, with government subsidies available, and less than 1 % of the population is uninsured.¹⁸

In response to calls for a unified definition of frequent ED use and primary care-based interventions⁴, this RCT examined whether an interdisciplinary CM intervention, compared to standard emergency care, would reduce ED utilization among frequent users through an improved orientation to primary care and other community-based services within a universal health coverage system.

METHODS

Study design, setting and participants

Details on the study design and protocol were published in our previous work.¹⁹ Briefly, we conducted an RCT with a parallel design to compare CM with standard care among frequent ED users of the Lausanne University Hospital (Switzerland) ED between May 2012 and July 2013. The Lausanne University Hospital is one of five EDs in the canton (state) of Vaud, and serves 770,000 people, with over 35,000 ED visits annually.²⁰ We defined frequent ED users as those who made five or more ED visits during the prior 12 months, including the index visit, using a validated definition.¹ Participants were randomized to the CM intervention or control group, and were monitored over 12 months. The primary outcome was the number of ED visits made by participants over the 12 month follow-up.

Participants were required to be at least 18 years of age and able to communicate in any language spoken by the team (French, English, Spanish, German, or Italian) or through a professional interpreter. Patients were excluded from the study if they 1) were unable to give informed consent, 2) planned to stay in Switzerland less than 18 months, 3) were not expected to survive at least 18 months (based on clinical judgment of research team, with systematic, proactive input from clinical providers, e.g. cardiologists or oncologists), 4) were awaiting incarceration or currently incarcerated, 5) had already

received CM services, or 6) had a family member already enrolled in the study.

The trial was approved by the Human Research Ethics Committee of the Canton of Vaud, Switzerland (no. 32/12), and all participants provided written informed consent. The trial was funded by the Swiss National Science Foundation (no. 32003B_135762) and was registered on ClinicalTrials.gov (NCT01934322).

Sample Size

Based on results from a systematic review of the literature,⁷ the sample size estimate was calculated to detect an average difference of two ED visits annually between the two groups (i.e. four fewer intervention group visits compared to two fewer control group visits, with an anticipated standard deviation of four in both groups). Eighty-five participants were needed in both groups using a significance level of 0.05 and power of 0.9. We anticipated a dropout rate of 30 %, based on the increased mortality rate of frequent ED users,²¹ past research^{19,22} and clinical experience of the CM team (serving populations including forced migrants and homeless persons), due to the instability in this population. Thus, we aimed to enroll 250 frequent ED users (125 in each group).

Recruitment, randomization, allocation and blinding

We identified frequent users using a continuous automated detection system linked with ED patient tracking software. Study staff provided frequent users with oral and written information about the study. Due to pragmatic constraints (e.g. after hours; simultaneous participants), the single research nurse was not able to approach all eligible frequent users. If a frequent user left the ED prior to contact with the study staff, a team member attempted to reach him/her by telephone up to three times within 24–72 hours, to explain the study and schedule a meeting. If a frequent user declined to enroll, we asked an open-ended question on the reason for declining. With the participants' permission, a CM team member contacted their primary care physician (PCP), if present, to inform him/her about the study and gather information.

Randomization was computer-generated and concealed from patients.¹⁹ The research nurse, CM team, ED staff and data collection manager were not blinded to participant allocation, due to their activities and contacts. We informed study participants that they might receive CM services, without informing them of their group allocation. The statistician was blinded until the analyses were completed.

The CM team administered the intervention for 6 months following enrollment (until January 2014); patients were followed during the 6-month intervention and for an additional 6 months, for a total of 12 months (through July 2014).

CM intervention and control groups

In addition to standard emergency care, participants in the intervention group received the CM intervention at baseline and at 1, 3, and 5 months (Online Appendix 1). The baseline visit lasted 1.5 h, and follow-up visits took 30–60 min. An interdisciplinary mobile team consisting of four nurse practitioners and a chief resident²³ provided the intervention in an ambulatory care, hospital, or home setting. With our “open-door policy,” participants were given the telephone number and address of the CM team and could make contact between scheduled appointments.

The CM team provided individualized services to each participant in the intervention group, emphasizing care coordination and facilitating communication between health care team members. Specifically, CM team members provided counseling, based on motivational interviewing and cross-cultural competences, on substance abuse (if applicable) and use of medical services. After assessing individual participant needs, we offered assistance to obtain income entitlements, improved housing (e.g. homeless shelters or asylum seeker housing), health insurance, domestic violence support and educational opportunities, to address these social determinants of health (SDH). Referrals were made to mental health services, substance abuse treatment or a new PCP on a case-by-case basis. As part of the CM intervention, we created a comprehensive care plan (Online Appendix 2) with practical recommendations for all of the participants’ health care providers (PCP, psychiatrist, etc.). A key element of the intervention was establishing a link between providers and services at the hospital and community levels, promoting care continuity and improved orientation in the health care system.

Control group participants received only standard emergency care, but also met with a researcher during the 12 month follow-up (at 2, 5.5, 9 and 12 months), completing questionnaires related to outcomes which are not the focus of this paper (e.g. quality of life and the perception of discrimination²⁴). Control group participants also received the CM team contact information, and anyone who contacted the team was eligible to receive CM services after the study.

Study Data and Outcome Measures

The primary outcome (number of ED visits) was obtained via the Lausanne hospital/ambulatory electronic records system and hospital/ambulatory administrative databases for each participant during the 12 months prior to and 12 months following enrollment.

Using validated standardized scales at baseline, we collected data on patient sociodemographic characteristics, SDH (including Medical Outcomes Study [MOS] survey²⁵ and subjective social status²⁶), somatic (Charlson comorbidity index²⁷) and mental health factors (Patient Health Questionnaire [PHQ]²⁸, Mini-International Neuropsychiatric Interview [M.I.N.I.]²⁹), at-risk behaviors (Alcohol, Smoking and

Substance Involvement Screening Test [ASSIST]³⁰), and health care utilization.²²

Statistical Analysis

Statistical analyses were performed using STATA software (version 14; StataCorp LP, College Station, TX, USA), with the significance level set at $p = 0.05$. All analyses followed intention-to-treat standards. Descriptive statistics were computed using means and standard deviations for continuous variables, and absolute frequencies and percentages for categorical variables. We applied a generalized linear model for count data (negative binomial distribution) using the number of ED visits during the 12 months following enrollment as the dependent variable. We included an offset variable (corresponding to the logarithm of survival time) to account for participants who died during the study. First, we performed bivariate analyses to test the effect of the participant group (intervention or control), the number of visits at baseline (12 months before enrollment), age, gender, education, citizenship, French proficiency, PCP, somatic, mental and social determinants, and at-risk behaviors as independent variables on the use of ED services during the 12 month follow-up. Second, we ran a stepwise regression including all these independent variables in order to select the predictive variables ($p = 0.10$) to be included in the multivariate model. Ratio and 95 % confidence intervals were computed to estimate the effect size.

RESULTS

Of the 1145 frequent ED users identified during the recruitment period, we could not approach 217 (Fig. 1) due to pragmatic constraints for the single research nurse recruiting during periods of heavy patient influx, and 231 did not meet eligibility criteria. We were unable to contact 171 (after initial contact in the ED, they did not respond to follow-up calls), and 276 refused to participate. Reasons for declining included no expected benefit, not being satisfied with the hospital, and recent participation in another study. Those who refused did not differ in sex or nationality, but were older than enrolled participants (52.3 vs. 48.6 years old, $p = 0.03$). Overall, 250 (47.5 %) agreed to participate and were allocated to the intervention ($n = 125$) or control group ($n = 125$).

Participant Characteristics (Table 1)

The mean age of the participants was 48.5 years (± 18.9), and 57.2 % were men. The intervention group had significantly lower educational attainment than controls. Participants reported high levels of poor SDH, including inadequate housing, lack of employment, and problems with immigration status. The majority suffered from a chronic condition, medical co-morbidity or psychiatric illness, and a third reported at-

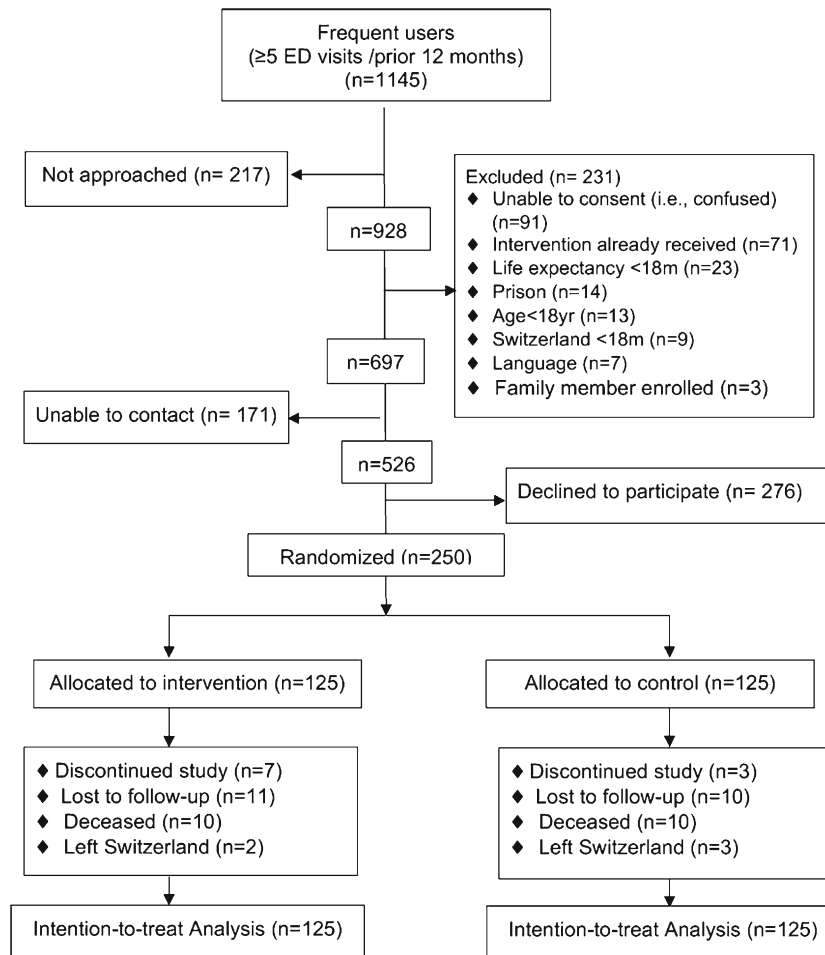


Figure 1 Enrollment flow chart.

risk behaviors. Only 14 % did not have a PCP. The groups had an equal number of ED visits in the 12 months prior to enrollment.

Study Implementation

All 125 intervention group participants received the intervention at baseline, 106 (84.8 %) at 1 month, 98 (78.4 %) at 3 months, and 93 (74.4 %) at 5 months; 108 (86.4 %) intervention group participants contacted the CM team between study visits. No control group participants contacted the CM team proactively. Twenty participants (10 in each group) died during the study.

The CM team referred 66 participants (52.8 %) to mental health professionals and 34 (27.2 %) to substance abuse treatment. Sixty participants (48.0 %) received additional social services, and 83 (66.4 %) were referred to specialized medical doctors.

Outcome (Table 2)

During the 12 month follow-up, control group participants made an average of 3.35 ± 0.32 ED visits, whereas intervention group participants made 2.71 ± 0.23 visits, corresponding to 19 % fewer ED visits (ratio = 0.81, 95 % CI = 0.63 to 1.02).

The effect of the CM intervention (i.e. group) on the number of ED visits was not statistically significant in the bivariate model, ($b = -0.217$, $p = 0.080$) (Table 2). The association between social determinants and the number of visits approached statistical significance ($b = 0.272$, $p = 0.055$), with poor SDH being associated with higher ED use, in the bivariate model. Group assignment (intervention or control) and social determinants were used in the stepwise multivariate regression. In this model, the effect of the group approached significance ($b = -0.219$, $p = 0.075$), with the intervention group making fewer ED visits compared to the control group. The presence of poor SDH was significant in the final model ($b = 0.280$, $p = 0.048$).

DISCUSSION

In this randomized controlled trial, a CM intervention led to 19 % fewer ED visits by frequent users, which approached statistical significance, through an improved orientation to and coordination of services within the health care system. Our results also demonstrate that the presence of poor SDH—including social isolation, housing instability, or financial insecurity—was associated with higher ED use among frequent users.

Table 1 Baseline Characteristics of the Study Population

	Total (n = 250)	Intervention group (n = 125)	Control group (n = 125)
Sociodemographic characteristics (% , n)			
Male	57.2 (143)	56.0 (70)	58.4 (73)
Age (mean, SD)	48.5(18.9)	48.4 (18.7)	48.6 (19.1)
Citizenship			
Switzerland	47.6 (119)	46.4 (58)	48.8 (61)
Europe	17.6 (44)	19.2 (24)	16.0 (20)
Other (e.g. Africa, Asia, Lat Am)	34.5 (86)	34.4 (43)	34.7 (43)
Education			
High school/vocational school	45.2 (113)	39.2 (49)	51.2 (64)
University/College	16.8 (42)	13.6 (17)	20.0 (25)
Compulsory school only, do not know or other	38.0 (95)	47.2 (59)	28.8 (36)
Uninsured	2.8 (7)	2.4 (3)	3.2 (3)
Limited French proficiency	18.8 (47)	18.4 (23)	19.2 (24)
No Primary care physician	14.0 (35)	16.0 (20)	12.0 (15)
Number of ED visits (mean, SD)			
5 (% , n)	54.8 (137)	51.2 (64)	58.4 (73)
6 (% , n)	20.8 (52)	24.0 (30)	17.6 (22)
7 (% , n)	9.2 (23)	10.4 (13)	8.0 (10)
8 (% , n)	6.0 (15)	5.6 (7)	6.4 (8)
9 (% , n)	3.6 (9)	4.8 (6)	2.4 (3)
10 or more (10–24) (% , n)	5.6 (14)	4.0 (5)	7.2 (9)
Social determinants (any) (% , n)*			
Complex family situation	43.6 (109)	45.6 (57)	41.6 (52)
Social isolation	31.2 (78)	30.4 (38)	32.0 (40)
Financial hardship	49.6 (124)	50.4 (63)	48.8 (61)
Inadequate housing (homeless or refugee housing)	24.0 (60)	26.4 (33)	21.6 (27)
Lack of employment or other activities	50.4 (126)	54.4 (68)	46.4 (58)
Limited French proficiency	16.0 (40)	12.8 (16)	19.2 (24)
Problem with immigration status	22.0 (55)	24.0 (30)	20.0 (25)
Somatic determinants (any) (% , n)†			
Chronic and/or acute severe illness	69.2 (173)	69.6 (87)	68.8 (86)
Comorbidity	59.2 (148)	61.6 (77)	56.8 (71)
Polypharmacy	23.2 (58)	24.0 (30)	22.4 (28)
Treatment non-adherence	17.2 (43)	20.0 (25)	14.4 (18)
Mental determinants (any) (% , n)‡	6.4 (16)	8.8 (11)	4.0 (5)
Depression	50.8 (127)	47.2 (59)	54.4 (68)
Anxiety disorder	27.2 (68)	23.2 (29)	31.2 (39)
Personality disorder	31.6 (79)	28.8 (36)	34.4 (43)
Psychotic disorder	6.0 (15)	4.8 (6)	7.2 (9)
At-risk behaviors (any) (% , n)§	3.2 (8)	2.4 (3)	4.0 (5)
Alcohol use	32.0 (80)	34.4 (43)	29.6 (37)
Tobacco use	27.6(69)	28.8 (36)	26.4 (33)
Illicit drug use	29.6 (74)	32.0 (40)	27.2 (34)
	10.8 (27)	11.2 (14)	10.4 (13)

**MOS Social Support Survey²⁵ and subjective social support survey²⁶

†Charlson score²⁷

‡PHQ²⁸ and M.I.N.I.²⁹

§ASSIST³⁰

While our main results do not achieve statistical significance, 19 % fewer ED visits is clinically relevant, given the significant time and resources required to care for frequent ED users.^{31–33} For example, in the USA (21–28 % of 130 million total visits), a reduction of the magnitude found in our study would translate into 5.1–6.8 million avoided visits annually.^{15,34} The non-significant reduction in ED use found in this study underscores the mixed evidence in the literature. At least seven prior studies^{12,13,35–39} showed ED use reductions following a CM or similar intervention, while five studies^{9,11,14,40,41} did not. In terms of study design, sample size and intervention (i.e. in-person CM intervention), our trial most closely matches that of Shumway,¹² who found an additional reduction of one ED visit. A 1997 RCT did not find a reduction in number of ED visits following a CM-like intervention¹¹; however, they defined frequent use as greater than 10 annual ED visits, and thus their results may be difficult

to compare to our own. Two RCTs conducted in Sweden used a lower threshold to define ED frequent use (>3 visits), and implemented interventions different from ours.^{13,14} Differences in the definition of frequent use and in intervention design and setting may have contributed to these varying results. Our results may have been influenced by the fact that despite our use of a validated definition,¹ most participants had only 5–6 visits at enrollment, and CM may be of greater benefit for those with higher baseline ED use, given the increased vulnerability of this group.^{12,42} Furthermore, over one-third of participants were from Africa, Latin America or Asia, regions of origin common for asylum seekers, refugees or undocumented immigrants living in Switzerland. The limited primary care services in these regions⁴³ may have led to increased ED use among these participants. Finally, significantly lower education among intervention group participants may have increased ED use in this group.⁴⁴

Table 2 Bivariate and Multivariate Models Predicting Number of ED Visits at Follow-Up

Variables	Bivariate models ^a		Multivariate final model ^{a,b}	
	<i>b</i> ^c	p value	<i>b</i>	p value
Intervention group ^d	-0.217	0.080	-0.219	0.075
Number of ED visits at enrollment (prior 12 months)	0.026	0.333	—	—
Male ^e	-0.119	0.342	—	—
Age	-0.003	0.416	—	—
Citizenship ^f				
Europe	-0.063	0.717	—	—
Other (e.g. Africa, Asia, Lat Am)	-0.022	0.872	—	—
Education ^g				
High school/vocational school	0.080	0.606	—	—
University/college	-0.050	0.799	—	—
Do not know/other	0.164	0.442	—	—
Limited French proficiency	-0.073	0.442	—	—
No primary care physician	-0.257	0.166	—	—
Social determinants ^h	0.272	0.055	0.280	0.048
Somatic determinants ⁱ	0.078	0.562	—	—
Mental determinants ^j	0.169	0.172	—	—
At-risk behaviors ^k	-0.003	0.980	—	—

^aGeneralized linear model for count data (negative binomial distribution)

^bStepwise regression ($p = 0.10$)

^c"*b*" is the coefficient of the regression model

^dReference category: controls

^eReference category: female

^fReference category: Swiss nationality

^gReference category: compulsory school only

^hSocial determinants (at least one determinant): complex family situation, social isolation, financial hardship, inadequate housing, lack of employment, limited French proficiency, problems with immigration status

ⁱSomatic determinants (at least one determinant): chronic and/or acute severe illness, comorbidity, polypharmacy, treatment non-adherence

^jMental determinants (at least one determinant): depression, anxiety, personality disorder, psychotic disorder

^kAt-risk behaviors (at least one determinant): alcohol use, tobacco use, illicit drug use

Another important consideration is that the number of ED visits decreased in both groups. Contact between control group participants and the research team may have introduced contamination bias, contributing to a reduction in ED use among controls. However, despite receiving information about the CM team at enrollment, no control group participant proactively contacted the team to seek out services. A second explanation is that ED use becomes less frequent over time (i.e. regression to the mean), even without intervention.^{7,19} Finally, the Hawthorne effect—that people have a tendency to change their behavior when under observation—may have influenced ED use among these participants. In the Reinius study,¹³ control participants were passively observed in a Zelen's design, adopted in part to avoid a Hawthorne effect.

This pragmatic RCT has several limitations and strengths. First, we conducted this study at a single site, the sole tertiary care center in the canton of Vaud and one of five academic medical centers in Switzerland. However, in order to maximize the generalizability of our findings, we recruited a representative study sample of frequent ED users.^{16,45} In addition, the design of the Swiss health system—privatized but with universal coverage—allows for generalization of our findings to North America, Europe and parts of Asia. Second, the enrollment rate of 47.5 % could have biased or contributed to our non-significant results. This suggests that CM services may not appeal to some frequent users, who may benefit from alternative outreach strategies. However, this enrollment rate is comparable to those of other studies,¹³ and we recruited an

adequate number of participants based on power calculations. Although we anticipated a dropout rate of 30 %, we retained 78 % of study participants. Our intention-to-treat analysis also reflects a "real world" scenario of caring for this highly vulnerable population. Third, we were unable to track the ED use of participants who visited an outside hospital or moved out of the area. Fourth, our small but experienced team was unable to approach 217 individuals during recruitment and were not blinded to allocation given their role in delivering the intervention; thus we cannot exclude a possible selection bias, despite specifically instructing our team against this. Fifth, excluding frequent users who had previously received CM services may have impacted our results. However, the characteristics of the frequent users we enrolled were qualitatively similar to participants in previous studies,^{16,22} suggesting that we recruited a representative sample. Finally, the 12-month study duration may have limited our ability to demonstrate the full scope of the benefit (or lack thereof) over a longer period. However, Shumway¹² performed sensitivity analyses demonstrating similar cost-effectiveness of a CM intervention at 12 months and 24 months, suggesting that 1 year may be an appropriate study length.

Evidence regarding the impact of the CM on ED use remains inconclusive. A key goal of this CM intervention was to offer improved orientation and redirection to a range of hospital and community-based services. While most participants already had a PCP, caring for these highly vulnerable patients independently in the community is challenging. The

main contribution of this intervention was to facilitate and coordinate care of frequent users, with the PCP integrated into this approach. The development of effective and efficient strategies to improve care for frequent users of the ED and other health services is an area of great interest. CM could serve as a link between disparate parts of complex health systems, with the PCP as the nexus for care continuity. CM teams should focus on modifiable SDH—such as housing or employment—in addition to traditional biomedical risk factors. Research investigating the impact of CM on specific highly vulnerable frequent users, such forced migrants or those with low health literacy, is warranted. Future research should explore patient-reported outcomes, and analyze costs at the institutional and community levels, taking into account the long-term needs of patients.

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- Swiss Society of General Internal Medicine 83rd Annual Congress, May, 20–22, 2015, Basel, Switzerland (oral presentation, 2nd prize among oral presentations)

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Compliance with Ethical Standards:

Conflict of Interest: The authors declare that they do not have a conflict of interest.

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