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# Patient Support Program and Healthcare Resource Utilization in Patients Using Clean Intermittent Catheterization for Bladder Management

Shaquib Al Hasan ◆ Levi Neal-Herman ◆ Holly S. Norman ◆ Julie Z. Zhao ◆ Angeline Carlson

## ABSTRACT

**PURPOSE:** The primary purpose of this study was to evaluate the impact of a patient-centered, chronic care self-management support program of clean intermittent catheterization (CIC) on emergency department (ED) visits and hospitalizations within the first 30 days of starting CIC. Secondary research objectives were to compare reuse of catheters, adherence to healthcare provider-instructed frequency of CIC, and reasons for nonadherence.

**DESIGN:** A correlational survey design with 2 respondent groups.

**SUBJECTS AND SETTING:** Four hundred forty-five respondents met inclusion criteria for this study; 321 respondents enrolled in an intermittent catheter manufacturer-supported CIC support program, and 124 respondents were not enrolled in a support program (comparison group).

**METHODS:** Participants completed a 37-item online questionnaire designed for purposes of this study. Chi-square test was used to assess differences in the proportions of patients with ED visits and overnight hospital admissions comparing respondents enrolled in the patient support program to those not enrolled. Regression analyses were performed to estimate the effect of the CIC support program on ED visit events and on hospital overnight stays.

**RESULTS:** Within the first month of CIC initiation, 16.1% and 10.2% of the respondents in the comparison group reported at least 1 ED visit and at least 1 overnight hospital stay, respectively. Respondents participating in the CIC support program experienced a 47% decrease in ED visits (adjusted rate ratio: 0.53; 95% confidence interval: 0.30-0.94,  $P = .036$ ) and a 77% decrease (adjusted rate ratio: 0.24; 95% confidence interval: 0.10-0.62,  $P = .002$ ) in hospital overnight stays within the first month of CIC initiation, while controlling for age, sex, education, duration of CIC use, region, health insurance status, and medical conditions necessitating CIC. Respondents in the CIC support program group reported an 8% higher adherence rate with the healthcare provider-instructed frequency of CIC usage compared to the comparison group (88% vs 80%,  $P = .039$ ).

**CONCLUSIONS:** The burden of CIC-related complications within the first month of CIC initiation is significant. A patient-centered, chronic care self-management program for CIC was associated with fewer ED visits and overnight hospital stays during the first month of CIC and improved adherence to prescribed frequency of CIC use.

**KEY WORDS:** Catheter self-management, Clean intermittent catheterization, Patient education, Urinary incontinence, Urinary retention.

## INTRODUCTION

Clean intermittent catheterization (CIC) is the bladder management method of choice for persons with persistent incomplete bladder emptying (with or without urinary incontinence) such as that seen with neurogenic lower urinary tract dysfunction associated with spinal cord injury (SCI) or spina-

bifida.<sup>1</sup> The lower rate of complications, such as urinary tract infections (UTIs), associated with CIC has resulted in preference for its use versus indwelling catheters.<sup>1-3</sup>

While CIC is the preferred bladder management strategy for many persons with persistent urinary retention, adherence to a routine catheterization regimen is a challenge.<sup>4</sup> A study of patients with SCI found that half of the patients changed their

**Shaquib Al Hasan, MS,** Social and Administrative Pharmacy Graduate Program, Department of Pharmaceutical Care and Health Systems, College of Pharmacy, University of Minnesota, Minneapolis, Minnesota.

**Levi Neal-Herman, MBA,** Coloplast Care, Coloplast Corp, Minneapolis, Minnesota.

**Holly S. Norman, PhD,** Coloplast Corp, Minneapolis, Minnesota.

**Julie Z. Zhao, MPH,** Department of Pharmaceutical Care and Health Systems, College of Pharmacy, University of Minnesota, Minneapolis, Minnesota.

**Angeline Carlson, PhD,** Department of Pharmaceutical Care and Health Systems, College of Pharmacy, University of Minnesota, Minneapolis, Minnesota.

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**Correspondence:** Angeline Carlson, PhD, Department of Pharmaceutical Care and Health Systems, College of Pharmacy, University of Minnesota, Weaver-Densford Hall, 308 Harvard St SE, Minneapolis, MN 55455 (angie@dataiq.com).

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bladder-emptying method within the first 5 years of starting CIC because adherence to a CIC regimen proved challenging.<sup>5</sup> Individuals must make lifestyle adjustments in order to successfully manage the underlying urinary retention, including having the ability to perform CIC in different locations and conditions and adjust to the challenges of different social situations.<sup>6</sup>

Education on catheter selection and proper use techniques and care such as positioning to insert the catheter, hand-washing, the timing and frequency of catheterization, and follow-up to detect potential complications is necessary for bladder management using CIC.<sup>6-8</sup> A qualitative study that conducted interviews with healthcare professionals in the continence care field identified the means of supporting patients with adherence to a CIC regimen.<sup>9</sup> Recommended approaches to improving CIC adherence included education that directly addresses individual anxieties, ensures correct understanding of the body and effect of regular CIC, and eliminates misconceptions about CIC.<sup>9</sup> Effective education and training related to CIC is important as the complex medical conditions (such as SCI, multiple sclerosis, or spina bifida), leading to neurogenic lower urinary tract dysfunction and CIC prescription, create challenges as patients attempt to adhere to the CIC-related management recommendations by their healthcare providers.<sup>10</sup> For example, many patients with neurologic disorders have limited hand dexterity or cognitive dysfunction that can interfere with their ability to perform CIC.<sup>11</sup> As some of the medical conditions that necessitate CIC limit dexterity and overall body movements, standard catheterization techniques may require individualization and additional accommodations with the help of continence nurse specialists or support program advisors.

The Consortium for Spinal Cord Medicine recommends education on proper techniques and care related to catheter use for all patients.<sup>7</sup> Acquiring the knowledge and skills needed to meet self-management challenges can be facilitated by providing educational materials and access to training to assist patients and their families to appropriately perform CIC.<sup>6</sup> An individualized approach to addressing the specific needs of each CIC patient is necessary to ensure that patients with mobility or other limitations are provided with adequate training and support to perform CIC.<sup>11</sup>

The clinical implications of CIC adherence and patient education are explored in a model of UTI risk factors.<sup>11</sup> Kennelly and colleagues<sup>11</sup> propose that one of the risk factors that have a relatively certain role in contributing to UTIs is nonadherence to CIC recommendations. Additionally, based on expert opinions, insufficient patient education is proposed as a contributing risk factor to UTIs in this model.

To provide CIC patients with adequate education to achieve goals of self-management, Coloplast Care, a chronic-care patient support program, was made available through an intermittent catheter manufacturer (Coloplast, Minneapolis, Minnesota). This CIC support program is free of charge and provides support to all enrolled patients regardless of type of catheter used to perform CIC. This program provides information on how to use the catheters, information on different product attributes and options, availability, suppliers, and how to develop self-support habits. As a chronic disease self-management support program, enrolling CIC patients in the support program qualifies as an improvement activity under the Centers for Medicare & Medicaid Services' (CMS's) Merit-based Incentive Payment System (MIPS). While any

CIC patient can enroll in the CIC support program regardless of the brand of catheter he or she uses, the majority are enrolled by a healthcare professional and use products manufactured by Coloplast, Inc. Once enrolled, the CIC patients receive assistance via 3 core components: (1) care advisor, (2) support tools, and (3) program wellness education.

Patients enrolled in the CIC support program are proactively contacted by a care advisor with training in CIC-related products. Care advisors provide product usage guidance, lifestyle advice, daily living and emotional support, and assistance in locating a catheter supplier that is in-network for their insurance plans. While care advisors do not have clinical degrees and do not provide medical advice, they undergo 12 weeks of training on a variety of topics such as CIC products and usage, product access issues in the US healthcare system, providing education and guidance on CIC usage and bladder health, and promoting adherence to a prescribed CIC regimen. A quality assurance team regularly monitors and assesses calls to ensure that care advisors address program members' concerns and help resolve catheter-related issues. Advisors describe the catheterization procedure over the phone and can provide step-by-step instructions while patients perform CIC including guidance for female users on how to sit and position the mirror when they have difficulty locating the urethra or guidance to SCI users in how to catheterize from a wheelchair.

The support program provides CIC patients with a one-time sex-specific care kit that includes requested Coloplast product samples, tools to assist in catheterization (such as a leg mirror for women, or extension tubing for SCI patients), instructions on hand hygiene, a bladder diary, CIC-specific educational content, and information about preventing UTIs. The CIC support program also provides wellness education available on the Internet, via email, and on a mobile phone application.

The overall goals of the program are to help patients gain confidence with CIC at home, promote adherence to the CIC prescription provided by the user's healthcare provider, and provide advice on preventing CIC-related complications such as UTI. The goal is to improve the individual's adjustment to a lifestyle that incorporates CIC. Research on adherence to CIC has been conducted previously reporting adherence rates ranging from 58% to 82% at 4 to 10 years.<sup>2,5,12</sup> However, evidence concerning the influence of a CIC support program on healthcare utilization is sparse. Blondal and colleagues<sup>13</sup> evaluated an educational effort focused on catheter use for nursing personnel on medical-surgical inpatient care units. They reported a reduction in the proportion of hospital inpatient days with a catheter, from 44% to 41% ( $P = .006$ ).<sup>13</sup> However, evidence concerning the influence of posthospital CIC-focused education/support programs on healthcare utilization related to CIC is missing.

Two of the studies collecting data from medical records and registry database found 58% and 71% adherence to CIC among patients with neurogenic lower urinary tract dysfunction based on sample sizes ranging from 89 to 164 participants.<sup>2,5</sup> An adherence rate of 82% was found in another study in which data were collected through telephone interview with 40 patients performing CIC to manage neurogenic lower urinary tract dysfunction.<sup>12</sup> However, adherence rates of CIC users of a support program and CIC users not using a support program have not been evaluated.

Healthcare utilization outcomes during the first 30 days after initiating CIC are of particular interest for 2 reasons.

First, we hypothesized that CIC users would experience the most significant adjustment challenges during the initial several weeks learning to preform CIC. Additionally, the first 30 days after initiating CIC is of interest because the CMS aims to reduce 30-day readmissions through the Hospital Readmissions Reduction Program.<sup>14</sup> Per the Hospital Readmissions Reduction Program, the CMS encourages communication and care coordination to reduce avoidable readmissions, which includes all-cause readmissions that happen within 30 days of initial admission to a hospital.<sup>14</sup> Because the 30-day time frame is relevant in the US healthcare reimbursement context and with regard to CIC user experiences and outcomes, this study focused on that 30-day time frame. Therefore, the primary aim of this study was to investigate the effect of a patient support program on healthcare utilization (emergency department [ED] visits and hospital admission) associated with catheter occurring within the first 30 days of initiating CIC. Secondary research objectives were to compare reuse of catheters, adherence to healthcare provider-instructed frequency of CIC, and reasons for nonadherence to a CIC program.

## METHODS

This study used a retrospective, cross-sectional, correlational survey design with 2 nonrandomized respondent groups and utilized a study-specific, online survey to guide data collection and analysis. Individuals using CIC for bladder management were identified from 2 proprietary databases: a catheter manufacturer database and a catheter distributor database. Potential participants within these databases who had previously given consent to be contacted for marketing or promotional purposes and provided an email address were contacted to complete the survey. Contact information was pulled from both databases and group membership (enrolled in CIC support program or not). Email addresses from both databases were deduplicated so that participants were not solicited to complete the survey twice.

Two different links to the same survey were emailed to CIC patients: one was sent to those in the CIC support program group, and a separate link was sent to the comparison group. Therefore, membership in the CIC support group was not dependent upon recall (thus enabling use of an intent-to-treat approach during analysis). A reminder email was sent to all email addresses that had not opened the first survey invitation email 1 week after the first survey invitation email was sent. All CIC patients who had been in the database for less than 3 months were removed for the purposes of reducing the burden of a survey on CIC patients who were still new to using CIC and reducing emails not related to aiding in CIC use during the initial training period. No follow-up survey was conducted as participation was anonymous and not tied back to participant records in the databases.

To minimize recall bias, only respondents using CIC for up to 24 months prior to the survey date were included in data analysis. Individuals were eligible for the study if they were at least 18 years old, actively used intermittent urinary catheters, and began using CIC within 24 months of the study. Individuals who were previous CIC patients but not current CIC patients or who were caregivers were excluded from the study. Individuals using CIC who were enrolled in patient support programs other than the CIC support program being studied were excluded from analysis due to the sample of these being too small to compare as a separate group ( $n = 3$ ). Study procedures were submitted to the University of Minnesota

Institutional Review Board and were determined to be exempt from review (STUDY00004134) on August 29, 2018. Nevertheless, the research team ensured that elements of informed consent were present. Respondents were divided into 2 groups, CIC support program participants and CIC patients not enrolled in any support program (comparison group). An overview of participant recruitment is included in Figure 1.

## Questionnaire

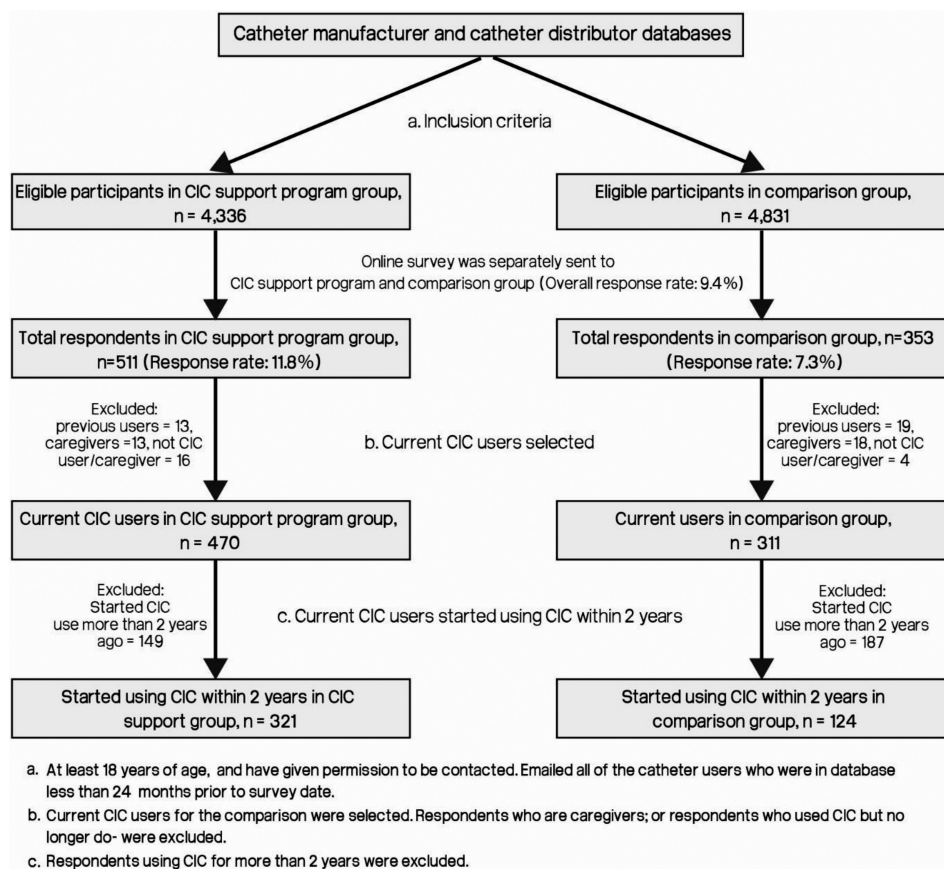
Items for the survey were generated by a group of nonclinician CIC experts from a catheter manufacturer, including one with health services research experience. The 4 members of this panel had CIC-related experience ranging from 2 to 22 years. Following the initial draft of the survey, an advisory board panel of 11 clinicians that included 2 occupational therapists and 9 nurses with specialties including pelvic floor, urology, and rehabilitation from across the United States provided feedback and revisions to the survey.

A 37-item survey was developed (see Supplemental Digital Content Survey Questionnaire, available at: <http://links.lww.com/JWOCN/A77>). The survey queried sociodemographic and group assignment information (9 items), pertinent clinical and inclusion criteria data (3 items), and study outcomes (24 items). Data collected included duration of CIC use and medical conditions necessitating use of CIC. The 3 items querying demographic and pertinent clinical data used to verify that respondents met the inclusion criteria were (1) whether or not the participant was a current CIC patient; (2) what bladder-emptying method they currently used for bladder management (if they no longer used CIC); and (3) when they start using intermittent catheters.

A portion of the 37-item survey contained a 16-item validated instrument, the Self-Confidence Scale for Clean Urinary Intermittent Self-Catheterization.<sup>15</sup> This instrument was validated in a group of 122 CIC users and 119 clinicians; internal reliability was robust with a Cronbach  $\alpha$  value of 0.944. The remaining items in the questionnaire were developed with face validity and were then edited to meet a Flesh-Kincaid eighth-grade reading level.<sup>16</sup> Items for primary and secondary research questions in this article were not subject to reliability or validity testing.

Primary research questions included ED visits and hospital admissions (overnight or longer) associated with catheter use that occurred within the first 30 days of initiating CIC. Survey participants were asked to identify the reasons for any ED visits or hospital admissions from a list of options or write-in "other" reasons. Options listed for ED visits and hospital admissions included dehydration, pain/difficulty with catheter insertion, blood in urine, UTI, kidney/bladder stones, epididymitis, urethral strictures, sepsis/bacteremia, I don't know, and other (with a write-in option). During the data analysis phase, responses pertaining to disease state or medical cause necessitating the use of CIC were reviewed with an RN to ensure accuracy in grouping health conditions.

Secondary outcomes of interest related to CIC use included questions related to reuse of catheters, adherence to prescribed CIC regimen, and reasons for nonadherence or change in frequency of CIC. Prescriptions for CIC include a certain number of catheterizations per day instructed by a healthcare provider; thus, this study examined adherence according to the pharmaceutical industry's approach. In the pharmaceutical industry, adherence is reported as the percentage of the prescribed doses of the medication actually taken by the patient over a specified period.<sup>17,18</sup> A full list of all study items including



**Figure 1.** Participant recruitment process. CIC indicates clean intermittent catheterization.

additional outcomes of interest not described can be accessed in the Supplemental Digital Content Survey Questionnaire, available at: <http://links.lww.com/JWOCN/A77>.

## Study Procedures

An invitation email with the study objectives was sent to the target population in October 2018. Eligible patients were provided access to the questionnaire through a URL containing the survey with informed consent information (Survey-Monkey, San Mateo, California, 2018). The survey was posted over a 17-day period, and 1 reminder email was sent 7 days following the first email to recipients who had not opened the first email.

## DATA ANALYSIS

All statistical analyses were performed using SAS software version 9.4 (SAS Institute, Cary, North Carolina, 2013). For purposes of data analysis, respondents were divided into 2 groups: CIC support program participants and CIC patients not enrolled in a support program (comparison group). Continuous variables were reported as means and standard deviation; categorical variables were reported as proportions. For categorical variables, group differences were assessed using the  $\chi^2$  statistic or Fisher exact test depending on expected cell frequencies. Group comparisons for continuous variables were analyzed using the student *t* test statistic. Results were considered statistically significant at  $P < .05$  level.

Poisson regression is used when the outcome variable is a count variable (eg, number of days in hospital) and the

variance of the outcome variable is relatively close to the mean of the outcome variable, and zero-inflated Poisson regression is used when there are excessive respondents having zero counts of the outcome (eg, zero days in hospital).<sup>19</sup> Since most of the CIC patients in this study had zero ED visits, a zero-inflated Poisson regression was used for comparing ED visits in the CIC support and comparison groups. Zero-inflated negative binomial regression is used when the outcome variable is a count variable with excessive respondents having zero counts of the outcome, and the variance of the outcome variable is much greater than mean of the outcome variable (which is called overdispersion).<sup>20</sup> In addition, since most of the CIC patients in this study had zero hospital overnight stays, and the variance of hospital overnight stays was much greater than the mean number of hospital overnight stays, a zero-inflated negative binomial regression was also used for comparing hospital stays. Covariates included in both multivariate regressions were age, sex, education level, duration of CIC use, geographical region, health insurance status, and medical conditions necessitating CIC.

The answer options for type of health insurance in the questionnaire were—no insurance, Medicare—Original Medicare—Medicare Advantage, Medicaid—State Medicaid—Private Medicaid or Managed Care, Private Insurance—Employer Sponsored—Healthcare Exchange Military Tricare, Other Insurance—County Based—Tribal Healthcare, and Department of Veterans Affairs. Health insurance status was recategorized as “Yes” if the participants had any type of health insurance and “No” if the participants did not have any health insurance.

Adherence to CIC regimen refers to the percentage of actual CIC use divided by the prescribed frequency of use. As the literature reveals a range of adherence rates from 58% to 82%, we selected a 70% cutoff because it was the average of what previous studies have used.<sup>2,5,12</sup> Patients having a cutoff point of at least 70% adherence to prescribed catheterizations per day were considered adherent to CIC regimen for the purposes of this study.

## RESULTS

An invitation to complete the survey was sent to 9167 eligible participants. This cohort comprised 4336 CIC support

program enrollees and 4831 CIC users not enrolled in a patient support program. The response rate to the invitation to participate in this cross sectional study was 9.4% (n = 864); respondents included 511 (11.8%) participants enrolled in the CIC support program, and 353 (7.3%) participants who did not participate in the program acted as a comparison group (Figure 1). Among 864 respondents, 42 respondents in the CIC support group and 41 respondents in the comparison group were excluded as they were caregivers or not current CIC users. A total of 470 respondents in the CIC support group and 311 respondents in the comparison group were current CIC users (n = 781). Among current CIC users, 149 respondents in the CIC support group and 187 respondents

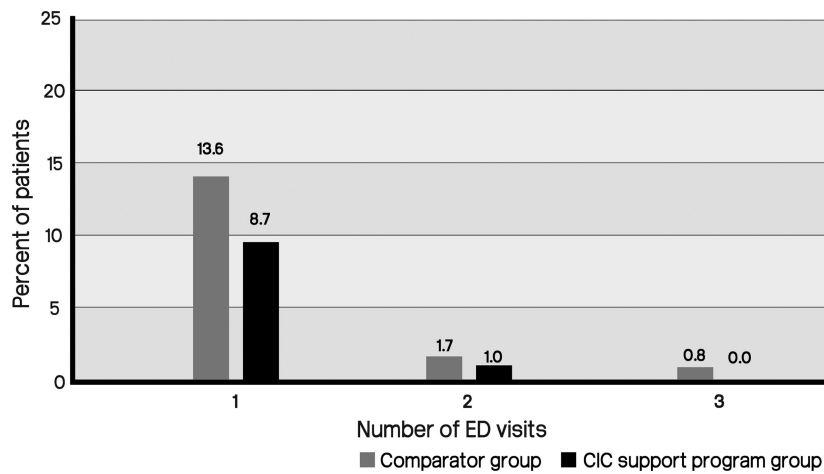
**TABLE 1.**  
Sociodemographic Characteristics of Participants

Characteristics	All Participants (N = 445), n (%)	Group		Comparison of Characteristics (P)
		CIC Support Group (N = 321), n (%)	Comparison Group (N = 124), n (%)	
Age, y				
18-50	25 (5.9)	16 (5.2)	9 (7.6)	.075
51-70	193 (45.5)	131 (42.8)	62 (52.5)	
≥71	206 (48.6)	159 (52.0)	47 (39.8)	
Sex				
Male	342 (81.4)	238 (78.5)	104 (88.9)	.017 <sup>a</sup>
Female	78 (18.6)	65 (21.5)	13 (11.1)	
Education				
Less than bachelor's degree	203 (48.1)	156 (51.3)	47 (39.8)	.034 <sup>a</sup>
At least bachelor's degree	219 (51.9)	148 (48.7)	71 (60.2)	
Medical condition <sup>b</sup>				
Neurogenic	104 (23.5)	69 (21.6)	35 (28.2)	.099
Structural	193 (43.6)	135 (42.3)	58 (46.8)	
Medical complications	107 (24.2)	82 (25.7)	25 (20.2)	
Others	39 (8.8)	33 (10.3)	6 (4.8)	
Health insurance status				.134
Yes	419 (98.8)	304 (99.4)	115 (97.5)	
No	5 (1.2)	2 (0.6)	3 (2.5)	
Duration of using CICs				
0-2 mo	32 (7.2)	21 (6.5)	11 (8.9)	.126
3-6 mo	94 (21.1)	73 (22.7)	21 (16.9)	
7-12 mo	115 (25.8)	89 (22.7)	26 (21.0)	
1-2 y	204 (45.8)	138 (43.0)	66 (53.2)	
Geographic region				
Northeast	101 (24.0)	70 (23.1)	31 (26.5)	.012 <sup>a</sup>
Southeast	108 (25.6)	88 (28.9)	20 (17.1)	
Midwest	122 (29.0)	92 (30.3)	30 (25.6)	
Southwest	46 (10.9)	29 (9.5)	17 (14.5)	
West Coast	44 (10.4)	25 (8.2)	19 (16.2)	

Abbreviation: CICs, clean intermittent catheterization.

<sup>a</sup>P value was calculated from  $\chi^2$  test significant if at  $P < .05$  (Fisher exact test was used for health insurance status). A P value of less than .05 indicates a significant difference in the demographic/health characteristic between groups.

<sup>b</sup>Medical conditions were grouped into 4 groups: neurogenic bladder (spinal cord injury, spina bifida, neurogenic bowel/retention, atonic bladder, Parkinson disease, multiple sclerosis), structural/anatomical issues (benign prostatic hyperplasia, stricture), medical complications (following surgery, following childbirth, cancer/cancer treatment, spastic bladder, kidney problem, IC, urinary tract infections, diabetes), and others.



**Figure 2.** Frequency of patients with ED visits within 30 days, by program enrollment status. CIC indicates clean intermittent catheterization; ED, emergency department.

in the comparison group were excluded as they started CIC use more than 2 years ago. Data analysis was based on 445 out of 864 (51%) respondents; this sample comprised 321 out of 511 (63%) in the CIC support group, and 124 out of 353 in the comparison group. An overview of participant recruitment and reasons for exclusion are shown in Figure 1.

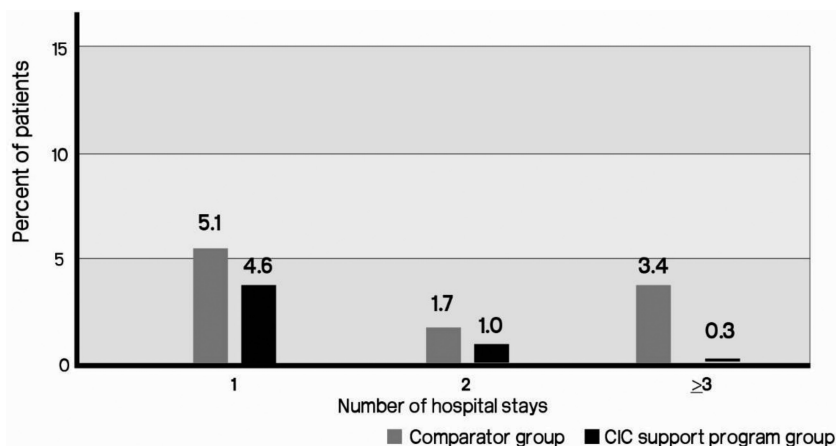
Sociodemographic characteristics of the study sample are summarized in Table 1. The mean age of study participants was 68.85 years (SD: 11.72). Compared to the comparison group, respondents in the CIC support group participants were more likely to have an age of 71 years or more ( $P = .075$ ), have less than a bachelor's degree ( $P = .034$ ), and be female ( $P = .015$ ). The 2 groups were similar in terms of health insurance status, reported medical conditions, and duration of using intermittent catheter.

Figures 2 and 3 illustrate the frequency of ED visits and hospital overnight stay events within the first 30 days after participants started CIC, respectively. Of the participants available for these analyses, a total of 9.7% ( $n = 30/309$ ) of CIC users in the CIC support group had at least 1 visit to ED compared to 16.1% ( $n = 19/118$ ) of the comparison group (Figure 2). A total of 5.9% ( $n = 18/307$ ) of CIC patients in the CIC support group had at least 1 hospital overnight stay

compared to 10.2% ( $n = 12/118$ ) of the comparison group (Figure 3).

Table 2 shows the results of multivariate zero-inflated Poisson regression for predicting ED visits. Compared to the comparison group, the CIC support group was associated with a 47% decrease in ED visits (adjusted rate ratio: 0.53; 95% confidence interval: 0.30-0.96,  $P = .036$ ) within the first month of CIC initiation, while controlling for age, sex, education, duration of CIC use, region of residence, health insurance status, and medical conditions. Other than the CIC support group, none of the covariates had a significant association with ED visits.

Table 3 summarizes the results of multivariate zero-inflated negative binomial regression for predicting hospital stays. Compared to the comparison group, participant in the CIC support group was associated with a 77% decrease (adjusted rate ratio: 0.23; 95% confidence interval: 0.09-0.59,  $P = .002$ ) in hospital overnight stays within the first month of CIC initiation, while controlling for age, sex, education, duration of CIC use, region of residence, health insurance status, and medical conditions. In addition to the significance of the CIC support group, 6 to 12 months of CIC use ( $P = .030$ ) and living in the Southwest region ( $P = .003$ ) had significant associations with hospital overnight stays, when adjusted for other variables.



**Figure 3.** Frequency of patients with hospital overnight stays within 30 days, by program enrollment status. CIC indicates clean intermittent catheterization.

**TABLE 2.**  
**Parameter Estimates of Zero-Inflated Poisson Regression for Emergency Department Visits<sup>a,b</sup>**

Parameter	df	Estimate	Standard Error	Wald 95% Confidence Limits		Wald $\chi^2$	P	Adjusted Rate Ratio (95% CI)
Intercept	1	-2.6791	1.2431	-5.1156	-0.2426	4.64	.031	
Comparison group	1	-0.6301	0.2999	-1.2179	-0.0423	4.41	.036 <sup>c</sup>	0.53 (0.30-0.94)
Duration, mo								
0-2	1	-23.9382	80958.76	-158700	158652.3	0.00	.999	4.02E-9 (0 to infinity)
3-6	1	0.4940	0.3806	-0.2520	1.2399	1.68	.194	1.64 (0.78-3.46)
6-12	1	0.4273	0.3359	-0.2310	1.0856	1.62	.203	1.53 (0.79-2.96)
Sex								
Male	1	0.5841	0.4780	-0.3528	1.5210	1.49	.222	1.79 (0.70-4.58)
Education								
Less than bachelor's degree	1	0.4695	0.2944	-0.1075	1.0465	2.54	.111	1.60 (0.90-2.85)
Region								
Northeast	1	-0.1967	0.5727	-1.3193	0.9259	0.12	.731	0.82 (0.27-2.52)
Southeast	1	0.3416	0.5344	-0.7057	1.3889	0.41	.523	1.41 (0.49-4.01)
Midwest	1	-0.2825	0.5636	-1.3870	0.8221	0.25	.616	0.75 (0.25-2.28)
Southwest	1	0.9103	0.5595	-0.1863	2.0068	2.65	.104	2.48 (0.83-7.44)
Medical conditions								
Neurogenic conditions	1	1.0941	0.7691	-0.4134	2.6015	2.02	.155	2.99 (0.66-13.48)
Structural	1	0.7549	0.7536	-0.7221	2.2319	1.00	.317	2.13 (0.49-9.32)
Medical complications	1	0.6603	0.7971	-0.9020	2.2226	0.69	.408	1.94 (0.41-9.23)
Health insurance	1	-0.5760	0.7792	-2.1033	0.9512	0.55	.460	0.56 (0.12-2.50)
Zero model								
Intercept	1	-0.6284	1.1388	-2.8604	1.6037	0.30	.581	
Age group, y								
18-50	1	0.0627	2.0545	-3.9641	4.0895	0.00	.976	
51-70	1	-1.9624	4.5872	-10.9532	7.0284	0.18	.669	

Abbreviation: CI, confidence interval.

<sup>a</sup>Dependent variable: number of emergency department (ED) visits.<sup>b</sup>Duration was categorized as less than 2 months, 2 to 6 months, 6 to 12 months, and 12 to 24 months (reference duration); age was categorized as 18 to 50 years, 50 to 70 years, and 70 years or more; sex was categorized as male and female (reference group); education was categorized as less than bachelor's degree and bachelor's degree or more (reference group); duration of CIC use was categorized as less than 2 months, 2 to 6 months, 6 to 12 months, and 12 to 24 months (reference group); region of residence was categorized as Northeast, Southeast, Midwest, Southwest, and West Coast (reference group); health insurance status was categorized as "Yes" if participants had health insurance and "No" if participants did not have any health insurance (reference group); medical conditions were grouped into 4 groups: neurogenic bladder (spinal cord injury, spina bifida, neurogenic bowel/retention, atonic bladder, Parkinson disease, multiple sclerosis), structural/anatomical issues (benign prostatic hyperplasia, stricture), medical complications (following surgery, following childbirth, cancer/cancer treatment, spastic bladder, kidney problem, IC, urinary tract infections, diabetes), and others. Zero-inflated Poisson regression analysis shows that clean intermittent catheterization support program was associated with a 47% reduction in number of ED visits (adjusted rate ratio = 0.53, 95% confidence interval: 0.30-0.94).<sup>c</sup>Significant predictor of number of ED visits at a level of significance of .05.

Tables 4 and 5 further explores top 3 reasons for ED visits and hospital overnight stays within 30 days after starting use of CIC. The top 3 reasons for ED visits within 30 days after starting use of CIC were UTI, hematuria, and pain/difficulty in inserting catheter. A total of 16 (4.98%) patients in CIC support group and 8 (6.45%) patients in comparison group indicated UTI as the reason for ED visits. There were no significant differences in the proportion of patients having these reasons for ED visits in CIC support group and comparison group. The top 3 reasons for hospital overnight stays within 30 days were UTI, hematuria, and sepsis/bacteremia. A total of 12 (3.74%) patients in the CIC support group and 2 (1.61%) patients in the comparison group indicated UTI as the reason for hospital

admissions. However, there were no significant differences in the proportion of patients having these reasons for hospital overnight stays in CIC support group and comparison group.

### Secondary Outcomes

Secondary outcomes explored in this study were reuse of catheters, adherence to prescribed frequency of CIC, reasons for nonadherence (Table 6). Respondents in the CIC support program group were more likely to be adherent to prescribed CIC frequency (281 out of 324, 87.5%) than the comparison group participants (99 out of 124, 79.8%) ( $P = .039$ ). A total of 20.2% ( $n = 25/124$ ) of patients in the comparison group were nonadherent with prescribed CIC frequency compared

**TABLE 3.** Parameter Estimates of Zero-Inflated Negative Binomial Regression for Hospital Stays<sup>a,b</sup>

Parameter	df	Estimate	Standard Error	Wald 95% Confidence Limits		Wald $\chi^2$	P	Adjusted Rate Ratio (95% CI)
Intercept	1	-1.8389	1.8948	-5.5526	1.8749	0.94	.332	
Comparison Group	1	-1.4711	0.4822	-2.4161	-0.5260	9.31	.002 <sup>d</sup>	0.23 (0.09-0.59)
Duration <sup>c</sup> (vs 12-24 mo)								
0-2 mo	1	-1.8538	1.3465	-4.4928	0.7853	1.90	.169	0.16 (0.01-2.19)
3-6 mo	1	0.7545	0.9591	-1.1253	2.6342	0.62	.432	2.13 (0.32-13.93)
6-12 mo	1	-1.4359	0.6617	-2.7328	-0.1391	4.71	.030 <sup>d</sup>	0.24 (0.07-0.87)
Male <sup>e</sup> (vs female)	1	1.1947	0.9317	-0.6314	3.0208	1.64	.200	3.30 (0.53-20.51)
Less than bachelor's degree (vs bachelor's degree or more)	1	-0.2113	0.5804	-1.3489	0.9263	0.13	.716	0.81 (0.26-2.53)
Region <sup>e</sup> (vs Midwest)								
Northeast	1	1.0255	0.7236	-0.3926	2.4437	2.01	.156	2.79 (0.68-11.51)
Southeast	1	0.0492	0.8358	-1.5889	1.6874	0.00	.953	1.05 (0.21-5.41)
Midwest	1	0.2823	0.6487	-0.9891	1.5537	0.19	.664	1.33 (0.37-4.73)
Southwest	1	2.8868	0.9729	0.9799	4.7937	8.80	.003 <sup>d</sup>	17.94 (2.66-120.75)
Medical conditions <sup>c</sup> (vs other conditions)								
Neurogenic conditions	1	-0.2976	1.6325	-3.4972	2.9020	0.03	.855	0.74 (0.03-18.21)
Structural	1	-0.9491	1.6864	-4.2545	2.3562	0.32	.574	0.39 (0.01-10.55)
Medical complications	1	0.9156	1.4522	-1.9306	3.7618	0.40	.528	2.50 (0.15-43.02)
Health insurance <sup>e</sup> (vs no insurance)	1	1.4843	1.2479	-0.9617	3.9302	1.41	.234	4.41 (0.38-50.91)
Zero model								
Intercept	1	2.0699	0.3536	1.3768	2.7629	34.27	<.0001	
Age group <sup>e</sup> , y								
18-50	1	-1.7364	0.8347	-3.3723	-0.1005	4.33	.038	
51-70	1	-0.2405	0.4480	-1.1185	0.6376	0.29	.591	

Abbreviation: CI, confidence interval.

<sup>a</sup>Zero-inflated negative binomial regression is used when the outcome variable is a count variable with excessive respondents having zero counts of the outcome, and the variance of the outcome variable is much greater than mean of the outcome variable (which is called overdispersion). Since most of the participants in clean intermittent catheterization (CIC) support group in this study had zero hospital overnight stays, and the variance of hospital overnight stays was much greater than the mean number of hospital overnight stays, a zero-inflated negative binomial regression was used for comparing hospital stays.

<sup>b</sup>Dependent variable: number of hospital overnight stays.

<sup>c</sup>Duration was categorized as less than 2 months, 2 to 6 months, 6 to 12 months, and 12 to 24 months (reference duration); age was categorized as 18 to 50 years, 50 to 70 years, and 70 years or more (reference group); sex was categorized as male and female (reference group); education was categorized as less than bachelor's degree, and bachelor's degree or more (reference group); duration of CIC use was categorized as less than 2 months, 2 to 6 months, 6 to 12 months, and 12 to 24 months (reference group); region of residence was categorized as Northeast, Southeast, Midwest, Southwest, and West Coast (reference group); health insurance status was categorized as "Yes" if participants had health insurance and "No" if participants did not have any health insurance (reference group); medical conditions were grouped into 4 groups: neurogenic bladder (spinal cord injury, spina bifida, neurogenic bowel/retention, atonic bladder, Parkinson disease, multiple sclerosis), structural/anatomical issues (benign prostatic hyperplasia, stricture), medical complications (following surgery, following childbirth, cancer/cancer treatment, spastic bladder, kidney problem, IC, urinary tract infections, diabetes), and others. Zero-inflated negative binomial regression analysis shows that CIC support program, 6 to 12 months of CIC use, and Southwest region were significantly associated with number of hospital overnight stays. The CIC support program was associated with a 77% reduction in number of emergency department visits (adjusted rate ratio = 0.23, 95% confidence interval: 0.09-0.59).

<sup>d</sup>Significant predictor of hospital overnight stays at a level of significance of 0.05 compared to reference group.

to 12.5% (n = 40/321) of participants in the CIC support group. There were no significant differences in other secondary outcomes—reuse of catheters (P = .121) and actual frequency of CIC (P = .070).

The self-reported reasons for nonadherence to prescribed CIC frequency in study respondents are shown in Table 7. The top 3 reasons in the CIC support program group were difficulty in catheterization due to daily schedule or lifestyle (n = 31; 9.66%), embarrassment or stigma (n = 5; 1.56%), and problems with health insurance (n = 5; 1.56%). The top 3 reasons in the comparison group were difficulty in catheterization due to daily schedule or lifestyle (n = 8; 6.45%), desire to save

money (n = 7; 5.65%), and problems obtaining catheters and supplies (n = 5; 4.03%). Reporting catheter-related supply issues and concern about saving money were significantly lower in the CIC support program group than in the comparison group. There were no other group differences in reported reasons for nonadherence.

**DISCUSSION**

Within the first 30 days of initiating CIC, the participants of the CIC support program reported a significantly lower likelihood of ED visits (P = .036) and hospital stays (P = .002) than participants in the comparison group (Tables 2 and 3).



**TABLE 4.****Top 3 Reasons for ED Visits Within 30 Days**

Top 3 Conditions for ED Visits Within 30 d	CIC Support Group (N = 321)	Comparison Group (N = 124)	P	Both Groups (N = 445)
Urinary tract infection, n (%)	16 (4.98)	8 (6.45)	.5390 <sup>a</sup>	24 (5.39)
Hematuria, n (%)	7 (2.18)	5 (4.03)	.3281 <sup>b</sup>	12 (2.70)
Pain/difficulty inserting catheter, n (%)	4 (1.25)	3 (2.42)	.4040 <sup>b</sup>	7 (1.57)

Abbreviations: CIC, clean intermittent catheterization; ED, emergency department.

<sup>a</sup>Chi-square test has been used to compare CIC support group and comparison group.

<sup>b</sup>Fisher exact test was used to compare CIC support group and comparison group as some cells have expected counts less than 5, and  $\chi^2$  may not be a valid test.

We searched the literature but found no published studies that examined the effects of patient support or education programs on either ED visits or hospital admissions among individuals using CIC to manage bladder function.

While we did not collect data on healthcare costs related to ED visits or hospital admissions, the reduction in the likelihood of ED visits and hospitalization in the CIC support program group may have implications for a reduction in healthcare costs for CIC patients. Turner and colleagues<sup>21</sup> compared the cost of treating complicated UTIs (defined as a UTI occurring in the presence of an abnormal or dysfunctional urinary tract) requiring ED or inpatient treatment and those treated in outpatient settings. Overall, medical costs were significantly higher when ED or inpatient treatment was required compared to outpatient treatment.<sup>21</sup>

Patient support and education interventions have the potential to reduce overall healthcare costs in this patient population, although additional research is needed to confirm this outcome. The top 3 reported reasons for ED visits within 30 days of initiating CIC were UTI, hematuria, and pain/difficulty inserting catheter (Table 4). The top 3 reported reasons for hospital overnight stays were UTI, hematuria, and sepsis/bacteremia (Table 5). In a review of published evidence related to complication of CIC, UTIs were the most commonly reported complication; 4 studies reported a range 62% to 77% annual incidence, and the mean of 2.6 to 2.7 UTI was reported by 2 studies.<sup>4</sup>

There are fewer studies examining the prevalence of hematuria among individuals using CIC to manage bladder function. In a survey of adults using CIC, Bolinger and Engberg<sup>8</sup> reported that 23% of the 44 respondents reported bleeding associated with CIC.

### Importance of Patient Support and Education

The prevalence of these complications and their potential to lead to ED visits and hospital admissions makes them important concerns for healthcare systems that call for additional patient education and support. Within the first 30 days of

initiating CIC, the CIC support program reported a significantly lower likelihood of ED visits ( $P = .036$ ) and overnight hospital stays ( $P = .002$ ) contrasted with the comparison group (Tables 2 and 3). Beyond the patient education content, the call protocol of the CIC support program may have more significantly contributed to the better healthcare utilization outcomes reported. Care advisors from the CIC support program call enrollees within 24 hours of enrollment and proactively call at least 2 additional times within the first 30 days. Care advisors will call more frequently if the user indicates that they are struggling with their CIC program or would like additional phone calls and assistance. By proactively engaging CIC users who may be too afraid or embarrassed to reach out for assistance, the CIC support program may resolve product access, product usage, and hygiene practice issues before they become so problematic that they contribute to clinical complications thus requiring an ED visit or hospitalization. The rapport built by having 1 dedicated care advisor may serve to build trust with the CIC user and thereby increase the likelihood that CIC users will disclose personal yet relevant details of their catheterization regimens that may have clinical implications if issues are left unaddressed or unresolved. Additionally, the reported reduction in the likelihood of ED visits and hospitalization in the treatment program group may reduce healthcare costs for CIC patients.

### Adherence

More respondents in the CIC support program adhered to recommended CIC frequency than did comparison group respondents. Using a definition of at least 70% adherence with the prescribed frequency of CIC, this study found a significantly higher proportion of patients in the CIC support program group adherent than the comparison group (88% vs 80%,  $P = .039$ ) (Table 6).

The CIC support program advisors discuss CIC adherence issues on phone calls with CIC patients and emphasize the importance of being adherent to their prescribed catheterization frequency. These discussions include a thorough

**TABLE 5.****Top 3 Reasons for Hospital Stays Within 30 Days**

Top 3 Conditions for Hospital Overnight Stays Within 30 d	CIC Support Group (N = 321)	Comparison Group (N = 124)	P	Both Groups (N = 445)
Urinary tract infection, n (%)	12 (3.74)	2 (1.61)	.3674 <sup>a</sup>	14 (3.15)
Hematuria, n (%)	4 (1.25)	2 (1.61)	.6726 <sup>a</sup>	6 (1.35)
Sepsis/bacteremia, n (%)	4 (1.25)	1 (0.81)	1.000 <sup>a</sup>	5 (1.12)

Abbreviation: CIC, clean intermittent catheterization.

<sup>a</sup>Fisher exact test was used to compare CIC support group and comparison group as some cells have expected counts less than 5, and  $\chi^2$  may not be a valid test.

**TABLE 6.**  
**Comparison of Catheter Reuse and Patient-Reported Adherence**

Characteristics	CIC Support Group (N = 321)	Comparison Group (N = 124)	P
Reuse of catheters, n (%)			
Yes	20 (6.3)	13 (10.6)	.121
No	300 (93.7)	110 (89.4)	
Recommended frequency of CIC, mean ± SD	3.77 ± 1.68	4.31 ± 1.65	.003 <sup>a</sup>
Actual frequency of CIC, mean ± SD	3.54 ± 1.58	3.85 ± 1.63	.070
Adherent <sup>b</sup> , n (%)			
Yes	281 (87.5)	99 (79.8)	.039 <sup>a</sup>
No	40 (12.5)	25 (20.2)	

Abbreviation: CIC, clean intermittent catheterization.

<sup>a</sup>Significant difference at *p* value of less than .05.

<sup>b</sup>Respondents were considered adherent if they followed at least 70% of recommended frequency of CIC use.

description of and educational literature on how the bladder functions and empties, why CIC for bladder management is important for CIC patients, and the likelihood of UTIs increasing when the bladder is not emptied fully or frequently enough. Because the CIC support program provides detailed education and explanation on the importance of CIC adherence, these components of the program may have contributed to higher reported rates of adherence in the CIC support program group.

The most frequent reasons for nonadherence mentioned by respondents in the CIC support program group were difficulty in catheterization, given their daily schedule or lifestyle, embarrassment or public stigma, and problems with

**TABLE 7.**  
**Reasons for Nonadherence to Recommended Daily Frequency of CIC, by the Enrollment Status in Patient Support Program**

Top Frequency Gap Reasons	CIC Support Group (N = 321), n (%)	Comparison Group (N = 124), n (%)	P
Hard with schedule or lifestyle	31 (9.66)	8 (6.45)	.2836 <sup>a</sup>
Embarrassing/public stigma	5 (1.56)	3 (2.41)	.6912 <sup>b</sup>
Insurance problem	5 (1.56)	3 (2.41)	.6912 <sup>b</sup>
It is physically a challenge, or I need a caregiver	3 (0.93)	2 (1.61)	.6213 <sup>b</sup>
Feel physical pain	3 (0.93)	2 (1.61)	.6213 <sup>b</sup>
Supply issue	2 (0.62)	5 (4.03)	.0200 <sup>b,c</sup>
To save money	1 (0.31)	7 (5.65)	.0007 <sup>b,c</sup>
Feel anxious/afraid/nervous	3 (0.93)	1 (0.81)	1.0000 <sup>b</sup>

Abbreviation: CIC, clean intermittent catheterization.

<sup>a</sup>Chi-square test has been used to compare CIC support group and comparison group.

<sup>b</sup>Fisher exact test was used to compare CIC support group and comparison group as some cells have expected counts less than 5, and  $\chi^2$  may not be a valid test.

<sup>c</sup>Significant difference at *P* value of less than .05.

health insurance. Difficulty in catheterization with daily schedule or lifestyle, saving money, and supply problem were the most frequent reasons for nonadherence mentioned by respondents in the comparison group. The finding that the presence of a supply issue and concerns about saving money were significantly higher in the comparison group suggests that the CIC support program was effective in helping participants find a supplier in-network with their insurance (a core component of the program).

Anxiety and embarrassment were reported as reasons for nonadherence in both the CIC support program and comparison groups. A study by Logan and colleagues<sup>22</sup> found that effective communication and the positive attitude of nurses helped alleviate embarrassment among patients performing clean CIC. Healthcare providers and patient support programs should focus on minimizing anxiety and helping patients cope with embarrassment related to CIC.

No other studies were identified that examined the effect of support/educational programs on adherence to CIC. The higher rate of adherence in the CIC support program group may have been a factor in the reduced odds of ED visits and hospital admissions during the first 30 days after starting CIC.

**Strengths and Limitations**

Several limitations may have affected the external validity of our findings. Electronic surveys show lower response rates than traditional survey methods, such as postal and telephone surveys.<sup>23</sup> The response rate for our study was low (9.4%); however, electronic surveys have several advantages such as immediate survey delivery, real-time data tracking, inexpensive costs, and greater individual anonymity.<sup>24</sup> Since respondents were identified from a comprehensive patient registry of CIC patients, we believe that reasonable representativeness is likely. Furthermore, the report of ED visits and hospitalizations was based on patient self-report without medical record verification. Self-report may vary from actual healthcare utilization, depending on patient recall.<sup>25</sup> Finally, patient adherence with recommended CIC use was also based on self-report. Although a cutoff point of 80% of prescribed medication doses taken is frequently quoted to categorize good versus poor adherence in medication studies, in some studies this can be as low as 60%.<sup>26</sup> However, no clear cutoff point for adherence to CIC is reported in previous research regarding catheterization. Additionally, since the group assignments were not random, and the majority of CIC support group members were enrolled by their clinicians, there could be selection bias and differences in the experiences of patients who are enrolled in a CIC support group or in the quality of healthcare they receive from their providers.

**CONCLUSIONS**

The potential burden of CIC-related complications within the first month of CIC initiation is significant. Findings from this study indicated that within the first month following CIC initiation, 16.1% and 10.2% of the subjects in the comparison and support groups reported at least 1 ED visit and at least 1 overnight hospital stay, respectively. A patient-centered, self-management support program for CIC was associated with a 47% decrease in ED visits and a 77% reduction in hospital stays attributable to CIC and improved adherence to frequency of CIC use. A decrease in the likelihood of ED

visits and hospital stays may contribute to a reduction in healthcare costs of CIC patients, which could be attributed to this patient support program. Higher adherence rates of 8% improvement in the CIC patient support group suggest improved outcomes for CIC users participating in such patient support programs.

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