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Citation

Bentvelsen, R. G., Bonten, T., Vaart, R. V., Hetem, D. J., Soetekouw, R., Geerlings, S. E., ... Veldkamp, K. E. (2024). Patient engagement to counter catheter-associated urinary tract infections with an app (PECCA): a multicentre, prospective, interrupted time-series and before-and-after study. *Journal Of Hospital Infection*, 147, 98-106.
doi:10.1016/j.jhin.2023.11.005

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Note: To cite this publication please use the final published version (if applicable).



Patient engagement to counter catheter-associated urinary tract infections with an app (PECCA): a multicentre, prospective, interrupted time-series and before-and-after study

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ARTICLE INFO

Article history:

Received 12 September 2023

Accepted 15 November 2023

Available online 29 November 2023

Keywords:

Infection control

Catheter-associated urinary tract infections

Urinary catheter

Patient participation

Patient engagement

eHealth



SUMMARY

Background: The risk of urinary tract infections (UTIs) is increased by unnecessary placement and prolonged use of urinary catheters.

Aim: To assess whether inappropriate use of catheters and catheter-associated UTI were reduced through patient participation.

Methods: In this multicentre, interrupted time-series and before-and-after study, we implemented a patient-centred app which provides catheter advice for patients, together with clinical lessons, feedback via e-mails and support rounds for staff members. Data on catheter use and infections were collected during a six-month baseline and a six-month intervention period on 13 wards in four hospitals in the Netherlands. Dutch Trial Register: NL7178.

Findings: Between June 25th, 2018 and August 1st, 2019, 6556 patients were included in 24 point-prevalence surveys, 3285 (50%) at baseline and 3271 (50%) during the intervention. During the intervention 249 app users and a median of seven new app users per week were registered (interquartile range: 5.5–13.0). At baseline, inappropriate catheter use was registered for 175 (21.9%) out of 798 catheters, compared to 55 (7.0%) out of 786 during the intervention. Time-series analysis showed a non-significant decrease of inappropriate use of 5.8% (95% confidence interval: –3.76 to 15.45; $P = 0.219$), with an odds ratio of 0.27 (0.19–0.37; $P < 0.001$). Catheter-associated UTI decreased by 3.0% (1.3–4.6; $P = 0.001$), with odds ratio 0.541 (0.408–0.716; $P < 0.001$).

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Conclusion: Although UTI significantly decreased after the implementation, patient participation did not significantly reduce the prevalence of inappropriate urinary catheter use. However, the inappropriate catheter reduction of 5.8% and an odds ratio of 0.27 suggest a positive trend. Patient participation appears to reduce CAUTI and could reduce other healthcare-associated infections.

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Introduction

Catheter-associated urinary tract infections (CAUTIs) are a main cause of healthcare-associated infections that lead to an increased burden of disease, increased use of antibiotics and prolonged hospital stay [1]. A large proportion of hospitalized patients require a urinary catheter during admission, ranging from 18% in the UK, 19% in the USA to 21% in the Netherlands [2–4]. However, unnecessary placement and prolonged use of catheters have been associated with an elevated and preventable risk of infection [5]. Guidelines and protocols describe appropriate catheter indications and other measures for preventing CAUTIs, but prudent use of catheters remains challenging [6].

Most previously reported strategies to prevent CAUTIs attempted to increase healthcare provider awareness of inappropriate catheter use via education, increased surveillance with feedback, and reminders for timely removal [7–9]. These interventions have shown varying degrees of success. So far, patients have not often been actively involved in decision-making regarding catheter use [10]. However, patient engagement is in line with the transition to shared decision-making [11]. One approach that can play an important role in patient engagement is eHealth. Whereas eHealth is a rapidly growing field of technology, promoting patient engagement through eHealth (and mHealth) and its adoption in hospitals is still in its infancy [12]. Interventions that incorporate patient-centred decision aids could support the development of informed patient preferences, and consequently patient engagement could help to optimize the practice of evidence-based medicine [13]. Patients prefer to be involved in their treatment. When given the choice, patients tend to prefer a less invasive treatment option [14]. Hence, patient engagement may reduce overuse of healthcare interventions. Moreover, patients are more satisfied and have more knowledge and less decisional conflict when they are involved in the decision-making process [15,16].

The smartphone app Participatient was developed to prevent CAUTIs by involving patients in the decision-making about catheter use [17]. The app engages patients by providing personalized information regarding the appropriateness of their catheter indication. The app was implemented to increase patient participation through dialogue on catheter indications. The intervention was hypothesized to increase awareness among nurses and physicians, to reduce inappropriate catheter use, and thus to limit infections.

The aim of this implementation study was to assess whether the number of catheters with an inappropriate indication and the number of CAUTIs were reduced after the introduction of the smartphone app Participatient to stimulate patient participation in catheter care.

Methods

Study design and participants

A multicentre, interrupted time-series and before-and-after study was conducted in four hospitals in the Netherlands. Per hospital, four to six wards were selected that had a high prevalence of urinary catheter use. Based on a sample size analysis, nurses on these wards were invited to include 70 to 100 patients per hospital and per specialty for each point-prevalence survey moment. All admitted adult patients were eligible for inclusion in the surveys unless they had opted out on the use of their data for research. Patients were excluded if they were not present on the ward during the surveys or if they were admitted on the day of the surveys.

The research team consisted of the primary research physician, three junior researchers and one research nurse. This team was supported by an infection prevention professional and by a senior expert in infection prevention.

The study was approved by the Medical Ethical Committee (MEC) Leiden–Den Haag–Delft (approval number P18.070). Hospital-level consent was granted by the relevant institutional review boards with a waiver of individual patient consent. This trial was registered at the Dutch Trial Register, NL7178. Considering the previously published protocol, results on patient satisfaction with care will be presented in another paper [18].

Data collection

Two researchers collected data once every two weeks during six months in the baseline period (12 moments), followed by a month for clinical lessons and introduction of the app, and during six months in the intervention period (12 moments) [19]. Data were collected on the prevalence of indwelling urethra catheters through bedside observations. Additional data on catheter use indications, and duration up to the survey date, were retrieved from the patients' electronic medical records (EMRs) [20]. Next, the point prevalence of CAUTIs was measured using internationally accepted criteria for CAUTIs, which were reported as CAUTI or as probable CAUTI (Box 1) [21,22].

If data on the catheter indication were not available and could not reasonably be deduced from the context, the indication was scored as 'not registered' and thus as not appropriate. Two trained observers independently surveyed all the EMR data to reduce bias in measuring the outcome 'indication for catheter use' and 'infection' [23]. In case of discrepancies between the observations, the observers consulted a senior expert in infection prevention.

In the intervention period, admitted patients were invited to download the app for use during their stay. If a patient

Box 1

Appropriate indications for indwelling urinary catheter use and UTI*Appropriate indications for urinary catheter use*

- Accurate measurements of urinary output in patients who are critically ill if required for treatment
- Acute urinary retention or bladder outlet obstruction (≥ 150 mL)
- Assistance in healing of open sacral or perineal wounds in patients with urinary incontinence
- Continuous bladder irrigation for haematuria
- Prolonged immobilization (e.g. potentially unstable thoracic or lumbar spine or multiple traumatic injuries, such as pelvic fractures)
- Before or after surgery according to (local) protocol
- Volume measurements of urine output for diagnostics (24 h urine), if no other collection strategies are possible
- As palliative care when needed
- Administration of medication in the urinary bladder
- Other appropriate reasons, e.g. urinary tract surgery with catheter, the need for wound healing

Criteria for urinary tract infection

- At least one of the following signs or symptoms with no other recognized cause: fever (>38 °C), urgency, frequency, dysuria, or suprapubic tenderness.

AND

- A positive urine culture, that is, $\geq 10^5$ micro-organisms per mL of urine with no more than two species of micro-organisms.

Additional criteria for CAUTI

- A catheter was in place in the 48 h before the onset of symptoms (CAUTI)

Additional criteria for probable CAUTI

- A catheter was in place in the 7 days before onset of symptoms (probable CAUTI)

These criteria are in accordance with nationwide and worldwide guidelines [21,22].

evaluate the app (Figure 1). New app users were asked to provide information regarding their ward of admission, sex and age group, their interest in eHealth, and their experience with health-related apps as a proxy for eHealth literacy.

In the Catheter Check, patients are encouraged to assess their own catheter indication by answering up to eight questions. The answers yield a result derived from the criteria on appropriate use (Box 1). The result is displayed with personalized suggestions, and, if necessary, motivating them to speak with medical or nursing staff about the need for continued use of the catheter. Patients are motivated through daily reminders, to regularly check the indication of their catheter.

In preparation for the implementation of the app, the nursing teams were trained in clinical lessons on the prevention of UTIs, catheter use indications, and patient participation. Per ward, we recruited several nurses as ambassadors to promote the project. These very important participants (VIPs) could suggest app improvements, such as specific ward services or medical information.

Additionally, the researchers organized various activities to motivate the nurses to promote patient participation [20]. Per ward, a kick-off day was organized, which involved a demonstration of the app during an interactive session with the research team. Leaflets, infographic posters, and roll-up banners were supplied to promote participation on the wards.

During the intervention, from admission onwards, nurses invited patients or their visiting family and friends to download the app using an information leaflet. Project update e-mails were sent to the nurses including feedback on app use per ward, and sessions for technical support were held once every two weeks coinciding with the surveys on catheter use (Supplementary Table S1).

Outcomes

The primary outcome was the percentage of patients with a urinary catheter without an appropriate indication, because this is the main risk factor for CAUTIs and the factor on which the intervention could have an effect. The secondary endpoint was the rate of CAUTIs.

Statistical analysis

The sample size was based on our objective of a 15% reduction in the number of inappropriate indications for urinary catheters, with a power of 80% to detect a difference with a 0.05 two-sided significance level [24]. Data were extracted on the prevalence of inappropriate catheter use from previous studies in similar healthcare systems, which was $\sim 40\%$ [5,20,25]. The study aimed to collect a time-series of nine to 12 data points in both the baseline and the intervention period from around 100 patients per survey date per hospital. After correcting for 10–15% missing data, the sample size was set at 1320 to 1380 patients in both the baseline period and the intervention period [18].

Categorical data are reported as frequencies and percentages, and continuous data as median (interquartile range: IQR). For comparisons before and after intervention for categorical data we used χ^2 -tests. Subgroup analyses were performed to check for potential confounders on the basis of risk factors for catheters and UTIs, including the medical specialty of admission, age group, and sex.

consented to the use of their data, the app recorded non-identifiable data. Analytic data were collected on the number of unique new app users and on the number of page views, combined with the user-provided data such as age group and ward of admission.

Intervention

Before this study, we developed the smartphone app 'Participant' which was possible to implement with 8.8% app use on a clinical ward in a feasibility study [18,20]. The app can be downloaded cost-free from the Apple App store and Google Play store. It comprises five content sections: Pain Score, Catheter Check, My Ward, More Information, and a Questionnaire to

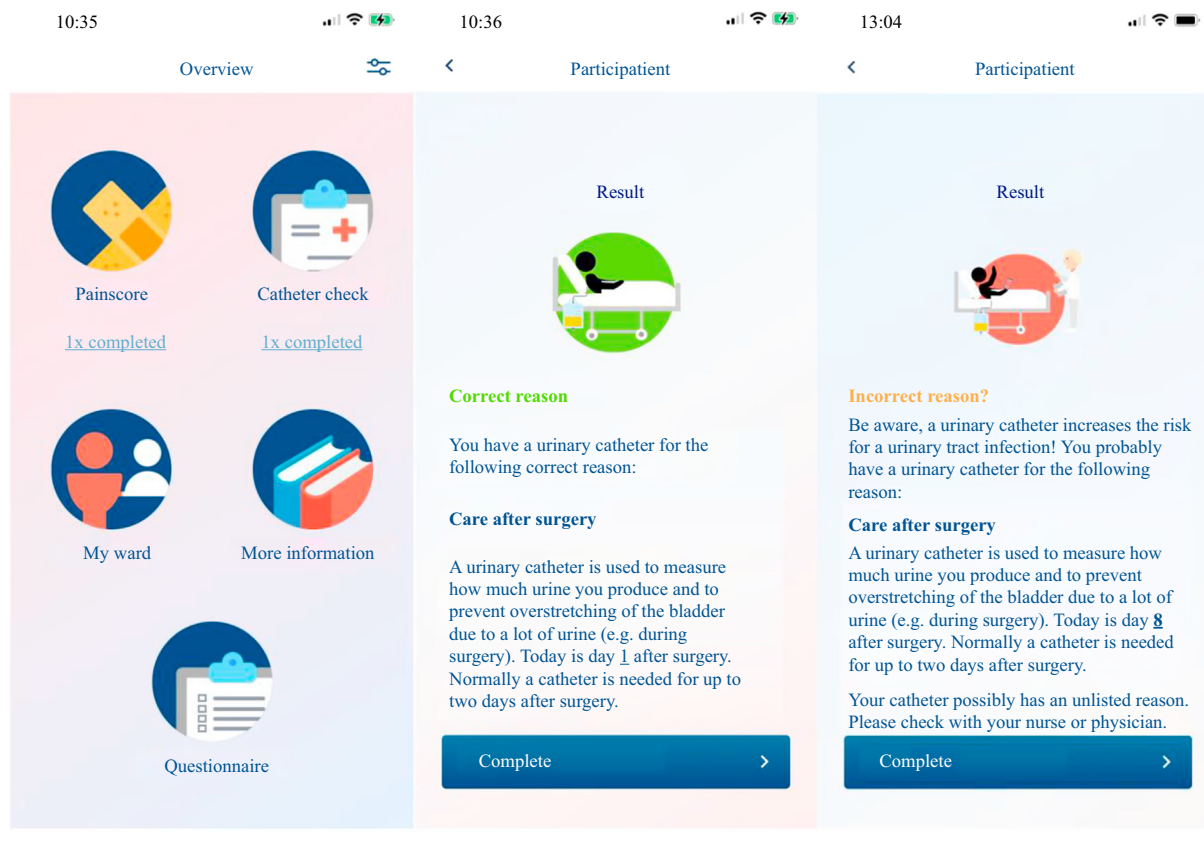


Figure 1. The Participatient app content. From left to right: Overview of the app, Catheter Check Result screen with correct and possibly inappropriate indication for urinary catheter use. More app screenshots are available online at <https://participatient.eu/>.

The time-series data were analysed with segmented linear regression analysis to detect trend and level changes after the intervention. Because our outcomes over time could be affected by other changes in catheter usage, data were collected on potential confounders (age, sex, and ward of admission), autocorrelation, and the underlying secular trend before and during the intervention [19].

Trends and intervention effects are visualized using graphics. Before-and-after analysis differences are presented as odds ratios with 95% confidence intervals. The outcomes of the time-series analyses are presented as differences in prevalence with a 95% confidence interval. Differences were considered significant if $P < 0.05$. Autocorrelation was checked with the Durbin–Watson test. All data were analysed using SPSS (version 28.0).

Results

The study was performed in two university medical centres and two general hospitals (Supplementary Figure S1). After ranking and selection based on catheter use, 13 wards of these hospitals were enrolled in the trial. The study included four wards with internal medicine patients, four wards with oncology, pulmonology, and gastrointestinal patients, three larger wards with surgical patients, and two wards with gynaecology and neurology patients. Of these 13 wards, four had previously

participated in a previous trial to reduce inappropriate catheter use [6].

Between June 26th, 2018 and July 31st, 2019, a total of 6556 patients were included for the point-prevalence surveys, 3285 (50.1%) in the baseline period and 3271 (49.9%) in the intervention period. There were no differences between the patient characteristics in the baseline period and the intervention period. Urinary catheter prevalence was similar during baseline (798/3285, 24.3%) and intervention (786/3271, 24.0%) (Table I). However, in the miscellaneous wards (neurology, ophthalmology, ear/nose/throat, and obstetrics and gynaecology), urinary catheter use decreased from 30.5% (124/407) to 22.2% (99/445; $P = 0.006$) (Supplementary Table S2).

In total, 249 users of the Participatient app were registered after consenting to share user data. They completed 260 sessions of use with 2002 page views. Per week, a median of 7 (IQR: 5.5–13) new users registered. Among the app users, half of responders were male (114 (50%)) and age groups in decennia ranging from 18 to ≥ 70 were all represented. Of the respondents, 134 (54%) indicated that they sometimes used other eHealth services, and 56 (23%) indicated that they used eHealth often. Other smartphone apps for health were used occasionally by 91 (37%) and often by 21 (8%) of the Participatient users (Supplementary Tables S3 and S4).

Table I
Baseline characteristics by study period

Variable	Total	Baseline	Intervention
Total patients	6556	3285 (50.1%)	3271 (49.9%)
Female	3095 (47.2%)	1590 (48.4%)	1505 (46.0%)
Male	3461 (52.8%)	1695 (51.6%)	1766 (54.0%)
Age group (years)			
18–29	292 (4.5%)	157 (4.8%)	135 (4.1%)
30–39	409 (6.2%)	188 (5.7%)	221 (6.8%)
40–49	618 (9.4%)	279 (8.5%)	339 (10.4%)
50–59	1110 (16.9%)	570 (17.4%)	540 (16.5%)
60–69	1562 (23.8%)	823 (25.1%)	739 (22.6%)
70–79	1555 (23.7%)	773 (23.5%)	782 (23.9%)
80–89	845 (12.9%)	414 (12.6%)	431 (13.2%)
≥90	165 (2.5%)	81 (2.5%)	84 (2.6%)
Length of stay ^a			
Median days (IQR)	5 (2–11)	5 (2–10)	5 (2–12)
Ward type			
Medicine, nephrology	1781 (27.2%)	906 (27.6%)	875 (26.8%)
Oncology, GE, and pulmonology	1797 (27.4%)	922 (28.1%)	875 (26.8%)
Surgery, trauma	2126 (32.4%)	1050 (32.0%)	1076 (32.9%)
Miscellaneous	852 (13.0%)	407 (12.4%)	445 (13.6%)
Urinary catheter			
Prevalence	1584 (24.2%)	798 (24.3%)	786 (24.0%)
Median duration in days (IQR) ^b	3 (1–8)	3 (1–8)	3 (1–8)
Hospital			
A (academic)	2247 (34.3%)	1115 (33.9%)	1132 (34.6%)
B (academic) ^c	1300 (19.8%)	660 (20.1%)	640 (19.6%)
C (general)	1791 (27.3%)	887 (27.0%)	904 (27.6%)
D (general) ^d	1218 (18.6%)	623 (19.0%)	595 (18.2%)

IQR, interquartile range; GE, gastroenterology.

The miscellaneous wards were neurology, ophthalmology, ear/nose/throat, and obstetrics and gynaecology.

^a Admission up to point-prevalence survey date.

^b Catheterization up to point-prevalence survey date.

^c Three wards, all of which participated in a prior trial to reduce inappropriate catheter use [6].

^d One of the two wards of this centre participated in a prior trial to reduce inappropriate catheter use [6].

Of the urinary catheters used during the baseline period, 21.9% (175/798) had no appropriate indication (Table II, Supplementary Table S5). During the intervention period, an appropriate indication was missing for 7.0% of the catheters (55/786). No indication, appropriate or inappropriate, was registered for 11.3% (90/798) of the catheters at baseline and for 2.4% (19/786) during intervention (Supplementary Table S6). These catheters were scored as inappropriate use according to guidelines. The before-and-after analysis showed a reduction of 14.9% in inappropriate use of catheters, odds

ratio 0.27 (95% CI: 0.19–0.37; $P < 0.001$). The decrease in inappropriate use of catheters was noted in patients of both sexes and all age groups, and in all ward types and hospitals (Supplementary Table S5).

Time-series analysis of the level of inappropriate use of urinary catheters found that the decrease was not significant with 5.8% (95% CI: –3.76 to 15.45; $P = 0.219$) (Figure 2 and Supplementary Figure S2). The Durbin–Watson test statistic for autocorrelation of 1.952 ($P < 0.001$) indicated no substantial serial autocorrelation of the error terms in the regression models [19].

Table II
Number and prevalence of urinary catheter use, UTI and CAUTI

Variable	Baseline	Intervention	OR (95% CI)	P-value	Red.
Inappropriate UC at insertion	78/798 (9.8%)	12/786 (1.5%)	0.14 (0.08–0.27)	<0.001	84%
Inappropriate UC at survey	175/798 (21.9%)	55/786 (7.0%)	0.27 (0.19–0.37)	<0.001	68%
UTI	268/3285 (8.2%)	161/3271 (4.9%)	0.58 (0.48–0.71)	<0.001	39.7%
CAUTI Box 1	142/3285 (4.3%)	78/3271 (2.4%)	0.541 (0.408–0.716)	<0.001	44.8%
Probable CAUTI	150/3285 (4.6%)	87/3271 (2.7%)	0.571 (0.437–0.747)	<0.001	41.8%

OR, odds ratio; CI, confidence interval; Red., reduction in prevalence percentage in the intervention period compared to baseline; UC, indwelling urinary catheter; UTI, urinary tract infection.

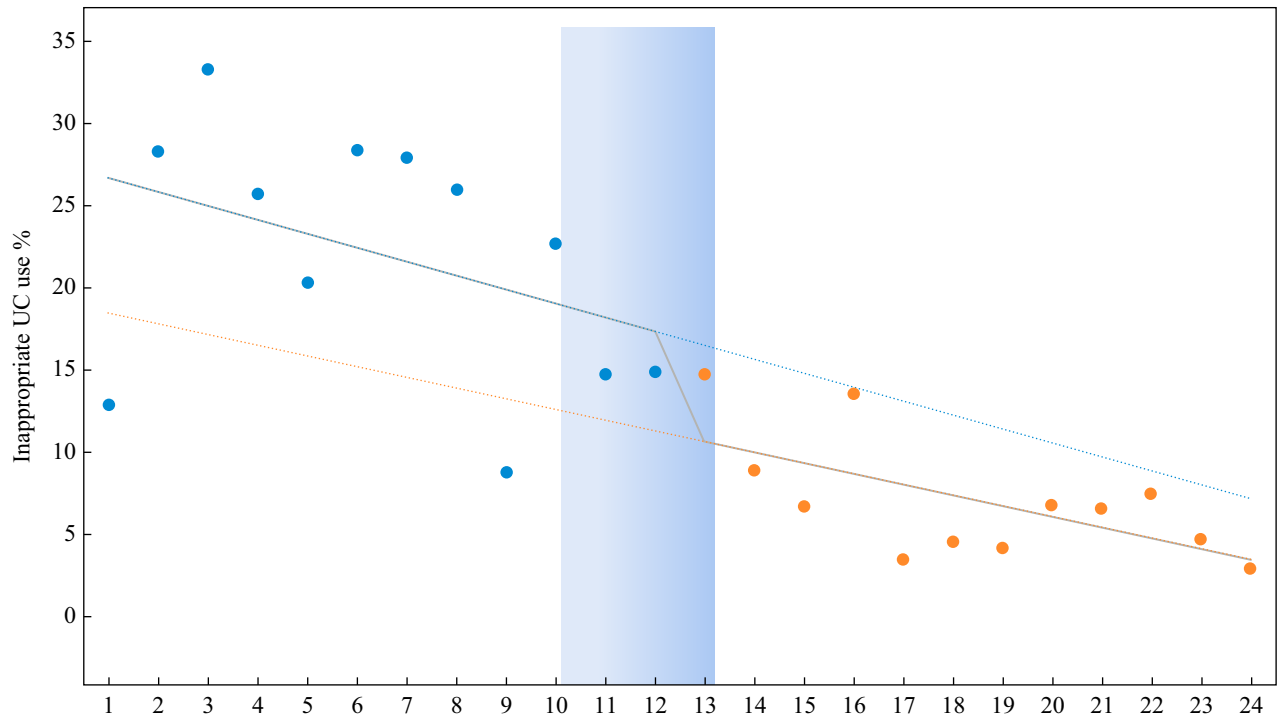


Figure 2. Time-series analysis of inappropriate urinary catheter (UC) use. Over time, the fraction of surveyed urinary catheters with inappropriate use decreased, trendline calculated with linear regression per time point. Data per time point as the sequential fortnightly point prevalence survey (PPS) follow-up moment, with datapoints six months (12 PPS) at baseline and six months (12 PPS) during intervention period.

The number of urinary tract infections (UTI) was 39.7% lower after intervention. Moreover, we found 44.8% less catheter-associated UTI (CAUTI) and 41.8% less probable (Table II).

Time-series analysis showed a significant decrease in UTI of 4.2% (95% CI: 1.4 to 7.7; $P = 0.005$), in catheter-associated UTI of 3.0% (95% CI: 1.3 to 4.6; $P = 0.001$), and in probable CAUTI of 2.7% (95% CI: 1.2 to 4.2; $P = 0.001$). However, the Durbin–Watson test values of 1.1–1.4 showed possible autocorrelation, suggesting a reduced fit of the linear model (Supplementary Figure S2).

Discussion

The aim of this implementation study was to assess whether the number of catheters with an inappropriate indication and the number of CAUTIs were reduced after the introduction of the smartphone app Participatient to stimulate patient participation in catheter care. There was a substantial mean reduction of inappropriate use of urinary catheters of 14.9%. However, in the interrupted time-series analysis, the absolute decrease was 5.8%, which was not statistically significant. In further sensitivity analyses, the level and trend reduction during intervention was larger, although still not statistically significant, which might indicate a possible underestimation of the intervention effect in the primary interrupted time-series analysis.

The non-significance of the primary interrupted time-series outcome could be due to several reasons. First, at baseline, measurements could have been affected by a prevalent observer effect, also known as the Hawthorne effect [26]. During measurements, support rounds and clinical lessons, the

team was present on the wards, which could have prompted awareness among team members, which in turn could explain the decreasing trend before the start of the intervention, especially at the last two timepoints of the baseline period (Figure 2, Supplementary Figure S2). Second, segmented regression typically aggregates individual-level data per timepoint, which does not account for the large number of observations per timepoint [6,19]. The calculated confidence interval and standard error usually account for the sample size. Underestimation of effect can occur when variance parameters for time-series are estimated with a small number of timepoints [27]. Third, the case-mix before and after the intervention could have differed. We registered age groups, sex, and ward type, but no data were available on admission and comorbidity, e.g. the Charlson Comorbidity Index. Although there is no indication of a change in the case-mix before and after intervention, this might have affected primary and secondary outcomes.

Furthermore, there was a relative reduction in CAUTIs of 44.8% and a significant absolute reduction in interrupted time-series of 3.0%. These findings are in line with previous studies showing that inappropriate catheter use can be reduced with various strategies, such as a national prevention programme that reduced catheter use and CAUTIs in non-intensive care units [6,9]. However, to the best of our knowledge, this is the first project to include patient participation and eHealth in an intervention to reduce inappropriate catheter use.

App use was limited to a median of seven new app users per week and 249 registered app users from a total of 3271 patients (7.6%) during bi-weekly intervention surveys, which is in line with the 8.8% of patients who used the app in our feasibility

trial [20]. This outcome was not unexpected as the app should be seen as part of the intervention to create awareness on the ward as a whole. Also, we observed that the trend in new users per week corresponded with the presence of the research team on the wards and with actions such as the kick-off event (Supplementary Figure S3). App use might be improved by encouraging patients to use the app and by employing nurse ambassadors who promote the app. On the other hand, patients concerned with their privacy may be deterred from installing the app because they distrust the registration of their data through the app.

We found large variations in urinary catheter use and inappropriate catheter use between hospitals (Table II, Supplementary Table S5), which is in line with previous reports [5]. These variations could be due to the different types of included wards and hospitals. Four wards had participated in a recent prior trial to reduce inappropriate catheter use without patient participation. Remarkably, the impact of the present intervention was not smaller in these wards than in the other wards, but additional to the previously achieved improvements (Supplementary Table S5), possibly suggesting an effect of the patient engagement. However, the intervention should be regarded as a bundle and the isolated impact of patient engagement cannot be assessed.

Remarkably, in contrast to the reductions in inappropriate use and CAUTI rates, the total urinary catheter prevalence did not decrease after the intervention. A possible explanation could be a better registration of the indication for catheter use in the EMR during the intervention period. Though improved registration alone would not explain the decrease in CAUTI, better registration of the catheter indication could signify better catheter care, which may lead to a reduction of infections. The unchanged catheter prevalence might be explained by a different case-mix after the intervention, as there was a non-significant shift in catheter prevalence between age groups and wards (Supplementary Table S2); however, this study did not include an analysis of comorbidities and reasons for admission.

Our finding that CAUTI rates decreased whereas catheter use did not decrease is in line with the outcomes of an American study by Saint *et al.*, who showed that CAUTI rates in the non-ICU setting were reduced via tailored technical and socio-adaptive interventions in a national CAUTI prevention programme [9]. Even though CAUTI rates decreased considerably (incidence rate ratio: 0.68; 95% CI: 0.56–0.82), catheter use decreased only slightly (0.93; 0.90–0.96).

We described CAUTI rates using two sets of criteria, one for CAUTI and one for probable CAUTI. To align CAUTI with criteria on other device-associated infections, in 2009 the Centers for Disease Control and Prevention shortened the timeperiod for follow-up surveillance after catheter removal from seven days to 48 h. However, the European and Dutch national criteria define UTI as catheter-associated if a catheter was in place up to seven days before onset of symptoms [21,22]. Therefore, we defined the onset of symptoms within 48 h after catheter removal as CAUTI, and within seven days after catheter removal as probable CAUTI.

Since the study was not a randomized trial, the outcomes could have been influenced by confounding variables that were not measured. Also, secular trends over time could have been a bias, as is often the case in quality improvement projects [28].

However, to minimize the effect of unmeasured confounders and secular trends, we used the interrupted time-series design over a substantial period of time. Interrupted time-series is the strongest, quasi-experimental approach for evaluating longitudinal effects of interventions [19].

Several limitations of the study should be considered. First, our primary outcome was the reduction in urinary catheters without an appropriate indication, as registered in the EMR. In another study comparing catheter survey methods, the optimal survey method for catheter prevalence and indication was through assessing the staff notes in the EMR [20]. If no appropriate indication was noted in the EMR, such catheter use was categorized as inappropriate according to international standards [21,22]. However, nurses and medical specialists work in shifts and brief each other verbally and through the EMR. The common policy is to note relevant information in the EMR, but the outcome could reflect a registration problem rather than actual inappropriate catheter use. However, additional analyses that excluded cases without indication registration still showed a reduction in inappropriate catheter use in the intervention period (Supplementary Figure S2).

Second, in each participating hospital, we invited those wards that had the highest catheter prevalence, which may potentially have led to selection bias. Although the procedure of selecting the wards was inevitable for the purpose of this study and wards from a broad range of medical specialties are represented, our findings might not be generalizable to all ward types.

Finally, a decreasing trend in inappropriate indications could be observed just before the intervention (Figure 2, Supplementary Figure S2). This decrease could have been due to the presence of the research team for surveys and training on the wards before the intervention. The presence of the team could have stimulated app use and probably also raised awareness of correct catheter use. Interrupted time-series in part corrects for the changes during the baseline and intervention period and focuses on changes from baseline to intervention.

Although UTIs and CAUTIs significantly decreased after the implementation, we found that the implementation of this intervention to encourage patient participation did not significantly reduce the prevalence of inappropriate urinary catheter use. However, the inappropriate catheter reduction of 5.8% and an odds ratio of 0.27 suggest a positive trend. Patient participation appears suited to improve catheter care and reduce CAUTI and could possibly reduce other healthcare-associated infections.

Acknowledgements

We thank the hospitals that participated in this study, especially all physicians and nurses from the participating wards of the Leiden University Medical Centre, Academic Medical Centre Amsterdam, Spaarne Gasthuis Haarlem, and HMC Den Haag. We also thank M.L. Bruijning the research nurse, P. Menken and the junior researchers E. Holten, T. Bevers, and C. Belkasmı (Medical Microbiology, LUMC, Leiden, The Netherlands) for their help with data collection. For help with the statistical analysis, we thank Professor J.J. Goeman of

the Department of Biomedical Data Sciences, Leiden University Medical Center. For project conceptualization we thank Dr C.H. Martini of the Department of Anaesthesiology, Leiden University Medical Centre, Leiden, The Netherlands; Professor W. Kraaij, of the Leiden Institute of Advanced Computer Science, Leiden University, Leiden, The Netherlands; and Professor A.W.M. Evers, of the Health, Medical & Neuropsychology Unit, Institute of Psychology, Leiden University, Leiden, The Netherlands; Leiden Institute for Brain and Cognition, Leiden, The Netherlands; Department of Psychiatry, Leiden University Medical Centre, Leiden, The Netherlands.

Author contributions

R.G.B., N.H.C., and K.E.V. designed the study. R.G.B. and K.E.V. arranged the funding application. R.G.B. recruited patients, collected data, supervised the research nurse and the junior researcher, analysed the data, and wrote the first and final drafts of the manuscript. T.B. and J.J.G. were consulted for the statistical analyses. All authors interpreted the data and revised the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Conflict of interest statement

None declared.

Funding source

This work was supported by the Netherlands Organization for Health Research and Development (ZonMw) for funding the study (competitive grant 522004007). The funder of the study had no role in the study design nor in the collection, analysis, or interpretation of the data, in the writing of the report nor in the decision to submit the paper for publication. The corresponding author had full access to all the data in the study and had the final responsibility for the decision to submit for publication.

Data sharing

The study protocol is made freely available online for researchers to access. Data collected from this study, including de-identified individual participant data and a data dictionary, will be made available to investigators. Data will be available beginning three months and ending 10 years following article publication. Researchers must have their study protocol approved by an independent review committee identified for this purpose. Proposals should be directed to the chief investigator, Dr K.E. Veldkamp (k.e.veldkamp@lumc.nl); to gain access, data requestors will need to sign a data access agreement.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jhin.2023.11.005>.

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