

# Implementing a New Postoperative Urinary Retention Protocol Using the Individual Maximum Bladder Capacity as Threshold for the Maximum Bladder Volume: A Clinical Observational Study

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## ABSTRACT

**Background:** In three different sized hospitals we investigated the feasibility of implementing a new postoperative urinary retention (POUR) protocol. We used the individual maximum bladder capacity (MBC) as a threshold for bladder catheterization, instead of a fixed bladder volume limit of 500mL. The implementation was stated to be successful when over 80% of the eligible and participating patients were treated following this protocol.

**Method:** General surgical patients were included if they were between 18 to 60 years old and operated under spinal or general anesthesia without an indwelling urinary catheter. Consenting patients measured their maximum bladder capacity at home, which was recorded in the Electronic Health Record. Postoperatively, patients were intended to be treated according to the new POUR-protocol. The nursing staff was informed by personal information sessions, classical lessons and e-mail.

**Results:** Of the 338 eligible patients 210 gave informed consent. At the Post Anaesthesia Care Unit 170 patients had measured and registered their maximum bladder capacity. Finally, 114 patients followed the new POUR-protocol (67%). The primary outcome in the largest hospital was 100%, for the medium sized hospital this was 60% and for the smallest hospital this was 58%.

**Conclusion:** The implementation was successful for the largest hospital (>80%) but not in the other two hospitals. For successfully implementing a new POUR-protocol many barriers need to be addressed. The most important barriers were (1) to achieve commitment from surgical patients who are not aware of POUR, and (2) to achieve commitment from all involved health providers to adhere to a postoperative urinary retention protocol. Anesthesiologists, surgeons and nurses should be aware of their role in preventing POUR and how their actions can influence the quality of care for their patients.

**Keywords:** Anesthesia, Implementing, Maximum bladder capacity, Postoperative urinary retention, Protocol, Surgery.

## INTRODUCTION

The use of patients' individual maximum bladder capacity (MBC), as threshold for a maximum postoperative bladder volume, reduces the incidence of postoperative urinary catheterization [1]. In this randomized controlled trial we demonstrated that using the MBC was especially beneficial for surgical patients between 18 till 60 years old; who were operated under general or spinal anesthesia; and for whom no indwelling urinary catheter was indicated perioperatively. We asked ourselves if such a quality improving protocol could successfully be implemented in daily clinical practice. To prove this hypothesis, we investigated the feasibility of implementing a new

postoperative urinary retention (POUR) protocol in a multi-center study. We used the individual MBC as threshold for postoperative urinary catheterization instead of a fixed bladder volume limit (for example 500mL). This 'new' POUR-protocol was implemented and tested in three different sized hospitals in the Netherlands.

## Objective

To analyze the effect of implementing a new POUR-protocol. The implementation was prospectively stated to be successful when more than 80% of the eligible and participating patients were treated following the new POUR-protocol. The main factors

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affecting success of implementation were considered the willingness of patients to participate and the adjustment of the nursing staff to the new protocol [2,3].

## LITERATURE REVIEW

This is a new study about implementing a new protocol for postoperative urinary retention at the post anesthesia care unit (PACU) and surgical wards in three different hospitals. There are many studies about implementing a new kind of protocol [4-6]. There are no published studies about implementing a POUR-protocol. Our main question was if implementing this new protocol to prevent bladder over distention would be feasible. The assumption was that a POUR-protocol was routinely used in these hospitals.

From literature is known that a successful implementation depends, among other things, on the level of the innovation, on the provider, on the patient and on the organizational and structural context [7,8]. We used parts of the Consolidated Framework for Implementation Research (CFIR) as a guide [9,10]. We involved the stakeholders (head nurses and software supporting staff) in the design of the implementation [11,12].

## METHODOLOGY

### Ethics

Ultrasound is considered a routine diagnostic procedure to measure postoperative bladder volumes non-invasively [4-6]. Therefore, the Ethical Review Board of the Medical Center Leeuwarden approved that this implementation study did not need to comply to the Dutch Research Act (Wet Medisch Wetenschappelijk Onderzoek = WMO) (Medical Center Leeuwarden RTPO reference number 1030A March 27<sup>th</sup>, 2018) [7]. The study applied to the Dutch rules of the Medical Treatment Agreement Act (Wet Geneeskundige Behandelovereenkomst WGBO), Personal Data Protection Act (Wet bescherming persoonsgegevens WBP) and General Data Protection (Algemene Verordening Gegevensbescherming AVG). All patients were informed about the study in person and by an information letter. Written informed consent was obtained from all participants. This multi-center study was approved by all three hospital boards.

### Design and Setting

This is an observational multi-center study about the feasibility of implementing a new POUR-protocol in three different hospitals. These hospitals were chosen because the anesthesiologists were enthusiastic to participate, and the hospitals differed in size, meaning in number of operations performed per year. This provided the possibility to investigate whether 'size of the hospital' interferes with the implementation process.

The participated hospitals were the Medical Center in Leeuwarden (hospital 1), a large referral hospital performing about 20.000 surgical procedures per year; the 'Tjongerschans' hospital in Heerenveen (hospital 2), a middle-sized hospital performing about 12.000 surgical procedures per year; and the 'Röpcke-Zweers' hospital in Hardenberg (hospital 3), a small general hospital, performing about 8.000 surgical procedures per year.

### Participants

Eligible patients were between 18 to 60 years old; planned to be operated under general or spinal anesthesia; without an indication for an indwelling urinary catheter perioperatively. Exclusion

criteria were a language barrier; gynaecology surgery; and expected procedure duration longer than 180 minutes. These selection criteria were based on the results of the original randomized controlled trial (RCT) [1]. All eligible patients visiting the pre-anesthesia assessment clinic (PAC) were asked to participate in the study. It was unknown how much time it would take to perform the study per hospital. Therefore, the total of number of patients needed per hospital (n=100) was chosen for practical reasons, allowing follow up on patients. The study started on April 16<sup>th</sup>, 2018 in hospital 1, followed in June by hospital 2 and in August by hospital 3. The study ended in October 2018.

### Method

All health care providers working at the PAC, PACU and surgical wards were informed via interactive educational meetings and by e-mail. We explained the benefits for the patients and the changes in the protocol with emphasis on patient safety. Further, they were informed about changes that were made in the EHR and how they could recognize eligible and participating patients. Before the study started the research assistant (SW) visited the PAC, Holding, the PACU and the different wards multiple times for one-on-one tutorial lessons. During the study, she was readily available to answer questions about the study. However, she was not present at the different wards to prevent interference with the study protocol.

Patients were alerted to the study with a banner that was placed in the waiting room at the PAC of each hospital. Eligible patients were recognized by the medical secretaries or the nurses at the PAC, based on the inclusion criteria. The recognition of eligible patients was supported by a notification message that appeared in the EHR. Eligible patients received an information form that they could read while waiting in the waiting room. During consultation, the medical secretaries, nurse anesthetist or the anesthesiologist gave further explanation about the study and they asked the patient to participate.

Consenting patients received a measuring bowl (Colad™, Zwolle, The Netherlands) with instructions to measure their MBC at home. The necessary data of consenting patients were entered in the EHR. At home, consenting patients were instructed to postpone voiding until a strong urge that could no longer be ignored. Then they voided in the measuring bowl to determine their maximum bladder capacity. To ensure reliability of the measurement patients were asked to repeat this procedure at three different moments during the week. The highest measured value was recorded as the MBC of the patient. At the day of surgery, consenting patients were recognized at the Holding area via a notification message that appeared in the EHR and/or via the patients themselves, indicating that they had measured their MBC and were participating in the study. Their MBC was recorded in the EHR and was displayed in the main header of the patient's health record. Anesthesia technique, medication used, and amount of fluid infused perioperatively was decided by the responsible anesthesia-team.

Postoperatively, at the PACU, a notification with the MBC value appeared (EPIC) or the MBC value was displayed in the header (HiX), to remind the nurse that the patient participated in the study. The nurses scanned the patient's bladder after the patient arrived at the PACU and on to the surgical ward. If the scanned volume exceeded the patient's MBC, the patient was encouraged to void. If the patient was unable to void spontaneously urinary catheterization was performed (see appendix MBC-protocol). The 'standard' protocol for postoperative urinary catheterization

(threshold 500mL) was used for consenting patients whose MBC was unknown.

### Electronic Health Record

Hospital 1 used EPIC (Epic™ 2017, Verona, WI, USA) and hospital 2 and 3 used HiX® (ChipSoft™, Amsterdam, The Netherlands) as their EHR. Hospital software specialists made the necessary adjustments in the EHR to support the study. Registered patient data consisted of age, gender, anesthesia technique, MBC value and scanned bladder volumes postoperatively.

### Material

Hospital 1 and 2 used the BladderScan BVI9400® for measuring postoperative bladder volumes non-invasively. Hospital 3 was supplied with the new BladderScan PRIMEPlus® (Verathon™ Inc., Bothell, WA, USA). All the involved nurses in hospital 3 were first instructed how to use this new ultrasound device before starting the study according to the Dutch law about using Medical Devices. The information forms, informed consent forms, measuring bowls, the banner, BladderScanners and the adjustments in the EHR were available before the start of the study.

### Primary and Secondary Outcomes

The primary outcome was the percentage of patients that were treated in accordance with the new POUR-protocol, defined as the percentages of eligible patients that (1) met the inclusion criteria, (2) had a registered MBC in the EHR and (3) were scanned postoperatively following the new protocol. Secondary outcomes included (1) the number of eligible patients that were missed at the PAC, (2) included patients who did not measure their MBC

and (3) the number of included patients who were not treated according to the new protocol at the PACU and ward.

### Statistical analysis

In this study, descriptive statistics (numbers and percentages) were used, with exact Clopper-Pearson 95% confidence intervals (CI) for the primary outcome. The calculated sample size showed that 100 patients per hospital were enough for demonstrating significance.

## RESULTS

The results of the primary and secondary outcome are depicted in the flow charts (Figures 1-3) for each hospital, and in Tables 1 & 2. During the study period 338 patients were eligible to participate in the study, of which 296 patients were asked to participate. For the primary outcome, in total 67% of the patients (N=114) were treated following the new POUR protocol (95%CI 59% to 74%). For hospital 1, 100% of the patients (N=33) were treated following the new POUR protocol (95%CI 89% to 100%), for hospital 2 this was 60% (N=42)(95%CI 48% to 72%) and for hospital 3 this 58% (N=39)(95%CI 46% to 70%).

The secondary outcomes are also depicted in the different flowcharts and in Table 2. Patients could not be included in the final analysis due to several reasons: (1) eligible patients were missed at the PAC, (2) the MBC value was not known before surgery, (3) patients did not measure their MBC at home and (4) for some patients the MBC was not recorded in the EHR and at last (5) some patients did not had surgery at the end of the study period. In total, 56 patients were not treated following the new POUR-protocol; zero patients in hospital 1 (=0%), 28 patients in hospital 2 (=40%) and 28 patients in hospital 3 (42%).

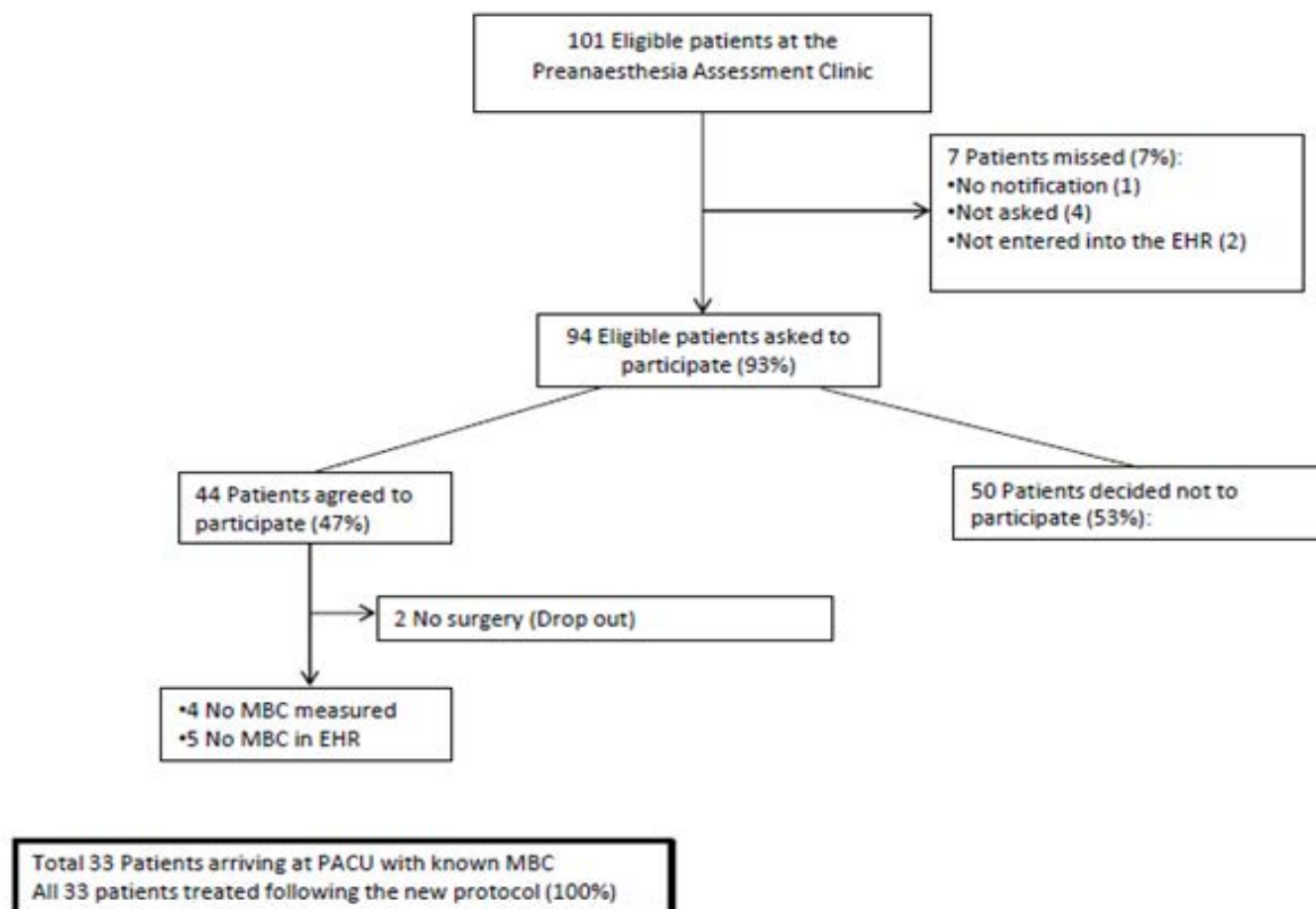


Figure 1: Flowchart Hospital 1.

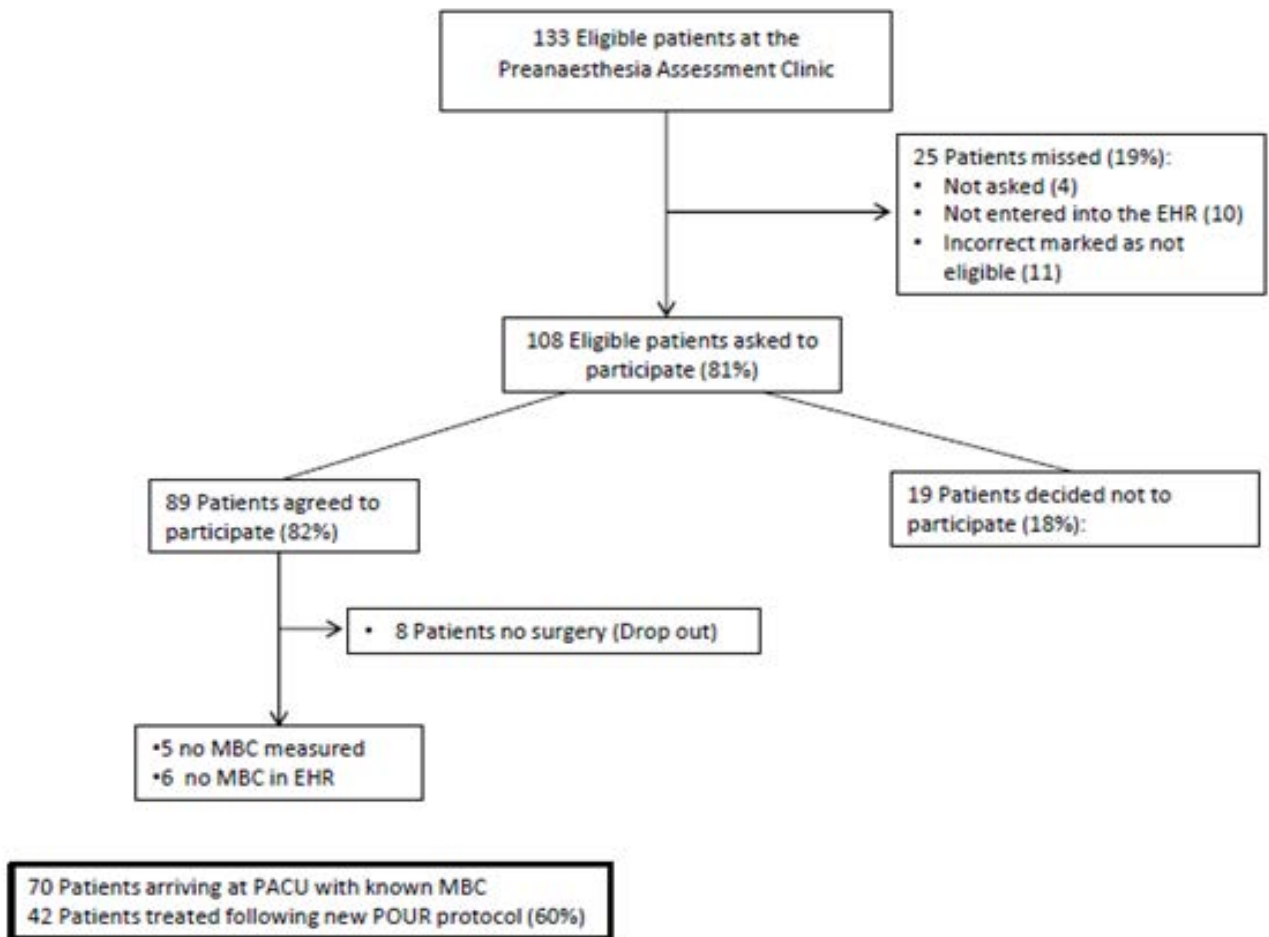


Figure 2: Flowchart Hospital 2.

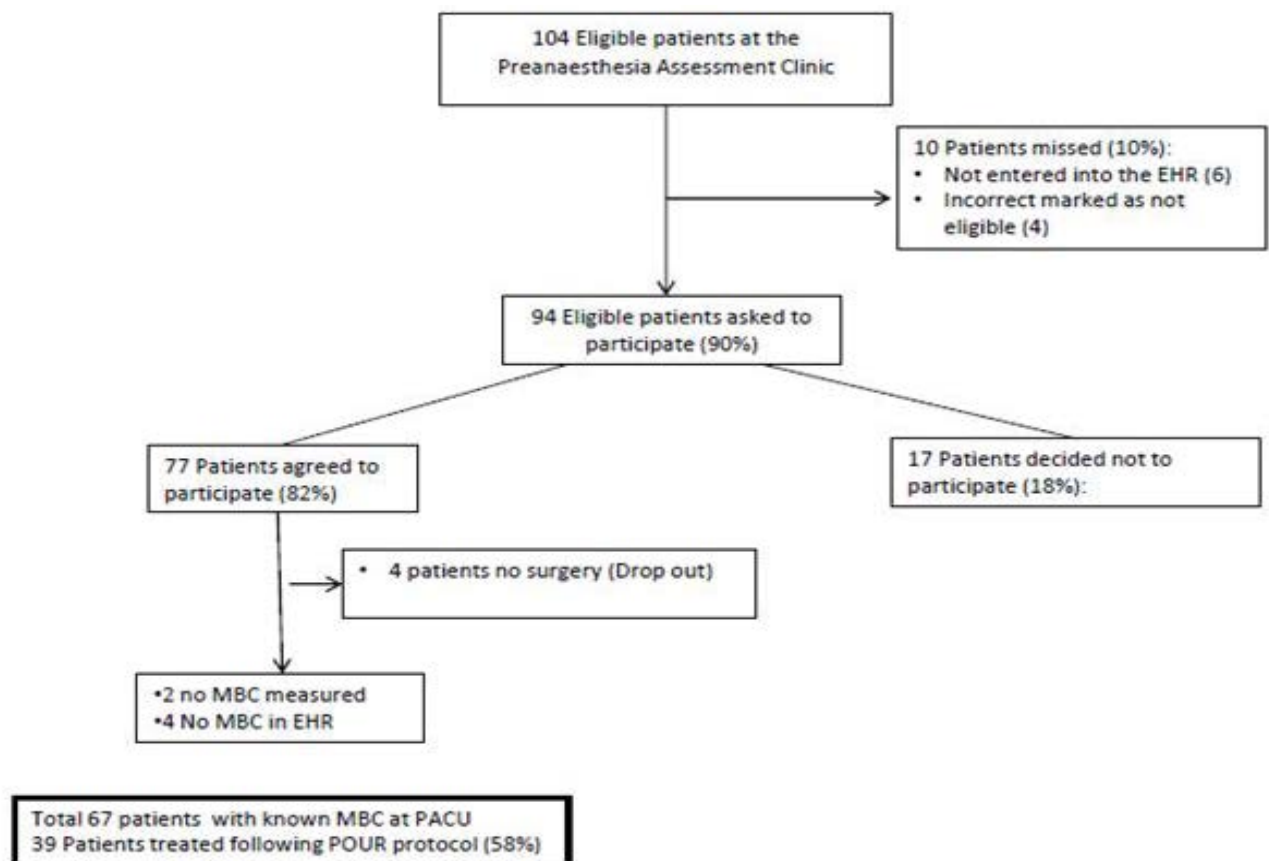


Figure 3: Flowchart Hospital 3.

Table 1: Baseline Characteristics.

	HOSPITAL 1	HOSPITAL 2	HOSPITAL 3
Eligible (N)	101	133	104
Known MBC at PACU (N, %)	33 (33%)	70 (53%)	67 (64%)
Male (N, %)	17 (52%)	45 (64%)	29 (43%)
Female (N, %)	16 (48%)	25 (36%)	38 (57%)
Age (y, min-max)	38 (19-59)	43 (18-59)	43 (18-59)
MBC (mL, min-max)	586 (125-1150)	529 (200-1000)	557 (150-1450)
General Anesthesia (N, %)	26 (79%)	56 (80%)	47 (70%)
Spinal Anesthesia (N, %)	7 (21%)	14 (20%)	20 (30%)

Table 2: Primary and Secondary Outcomes (see Flow chart).

	HOSPITAL 1	HOSPITAL 2	HOSPITAL 3	TOTAL
Patients (N, %)	101 (30)	133 (39)	104 (31)	338 (100)
Missed at PAC (N, %)	7 (7)	25 (19)	10 (10)	42(12)
Asked to participate (N, %)	94 (93)	108 (81)	94 (90)	296 (88)
Informed Consent (N, %)	44 (47)	89 (82)	77 (82)	210 (62)
Did not measure MBC	4 (9)	5 (6)	2 (3)	11 (5)
MBC not registered in EHR	5 (11)	6 (7)	4 (5)	15 (7)
No surgery yet	2 (5)	8 (9)	4 (5)	14 (7)
Known MBC at PACU (N, %)	33 (75)	70 (79)	67 (87)	170 (81)
MBC-protocol (N, %)*	33 (100)	42 (60)	39 (58)	114 (67)
General (N, %)	26 (79)	30 (71)	22 (56)	78 (68)
Spinal (N, %)	7 (21)	12 (29)	17 (44)	36 (32)
Did not follow protocol (N, %)		28 (40)	28 (42)	56 (33)
General (N, %)		26 (93)	25 (89)	51 (91)
Spinal (N, %)		2 (7)	3 (11)	5 (9)

Note: \* Primary outcome

## DISCUSSION

The implementation of the new POUR-protocol was stated to be successful when more than 80% of the eligible patients were treated following this protocol. This a priori set target was based on consensus between the authors, knowing that an existing POUR protocol was already in use in these hospitals. In literature different percentages are used for a successful adherence to a new protocol [13,14]. It is difficult to compare these success rates between implementation studies, due to different aims, subjects etc. In our study the adherence to the new protocol for the three hospitals was 100%, 60% and 58% for hospital 1, 2 and 3, respectively. Based on the set target of 80% it can be concluded that the implementation was successful for hospital 1, but not for hospital 2 and 3.

Guidelines and protocols are considered to be systematically developed recommendations to assist practitioners (and patients) in decisions about appropriate healthcare for specific clinical circumstances. Guideline adherence can improve patient outcomes, but adherence to guidelines or protocols in hospitals can vary from zero to over 90% [13,15]. Many factors may have played a role in the variable success rate of the implementation of this new POUR-protocol. Several studies have published results of a theoretical framework for guiding and evaluating a guideline implementation process in a hospital-based nursing practice [8-11]. They defined factors that can be related to the level of the innovation; the provider; the patient; and the organizational and structural context.

On the level of innovation, we expected that the 'new' POUR-protocol was not much different from the existing POUR-protocol

used in the hospitals. We assumed that the nursing staff was familiar with and acted according to this protocol. The POUR-protocol was written with the intention to assist practitioners and gives recommendations in handling POUR. For this multi-center study, the only difference in the POUR-protocol was the change from a fixed bladder volume limit of 500mL into the patient's own maximum bladder capacity. Therefore, preparing the nursing staff, the emphasis was on factors we considered as the most important changes in their standard routine clinical care of handling POUR. These factors were the benefit for the patients; how to recognize eligible patients at the PAC; and the changes that were made in the EHR to support the study. The emphasis was not on the protocol itself. Multiple group and face-to-face lessons were given to explain these changes.

During assessment at the PAC some eligible patients were missed and not asked to participate. On the provider level this could be caused by misjudgment of the medical secretaries. On the organization level, a couple of possible eligible patients were not recognized by the EHR as such, due to missing inclusion data. The willingness of patients to participate might depend on the person who provided the initial information. More than half of the patients in hospital 1 did not want to participate, despite a banner, information form and personal explanation. In hospital 1, patients were informed by medical secretaries, who had no clinical experience. This in contrast to hospital 2 and 3, where nurse anesthetists provided the information to the patient. Their greater knowledge and clinical experience about POUR may have influenced the willingness of patients to participate in the study.

This was expressed in the fact that more than 80% of the eligible patients were willing to participate in hospital 2 and 3, compared to only 47% in hospital 1.

On the patient level, patients' prior knowledge of POUR and eventually urinary catheterization might have been an important factor in participating. In the original RCT, performed in hospital 1, half of the patients refused to measure their MBC at home after hearing the word 'catheterization'.<sup>1</sup> Since most patients do not know that urinary catheterization can happen after surgery, they are not aware of the potential advantage of this new POUR-protocol. At present, surgical patients are not adequately informed about a possible postoperative urinary catheterization and the chance that it might happen to them (incidence varies from 5% to over 60%).<sup>4</sup> Still, when asked, most patients were willing to measure their MBC at home, if this could help in preventing unnecessary urinary catheterization. Only a few patients had problems to void in a measuring bowl [1]. Less than 10% of the participating patients did not measure their MBC preoperatively. They were too busy and forgot to measure their MBC.

In hospital 1, all consenting patients with a known MBC were scanned following the new implemented POUR-protocol (100%). For hospital 2 and 3 this was only true for 60% and 58% of the patients. On the organizational level, these differences in adherence to the protocol might be explained by how the "old" POUR-protocol was used. In hospital 1 postoperative measuring bladder volume with ultrasound has turned into a verb 'scanning' and has involved in a routine procedure, just like measuring postoperative heart rate, blood pressure and oxygen saturation. In the other two hospitals using ultrasound for measuring bladder volume at the PACU or at the surgical wards was not performed routinely, notwithstanding the presence of an existing POUR-protocol. Especially, it was not common to scan the bladder after general anesthesia due to the believe that POUR did not occur after general anesthesia. During the study period, only 53% and 47% of the included patients in hospital 2 and 3 were scanned after general anesthesia, compared to 86% and 85% after spinal anesthesia.

Unfortunately, some nurses at the PACU and surgical wards in hospital 2 and 3 did not adhere to the new MBC protocol. They may not have been aware of the study or not being convinced about the advantage using the MBC as a threshold for a bladder volume limit. They used their own interpretation of the POUR-protocol. This was despite the received information via leaflets, e-mails, training and adjustments in the EHR. All this might be related to the structural context of working in a hospital, where part-time working is common. Despite our effort, not all involved nurses might have been informed about the study.

On the structural level, size of the hospital did not seem to influence the implementation. It was expected that the larger the hospital, the more hospital staff involved, the more difficult the implementation. This did not apply for our study. In fact, the largest hospital showed better adherence. Size alone is not the only barrier that will have an effect on a successful implementation.

Implementing this study may have been hindered by other issues. A measuring bowl is needed to measure the MBC at home. Considering the low costs versus the high cost if bladder over distention happens, it can be easily provided by the hospital. However, it is a new procedure that needs to be implemented. Voiding in a bowl and measuring the voided volume was not considered a problem by the patients [1].

During the study a proper functioning EHR was crucial for implementing the new protocol. Without the adjustments made in the EHR it would have been impossible to recognize the eligible and participating patients and to register the MBC. The adjustments in the EHR were the most time-consuming part in organizing the study. The adjustments needed to be developed, executed and validated. However, once this new protocol is implemented only the MBC value has to be registered in the EHR, which should be rather easy to organize.

A last, for consideration, among health care providers there is no consensus that bears responsibility for POUR. In the studied hospitals some anesthesiologists, but not all, felt responsible for POUR and its possible adverse consequences. In other hospitals, or in other countries, POUR is considered the responsibility of the surgeons. POUR is often not high on the priority list of anesthesiologist and surgeons. They leave the care for POUR to the nursing staff. Often it is unknown to anesthesiologists and surgeons if the nurses adhere to the POUR protocol. Unfortunately, adverse events such as bladder distention and bladder damage are often not official registered. Raising awareness among health care providers may prevent POUR and can prevent its sometimes devastating adverse events [16,17].

## CONCLUSION

To improve patient care successful implementing a new protocol for postoperative urinary retention can be feasible. Of course, there are barriers that need to be addressed before implementing a new POUR-protocol. Suggestions before implementing are: make surgical patients aware about POUR and the possibility of urinary catheterization; make an inventory of hospital specific barriers that need to be addressed; achieve commitment from all involved personal and appoint a responsible stakeholder; and facilitate the changes needed in the EHR to register 'the home' measured MBC.

Anesthesiologists, surgeons and nurses should be aware of their role in preventing POUR and how their actions can influence the quality of care for their patients.

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A presentation of the results was given for the involved hospital staff in each hospital.

## ETHICAL APPROVAL

Not applicable.

## AUTHOR CONTRIBUTION

Brouwer TA - Study design, data acquisition & analysis, interpretation of data, writing manuscript

Weiland S - Study design, data acquisition. Data analysis, interpretation of data, writing manuscript

van Roon EN - Study design, interpretation of data, writing manuscript

Kalkman CJ - Study design, writing manuscript

Veeger N - Study design, data analysis, interpretation of data, writing manuscript

## COMPETING INTERESTS

The authors declare that they have no competing interests.

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