

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Will More Restrictive Indications Decrease Rates Of Urinary Catheterization? An Historical Comparative Study
AUTHORS	Zvi Shimoni, Joseph Rodrig, Nama Kamma and Paul Froom

VERSION 1 - REVIEW

REVIEWER	Jennifer Meddings MD, MSc Assistant Professor University of Michigan USA Potential Competing Interests: I perform research in the area of catheter-associated UTI prevention, and have published a systematic review and meta-analysis that is cited in this manuscript.
REVIEW RETURNED	13/11/2011

THE STUDY	<p>The authors designed an important intervention (urinary catheter restrictions) to decrease the most common nosocomial infection (catheter-associated UTI). They collected and analyzed a large amount of data involving catheter use, which requires a good deal of effort.</p> <p>However, it was challenging to read this manuscript in order to understand the study. After reading it several times, I think I understand the major parts of the study and outcomes they were interested in, but the details of the intervention and the actual outcomes are hard to decipher. There are typos in the manuscript...such as in the abstract ("Man outcome measures") and text "Internal Medicine B Department" - why the B? The English language sentences and phrases are a bit rough. This manuscript would benefit from further review and revision regarding language and intended meanings. I suspect some of the awkwardness is simply changes in meaning with translation. The details of the intervention and patient outcomes are also challenging to understand...is an "in and out procedure" the same thing as intermittent straight catheterization, or is it a short duration of an indwelling catheter? From the description in the manuscript, I suspect it was short duration of indwelling catheter, which leads me to ask how often intermittent straight catheterization was used?</p> <p>The intervention (policy to restrict urinary catheterization) really needs to be described further regarding how it was actually implemented. To my understanding from the manuscript, it sounds like a written policy that included educational meetings with physicians, but this leaves much to be desired in order for readers to consider implementing this intervention in their own hospital. Who was involved in the "daily morning patient review meetings"...were these new meetings, or was the intervention implemented as part of</p>
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	<p>a checklist...was catheter use brought up by physicians, nurses, or a research team member? Is there any information about how often catheter use was actually discussed in these meetings...that is, how well was the intervention actually implemented?</p> <p>It is a bit puzzling why the study approval occurred in 2011, which is long after the observational period, and intervention. The data collection appears to be retrospective review of hospital data records created in usual fashion. However, the data collected is unusual for routine medical records in most hospitals because these types of variables (amount of residual urine, reason for catheterization) are often not routinely recorded. Was there some sort of required form or catheter-generating order that healthcare providers had to fill out during routine patient care to provide this sort of detailed data?</p> <p>The catheter restrictions developed seem appropriate for most general non-ICU patient populations. However, this study also included ICU patients. Were ICU physicians/nurses involved in the development of the catheter restrictions? There were many "unjustified" catheter days in patients with coma and respirator support - did many of these patients receive paralytic medications?</p>
RESULTS & CONCLUSIONS	As described above, most parts of this manuscript are hard to read due to language limitations. Thus, it is hard to really understand if the results and interpretations are truly warranted and likely to be reproducible because of this limitation.
REPORTING & ETHICS	<p>There is no information on how well the intervention was implemented, or sufficient data regarding the intervention for it to be reproduced.</p> <p>Consent, ethical approval are discussed...but as described above, not sure how this type of data was collected retrospectively from usual medical record review without more specific documentation requirements also being implemented (not discussed) which would not have been expected since approval of study was given after the intervention and patient admissions/discharges had already occurred.</p> <p>I could not access the cited study of the observational data period (reference #3) to be able to compare how much of this current manuscript is similar to the prior published study. I recommend this article be provided as a PDF to future reviewers of this study.</p>

REVIEWER	<p>P.J. van den Broek Emeritus professor of infectious diseases Leiden University Medical Center The Netherlands</p> <p>No competing interests to declare.</p>
REVIEW RETURNED	13/12/2011

THE STUDY	<p>See comments to authors. The study is presented as a before-after study but it seems not to be designed as such. Actually a second measurement is compared with a historical measurement.</p> <p>See comments to authors for specific questions about methodology. The apparent fortuity of the study and the proces of judgement of justification of catheterization are weaknesses that should be discussed.</p> <p>No supplemental data available.</p>
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RESULTS & CONCLUSIONS	See comments to authors. Table 2 should be given in another layout. The intervention is not clearly described, therefore, it is not clear what the authors may conclude. The only thing they can see is that what they did has led to the result they have found. However what exactly they did should be described more clearly.
GENERAL COMMENTS	<p>Page 5, line 50 It seems that the study was not designed as a before-after intervention study. The time between the first and second period of observations is two and a half year. The results of the first period are published as a separate study and in the present manuscript indicated as 'previous study'. This raises the question whether the study can be presented as a before-after study. Taking into account the long period between the measurements, the before data bear the mark of a historical control group. When the study had been designed as a before-after study the appropriate design would have been to continue collecting data after the first period and applying time series analysis to see whether the long-lasting intervention was effective or not. The authors should pay more attention to this weakness of the study then they do in the present manuscript.</p> <p>Page 6, line 10 Why were patients less than 30 years old excluded? The authors should explain this.</p> <p>Page 7, line 23. Indicate that the follow-up period was 14 days. Or was it more, seeing the remark in line 47: 14 days or more?</p> <p>Page 7, line 38 Two authors reviewed the charts to classify catheterizations as justified or not. Did they do the assessment independently, what would surely be the best way to do it? If they did independently, what was the agreement (Kappa coefficient) between the reviewers? If they did independently what was done to come to consensus? The process of judgement should be described in more detail. When the judgement were not made independently, this should be discussed as a weakness of the study.</p> <p>Page 8, line 43 The 'after policy change period' is the same as what before was called 'intervention' (page 5, line 52) and 'after the intervention' (page 7, line 57, page 8 line 3) and in table 1 'during the intervention'? The authors should choose one name for each of the three phases of the study. Page 2, line 33 suggests that the intervention went on during the second measurement. The authors should clarify the design of the study and describe more clearly what exactly the intervention activities were, when they were started and how long they went on. It seems that there was a gradual change in policy over the years. Why was the second measurement done after two and a half year and not after a year or three years or whatever? Why was this moment chosen?</p> <p>Page 8, lines 43-50 The total of catheterization days during the second measurement was 390. 130 days were justified and 234 days unjustified. $130 + 234 = 364$. 26 days are missing.</p> <p>Page 9, line 5. This is not correctly formulated. The situation is that the percentage could have been 2.6% if the intervention had been 100% successful. Or what else do the authors mean?</p>

	<p>Page 9, line 25 The methods give no information how patients were checked for infection and no definitions of urinary tract infection are given. Was urine routinely checked, cultured in all patients or only in case of clinical suspicion of infection? Without this information the data about infection can not be interpreted.</p> <p>Page 10, line 27 Explain what 'potential' means. See remark page 9. line 5.</p> <p>Page 10, line 36 This sentence is misleading. There were 10 catheterizations during admission of which one was justified.</p> <p>Page 11, line 48 Why 'might require'? The intervention is not clearly described (see also remark page 8, line 43), but the abstract suggests that the authors paid explicit attention during daily rounds as part of the intervention. The authors can only argue that what they did as intervention has led to the change they describe.</p> <p>Table 1 The information about residual volumes should be left out. It is enough to mention in the text that no differences had been found.</p> <p>Table 2 Table 2 is poorly organized. The chosen lay out makes the table difficult to read.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1.

R1. This manuscript would benefit from further review and revision regarding language and intended meanings. I suspect some of the awkwardness is simply changes in meaning with translation.

A1. We made numerous revisions in an attempt to improve the language and intended meanings.

R1. "in and out procedure" the same thing as intermittent straight catheterization, or is it a short duration of an indwelling catheter? From the description in the manuscript, I suspect it was short duration of indwelling catheter, which leads me to ask how often intermittent straight catheterization was used?

A2. Page 7, line 12... We added- Physicians were instructed to remove a catheter inserted in the emergency department immediately after hospitalization if not indicated, and this was classified as a short duration indwelling catheter. Intermittent straight catheterization was not used.

R1. The intervention (policy to restrict urinary catheterization) really needs to be described further regarding how it was actually implemented.

A3. Page 7, line 10.... Was changed to- Over the interim 2-year period after the first study the restrictions were added. A lecture was given to the emergency and internal medicine department physicians with an emphasis on findings from the first study.
This was continued on line 16..... The new policy was introduced and discussed during daily morning patient electronic chart review meetings, where the entire staff (physicians and nurses) discussed all new admissions, including the reason for a new urinary catheter insertion.

R1. It is a bit puzzling why the study approval occurred in 2011, which is long after the observational

period, and intervention.

A4. Page 8, line 19.... The approval did not include the change in policy that was considered by the department to be good clinical practice, but only for retrospective patient chart review and publication. For the same reason no patient consent was needed.

R1. However, the data collected is unusual for routine medical records in most hospitals because these types of variables (amount of residual urine, reason for catheterization) are often not routinely recorded.

A5. Page 8 , line 2.... The residual volume for all catheterizations and the number of days with an indwelling urinary catheter were recorded (mandatory fields in the emergency department chart).

R1. The catheter restrictions developed seem appropriate for most general non-ICU patient populations. However, this study also included ICU patients. Were ICU physicians/nurses involved in the development of the catheter restrictions? There were many "unjustified" catheter days in patients with coma and respirator support - did many of these patients receive paralytic medications?

A6. We hope this clarifies the issue. This is not an ICU, but rather beds in the department that have the capacity to monitor and provide respiratory support.

Page 6, line 7 was changed... Patients were hospitalized in a regional 400 bed hospital in an internal medicine department that has 42 general medicine beds, including 6 beds providing monitoring and treatment of patients needing respiratory support.

Reviewer 2.

R2. The study is presented as a before-after study but it seems not to be designed as such. Actually a second measurement is compared with a historical measurement.

See comments to authors for specific questions about methodology.

The apparent fortuity of the study and the proces of judgement of justification of catheterization are weaknesses that should be discussed.

No supplemental data available.

A7. The title was changed to: WILL MORE RESTRICTIVE CRITERIA DECREASE RATES OF URINARY CATHETERIZATION? – AN HISTORICAL COMPARATIVE STUDY

-Page 2, line 2 Design- An historical comparative observational study

-Page2, line 6 Participants- We compared 882 patients hospitalized after a change in policy to an historical cohort of 690 hospitalized patients.

-Page 4, line 15... There were only historical controls for comparison

-Page 6, line 12.... The historical control group consisted of 690 patients, consecutively admitted to the internal medicine department over a 3-month period.(3) After instituting a change in policy, we decided to prospectively follow-up 882 consecutive patients also admitted over a 3-month period: the inception date was chosen for convenience

-Page 11, line 25 and on to the beginning of page 12.... Catheterization rates were compared to an historical control group rather than by using a concurrent control group, introducing the possibility that other factors influenced outcomes. No data were available during the interim period and there are no data available to determine if the intervention will continue to be effective.

R2. Table 2 should be given in another lay out.

A8. Page 18, We hope the table is now acceptable.

R2. The intervention is not clearly described, therefore, it is not clear what the authors may conclude. The only thing they can see is that what they did has led to the result they have found. However what exactly they did should be described more clearly.

A9. See above

R2. Why were patients less than 30 years old excluded? The authors should explain this.
A10. Page 6, line 12 we added... (because of small numbers)

R2. Page 7, line 23. Indicate that the follow-up period was 14 days. Or was it more, seeing the remark in line 47: 14 days or more?

A11. Page 8, line 3... catheter 14 days or more after discharge.

Page 10, line 18.... Before the change in policy 4 patients without indications had prolonged post-discharge catheterization (14 days or more) and one was re-hospitalized with urosepsis.(3)

Page 7, line 17..... The patient's health provider or family member was contacted at least 14 days after discharge if the catheter was not removed during hospitalization.

R2. Two authors reviewed the charts to classify catheterizations as justified or not.

A12. page 12, line 11 under limitations. Finally a potential weakness was that the classification of the catheterization as justified or not was not made independently by the two authors. The clarity of the more restrictive criteria however, leaves little room for misinterpretation.

R2. Why was this moment chosen.

A13, Page 6, line 14.... After instituting a change in policy, we decided to prospectively follow-up 882 consecutive patients also admitted over a 3-month period: the inception date was chosen for convenience.

R2. The total of catheterization days during the second measurement was 390. 130 days were justified and 234 days unjustified. $130 + 234 = 364$. 26 days are missing.

A14. page 9, line 10.. . Most of the unjustified days (234 of 260 (90.0%)) were in patients not receiving paralytic medications with coma and/or needing respiratory support.

R2. This is not correctly formulated. The situation is that the percentage could have been 2.6% if the intervention had been 100% successful. Or what else do the authors mean?

A15. page 9, line 17.... Total adherence to the new policy would have decreased the catheterization rate to 2.6% (23/882).

Also see page 11, line 3

R2. Page 9, line 25

The methods give no information how patients were checked for infection and no definitions of urinary tract infection are given. Was urine routinely checked, cultured in all patients or only in case of clinical suspicion of infection? Without this information the data about infection can not be interpreted.

A16. page 8, line 4..... No routine urine cultures were done and a nosocomial infection was defined for this study as urine cultures with 100,000 organisms/mL or more in a symptomatic patient. (12)

R2. Page 10, line 27

Explain what 'potential' means. See remark page 9. line 5.

A17. We left that out.

R2. Page 10, line 36

This sentence is misleading. There were 10 catheterizations during admission of which one was justified.

A18. page 11, line 7.... Our policy did not lead to the need for a justified post-admission urinary

catheterization, except for one patient hospitalized for palliative treatment.

Page 11, line 48

Why 'might require'? The intervention is not clearly described (see also remark page 8, line 43), but the abstract suggests that the authors paid explicit attention during daily rounds as part of the intervention. The authors can only argue that what they did as intervention has led to the change they describe.

A19. see above, hopefully answers this comment.

Table 1

The information about residual volumes should be left out. It is enough to mention in the text that no differences had been found.

A20. left out.

VERSION 2 – REVIEW

REVIEWER	P.J. van den Broek Professor of Infectious Diseases Leiden University Medical Centre The Netherlands
REVIEW RETURNED	13/01/2012

THE STUDY	<p>The revision is improved on many points compared with the first draft. However, the new version leaves several questions and remarks.</p> <p>The time schedule of the intervention remains vague. When was the lecture given, shortly after the first measurement or was it given shortly before the second measurement? When were the daily discussions introduced and did these discussions go on during the second measurement or were they stopped? The authors can give this information as months after or before the measurements.</p> <p>There is still a language problem that even causes confusion on some places. Just a few examples and suggestions. The authors should consult someone who is familiar with the English language. Title: indications may be better than criteria. Page 2, line 51 and many other places in the draft: fever of unknown source is fever of unknown origin? Page 6, line 32. The sentence says that the authors planned to follow up 882 patients. That is probably not what they planned. They planned to do a second measurement for three months. (The number of patients is a result). Page 6, lines 43-48: a better option is: The charts.... were reviewed by two (?) of the authors using previously reported criteria for appropriateness of catheterization. Page 6, line 52: terminally ill: palliative care for terminal patients Page 7, lines 3, 7 and 12; a better word for justified is accepted? Page 7, lines 8-10: a better option is: 2. Catheterization for palliative care is accepted only when informed consent has been given by the patient or family. Page 7, lines 47-54: Patients were not extracted from the data base: We extracted age, gender and the diagnosis on admission (..... Page 9, lines 12-16: The sentence says that the rate of catheterization occurred in all age groups. Probably the authors mean to say that the decrease was observed in all age groups.</p>
GENERAL COMMENTS	One of the patient groups is formed by the patients with fever of

	<p>unknown source (origin?). On page 9, line 32 this groups is indicated as 'patients with fever of unknown source who were unable to give a urine sample' and on page 10, line 12 the authors speak about 'fever of unknown source in incontinent patients'. See also page 11, line 3 and page 12, line 34. Are these three different groups of patients or are they all the same? Why this addition of incontinence and inability of bladder voiding?</p> <p>Page 12, line 41-43. it is not clear what the authors mean. Their finding is that the incidence of urine catheters decreases by introducing daily chart reviews. The question is whether the same will happen in other departments when daily chart reviews are introduced. This seems not to be a problem of extrapolation.</p> <p>Table 2. What kind of diagnosis is '6. No listed criteria'?</p> <p>Table 3. What kind of information is given in the first column? The reason to be discharged with a catheter? If so, did patients go home when they were in coma and on a respirator, or is it the original indication for catheterization?</p>
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REVIEWER	<p>Jennifer Meddings Physician University of Michigan USA</p> <p>Conflicts: I also perform and publish research in the area of interventions to decrease rates of inappropriate catheter use, and CAUTI outcomes.</p>
REVIEW RETURNED	30/01/2012

THE STUDY	<p>The English is better than before, but several sentences read rough, have to read several times to decipher meaning. For example, in abstract, the primary outcome measure "was admission diagnosis specific catheterization rates"...this is more easily described and read as catheterization rates, by admission diagnosis. "The study involved only one internal medicine department and chart review of newly hospitalized patients included the entire staff, a policy that might not be practical in other settings." Do you really mean included? or including?...and how was the chart review including the entire staff...the intervention involved the entire staff, not the chart review.</p> <p>This manuscript clearly still needs to go to an English editor.</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewer: P.J. van den Broek
Professor of Infectious Diseases
Leiden University Medical Centre
The Netherlands

The revision is improved on many points compared with the first draft. However, the new version leaves several questions and remarks.

1. The time schedule of the intervention remains vague. When was the lecture given, shortly after the first measurement or was it given shortly before the second measurement? When were the daily discussions introduced and did these discussions go on during the second measurement or were they stopped? The authors can give this information as months after or before the measurements.

1a. page 7, line 8. We changed the text to: A few months after completion of the first study period, we presented the findings of the study to the emergency and internal medicine department physicians and added the additional restrictions.

1a. page 7, line 13. We added: The entire staff (physicians and nurses) discussed all admissions, and reasons for new urinary catheter insertions during the interim period and until the end of the second study period.

2. There is still a language problem that even causes confusion on some places. Just a few examples and suggestions. The authors should consult someone who is familiar with the English language.

2a. We had help in rewriting the manuscript, see bold marked changes.

3. Title: indications may be better than criteria.

3a. We changed the title to indications and also changed criteria to indications throughout the text.

4. Page 2, line 51 and many other places in the draft: fever of unknown source is fever of unknown origin?

4a. We changed this throughout the text to: in patients with an admission diagnosis of fever unable to provide a urine sample for culture.

5. Page 6, line 32. The sentence says that the authors planned to follow up 882 patients. That is probably not what they planned. They planned to do a second measurement for three months. (The number of patients is a result).

5a. The number was removed.

6. Page 6, lines 43-48: a better option is: The charts... were reviewed by two (?) of the authors using previously reported criteria for appropriateness of catheterization.

6a. page 6, line 18: We changed the text to; During the first study period the charts of all patients catheterized within 24-hours of admission were reviewed in detail by two of the authors (Z.S and P.F.) using previously reported indications for catheterization.

7. Page 6, line 52: terminally ill: palliative care for terminal patients

7a. page 6, line 22; changed to terminal patients.

8. Page 7, lines 3, 7 and 12; a better word for justified is accepted?

8a. The word justified was changed to accepted throughout the text.

9. Page 7, lines 8-10: a better option is: 2. Catheterization for palliative care is accepted only when informed consent has been given by the patient or family.

9a. page 7, line 3; changed as suggested.

10. Page 7, lines 47-54: Patients were not extracted from the data base: We extracted age, gender and the diagnosis on admission (.....

10a. page 7, line 20; We extracted from the hospital data base reasons for catheterization, age, gender and diagnosis on admission (International Classification of Disease 9).

11. Page 9, lines 12-16: The sentence says that the rate of catheterization occurred in all age groups. Probably the authors mean to say that the decrease was observed in all age groups.

11a. Page 9, line 6; The overall rate of catheterization decreased from 17.5% (121/690) to 6.6% (58/882) ($p < 0.001$) (Table 1), and was observed in all age groups.

12. One of the patient groups is formed by the patients with fever of unknown source (origin?). On page 9, line 32 this groups is indicated as 'patients with fever of unknown source who were unable to give a urine sample' and on page 10, line 12 the authors speak about 'fever of unknown source in incontinent patients'. See also page 11, line 3 and page 12, line 34. Are these three different groups of patients or are they all the same? Why this addition of incontinence and inability of bladder voiding?

12a. as in 4. : in patients with an admission diagnosis of fever unable to provide a urine sample for culture.

13. Page 12, line 41-43. it is not clear what the authors mean. Their finding is that the incidence of urine catheters decreases by introducing daily chart reviews. The question is whether the same will happen in other departments when daily chart reviews are introduced. This seems not to be a problem of extrapolation.

13a. page 12, line 22; changed to; Further studies are warranted in other settings to determine if our findings can be extrapolated to other internal medicine departments with different mixes of diseases and disease severities.

14. Table 2. What kind of diagnosis is '6. No listed criteria'?

14a. The number was a mistake and was removed.

15. Table 3. What kind of information is given in the first column? The reason to be discharged with a catheter? If so, did patients go home when they were in coma and on a respirator, or is it the original indication for catheterization?

15a. We removed the word "home".

Reviewer: Jennifer Meddings

Physician

University of Michigan

USA

Conflicts: I also perform and publish research in the area of interventions to decrease rates of inappropriate catheter use, and CAUTI outcomes.

1. The English is better than before, but several sentences read rough, have to read several times to decipher meaning. For example, in abstract, the primary outcome measure "was admission diagnosis specific catheterization rates"...this is more easily described and read as catheterization rates, by admission diagnosis. "The study involved only one internal medicine department and chart review of newly hospitalized patients included the entire staff, a policy that might not be practical in other settings." Do you really mean included? or including?...and how was the chart review including the entire staff...the intervention involved the entire staff, not the chart review.

1a1. Page 2, line 13; The primary outcome measure was catheterization rate by admission diagnosis.

1a2. Page 4, line 13: All nursing and medical staff participated in chart review of newly hospitalized patients, a policy that might not be practical in other settings

2. This manuscript clearly still needs to go to an English editor.

2a. We hope the manuscript is improved.