

Synopsis

National 'progress! Safe urinary catheterization' Programme

Sponsor	Patient Safety Foundation Switzerland Asylstrasse 77 8032 Zurich
Project Title:	National 'progress! Safe urinary catheterization' Programme
Short Title/Project ID:	progress! pilot programme on safe urinary catheterization
Project Plan Version and Date:	Version 1.0, 26.04.2016
Risk categorization	A
Type of Research	Project in which health data is collected from persons
Project design	Quality assurance project, use of routine health data
Background and Rationale:	<p>Nosocomial infections are an enormous problem in the healthcare sector. One American study shows that about 4% of all hospitalized patients contract a nosocomial infection while in hospital (1). According to a pilot study by the European Centre for Disease Prevention & Control (ECDC), in Europe the proportion is about 7.1% (2).</p> <p>A significant proportion of all nosocomial infections (1;2) are urinary tract infections, and 70–80% of these are associated with a urinary catheter (3;4).</p> <p>Roughly one in five patients will have a urinary catheter inserted while in hospital (1–2;5–6). These figures show that catheter-associated urinary tract infections are a frequent and substantial risk for patients during their stay in hospital.</p> <p>Complications related to urinary catheters are associated with higher mortality rate (7). Additionally, studies clearly show that the infections are a significant health risk for the patients affected and lead to further treatment in the form of drug administration and prolonged hospitalization (5;8).</p> <p>Besides the direct health consequences for the patients concerned, nosocomial urinary tract infections also have considerable economic repercussions (5).</p> <p>Another topic that receives less attention yet remains important is non-infectious complications associated with urinary catheters. Study results show that infections are not the only risk, but that there is a potential risk of injury during catheterization 9, 10).</p> <p>In the last few years, various studies have highlighted effective measures that can be taken to significantly reduce the incidence of catheter-associated urinary tract infections (5;8;11-13).</p> <p>Studies also show that between 20% and 55% of all catheters are inserted without any clear medical indication (8;13). One effective intervention to reduce the frequency of catheterization from the outset has been to draw up a list of indications for the use of a urinary catheter, with</p>

strict criteria (8;11).

Another effective intervention has been to introduce so-called catheter reminders / stop orders to reduce the duration of catheterization and increase awareness of the presence of urinary catheters (12;14). A study by Saint et al. showed that up to 28% of medical staff do not know that/whether their patients have had a catheter inserted. The study also revealed that the probability of appropriate catheterization was greater if the medical staff were aware that the catheter had been inserted (15). In such cases, the use of reminders and stop orders proves to be an effective intervention as they increase awareness.

Meddings et al. state that training those staff who insert the catheters is also an important step (8). This enables injuries and infections to be avoided during insertion (16). Alternatives to long-term catheters (e.g. condom catheters for men, see Saint et al. (17)) have also been discussed as a way to reduce catheter-associated urinary tract infections. The most effective way to reduce catheter-associated urinary tract infections, however, is with an overall reduction in the number of catheters inserted and the length of time they are left in place (e.g. Meddings et al. (8)).

Most of the interventions that have actually been put into practice are a combination of several of the above measures. Overall, studies show a significant measurable effect of this bundle of interventions in reducing the frequency and duration of catheter use. It also reduced the frequency of catheter-associated urinary tract infections (18;19).

In conclusion, it may be deduced from the above-mentioned studies that catheter-associated urinary tract infections and non-infectious complications are a substantial problem in the healthcare sector. There are not only significant consequences for the patients concerned but also economic repercussions. International experiments show that effective measures do exist to reduce the frequency and duration of catheterization and these translate into a reduction of catheter-associated urinary tract infections and injuries.

A large number of recommendations have been made around the world to prevent catheter-associated infections. These include, to name but a few, the HICPAC Guideline (20), the SHEA /IDSA Practice Recommendation (21;22) and, in German-speaking countries, the recommendation from the commission for hospital hygiene and infection prevention (KRINKO), at the Robert Koch-Institut (23).

The amount of data for Switzerland is still meagre. In a 2005 Swissnos report on nosocomial infections, urinary tract infections constitute about 20% of all nosocomial infections. The report also shows that even in Switzerland around one in four hospitalized patients will have a urinary catheter inserted (24). So, it may be presumed that catheter-associated urinary tract infections are also a major problem in the Swiss healthcare sector. To our knowledge, three studies have been carried out so far on the reduction of catheter use in clinical practice in Switzerland (25–27).

All three studies showed significant reductions in the frequency and duration of catheterization. There was also a significant reduction in catheter-associated urinary tract infections.

The data and studies therefore confirm that action needs to be taken to

	reduce urinary catheter use. The three studies (25–27) also show that adapting and applying evidence-based intervention bundles also leads to a significant improvement in Switzerland.
Objective(s):	Introducing a quality improvement programme in 7 pilot hospitals based on an evidence-based intervention bundle with the aim of reducing the use and duration of urinary catheters and improving the quality of insertion and care of urinary catheters. This should lead to a reduction in nosocomial infections and non-infectious complications.
Endpoint(s)	<p>Primary outcome:</p> <p>Changes in clinical practice in the way urinary catheters are handled, measured by the frequency and duration of catheterization and catheter-associated complications:</p> <ul style="list-style-type: none"> - Number of catheter-days / 100 patient-days - Number of patients with urinary catheters / Total number of patients - Number of clinically indicated catheters / Total number of catheters - Number of patients with symptomatic catheter-associated urinary tract infections (CAUTI) / 100 patient-days - Number of CAUTI / 1,000 catheter-days - Number of patients with non-infectious complications of the urinary tract / 100 patient-days - Number of non-infectious complications / 1,000 catheter-days - Number of re-evaluations / 1,000 catheter-days <p>Secondary outcomes:</p> <p>Changes in knowledge, attitudes and behaviour among medical staff (doctors and nurses) in the way they handle urinary catheters:</p> <ul style="list-style-type: none"> - Changes in knowledge: expertise about indications, care, and alternatives to urinary catheters - Change in attitudes towards and perception of the value of urinary catheters as a medical procedure - Changes in behaviour: insertion procedure, evaluation of the professional's own skill at inserting a catheter properly, everyday procedures <p>Other variables:</p> <ul style="list-style-type: none"> - Factors helping or hindering the introduction of the intervention bundle
Inclusion/Exclusion Criteria:	As part of the follow-up project, the intervention bundle was implemented throughout the pilot hospital, or in all organizational units taking part. The staff (doctors and nurses) put the improvements into practice and they affect the quality of treatment and nursing received by all patients.
Project assessments, procedures:	<p>The intervention bundle that was introduced and used in the follow-up project in the pilot hospitals comprises the following evidence-based components:</p> <ol style="list-style-type: none"> 1. Provision and implementation of a clear list of indications: The defined indications are known and as far as possible whenever a decision needs to be taken in favour of or against a urinary catheter

	<p>they are consulted, complied with and documented.</p> <p>2. Regular re-evaluation of the indication every 24 hours: The need for the catheter is verified every day using the defined indications and is documented.</p> <p>3. Urinary catheters are only handled by trained and relevantly qualified staff.</p> <p>The improvement procedure in the follow-up project is evaluated to check whether the intervention bundle leads to an improvement in the procedures and consequently also a reduction in catheter-associated infections and injuries. The evaluation comprises the following elements:</p> <p>Surveillance: Surveillance records the frequency and duration of catheterization over a specific period of time, whether it is appropriate according to the prescribed indications, any non-infectious and infectious complications, selected process variables, and general demographic data to gather information about the potential for improvement in the pilot hospitals and demonstrate the effectiveness of the intervention bundle. Surveillance is carried out as two 3-month periods of monitoring before and after the intervention bundle is introduced (baseline and post-introduction surveillance).</p> <p>During the pilot programme Swissnoso is in charge of developing the surveillance process and carrying it out. Swissnoso provides the pilot hospitals taking part in the process with a surveillance tool that has already been tested in two trial hospitals (Inselspital Bern, Universitätsspital Basel) for functionality and practical feasibility in everyday clinical practice. This tool comprises a structured data collection form that can be used either as a hard paper copy or electronically in the hospital's own information system and is used to gather information together with a database for web-based data capture.</p> <p>Staff questionnaire: The improvement process is based on a systematic staff survey. A questionnaire is used to collect information on staff knowledge and use of urinary catheters. The questionnaire will be developed by the Patient Safety Foundation Switzerland and covers the following topics:</p> <ul style="list-style-type: none"> - Knowledge (expertise about indications, care, and alternatives to urinary catheters) - Practice (insertion procedure, evaluation of the professional's own skill at inserting a catheter properly, everyday procedures) - Attitudes towards urinary catheters as a medical procedure <p>Participation is voluntary and anonymous.</p> <p>Process evaluation: Information is collected on the process for the purpose of evaluating the way the process is applied, factors helping or hindering implementation, and the extent of compliance with the measures. The process is evaluated at regular intervals throughout the duration of the improvement process and is aimed at all staff taking part in the follow-up project at the pilot hospital. Information are gathered by telephone interviews of a member of the project group and analysis of the material and tools used by the pilot hospitals. The process evaluation is developed and carried out by the Patient Safety Foundation Switzerland. Apart from the surveillance of the daily reevaluation of the catheter indication, the collection of these data is not patient-related.</p>
Number of Participants	See statistical considerations

<p>Project Duration, schedule:</p>	<p>The <i>progress!</i> Safe urinary catheterization pilot programme runs from early 2015 to mid-2018.</p> <p>Introduction of the intervention bundle in the pilot hospitals: The pilot hospitals have time from January 2016 to January 2017 to decide how they want to introduce the intervention bundle in their organization. The pilot hospitals then present their project to the other participating hospitals at a workshop scheduled for January 2017. The pilot hospitals then have until May 2017 to test and adapt the procedures. The pilot hospitals carry out the implementation from May 2017.</p> <p>The baseline surveillance will be carried out from August to October 2016 (3 months). The post-surveillance will be carried out one year later from August to October 2017 (3 months).</p> <p>The staff survey will be carried out in the last third of each surveillance period, i.e. in October 2016 and October 2017.</p> <p>The process evaluation is carried out at regular intervals throughout the duration of the follow-up project, i.e. from January 2017 to October 2017.</p>
<p>Project Centre(s):</p>	<p>The following hospitals are taking part in the pilot programme <i>progress!</i> Safe urinary catheterization:</p> <ul style="list-style-type: none"> - Inselspital Bern - Ente ospedaliero cantonale (EOC) Lugano Civico - Spital Lachen - L'hôpital neuchâtelois (La Chaux-de-Fonds, Pourtalès) - Kantonsspital Lucerne - Kantonsspital Winterthur - UniversitätsSpital Zurich
<p>Statistical considerations</p>	<p>Sample size determination:</p> <p>To show significant effects with a power of 0.80 on a two-side significance level α of 0.05 between the two surveillance phases, a number of cases of 1,724 patients is needed per hospital (862 patients before and 862 patients after the intervention). The number of cases relates to an average prevalence of urinary catheters of 15% and a potential reduction of about 30%, i.e. a reduction of prevalence from 15% to 10.5% (see Appendix 2).</p> <p>About 100–150 beds were included per pilot hospital (whole hospital or selected individual organizational units, which with an average 7-day hospitalization duration over a period of 3 months gives a total of 1,300 – 2,000 patients per hospital, about 15% of whom will be fitted with urinary catheters). The aim is to obtain a sufficient number of cases for the evaluation while not overburdening the pilot hospitals collecting the data. If seven pilot hospitals take part, there would potentially be 2,730–4,200 patients who would have a urinary catheter inserted during the two 3-month surveillance periods.</p> <p>Statistical analysis:</p> <p>The collected surveillance data will be verified regarding correct coding, outliers, missing values and inconsistencies between the variables. Inaccurate values will be reported to the hospitals for correction. A descriptive analysis will be done for both surveillance periods. All endpoints (catheter use, complications and re-evaluations) will be shown with a 95% confidence interval. In the second analysis after the post-surveillance period the variables will be additionally compared regarding the collection period. The analyses will be corrected for age, sex,</p>

	<p>organizational unit and origin of the patient. Differences between the periods will be shown as odds-ratios for binary endpoints and rate-ratios for count endpoints, each with a 95% confidence interval. P-values of <0.5 will be considered as significant. The analyses will be performed using the statistical program R (R-project 3.2). If there will be missing data in the endpoints, the respective patients will be excluded from the analysis. If the proportion of missing data regarding the endpoints will be more than 5%, the missing data will be imputed by a sensitivity analysis. Deviations from the original planned statistical analysis will be described and justified in the final statistical report.</p>
Other methodological Considerations	n.a.
Risk-benefit statement	<p>The aim of the third <i>progress!</i> Safe urinary catheterization pilot programme is to prevent patients being harmed by reducing the use and duration of urinary catheterization thereby reducing the associated incidence of catheter-associated urinary tract infections and non-infectious complications. The reduction should be obtained by introducing a viable long-term intervention bundle comprising a clear indication list, regularly checking the indication, and training the staff handling catheters. The goal to strive for is a cultural change that raises awareness of the medical staff on catheter-associated problems. Finally, all hospitalized patients will profit from this awareness.</p> <p>The indication list covers all medical situations in which a urinary catheter is needed to drain the urine. The patients therefore have an extremely small risk of any medical complication owing to the lack of a urinary catheter, such as acute urinary retention.</p> <p>Risks are nevertheless conceivable. For example, in the absence of a urinary catheter, it is possible that some patients will find the alternative methods for draining the urine (condom catheter, bedpan, urine bottle, etc.) unpleasant. Acceptance of alternative methods can be increased by better informing patients of the risks associated with a urinary catheter. If patients get out of bed to go to the toilet, there is the risk that they may fall over. This undesirable consequence can be minimized if patients are accompanied by a nurse. There is also the potential risk of the catheter being removed too early and it being necessary to re-insert a catheter because of urinary retention.</p>

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