ORIGINAL PAPER

ASSESSING THE METHODOLOGICAL QUALITY OF CLINICAL PRACTICE GUIDELINES FOR PREVENTING INTRAVASCULAR CATHETER-RELATED INFECTIONS

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Received October 12, 2014

Accepted December 1, 2014

Abstract

Aim: The study aimed at assessing the methodological quality of selected clinical practice guidelines (CPGs) for preventing intravascular catheter-related infections. **Methods:** CPGs were systematically searched in electronic databases and on websites of organizations, colleges and societies based on predefined criteria and keywords over a period of 2000–2013. After sorting and analyzing 104 documents, the methodological quality of three selected CPGs was assessed with the AGREE II generic instrument. **Results:** All the CPGs obtained the highest domain scores in the dimensions Scope and Purpose (87%), Stakeholder Involvement (85%) and Clarity and Presentation (87%). Significantly lower scores were noted in the other domains, that is, Applicability (62%), Rigor of Development (55%) and Editorial Independence (30%). The highest overall methodological quality was observed in the Care and Maintenance to Reduce Vascular Access Complications (RNAO). **Conclusion:** The methodological quality of the CPGs was relatively high, the only exceptions being the domains Editorial Independence and Rigor of Development. The assessment was a part of the process of adaptation of a selected guideline for the Czech health care setting. The AGREE instrument is suitable for development of completely new CPGs and for adaptation of existing CPGs for other socio-cultural and organizational conditions.

Key words: clinical practice guidelines, prevention of catheter-related infections, methodological quality, AGREE II.

Introduction

Currently, many definitions agree on an interpretation of clinical practice guidelines (CPGs) as evidence-based statements formulated to improve the quality and effectiveness of health care (Field, Lohr, 1992, p. 26–27; Keffer, 2001; McMaster et al., 2007; Qaseem et al., 2012). The objective of CPGs is to make explicit recommendations for physicians, surgeons, nurses and other health professionals. Numerous studies have shown that following evidence-based recommendations does enhance the quality of care provided (Grimshaw et al., 2004; Grimshaw et al., 2006; Vecchio et al., 2011). In health practice, however, a gap exists between health research outcomes and recommendations and the actual practice. Good-quality CPGs should be scientifically valid, effective and aimed at improving patient outcomes.

Since the 1990s, CPGs have been systematically developed and their quality has gradually improved (Burgers et al., 2004). Given the fact that the number of new CPGs produced by many organizations has dramatically increased in recent years, their quality and validity must be sophisticatedly assessed before they are implemented into clinical practice. High-quality CPGs involve recommendations based on systematic evidence reviews, assessment of patient benefits and harms and transparency of the evidence (Holmer et al., 2013). Since they have an impact on the quality and costs of health care provided, their own quality is critically important (Woollf et al., 1999). A multidisciplinary approach, systematic review of current literature and recommendations based on supporting evidence are the key principles for producing high-quality CPGs.

Catheter-related infections belong to the most severe nosocomial infections, with mortality rates exceeding 50%. Indwelling central venous catheters account for approximately 90% of these infections (Maďar, 2006, p. 78). In intensive care units, catheter-related infections are linked to higher morbidity and mortality rates in patients, prolonged hospital stays

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and increased care costs (Křikava, Ševčík, 2008, p. 210). In the USA, costs associated with the treatment of approximately 80,000 cases of catheter-related infections are estimated at 0.3 to 2.3 billion dollars (Szturz, 2010, p. 33). In the Czech Republic, no data on the costs of treatment of catheter-related infections are available. Given the consequences of their complications, attention is mainly paid to preventive measures that include, among others, professional nursing care based on the best evidence available. CPGs focused on catheter-related infections have been developed since the 1990s and their number continues to rise. According to the MEDLINE database, the number of publications indexed under the types *guideline*, *meta-analysis* and *systematic review* and the subject heading term *prevention of intravascular catheter-related infections* has increased from two in 1998 to 25 items published until 2014. Some of the studies, however, pointed to the heterogeneity between various guideline programs and the low quality of CPGs (Ward et al., 1996; Graham et al., 2001; Burgers et al., 2004).

In most developed countries worldwide, good-quality and adequate health care, including nursing care, is provided in accordance with CPGs. In the Czech Republic, there are neither national standards nor CPGs for nursing care. In an uncoordinated and non-systematic way, individual health facilities produce their own, locally valid, guidelines that do not meet the basic methodological requirements; among others, they do not include clinical recommendations based on scientific evidence (Suchý, 2012, p. 23). Given the fact that the development of new CPGs is a rather complex and expensive process (Steinbrook, 2007), a CPG may be produced using the so-called trans-contextual adaptation, that is, derived from an already existing CPG adapted to the given socio-cultural and organizational setting (Líčeník, 2009, p. 33). One of the initial steps in the adaptation process is assessing the methodological quality of a CPG with the AGREE generic instrument.

Aim

The study aimed at assessing the methodological quality of selected CPGs for preventing intravascular catheter-related infections with the AGREE generic instrument.

Methods

Design

A descriptive study using qualitative research techniques.

Eligibility criteria

The search involved CPGs published in 2000–2013, CPGs generally targeted at adult patients in secondary care, GPGs published in full including methodology of their development, CPGs published in English language, and CPGs freely available in an electronic (or printed) version.

Sources and search

CPGs for preventing intravascular catheter-related infections were searched using the keywords *intravascular catheter-related infections*, *intravascular catheter-related bloodstream infections*, *clinical practice guidelines*, and *prevention* in the electronic bibliographic databases CINAHL, Cochrane Collaboration, Cochrane Library, EBSCO, Geobase, MEDLINE, PROQUEST, PubMed, Web of Knowledge and Science Direct, G-I-N (database of CPGs), and on websites of organizations, societies and colleges that develop CPGs – the Australian College of Critical Care Nurses (ACCCN), Australian & New Zealand Intensive Care Society (ANZICS), Joanna Briggs Institute (JBI), National Health and Medical Research Council (NHMRC), Australasian Society for Infectious Diseases (ASID), NSW Intensive Care Coordination and Monitoring Unit (ICCMU), Institute for Clinical Systems Improvement (ICSI), Centers for Disease Control and Prevention (CDC), American Association of Critical-Care Nurses (AACN), Agency for Healthcare Research and Quality (AHRQ), American Society of Critical Care Anesthesiologists (ASCCA), American Society of Anesthesiologists (ASA), National Guideline Clearinghouse (NGC), Society of Critical Care Medicine (SCCM), Infectious Diseases Society of America (IDSA), Canadian Association of Critical Care Nurses (CACCN), Canadian Critical Care Society (CCCS), Canadian Critical Care Trials Group (CCCTG), Registered Nurses' Association of Ontario (RNAO), World Federation of Societies of Intensive and Critical Care Medicine (WFSICCM), World Federation of Critical Care Nurses (WFCCN), European Federation of Critical Care Nursing Associations (EfCCNa), Česká společnost anesteziologie, resuscitace a intenzivní medicíny (ČSARIM), Česká společnost intenzivní medicíny (ČSIM), Accident Compensation Corporation (ACC), New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), National Institute for Health and Care Excellence (NICE), Royal College of Nursing (RCN), British Association of Critical Care Nurses (BACCN) and Scottish Intercollegiate Guidelines Network (SIGN).

Selection and analysis of studies

In electronic libraries and databases, a total of 104 relevant documents were found among 10,772 results displayed based on the search strategy and defined criteria. The documents were sorted according to criteria defined for inclusion of CDPs in the study.

Further sorting was performed to exclude duplicate and outdated CPGs, specifically targeted CPGs (e.g. for the pediatric population) and CPGs that did not include comprehensive data (Figure 1). The basic sample for assessing the methodological quality comprised three CPGs (Table 1).

Figure 1 Flowchart for sorting CPGs for preventing intravascular catheter-related infections

Table 1 List of the assessed CPGs for preventing intravascular catheter-related infections

Guidelines for the Prevention of Intravascular Catheter-Related Infections. Centers for Disease Control and Prevention, USA. 2011. (CDC)
Care and Maintenance to Reduce Vascular Access Complications. Registered Nurses' Association of Ontario, Canada. 2008. (RNAO)
Prevention of Intravascular Catheter-Related Infection in Ireland. SARI by HSE Health Protection Surveillance Centre, Ireland. 2010. (SARI)

The selected documents retrieved from electronic databases were independently assessed by four independent experts (2 physicians specializing in intensive care medicine, 1 nurse specializing in intensive care medicine and 1 academic worker, an evidence-based practice methodologist) using the Czech version of the AGREE II instrument (Ličenik et al., 2013). The Appraisal of Guidelines and Research and Evaluation (AGREE) is a validated generic instrument for assessing the methodological quality of CPGs applicable to all areas of health care.

The instrument was produced by a group of experts from 10 European countries, Canada, New Zealand and USA, verified and validated by assessing 100 CPGs from 13 countries of the world, and published in 2003 (Gallardo et al., 2010; Kinnunen-Amoroso et al., 2009; Loveday et al., 2010; Yu et al., 2011; Vecchio et al., 2011). The modified AGREE II version was published in 2009 and the Czech version in 2013. The AGREE II instrument consists of 23 items organized within 6 basic domains (*Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity of Presentation, Applicability,*

and *Editorial Independence*), each capturing a unique dimension of guideline quality. Each of the items is rated on a 7-point Likert scale (from 1 – strongly disagree to 7 – strongly agree). The more considerations have been taken into account in the guideline, the higher the score the guideline should receive on that item from the appraiser (total score from 23 to 161 points). According to the AGREE II recommendations, the scaled domain score for each guideline (on a scale from 0 to 100) is calculated by summing up scores from all appraisers and by scaling the total as a percentage of the maximum possible score for that domain: $[(\text{obtained score} - \text{minimum possible score}) / (\text{maximum possible score} - \text{minimum possible score})] \times 100$. Two overall assessment items require the appraisers to make a judgment as to the global quality of the guideline; the appraisers are asked whether they would recommend use of the guideline (yes – yes, with modifications – no). The instrument does not assess the clinical content of CPGs. The AGREE II user's manual recommends that CPGs are assessed by at least 2, and preferably 4, appraisers to increase the reliability of the assessment (Brouwers et al., 2010).

Results

The lowest scaled domain scores were obtained by the domains *Editorial Independence* (30%) and *Rigor of Development* (55%). By contrast, very high scores were noted for *Scope and Purpose*, *Stakeholder Involvement* and *Clarity and Presentation* (85–87%) (Table 2).

The domain *Scope and Purpose* is concerned with the overall aim of the CPG, specific health questions and whether the target population is specifically described. The mean score of the domain was 87% (range, 80–96%). Lower scores were attributed to the CDC and SARI guidelines in which the health questions and patient populations were not clearly specified. The RNAO guideline, on the other hand, was very precise in describing the aims, health questions and populations.

The mean score of the domain *Stakeholder Involvement* was 87% (range, 83–89%). The involvement of appropriate stakeholders was best described in the CDC and SARI guidelines. In none of the CPGs, however, information about considering the views and preferences of the target organization was found. In the RNAO guideline, individuals from all relevant professional groups were not included in the guideline development group as experts in microbiology or infection control, for instance, were

missing. None of the CPGs were piloted among the target users before validation.

As for the domain *Rigor of Development* concerned with the use of systematic methods to search for evidence, only two guidelines reported the strategy used in the development process. The CDC guideline was developed according to an older methodology used until 2009; this, however, was neither included in the current 2011 guideline nor available on the authors' website. Moreover, the CDC guideline did not contain information on whether it had been externally reviewed by experts. When assessing the congruency between recommendations and supporting evidence, the RNAO guideline linked the recommendations to references such as studies. Frequently, however, the study results were not compared and no analyses leading to particular recommendations were reported. This was one of the AGREE domains with low mean scores (55%).

Generally, the *Clarity and presentation* domain criteria were stated explicitly in most of the CPGs (a mean domain score of 85%). The recommendations were most specific and unambiguous and the key recommendations were most easily identifiable in the CDC guideline. In case of the RNAO guideline, the appraisers differed in their opinion, mainly on easy identification of the key recommendations. The guideline had the lowest score in this domain.

The domain *Applicability* describes how the guideline implementation is facilitated. This domain had relatively low mean score (62%). A very low score of 28% was attributed to the CDC guideline which only briefly outlined the facilitation of its implementation. The SARI guideline described the process of implementation but the other items assessed in the domain were only briefly mentioned and were rather general. The highest rating was given to the RNAO guideline that provided an educational tool as well as a comprehensive implementation strategy including links to the association's website with additional information and guides.

The domain *Editorial Independence* assesses whether the final recommendations were influenced by the views or interests of a funding body or whether competing interests of the guideline authors were addressed. The mean score was significantly the lowest (30%) among all AGREE instrument domains. Transparency of opinion was not mentioned in the RNAO guideline. Although the CDC guideline did not explicitly state editorial independence, general information could be found on the centers' website. No information on any of the items in this domain was stated in the SARI guideline.

Table 2 Assessment of the methodological quality of CPGs for preventing intravascular catheter-related infections (AGREE II)

AGREE II domains	CDC n / %	RNAO n / %	SARI n / %
SCOPE AND PURPOSE	70 / 80%	81 / 96%	74 / 86%
The overall objective(s) of the guideline is (are) specifically described.	26	27	27
The health question(s) covered by the guideline is (are) specifically described.	20	27	23
The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	24	27	24
STAKEHOLDER INVOLVEMENT	76 / 89%	75 / 88%	73 / 85%
The guideline development group includes individuals from all relevant professional groups.	28	20	27
The views and preferences of the target population (patients, public, etc.) have been sought.	21	27	19
The target users of the guideline are clearly defined.	27	28	27
RIGOR OF DEVELOPMENT	101 / 36%	207 / 91%	109 / 40%
Systematic methods were used to search for evidence.	9	28	4
The criteria for selecting the evidence are clearly described.	7	27	4
The strengths and limitations of the body of evidence are clearly described.	7	24	4
The methods for formulating the recommendations are clearly described.	7	25	4
The health benefits, side effects, and risks have been considered in formulating the recommendations.	16	27	25
There is an explicit link between the recommendations and the supporting evidence.	28	22	20
The guideline has been externally reviewed by experts prior to its publication.	8	27	28
A procedure for updating the guideline is provided.	19	27	20
CLARITY AND PRESENTATION	83 / 99%	56 / 61%	81 / 96%
The recommendations are specific and unambiguous.	28	20	27
The different options for management of the condition or health issue are clearly presented.	28	19	27
Key recommendations are easily identifiable.	27	17	27
APPLICABILITY	43 / 28%	97 / 84%	88 / 75%
The guideline describes facilitators and barriers to its application.	7	24	22
The guideline provides advice and/or tools on how the recommendations can be put into practice.	14	27	24
The potential resource implications of applying the recommendations have been considered.	18	19	20
The guideline presents monitoring and/or auditing criteria.	4	27	22
EDITORIAL INDEPENDENCE	36 / 58%	35 / 56%	8 / 0%
The views of the funding body have not influenced the content of the guideline.	11	10	4
Competing interests of guideline development group members have been recorded and addressed.	25	25	4
Total sum of assessment	409 / 63%	551 / 58%	433 / 75%

n - sum of items score of four evaluators, % - standardized domain scores

Discussion

Clinical practice, which reflects scientific knowledge and which has been used globally for more than 100 years, has witnessed significant changes in the last two decades (Líčeník, 2009, p. 5). These have been related to the development of evidence-based medicine (EBM) in the 1990s (Sackett et al., 1996). Clinical practice guidelines, as systematically developed statements reflecting the philosophy of EBM, are a tool to bridge the gap between scientific research and clinical practice (Líčeník, 2009, p. 5). The advances in EBM also have an impact on the development of CPGs, in particular their increasing quality and sophistication of production. The emphasis is placed on a systematic methodology for CPG development and there are noticeable changes in society's attitude toward health care. CPGs reduce undesirable variability in practices by eliminating those that are improper, untoward, dangerous for patients or inefficient (Suchý et al., 2012, p. 15).

The Czech health system continues to lack a systematically organized and continuously updated set of clinical recommendations based on scientific evidence, representing a national consensus and allowing the implementation and evaluation of care (Suchý et al., 2012, p. 121). On their websites, the Czech Society of Intensive Care Medicine (ČSIM) and the Czech Society of Anesthesiology and Intensive Care (ČSARIM) post mainly treatment recommendations and statements. Relatively rare are nursing care recommendations such as those for eye protection during general anesthesia (ČSARIM, 2014; ČSIM, 2014). On the Internet, numerous different recommendations aimed at various target groups can be found, that have been developed by health facilities, professional and interest groups, pharmaceutical companies and others. However, the quality of such recommendations is disputable and may significantly differ that in approved standard CPGs (Zvolský, 2010).

For assessment of the methodological quality of CPGs, the AGREE II generic instrument is recommended. In the present study, the Czech version of AGREE II was used for assessing three CPGs for preventing intravascular catheter infections, selected according to predefined criteria for adaptation and implementation in the Czech socio-cultural and organizational setting. The greatest problem for four expert appraisers of methodological quality was outdated or unavailable methodology for development of two CPGs produced by the CDC (Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011) and SARI (Prevention of Intravascular Catheter-Related

Infection in Ireland, 2010). The appraisers repeatedly contacted the organizations producing these CPGs but failed to obtain the methodology for guideline development. CPGs containing the methodology of their development are more transparent and, from the user's perspective, more trustworthy. Present-day users expect formally well-elaborated documents with valid recommendations (Zvolský, 2010). The overall methodological quality of CPGs assessed in the present study was relatively good, particularly in the domains *Scope and Purpose*, *Stakeholder Involvement* and *Clarity and Presentation*. By contrast, significantly low methodological quality was manifested in the domains *Editorial Independence* and *Rigor of Development*. For instance, the assessed CPGs did not explicitly state that the views of the body providing external funding to CPG development had not influenced their content. Two CPGs did not clearly prove that systematic methods had been used to search for evidence; moreover, the criteria for selecting evidence including the strengths and limitations of the body of evidence were not clearly described (*Rigor of Development*). When assessing the methodological quality of CPGs, the AGREE instrument domains *Editorial Independence* and *Rigor of Development* often receive the worst scores (De Haas et al., 2007; Hurdowar et al., 2007; Jo et al., 2013; Navarro Puerto, 2008). In one of the assessed CPGs, the facilitators and barriers to its application were insufficiently described, and so were monitoring and auditing criteria (*Applicability*). All the other items of the AGREE instrument domains were well described in the CPGs and had relatively high scaled scores.

The present study showed that the CPG quality can be relatively reliably assessed with the AGREE instrument, as seen from its use in other studies characterized by high reliability (Alonso-Coello et al., 2010; Esandi et al., 2008; Jo et al., 2013; MacDermid et al., 2005). The AGREE instrument evaluates the quality of CPGs by assessing the development methods and related properties (AGREE Collaboration, 2003). It is mainly concerned with how quality is maintained during the process of CPG development. However, the AGREE instrument does not assess the clinical contents of the guidelines. Low AGREE scores for particular CPGs may not necessarily mean low quality of their clinical content (Jo et al., 2013). However, a high-quality systematic process of CPG development increases the chances that the final CPG will have good content quality and it will contain relevant and appropriate recommendations (Hurdowar et al., 2007).

Study limits

The present study only involved CPGs published in English language and publically available in databases such as the G-I-N. Local guidelines, CPGs in other than English languages and those in other than electronic form were not included.

Conclusion

The study assessed three clinical practice guidelines for preventing intravascular catheter-related infections. The methodological quality of the CPGs was relatively high, the only exceptions being the AGREE instrument domains *Editorial Independence* and *Rigor of Development*. The assessment was a part of the process of adaptation of a selected guideline for the Czech health care setting. It is our opinion that the AGREE instrument is suitable for development of completely new CPGs (de novo) and also for adaptation of existing CPGs, when as part of the ADAPTE process assesses methodological quality of guidelines considered to trans-contextual adaptation.

Ethical aspects and conflict of interest

All the references in the list were cited. The authors declare that the study does not have any conflict of interest.

Author contributions

DJ: study conception and design, analysis and interpretation of data, supervision, draft of manuscript. PŽ: data collection, analysis and interpretation of data, critical correction of manuscript.

Acknowledgement

This work is dedicated by project SGS23/LF/2013 Adaptation and validation of clinical guidelines: Clinical guideline Prevention of pressure ulcers and Clinical guideline Prevention of catheter-associated infection.

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