

***NorthStar*, a support tool for the design and evaluation of quality
improvement interventions in healthcare**

Elie A. Akl¹, Shaun Treweek², Robbie Foy³, Jill Francis⁴, Andrew D Oxman⁵

On behalf of the ReBEQI group

¹ Department of Medicine, State University of New York at Buffalo, USA

² Tayside Centre for General Practice, Community Health Sciences Division, University of Dundee, UK

³ Centre for Health Services Research, Newcastle University, UK

⁴ Health Services Research Unit, University of Aberdeen, UK

⁵ Norwegian Knowledge Centre for the Health Services, Oslo, Norway

Corresponding author: Elie A. Akl

Email addresses:

EAA: elieakl@buffalo.edu

ST: stweek@mac.com

RF: R.C.Foy@ncl.ac.uk

JF: j.francis@abdn.ac.uk

ADO: oxman@online.no

Abstract

Background: The Research-Based Education and Quality Improvement (ReBEQI)

European partnership aims to establish a framework and provide practical tools for the selection, implementation and evaluation of quality improvement (QI) interventions. We describe the development and evaluation of the software tool *NorthStar*, a major product of the ReBEQI project.

Methods: We focused the content of *NorthStar* on the design and evaluation of QI interventions. A lead individual from the ReBEQI group drafted each section and at least two other group members reviewed it. The content is based on published literature as well as material developed by the ReBEQI group. We developed the software in both a Microsoft Windows HTML help system version and a web-based version. We surveyed 33 potential users to evaluate the perceived utility and acceptability of *NorthStar*.

Results: *NorthStar* consists of 18 sections covering the design and evaluation of QI interventions. The major focus of the intervention design sections is the use of determinants of practice while the major focus of the intervention evaluation sections is the cluster randomised trial design. The two versions of the software can be transferred by email and on CD, and downloaded from the Internet. The software offers easy navigation and various functions to access the content. Potential users (55% response rate) reported above moderate levels of confidence in carrying out QI research related tasks with *NorthStar* particularly developing a protocol for a cluster randomised trial

Conclusions: *NorthStar* is a single, accessible practical and acceptable tool to assist developers and evaluators of QI interventions.

Background

Clinical evidence is essential to enhance the delivery of care and improve patient outcomes. Yet the transfer of research findings into clinical practice tends to be a slow and haphazard process. One of the central aims of quality improvement (QI) activities is to enhance such transfer. In spite of the growing body of rigorously conducted studies on the effectiveness of various QI strategies [1], the strategies selected for QI activities tend to be based more upon prevailing disciplinary customs and habits than scientific evidence and explicit rationales [2, 3].

In 1999 the European Commission (EC) published a report that considered various ways of improving the effectiveness and efficiency of European health care systems [4]. The report recommended the prioritization of work to inform strategies for the effective dissemination and implementation of research findings. The Research-Based Education and Quality Improvement (ReBEQI) partnership group set out to improve QI work and respond to the EC recommendations [5]. The group comprised seven partners in six European countries (Appendix) each with substantial experience of QI research [6]. The group developed the ReBEQI project, a three year project (Dec 2002 - Nov 2005) funded by the European Commission's Quality of Life and Management Living Resources 5th Framework Program. The ReBEQI project had two objectives:

1. To establish a framework for the selection, implementation and evaluation of interventions aimed at improving clinical practice.
2. To provide clinicians, policy-makers and researchers with a suite of evidence-based, Internet tools to make it easier to transfer research findings into clinical practice.

In this paper we report the guiding principles, content development, software development and evaluation of *NorthStar*, a major product of the ReBEQI project. *NorthStar* is a piece of software that packages information on the design and evaluation of evidence-based QI interventions into a single, easily accessible and practical tool.

Methods

Guiding principles

The development of *NorthStar* was based upon four principles. First, the information and tools it offers need to be evidence-based - whilst being explicit about the limitations of existing evidence. Second, the searches for information and items to populate the *NorthStar* framework need to be pragmatic and focused rather than comprehensive. Third, *NorthStar* has to be appropriate to the varying needs of its target audience. Fourth, *NorthStar* has to be simple to read and navigate to ensure its relevance, acceptability and usefulness.

Content development

The target audience of the tool is QI researchers, healthcare professionals and managers responsible for developing, delivering and evaluating continuing education (CE) and QI programmes at a national or regional level. Consequently, the two areas we covered were the design of QI interventions and their evaluation. The intention was for the tool to be useful to both experienced and novice users and for the text to be instructional as well as informative. For example, when describing the different types of cluster randomised

controlled trials (cluster RCT), in addition to outlining the features of each type, the text would guide the user with regard to when the use of each design might be appropriate.

A lead individual from the ReBEQI group was identified for each section of the tool according to individuals' expertise. This lead person took responsibility for preparing the first draft of that section based on a review of the published literature as well as material developed for the ReBEQI project. At least two other ReBEQI members reviewed the section. An editor ensured that the different sections were consistent with regard to content, structure and writing style. All group members reviewed the final version for wider feedback and final approval.

The content builds on the framework developed by ReBEQI for the selection, implementation and evaluation of QI interventions. It emphasises the role of “determinants of practice” in designing the intervention and the cluster RCT as the preferred evaluation study design. The *NorthStar* section on cluster RCTs is based in part on the Trial Protocol Tool, a product of the Pragmatic Randomized Controlled Trials in HealthCare (Practihc) group [7].

Software development

We developed *NorthStar* as a Microsoft Windows HTML help system, the standard help system used with Windows 95 and above. This choice gives the tool a familiar Windows interface and provides a range of off-the-shelf functionality. The software for running Windows HTML help, including Internet Explorer upon which it relies, is part of the

Windows operating system. The basic HTML help development tool, Microsoft HTML Help Workshop, is available free from Microsoft's website. We also created a web-based version using chm2web by A!K Research Labs (<http://chm2web.aklabs.com/>) that is platform-independent and works with any modern browser.

For the content, we created HTML versions of Word documents using Mozilla 1.4 for Mac OS X. We then linked the HTML documents to the help system in HTML Help Workshop. The HTML documents themselves can contain links to the full spectrum of electronic document formats and can, therefore, include not only textual information but graphics, documents created by other programs, sound, video, links to websites and other programs. Once the HTML documents have been added or updated, the collection is compiled into a single file (a .chm file). The compiled .chm file included the main text of *NorthStar*, while we kept accompanying documents such as pdf or Word files as external files in the same folder as the compiled .chm file.

Evaluation

We undertook a questionnaire survey of two groups of potential *NorthStar* users. The first group comprised eight postgraduate students attending a research methodology course in Göteborg, Sweden. The course focused on the planning of intervention studies within the broader context of health systems research. The second group consisted of 25 individuals, nominated by the seven ReBEQI partners, responsible for developing, delivering and/or evaluating CE and QI activities. Most of them were based in the ReBEQI partner countries. We surveyed the first group during a class session in 2006 and

contacted the second group using email over 2005-2006. We sent non-responders one email reminder two weeks after the initial contact.

We asked respondents to spend around twenty minutes browsing *NorthStar* and then fill out a questionnaire. First, we asked respondents about their main professional roles, their roles in CE and QI, and their experience in QI research. We then asked them to estimate the time spent browsing *NorthStar* and which sections they spent most time looking at. We also asked respondents to use a 7-point scale (with 1 representing 'not at all' and 7 'a lot.') to rate their level of confidence, with the use of *NorthStar*, in carrying out ten named tasks relevant to QI research. A final question requested open-ended feedback on the format and user-friendliness of *NorthStar*. A copy of the questionnaire is available online from Implementation Science website. We used descriptive statistics to report aggregated responses from the two groups because of the relatively small number of participants from each.

Results

***NorthStar* Content**

NorthStar consists of 18 sections covering the design and evaluation of QI interventions. After two introductory sections (**About *NorthStar*** and **Introduction**) *NorthStar* discusses how to involve stakeholders (**Stakeholder involvement**). It then examines how to identify and select priorities in order to use resources efficiently (**Priority setting**). Next, it provides guidance on how to identify, critically appraise, adapt and develop relevant clinical practice guidelines (**Clinical Practice Guidelines**). It also discusses the

why, what and how of measuring baseline performance defined as the measurement of actual clinical practice and its comparison to desired clinical practice (**Measuring baseline performance**).

NorthStar discusses what the determinants of practice are and how to identify them using both explorative methods and theory based methods (**Identifying determinants of practice**). It then provides guidance on what intervention strategy to use, and how to select determinants of practice and use them to tailor the intervention (**Designing the intervention**).

NorthStar assists the user in the choice of appropriate study design to test the QI intervention (**Choosing the study design**). It then discusses the usefulness, limitations and types of pilot studies (**Pilot studies**). The major section of *NorthStar* is dedicated to the development of protocols for cluster RCTs (**Cluster RCT protocol tool**). Next, it examines when to use and how to design an interrupted times series evaluation (**Interrupted time series evaluation**). *NorthStar* reviews two other types of evaluation (**Process evaluation** and **Economic evaluation**). It also provides guidance on how to form or identify networks of QI researchers, health professionals, health service managers and policy makers (**CE and QI programs**). Finally *NorthStar* provides useful resources (**Glossary, Libraries** and **Web Resources**). Table 1 shows the general outline of each of these sections.

***NorthStar* software**

NorthStar is available as an HTML Help system or as a browser-based version. The Figure shows a sample screenshot from the browser-based version of *NorthStar*. Both versions can be transferred by email and on CD, and downloaded from the Internet (www.rebeqi.org). Once downloaded, neither version of *NorthStar* requires an Internet connection for use although, of course, the links to websites will not work. The current version (14/7/2006) of the tool comprises a compiled .chm file (808 kB), an external set of libraries (9.2 Mb), and a collection of other supporting external material (6.8 Mb). Significant amounts of *NorthStar* are also being translated into French and Italian.

The user can access the content of *NorthStar* using one of many functions in the help file:

1. *Contents*: an outline at the left helps the user to locate what she needs. “Books” can be expanded or collapsed by clicking on the +/- sign to the left of the book symbols.
2. *Search*: the user can search for words anywhere in the text.
3. *Hypertext*: the hypertext links help to navigate *NorthStar*, for example by bringing up relevant definitions or explanations in the glossary, examples or illustrations.
4. *Print*: selecting Print in the browser or from the Windows Help system will print the contents of the main *NorthStar* window.
5. *Libraries*: these can be accessed from the Libraries menu at the top of the screen or from the bottom of the contents and include: checklists, an annotated bibliography of key methodological papers, structured abstracts of selected references, summaries of key theories, and examples of protocols and final reports of evaluations of QI interventions.

***NorthStar* Evaluation**

Eight from the student group and ten from the ReBEQI nominees responded to the survey (total response rate 18/33; 55%). One respondent from the ReBEQI group used free text so we included only 17 responses in the quantitative analysis.

Fourteen (82%) respondents described themselves as health care researchers and nine (53%) reported intermediate levels of experience in QI research. The mean time spent browsing *NorthStar* was 20.6 minutes. Participants spent most time looking at 'identifying determinants of practice' (8/17; 47%) and 'designing the intervention' (6/17; 35%). The levels of confidence in carrying out, with the use of *NorthStar*, the ten tasks related to QI research, were all above the mid-point of the scale (i.e. four; Table 2). Respondents indicated greatest confidence in being able to develop a protocol for a cluster randomised trial (mean 5.7) and least confidence in being able to involve stakeholders in QI research and measuring baseline performance (both means 4.9).

Respondents generally made positive comments about the format and user-friendliness of *NorthStar* (illustrative comments in the Box). Some also mentioned technical problems around its use whilst others questioned its driving focus on RCTs as the 'gold standard' method for evaluating quality improvement strategies.

Discussion

NorthStar is a tool that aims to help the development and evaluation of interventions to improve the quality of healthcare. Its intended targets include QI researchers and

healthcare professionals and managers responsible for developing, delivering and evaluating CE and QI programmes at a national or regional level.

NorthStar has a number of strengths. The work reflects the collective experience of several established European inter-disciplinary collaborations but is also based on recent literature reviews and the ReBEQI group's own innovative methodological work. The development of the content was based on systematic processes of drafting, reviewing and editing. The resulting content is simple to read, pragmatic and focused on assisting the user in developing and evaluating the QI intervention. In addition *NorthStar* is available as both a browser-based version and an HTML help file version and will soon be available in French and Italian as well as English.

NorthStar has, however, a number of limitations. Because of the limitations of the existing evidence, many recommendations within *NorthStar* are based on pragmatic interpretations of that evidence. We used structured rather than systematic reviews to draft sections – although these drew upon systematic reviews. We do intend to incorporate into *NorthStar* further evidence on the effectiveness of QI strategies, as it becomes available.

Our modest evaluation suggests that *NorthStar* will form a useful reference and educational tool for QI research in general and developing a protocol for a cluster randomised trial in particular. Potential users seemed mostly interested in the sections around identifying determinants of practice and the design of interventions – which are

both recognised as challenges requiring greater attention in the implementation field [8]. However, one should treat these results cautiously. In fact, we have not evaluated the impact of the use of *NorthStar* on the processes of development and evaluation of QI interventions. Our evaluation was also restricted to a relatively small number of potential users. Although just over half of those contacted responded, our final sample did contain a spectrum of different levels of experience in QI research. It is also possible that actual or perceived technical barriers to using *NorthStar* put off some potential users.

Conclusions

NorthStar is a single, accessible and practical tool to assist QI researchers and healthcare professionals and managers responsible for developing, delivering and evaluating CE and QI programmes at a national or regional level. Our initial evaluation is broadly positive. In its current form *NorthStar* appears to be of greatest benefit to QI researchers.

Availability and Requirements

Project homepage

www.rebeqi.org

NorthStar is available from the 'Tools and databases' menu.

Operating system

Windows HTML Help version works in Windows 95 and above.

Web-based system works with Linux, Mac OS 9/OS X and Windows.

Other requirements

Windows HTML Help requires that Internet Explorer version 3 or above is installed. The browser-based version requires nothing more than a modern browser.

License

ReBEQI is happy to have its products used for personal and non-commercial use and at no charge in free educational programmes. However, when tuition is charged, ReBEQI royalty fee is 10% of gross receipts. If you are planning to use *NorthStar* within a for-profit organisation in any way, please contact us to discuss a donation to our work.

Competing interests

'The authors declare that they have no competing interests.

Authors' contributions

All authors participated in the development and evaluation of *NorthStar*. EAA and RF were the content editors. ST was responsible for the technical development of *NorthStar*. ADO was the central coordinator of the project. All authors read and approved the final manuscript.

Acknowledgements

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The ReBEQI partner managers are listed in the Appendix. A full list of individuals who have contributed to *NorthStar* is given in the Acknowledgements page of *NorthStar*.

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Appendix. Countries, partner organisations and partner managers of the ReBEQI project

France: Santé Publique et Informatique Médicale (SPIM), Faculté de Médecine

Broussais - Hôtel Dieu, Paris. Partner manager – Pierre Durieux

Italy: Unit of Clinical Governance, Agenzia Sanitaria Regionale (Regional Health Care Agency) of Emilia-Romagna, Bologna. Partner manager – Roberto Grilli

Italy: Center for the Evaluation of Effectiveness of Health Care (Ce.V.E.A.S.), Modena. Partner manager – Alessandro Liberati

The Netherlands: Centre for Quality of Care Research, University of Nijmegen. Partner manager – Richard Grol

Norway: Norwegian Health Services Research Centre, Oslo. Partner manager – Andy Oxman

Sweden: Division of International Health, Department of Public Health Sciences, Karolinska Institutet, Stockholm. Partner manager – Cecilia Stålsby Lundborg

United Kingdom: Centre for Health Services Research, University of Newcastle, Newcastle. Partner manager – Martin Eccles

Table 1. The general outline of NorthStar sections

This section contains the following	An outline of the section
Introduction	One or two paragraphs introducing the topic
Things to consider	Checklists; background information; protocol considerations (relating to writing the trial protocol); and practical considerations (relating to implementing the intervention)
Illustrative examples	Examples taken from protocols or final reports of cluster RCTs of QI interventions. They show either different aspects of the topic or how different studies addressed the same aspect
References	Journal articles or books referenced in the text
Resources	Useful documents (accessible directly in NorthStar), links to websites, software, and recommended further reading (brief and sometimes annotated bibliography of key references)

Table 2. Respondents' self-rated confidence in, with the use of NorthStar, carrying out tasks relevant to quality improvement research.

Task	Mean (range)
Involve stakeholders in quality improvement intervention research	4.9 (3-7)
Identify and select priorities in order to use resources efficiently	5.2 (4-6)
Critically appraise clinical guidelines	5.1 (4-7)
Measure baseline performance (defined as the measurement of actual clinical practice and its comparison to desired clinical practice)	4.9 (3-6)
Identify determinants of clinical practice	5.2 (4-6)
Decide what intervention strategy to use to improve the quality of care	5.4 (4-7)
Choose an appropriate study design to evaluate a continuing education or quality improvement strategy	5.5 (5-7)
Develop a protocol for a cluster randomised trial	5.7 (5-7)
Conduct a process evaluation	5.2 (4-6)
Design an interrupted time series evaluation	5.1 (4-6)

*Based on a 1-7 scale where 1=not at all confident and 7=very confident

Box. Illustrative comments on user-friendliness, format and other features of NorthStar.

User-friendliness	<p><i>Very impressive in its scope and quality but it's not always clear who the audience for the tool is</i></p> <p><i>It is indeed a very beautiful tool I found it user friendly, and particularly liked the sample-size calculation module for cluster randomization</i></p> <p><i>Consider developing a more detailed tutorial (in parts) to walk individuals through how to use NorthStar to its fullest capability</i></p> <p><i>My computer crashed twice when trying to access pdf files</i></p>
Format	<p><i>[NorthStar] provides a clear overview, helps me think in a constructive and orderly fashion about what I need to do, and leaves me inspired.</i></p>
Content	<p><i>I can see the purpose in encouraging people as often as possible to conduct randomised trials of QI initiatives, but in fact most evaluation will not be done in this way, and I'm not sure that those seeking to use NorthStar for the less rigorous designs will be well served</i></p> <p><i>I think you risk misleading people with that stated aim [..targeted at quality improvement researchers and healthcare professionals and managers..] - it looks great for researchers, but not for anyone else</i></p> <p><i>Service quality improvers ... are unlikely to want to 'test' interventions in the formal sense, but they might want help with choosing interventions and testing their effect in their own particular contexts</i></p>



- [-] ? About NorthStar
- [+] Introduction
 - [-] Stakeholder involvement
 - [-] Priority setting
- [+] Clinical practice guidelines
 - [-] Measuring baseline performance
- [+] Identifying determinants of practice
- [+] Designing the intervention
- [+] Choosing the study design
- [-] Pilot studies
- [-] Cluster RCT protocol tool
 - [-] Summary
- [+] Introduction
 - [-] The research question
 - [-] Trial population
 - [-] Allocation
 - [-] Interventions
 - [-] Outcome Measures
 - [-] Post-recruitment Retention Strategie
 - [-] Safety Monitoring and Adverse Even
 - [-] Data Management
 - [-] Sample size
 - [-] Analysis
 - [-] Ethical aspects of cluster RCTS
- [-] Trial Management
 - [-] Registering the trial
 - [-] **Managing the trial**
 - [-] Local coordination
 - [-] Research governance and good c
- [+] Reporting, dissemination and notifica
 - [-] References
- [+] Interrupted time series evaluation
- [+] Process evaluation
- [+] Economic evaluation
- [+] CE and QI programs
- [+] Glossary
- [+] Libraries
- [+] Web Resources

Managing the trial

This section contains the following:

- Introduction
- Things to consider
 - Trial Co-ordinating Centre
 - Trial Steering Group
 - Data Monitoring Committee
 - Protocol considerations
- Resources
 - Software
 - Useful documents
 - Links to websites
 - Further reading

Introduction

The trial management plan should include an outline of the arrangements for the day-to-day running of the trial (Trial Co-ordinating Centre), the supervision of the trial (Trial Steering Group) and monitoring of the trial (Data Monitoring and Safety Committee). It should also describe who will be responsible for essential activities, such as staff recruitment, supplying treatment, and data management. The management plan should set achievable targets (See [Gantt chart tool](#)), provide the framework for building an enthusiastic and efficient team, and detail and justify the necessary resources for delivering a successful trial.

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Things to consider

Trial Co-ordinating Center

Any substantial trial requires a Trial Co-ordinating Center to handle administrative matters once participants are being entered. This is usually the base for the Trial Management Group. A typical Trial Management Group