Quality Improvement in Acute Coronary Care

Combining the Use of an Interactive Quality Registry with a Quality Improvement Collaborative to Improve Clinical Outcome in Patients with Acute Myocardial Infarction

RICKARD CARLHED
Dissertation presented at Uppsala University to be publicly examined in Enghoff salen, Uppsala University Hospital, Entrance 50, Uppsala, Friday, October 26, 2012 at 13:00 for the degree of Doctor of Philosophy (Faculty of Medicine). The examination will be conducted in English.

Abstract


The quality of care for Swedish patients with acute myocardial infarction (AMI) is continuously increasing. Nevertheless, a great potential for improvement still exists.

The aim of the present study was to design and implement a systematic quality improvement (QI) collaborative in the area of AMI care, and to validate its usefulness primarily by analyzing its effect on hospital adherence to national guidelines. Also, the impact on patient morbidity and mortality was to be evaluated. The intervention was based on proven QI methodologies, as well as interactive use of a web-based quality registry with enhanced, powerful feedback functions.

19 hospitals in the intervention group were matched to 19 similar control hospitals. In comparison with the control group, the intervention group showed significantly higher post-interventional improvements in 4 out of 5 analyzed quality indicators (significance shown for ACE-inhibitors, Clopidogrel, Heparin/LMWH, Coronary angiography, no significance for Lipid-lowering therapy).

From baseline to the post-intervention measurement, the intervention hospitals showed significantly lower all-cause mortality and cardiovascular re-admission rates (events per 100 patient-years; -2.82, 95% CI -5.26 to -0.39; -9.31, 95% CI -15.48 to -3.14, respectively). No significant improvements were seen in the control group.

The improved guideline adherence rates in the intervention hospitals were sustained for all indicators but one (ACE-inhibitors), this during a follow-up measurement three months after study support withdrawal. No effects were seen on any indicators other than those primarily targeted.

In conclusion, by combining a systematic QI collaborative with the utilization of a national quality registry, significant improvements in quality of care for patients with AMI can be achieved.

Keywords: Quality Improvement, Quality Registry, Acute Coronary Care, Guideline Adherence

Rickard Carlhed, Uppsala University, Department of Medical Sciences, Cardiology, Akademiska sjukhuset, SE-751 85 Uppsala, Sweden.

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It is not enough to do your best; you must know what to do, and then do your best.

W. Edwards Deming

Dedicated to my beloved children, Elliot and Andrea, the sparkling stars in my universe.
List of Papers

This thesis is based on the following papers, which are referred to in the text by their Roman numerals.


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Abbreviations

ACE-I  Angiotensin converting enzyme
AMI    Acute myocardial infarction
ASA    Acetyl salicylic acid
CCU    Coronary care unit
CHF    Congestive heart failure
CV     Cardiovascular
CVD    Cardiovascular disease
IHI    Institute for Healthcare Improvement (USA)
LMWH   Low molecular weight heparin
LVEF   Left ventricular ejection fraction
NSTEMI Non ST – Elevation Myocardial Infarction
PCI    Percutaneous Coronary Intervention
QI     Quality improvement
RIKS-HIA Registry of Information and Knowledge about Swedish Heart Intensive Care Admissions
STEMI  ST- Elevation Myocardial Infarction
SWEDEHEART Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies
INTRODUCTION

Cardiovascular diseases (CVD) are the world’s largest killers, according to the World Health Organization globally claiming 17.1 million lives a year \[^1\]. In Sweden, 12% of the population suffers from these disorders, and 17% of all hospital-bound care episodes are due to CVD. CVD also is the most common cause of death, and stands for about one fourth of all deaths, the same level as all cancer-related deaths put together. Among the separate diagnoses of CVD, acute myocardial infarction (AMI) is responsible for the most fatalities. Of all deaths among men, AMI stands for 16%, and the same figure among women is 11%\[^2,3\].

When the annual costs for in-hospital care, medical treatments and coronary interventions are put together, it sums up to about 8.5 billion Swedish kronor\[^3\]. From the facts above, it is obvious that the demands on the healthcare organizations are two-sided: First, to decrease the CVD morbidity and mortality, the care must be of highest possible quality. But, at the same time, in order to spare patients from harmful side effects and avoid waste of resources, overtreatment must to be avoided.

The amount of information gained from medical, scientific research is overwhelming, and also increasing in an accelerating rate. This makes it hard for a medical practitioner to be up-to-date with the current evidence-based knowledge in a given medical field. As a means to manage this information overflow, and to improve and standardize the quality of care, various national and international health-care organizations compile the most relevant knowledge and then publish evidence-based guidelines.

In the case of AMI guidelines, the clinician can find reliable, stringent and updated recommendations on how to manage a patient suffering from an acute myocardial injury in an optimal way.

National as well as international surveys have shown that the quality of care in the AMI area has been continuously improving during the last decades \[^4-8\]. But, on the other hand, there still is a surprisingly large gap between the guideline recommendations and the actual performance levels in the care given. As a high level of guideline adherence has been shown to improve
clinical outcome\textsuperscript{[9-14]}, continued efforts must be made to achieve further improvements in the quality of care for the AMI patients.

In the present study, we evaluated the effect of a multi-centre and controlled quality improvement (QI) intervention aimed to increase the adherence to the Swedish AMI guidelines.
BACKGROUND

RIKS-HIA / SWEDHEART

In 1991, the Swedish quality registry RIKS-HIA (Registry of Information and Knowledge about Swedish Heart Intensive Care Admissions) was launched. From the start a few pioneering hospitals participated, but in 1995 the registry had expanded and became a national registry in the AMI area. In 2003, when the QUICC study was initiated, 73 out of a total of 78 Swedish hospitals with AMI care facilities participated and entered data into the registry. With this coverage, clinical data for more than 95% of all Swedish patients admitted to a coronary care unit (CCU) was at hand in the registry.

For each patient admitted to the CCU, about 110 separate variables are entered into the registry. These variables cover demographics, risk-factors, previous diseases, examinations, medications, interventions, time-delays and diagnoses.

The participating hospitals enter their data over the Web, and consequently, immediate performance feedback can be generated. In this way, local trends over time as well as comparisons with national averages and other centers may be presented. For this study, the feedback functionality in RIKS-HIA was further enhanced to facilitate powerful statistical analyses and distinct presentations of current local performance levels. A presentation of the RIKS-HIA technology is available at http://www.ucr.uu.se.

Up to 2008, separate annual reports were published by four Swedish quality registries covering different aspect of cardiovascular diseases. Besides RIKS-HIA these registries covered coronary angiography, coronary surgery and secondary prevention in cardiac intensive care.

As these registries both overlapped and also had a great potential to complement each other, the Swedish Association of Local Authorities and Regions (SALAR) that finances the registries put forth a demand that the registries were to be merged. This new registry, Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies (SWEDHEART), has been fully operative since 2010[15].
Clinical practice guidelines

Due to the vast and increasing amount of scientific knowledge about how to care for patients in an optimal way, a more condensed and accessible source of information is needed to aid the healthcare providers in clinical decision making. As a means to facilitate both the distribution and assimilation of the evidence-based and up-to-date recommendations, many organisations have made great effort to develop clinical practice guidelines.

The Institute of Medicine (USA) has made the following distinct definition of clinical practice guidelines: "Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." [16]

In Sweden, acting under a commission by the Swedish Government, the National Board of Health and Welfare published the first national guidelines for coronary care in 1996. The most recent was published in 2008 [17].

Other examples of influential national AMI guidelines are those published jointly by the American organizations American Heart Association (AHA) and American Collage of Cardiology (ACC) [18]. In Europe, the European Society of Cardiology has published several guidelines in the field of cardiology (Available at: http://www.escardio.org/guidelines ). As an example, a guideline for the management of patients with ST-elevation myocardial infarction (STEMI) was published in 2008 [19].

Quality indicators

A quality indicator used in health care is a measure that is meant to assess the quality performance of care, and can be used both by the public and the authorities for comparisons at multiple levels in the health systems, nationally as well as internationally [20]. In this circumstance, the term performance measure is a commonly used synonym.

The use of quality measures in health care has increased rapidly, and is now in use in most clinical areas in the majority of different global health care systems. With this widespread use, it is remarkable how recent it was that they actually came into use [21]. One of the very first national programs to measure hospital quality was originated in the United States in 1998, when the Joint Commission launched an initiative where hospitals were required to report only non-standardized data. Four years later, a standardized set of core measures were developed, this in four areas (acute myocardial infarction, heart failure, pneumonia, and pregnancy); a report from this survey was made public in 2004 [22].
In Sweden, the National Board of Health and Welfare in 2005 was requested by the Swedish Government to establish national quality indicators for the health care system as a whole. A full report from this was presented in 2009[23]. Before that, several separate clinical disciplines had developed their own indicators, often derived from indicators already listed in discipline-specific, national guidelines and often also included in the national quality registries that by then had been used for some years.

Without doubt, no quality improvement initiative, in any given area, can ever be successful if a sound process of selection, registration and evaluation of proper data does not occur [24]. From this, quality indicators also come into use when different improvement activities are to be initiated, since QI activities naturally focus on areas where the indicators have revealed poor performances. Subsequently, after completion, the QI efforts can be followed up by analysing the same indicators.

For the indicators to be applicable, it is essential that they are apparent, reliable, measurable, accepted and possible to record in different registries [17, 25].

The different national AMI guidelines cited above all presents several quality indicators reflecting different aspects of the AMI care processes. As the guideline-derived quality indicators usually are correlated to specific medical treatments or interventions, they can be graded according to the proven importance of the treatment they correlate to. From this, evaluations of the performance levels of any given healthcare organization usually are based on high rank (Class I) quality indicators [18]. Higher quality of AMI care, as verified by better performance based on these AMI quality indicators, has been shown to be associated with improved outcome[12].
Trends in AMI quality of care

Consecutive annual data compilations and presentations from RIKS-HIA have shown a continuous improvement of the hospital AMI care performance levels. An illustration of this is shown below (Fig. 1)

Figure 1. Proportion of Swedish AMI patients with STEMI or LBB where coronary angiography is performed. (RIKS-HIA 2007)

The continuous improvements in Swedish AMI quality of care are concordant with similar trends in Europe and USA, reflecting the fact that local treatment activities to a great extent are based upon internationally derived and distributed evidence-based recommendations [4-8].

As a result of these advances in treatment activities as well as improved diagnostic procedures, the clinical outcome also has improved [5-7, 26, 27]. As a good example of this, another presentation from RIKS-HIA concerning 30-day mortality is shown in Figure 2. Here, an obvious improvement is seen during the period 1995 to 2007.
Consequently, the quality of AMI care is generally improving, but these surveys have on the other hand shown that unacceptable treatment inequalities still exist, this with respect to age\cite{28-30}, race\cite{31, 32}, geographic location\cite{33,34}, and concurrent serious co-morbidities\cite{29, 35-37}. But, encouraging findings from the US-based group behind the Get With the Guideline-program show that a national QI effort might decrease these disparities\cite{38,39}.

In international surveys, also gender-related disparities have been shown\cite{29,31}, this in contrast with Swedish data were gender has no effect on treatment intensity\cite{40}.
Deviations from AMI guideline recommendations

Even though the quality of AMI care is steadily improving, and the correlated cardiac morbidity and mortality is decreasing, all hospitals still have a good opportunity for major improvements in most areas. Even in the best performing hospitals, it is common that no more than two thirds of the patients receive a recommended treatment. An example of this is shown in Figure 3.

These deviations from evidence-based recommendations is a problem not only in the Swedish AMI care, since numerous international surveys have reported similar shortcomings\(^{[41-43]}\).

\[\text{Figure 3. Treatment with ACE-inhibitors in AMI patients}\]

In addition to the inter-hospital variation described above, it is also apparent that there generally is significant intra-hospital variations over time\(^{[44]}\). In Fig.4, a typical example of this phenomenon is illustrated.
Earlier QI interventions in AMI care

Since deviations from evidence-based guideline recommendations have been shown to increase both mortality and morbidity\cite{10,45,46}, it is of utmost importance to improve the adherence to these AMI guidelines. With this aim, a handful of earlier quality improvement programs have been implemented.

In these, mere publications of guidelines\cite{47} and other forms of passive diffusion of educational information\cite{48} have been insufficient to improve clinical practice patterns. In a Cochrane Database Review (2008) of 23 studies, production of and a passive diffusion of Printed Educational Material showed a small effect on process outcome, but no effect on patient outcome\cite{49}.

The use of critical pathways has shown limited results\cite{50,51}, and local implementations have been difficult to disseminate to other areas. This latter weakness has been explained by the fact that the designs often depend upon local conditions such as available resources, staff, equipment, training, and the characteristics of the target population\cite{52}.

Another quite common attempt to disseminate the evidence-based knowledge is by the formal continuing medical education programs, but evaluations of these programs also has been discouraging\cite{53,54}. When feedback on the local hospital performances has been distributed to the specific care-
givers, the results have been weak and varying\textsuperscript{[55-57]}. Also, the assumption that public release of hospital performance data would stimulate hospitals to undertake QI activities has unfortunately been proved inaccurate\textsuperscript{[58, 59]}.

As the healthcare sector, like any other, is strongly influenced by economic incentives, a model where care-givers are financially rewarded with a pay-for-performance strategy is appealing. But, when such approaches have been evaluated, no significant quality improvements have been evident\textsuperscript{[60,61]}.

Thus, these previous studies were based on somewhat restricted approaches, and at best, had modest results. Instead, it has been shown that more successful QI interventions usually have been based on multifaceted approaches where multiple techniques and tools have been used in combination\textsuperscript{[62]}.

When, for example, the distribution and assimilation of performance feedback has been associated with subsequent local improvement activities, positive results have been noted\textsuperscript{[63, 64]}.

In the AMI area, a handful of studies have been based on various proven quality improvement (QI) strategies, such as the collaborative approach described in the Breakthrough Series developed by the Institute of Healthcare Improvement (IHI)\textsuperscript{[65]}.

In the Guideline Applied in Practice (GAP) QI initiative, which was based on a multidisciplinary QI collaborative, results from the initial implementation indicated improved guideline adherence rates\textsuperscript{[66]}. As an evaluation of the initial study indicated that use of guideline-based tools was positively correlated with higher guideline adherence rates, a follow-up study was designed with a greater emphasis on tool use. Here, the results verified that when barriers to tool use were identified and overcome, even higher adherence rates were achieved\textsuperscript{[67]}. In a more recent follow-up on the GAP initiative, a real-time performance feedback functionality was added to the GAP toolbox. With local hospital use of this addition, the improvements were further increased\textsuperscript{[68]}. From the same study, it has also been shown that improved guideline adherence rates in the GAP participating hospitals correlate to a decreased 1-year mortality\textsuperscript{[69]}.

Another, still on-going QI program for coronary disease is the Get-With-the-Guidelines (GWTG) initiative. This also is based on a collaborative model and includes a web-based, interactive Patient Management Tool (PMT) that provides patient-specific guideline information and tracks a specific hospital’s performance\textsuperscript{[70]}. Hospitals participating in the GWTG initiative have been shown to perform at a higher guideline adherence rate\textsuperscript{[71,72]}.
A third example is the CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the ACC/AHA Guidelines) QI initiative. In that initiative, participating centres entered patient data into an observational registry, and from this local feedback was generated and presented to each centre. Also, a Toolbox consisting of pocket cards, posters, standardized orders and discharge checklists was a central part of the intervention\cite{73,74}. Improved adherence rates as well as a positive impact on in-hospital mortality have been presented\cite{10}.

Though the results from these more elaborate QI interventions have been positive, regarding adherence rates as well as clinical outcomes, they all have a weakness due to the fact that they have been designed without properly selected control groups. From this, it has been difficult to confirm that the positive results have been due to the QI intervention itself, and not mere consequences of ongoing temporal trends.
AIMS OF THE STUDY

The aims of the study was to investigate to what extent a national, controlled, multicentre study based on proven quality improvement methods and the use of an enhanced interactive quality registry could improve the adherence to national guidelines for acute myocardial infarction (AMI).

More specific post-intervention aims were to evaluate:

- If AMI patients are more optimally treated with ACE-inhibitors, lipid lowering therapy, heparin/LMWH and clopidogrel according to the national guidelines.

- If more AMI patients are evaluated with coronary angiography.

- If the assumed positive effects in the previous two paragraphs are sustained over time.

- If improvements in adherence to the guidelines corresponds to improvements in clinical outcome (mortality, cardiac morbidity, bleeding complications).

- If any difference can be observed when two intervention models are compared, one somewhat more resource-demanding, and the other partially internet-based.

- If positive side-effects are observed, i.e. if the performances in other, adjacent treatment modalities also improve.
METHODS

Patients and hospitals
All consecutive patients younger than 80 years at admittance and with a discharge diagnosis of AMI (I21, International Classification of Diseases, 10th Revision) were eligible, and included. The age limit was used as a means to reduce for the effects of confounding factors that were difficult to control for, such as co-morbidities, multiple prescription medications and also known variations in the tendency to admit the very oldest patients to the CCUs.

All hospitals in Sweden managing patients with AMI, entering patient data into RIKS-HIA, and annually accounting for at least 80 patients with AMI were invited to participate in the QUICC study. Of 21 hospitals accepting to participate, one hospital never started, and another was closed during the study. The remaining 19 intervention hospitals (representing a quarter of all Swedish hospitals with CCUs) were subsequently stratified according to presence of in-house coronary angiography or not, and also according to historical treatment levels. For the latter stratifying parameter, we used a previously scoring system, where 10 key AMI treatments are analyzed. From this, the local performance levels are then graded in a combined activity index. The study hospitals were then stratified according to an activity index above or below the national median level. With these efforts, we achieved a good mixture of hospitals regarding size (which correlates with in-house angiography or not) and historical performance levels.

The control group of hospitals was selected from the remaining hospitals participating in RIKS-HIA. Here, 21 hospitals were matched to the intervention hospitals according to the stratification parameters presented above. These control hospitals were not aware of their status as controls. During the study, one hospital in the control group was closed, and another did not provide data into RIKS-HIA.

In summary, 19 + 19 hospitals were included as intervention and control hospitals, respectively. The intervention group as well as the control group both included 4 hospitals with in-house coronary angiography, 2 university
hospitals, and 10 hospitals with an activity index above the national median level.

RIKS-HIA

The Registry of Information and Knowledge about Swedish Heart Intensive Care Admissions, RIKS-HIA, is a national quality registry which has been in operation since 1991. In 2003, 73 out of a total of 78 Swedish hospitals with CCUs participated and entered data into this registry. With this, more than 95% of all Swedish patients with AMI are included. For each patient admitted to a CCU, about 110 variables are entered into the registry. These variables include demographics, risk factors, previous diseases, examinations, medications, interventions, time delays, and diagnoses.[75]

The participating hospitals enter their patient data over the Web. Consequently, immediate performance feedback may be compiled from RIKS-HIA, and comparisons both locally over time and with the national median levels can easily be generated. For this study, the feedback functionality was further enhanced by the addition of powerful statistical analyses and distinct presentation capabilities of current local performance levels.

Other national databases used in the study

To find out if a patient included at any of the hospitals had died or been rehospitalized during follow-up, other national databases were accessed. Time of death was extracted from the National Population Registry, while information on hospital re-admissions and associated diagnoses were extracted from the Swedish Hospital Discharge Registry. Both of these registries are managed by the Swedish National Board of Health and Welfare, and reporting into the registries is mandatory. The national coverage of the registries has been close to 100% since the 1980’s, and the validity of both registries has been proven to be excellent.

The QI intervention

Before the study intervention was launched, organization managers from each intervention hospital was requested to sign a formal commitment that their teams were to be assured time and other resources to be able to fulfil the expectations put forth by the inclusion in the study. After this agreement, each hospital then selected a multidisciplinary team, typically consisting of two cardiologists and two CCU nurses.
The general design of the present collaborative program has been influenced by proven QI methodologies such as the Model for Improvement\textsuperscript{24}, which in 1995 was adapted for use in health care systems in the Breakthrough Series compiled by the Institute for Healthcare Improvement, Boston, USA\textsuperscript{65,76}. The implementation of QI learning collaboratives often brings substantial improvements in quality of care, as exemplified by some successful QI interventions that have led to improved quality of care for pediatric inflammatory bowel disease\textsuperscript{77}, decreased emergency department waiting times\textsuperscript{78}, improved diabetes management\textsuperscript{79}, improved newborn preventive services\textsuperscript{80}, and decreased health care disparities\textsuperscript{81}.

With these experiences in mind, we designed our QI intervention in the way presented below.

In a randomized approach defined in the study protocol, we wanted to compare two alternative ways of implementing the QI program. One of the alternative schemes would presumably be a more resource-demanding approach with more centralized, face-to-face meetings, while the other scheme, to some extent, instead would rely on an internet-based supportive platform.

From this, the 19 intervention hospitals were randomly divided into two subgroups, A and B.

During the period of six months (November 1, 2002 through April 30, 2003), teams from both subgroups (A+B) were subjects to a somewhat intense intervention period of initiation, education, training, and implementation.

In Group A, the multi-disciplinary teams were brought together at four learning sessions, this during a period of six months. These sessions were conducted by the study management group, which was composed of experts from different areas such as improvement methodology, project management, and medical expertise in the field of cardiovascular disease.

**Learning Session 1**

At the first meeting, initial reviews of the current state in national AMI care was presented, followed by a discussion about the reasons for the current, suboptimal care for the AMI patients. The Project Vision was presented, which stated that every patient with suspected acute coronary disease would:

“Receive treatment and care according to local and national guidelines, not depending on day of the week, time of the day or which staff is working”.

In the project it was stated that the goal was to reach more than 90\% adherence to AMI guidelines, this in four medical treatments (ACE-inhibitor, lipid
lowering, low molecular weight heparin, and clopidogrel), and in use of coronary angiography. This goal was defined for “ideal patients”, that is patients with indications for each treatment, and at the same time lacking contraindications detectable in the RIKS-HIA registry.

During this session, the teams analyzed their current performance, processes and opportunities for improvement with different tools, such as, for example, brainstorming, process flowcharts, and cause-effect diagrams (Ishikawa)[24]. Furthermore, the importance of continuous measurements of performance levels and rapid feedback was stressed. For this, the teams were trained how to use the RIKS-HIA on-line report functionality, by which they could generate real-time national comparisons, as well as local time-series analysis and performance level measurements.

A take-home task to be finished before the next session was to establish continuous online registration of all patients.

**Learning Session 2**

At the second learning session, the focus was on basic QI methodology, and the Model for Improvement was presented to the teams. In this model, the use of the PDSA cycle[82] is interlinked with three fundamental questions:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What change can we make that will result in improvement?

The first question is designed to build knowledge about the current performance, and what areas are in need of improvements. The answer of the second question guides the teams how to select appropriate measures so that achieved improvements can be verified. Finally, answering the third question requires developing possible changes, a process where the use of the PDSA cycle is central. By this, ideas can be turned into action, and at the same time, action can be connected to learning.

At this session, important exercises were to analyze the measures and local change activities that had been done after Learning Session 1. Another assignment during this session was to create an action plan involving small and incremental changes according to the PDSA cycle.

Before attending at the third session, the teams were required to test and implement the changes described in the action plan in their local settings, and also to measure the impact of those changes.
Learning session 3
What lessons had been learnt so far? A key concept in a QI collaborative is to meet other participants, this to report their changes and results, share experiences, to get some education from experts about change concepts, and also be inspired and guided by successful process changes done at other sites[83]. Therefore, during this session, time was spent on sharing experiences, results and ideas between the teams.

Another topic at this session was to discuss some common barriers to successful implementations of a QI effort. The focus of this discussion dealt with the need of cultural transformation, both at a professional and organisational level[84].

From lessons learnt so far, new change implementations were planned.

Learning session 4
At the last learning session, the teams gave individual presentations of their efforts and achievements. Furthermore, continuous QI activities were discussed and then drafted to comply with local conditions.

For the teams in Group B, a compressed educational program was delivered. Here, only two learning sessions were given, and during the first meeting, the teams went through basically the same material as Group A did at Learning Sessions 1-3. Instead of more gatherings, the Group B teams were supported by a web-based portal, where information was presented, and the teams were able to communicate with the study managers as well as other teams.

Follow-up meetings
The teams from both groups (A + B) were brought together at two follow-up meetings. Here, the teams presented new results, lessons learnt, and ongoing improvement and change plans. The presentations were made both in a written report, and also displayed at a poster session.

In the periods between the learning sessions, the teams from both groups (A and B) had regular site visits and telephone calls from a coach, who assisted in different problems, and also made a follow-up on the progress.

The collaborative phase of the QUICC study is presented graphically in Figure 5.

A more in-depth description of the intervention is given in Paper I.
Timeline

During the baseline period of 12 month, July 1, 2001 to June 30, 2002 (Fig. 6), the pre-intervention performance levels of the quality indicators were retrospectively compiled from RIKS-HIA. Also, all patients included at the intervention and control hospitals during this period were followed until December 31, 2002, which corresponds to a median follow-up time of 12 months.

The intervention described above was carried out during 6 months, were the first 3 months, November 1, 2002 to January 31, 2003, comprised the training period. During the next 3 months, February 1, 2003 to April 30, 2003, the teams were expected to implement the local changes and present their ideas to the other teams.

During the post-intervention period of 12 month (Measurement 1: May 1, 2003 to April 30, 2004), the effect on the performance levels of the local changes at the intervention hospitals were recorded, this by prospective registration in RIKS-HIA. In the same manner as during the baseline period, all AMI patients in the control and intervention hospitals were followed for additionally 6 months, giving a median follow-up of 12 months.

To be able to analyze if the assumed positive effects of the intervention were sustained over time, the performance levels were again evaluated, this after a consolidation period of 3 months. Before this period, all support from the study management group were withdrawn. The re-evaluation period extended over 6 months, August 31, 2004 to January 31, 2005.
Quality indicators

This study focused on 5 quality indicators, each easily measurable by compilations from RIKS-HIA. The evaluation of baseline and post-intervention treatment levels for each of the indicators were based on “target patients”, which is patients with indications for each specific treatment (Table I).

Table 1. Quality indicators used in QUICC

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Eligibility</th>
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</thead>
<tbody>
<tr>
<td><strong>ACE-inhibitor at discharge</strong></td>
<td>Previous CHF; post-infarction CHF; LVEF &lt; 50%; diabetes mellitus; hypertension</td>
</tr>
<tr>
<td><strong>Lipid-lowering therapy at discharge</strong></td>
<td>Low-density lipoprotein &gt; 3.0 mmol/L (116 mg/dL); total-cholesterol &gt; 5.0 mmol/L (193 mg/dL)</td>
</tr>
<tr>
<td><strong>Clopidogrel at discharge</strong></td>
<td>Patients with non ST-elevation MI</td>
</tr>
<tr>
<td><strong>Heparin or LMWH during hospitalization</strong></td>
<td>Patients with non ST-elevation MI</td>
</tr>
<tr>
<td><strong>Performed coronary angiography</strong></td>
<td>Non ST-elevation myocardial infarction with at least one of the following risk factors</td>
</tr>
<tr>
<td></td>
<td>• Diabetes mellitus</td>
</tr>
<tr>
<td></td>
<td>• Previous myocardial infarction</td>
</tr>
<tr>
<td></td>
<td>• ST-segment depression</td>
</tr>
<tr>
<td></td>
<td>• Congestive heart failure</td>
</tr>
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</table>

Abbreviations: ACE, angiotensin converting enzyme; CHF, congestive heart failure; LVEF, left ventricular ejection fraction; MI, myocardial infarction; LMWH, low molecular weight heparin
Four of these indicators have been recommended for several years in national and international treatment guidelines\textsuperscript{[17,18]}, and have in the annual RIKS-HIA reports been shown to be under-utilized in Sweden (http://www.ucr.uu.se/rikshia/). The four established indicators analyzed were lipid lowering therapy at discharge, ACE-inhibitors at discharge, heparin or low molecular weight heparin (LMWH) during hospitalization and performed coronary angiography (or, for hospitals lacking in-house coronary angiography, referral to another hospital).

The fifth indicator, clopidogrel, was at the initiation of this study only recently recognized and included in present guidelines\textsuperscript{[85]}. We found this to be an excellent opportunity to study the impact of our study on a new treatment, and therefore included this as the fifth quality indicator. Theoretically, adding clopidogrel to aspirin in the setting of an acute coronary might increase the risk of bleeding complications, which had been shown to increase mortality\textsuperscript{[86]}. This concern has been dealt with in a study by Yusuf et al\textsuperscript{[87]}, where no increase in the risk of major bleedings were found when clopidogrel was used in treating AMI patients. Nevertheless, due to the relative inexperience of using this drug, we wanted to make sure that the incidence of major bleedings in our patients did not increase.

In Sweden, treatment levels with beta-blockers and aspirin are consistently very high, and since the need for improvement thus is limited, we chose not to include them as indicators in the present study.

Statistical methods

The evaluations of the intervention effects were made with hospitals as the unit of analysis. All data, baseline as well as prospective, were obtained from the registry RIKS-HIA.

In Paper II, the primary comparison of the pre- and post-intervention treatment levels of the quality indicators at the hospitals were made with paired t-tests for continuous variables.

Also in Paper II, differences of the absolute increases of treatment levels between control and intervention hospitals were made with independent-samples t-tests. In both analyses in Paper II, all confidence intervals were 95%, and p-values were 2-tailed and unadjusted for multiple comparisons. All statistical analyses in Paper II were made with statistical software (SPSS version 12.0.1).
In **Paper III**, the incidences of the analyzed events were calculated as incidence rates, i.e. the number of events divided by the total person-time followed. Four different clinical outcomes were analyzed; mortality (death all-causes), morbidity (cardiovascular readmissions), combined mortality/morbidity and bleeding complications. For each of these outcomes, the pre/post-intervention effects were modelled in a linear mixed-effect model with fixed effect factors; intervention hospital (yes/no), period (pre-/post-intervention) and interaction between intervention-hospital and period. To allow for different baseline levels and changes within hospitals, the intercept and slope was introduced as random effects.

The effect of intervention was found in the estimate of interactions between intervention hospitals and periods.

Furthermore, we also analyzed the effect of the intervention in an adjusted model with age, gender, smoking habits, hypertension, diabetes mellitus and renal failure as fixed effect covariates.

In **Paper IV**, we again used the dependent, paired t-test for intra-group analyses to evaluate the levels of sustainability between the two measurements. Later, when between-group comparisons were made to detect differences in absolute treatment levels in the last measurement period, independent t-tests were used. Confidence intervals and p-values were identical to the ones used in Paper II.
RESULTS

Guideline Adherence (Papers I and II)

Hospital and Patient Characteristics

During the measurement period 1 (M1: May 1, 2003 to April 30, 2004) a total of 3786 AMI patients younger than 80 years were registered at the 19 study hospitals (group A + B). During the same time, the 19 control hospitals accounted for 2940 AMI patients aged less than 80 years. There were no significant differences in mean age, sex distribution or other patient characteristics between control and intervention hospitals (Table 2).

Table 2. Patient characteristics during Measurement period 1

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Group A+B</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Included AMI patients, no</td>
<td>3786</td>
<td>2940</td>
<td></td>
</tr>
<tr>
<td>Age, mean</td>
<td>73,5</td>
<td>73,6</td>
<td>NS</td>
</tr>
<tr>
<td>Sex, women %</td>
<td>38,9</td>
<td>37,8</td>
<td>NS</td>
</tr>
<tr>
<td>Previous AMI, %</td>
<td>32,6</td>
<td>34,9</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>21,4</td>
<td>21,0</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>41,0</td>
<td>40,0</td>
<td>NS</td>
</tr>
<tr>
<td>Treated hyperlipidemia, %</td>
<td>24,1</td>
<td>23,6</td>
<td>NS</td>
</tr>
<tr>
<td>Current smoker, %</td>
<td>18,3</td>
<td>17,3</td>
<td>NS</td>
</tr>
</tbody>
</table>

Impact on Quality indicators

At baseline, there were no significant differences in adherence rates to the treatments between control and intervention hospitals (Paper II: Table 3). On the other hand, the adherence rates showed remarkable, but comparable, variations within both groups (Fig. 7a).
In the control group, a significant improvement from baseline to the post-intervention measurement was achieved only for the treatment levels of clopidogrel. No significant improvements were shown for the other four indicators in this group. In contrast, in the study group there were significant improvements in all of the five indicators (Paper II: Table 3). The post-intervention adherence variation was lower in the intervention group, both compared to the in-group baseline measurement and also with the post-intervention results in the control group (Fig. 7a and b).
There were no significant differences in the improvements of the five quality indicators between intervention groups A and B. Therefore, all comparisons with the control group are based on a combined group (A+B).

When comparing mean absolute improvement rates from baseline to the post-intervention measurement, significantly greater improvements were found in the (combined) intervention group compared to the control group for all separate indicators except lipid-lowering therapy (Fig. 8).

**Figure 8:** Mean absolute % changes of proportion of target patients treated in intervention (QUICC) and control hospitals

![Figure 8](image)

Clinical outcome (Paper III)

Patient characteristics

During the baseline period July 1, 2001 through June 30, 2002, 6878 consecutive AMI patients < 80 years were included at the intervention and control hospitals. These patients had a mean follow-up period of 12 months. During the post-intervention period of May 1, 2003 through April 30, 2004, 6484 patients were included and followed up in the same way. The patient characteristics did not differ significantly, neither between hospital groups nor between measurement periods (Paper III: Table 1).
Clinical outcomes expressed as mortality (death all-causes), cardiovascular (CV) readmission rate, combined mortality/CV readmissions and occurrence of bleeding complications are presented in Table 3.

**Table 3. Clinical outcomes expressed as events per 100 patient-years**

<table>
<thead>
<tr>
<th>Event</th>
<th>Control hospitals (n=19)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>QUICC hospitals (n=19)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline Events (SD)</td>
<td>Post interv Events(SD)</td>
<td>p-value</td>
<td>Baseline Events(SD)</td>
<td>Post interv Events(SD)</td>
<td>p-value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death, all causes</td>
<td>14.2 (4.2)</td>
<td>14.2 (4.5)</td>
<td>NS</td>
<td>14.2 (4.5)</td>
<td>11.4 (3.6)</td>
<td>0.03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CV readmissions</td>
<td>54.5 (15.8)</td>
<td>49.6 (12.2)</td>
<td>NS</td>
<td>49.5 (11.9)</td>
<td>40.2 (8.6)</td>
<td>&lt;0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death / Readmissions</td>
<td>73.6 (23.0)</td>
<td>67.4 (17.0)</td>
<td>NS</td>
<td>66.7 (15.5)</td>
<td>54.9 (12.9)</td>
<td>0.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding complications</td>
<td>1.0 (0.9)</td>
<td>1.9 (1.4)</td>
<td>&lt;0.01</td>
<td>1.8 (1.0)</td>
<td>1.9 (1.2)</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Morbidity comprises hospital care under the diagnoses of acute myocardial infarction, angina pectoris, congestive heart failure and cardiac arrest. Bleeding complications – hospital care with a diagnosis of a bleeding complication.

In the QUICC intervention group, baseline to post intervention comparisons demonstrated significant improvements in mortality, CV readmission rate and the combined mortality/readmission. In contrast, no significant improvement could be demonstrated in the control group of hospitals regarding mortality, CV readmission rates or the combined mortality/readmission indicator.

Concerning bleeding complications, the control hospitals actually demonstrated a negative outcome with a higher occurrence of bleeding complications. At the same time, the incident of bleeding complications in the intervention hospitals remained unchanged.
The differences between the control and intervention hospitals with regard to their respective changes from baseline to post-intervention are shown in Figure 9.

**Figure 9**: Differences of changes in clinical outcome

![Graph showing differences in clinical outcomes](image)

Vertical bars denote adjusted and unadjusted 95% confidence intervals for the difference of changes (intervention – control) between the two hospital groups. Horizontal bars denote mean values. Y-axis denotes events per 100 patient-years. Note different scale on the Y-axis for Bleedings. Grey line: Unadjusted values; Black lines: Adjusted values (model presented under Statistics above) P-values are presented above the graphs.

For unadjusted mortality, CV readmissions and the combination of the two there were numerically larger improvements in the intervention hospitals, although they did not reach formal statistical significance. However, the change in incidence of bleeding complications was significantly lower in the QUICC group. These findings were consistent also when the effects of the intervention were analyzed according to the augmented model adjusting for patient characteristics (Described under Statistics above).

**Sustainability and impact on adjacent areas (Paper IV)**

**Hospital and patient characteristics**

During the first measurement period (M1: May 1, 2003 to April 30, 2004), the 19 + 19 hospitals registered a total of 6885 consecutive AMI patients younger than 80 years. At the control hospitals, in average 160 patients were registered, while in the intervention group, the corresponding number of patients was 202. For the second measurement period (M2: August 1, 2004...
to January 31, 2005), the total numbers of AMI patients were 3401, while the average number per hospital in the control and intervention group was 78 and 102, respectively.

There were no significant differences in baseline characteristics of the patients between the two hospitals groups, except that the intervention hospitals had a slightly smaller proportion of patients with previous myocardial infarctions during both M1 and M2, and also a lower prevalence of diabetes mellitus during M2, (Paper IV: Table 1).

Sustainability of improvements
Above, and in Paper II, we presented significant improvements of guideline adherence in the intervention group of hospitals, this from baseline (BL) to the post-intervention measurement (M1). To analyze if the improvements were sustained over time, a new evaluation of the performance levels were made after a consolidation period of 3 months. Before this consolidation period, all kind of support from the study management group was withdrawn. The re-evaluation period (M2) extended over 6 months, August 1, 2004 to January 31, 2005.
Figure 10 gives a graphical presentation of the mean adherence rates for the intervention and control hospitals at Baseline (BL), Measurement 1 (M1) and Measurement 2 (M2), respectively.

Figure 10: Mean adherence rates at baseline (BL), measurement period one (M1) and measurement period two (M2)

Table 4 Differences in changes of mean adherence rates from Measurement 1 to Measurement 2

<table>
<thead>
<tr>
<th></th>
<th>Control hospitals (n = 19)</th>
<th>Intervention hospitals (n = 19)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M1</td>
<td>M2</td>
</tr>
<tr>
<td>ACE-Inhibitors</td>
<td>59.29</td>
<td>57.66</td>
</tr>
<tr>
<td>Lipid low. therapy</td>
<td>83.46</td>
<td>88.61</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>54.30</td>
<td>67.24</td>
</tr>
<tr>
<td>Heparin/LMWH</td>
<td>72.07</td>
<td>84.38</td>
</tr>
<tr>
<td>Coronary angiogr.</td>
<td>55.27</td>
<td>63.69</td>
</tr>
</tbody>
</table>

ACE-I indicates angiotensin converting enzyme inhibitor; LMWH, low molecular weight heparin; Cor-ai, coronary angiography

In Table 4, the corresponding mean adherence rates in M1 and M2, as well as the statistical significance for the intra-group changes from M1 to M2, are presented numerically.
From M1 to M2, the adherence rates for the intervention hospitals were sustained or improved for all but one indicator (ACE-inhibitors). During the same time, an evident catch-up effect was seen in the control group. As an effect, the large mean differences between the hospital groups in M1 had decreased substantially to M2. Still, for all indicators, the absolute adherence rates in M2 were numerically higher in the intervention group, although the difference was only significant for clopidogrel (79.0 vs. 67.2 %, p = 0.03).

Effects on adjacent clinical measures

Hopefully, a local, systematic and targeted QI effort would lead to somewhat of a cultural change, where an arising enthusiasm for quality improvements also would induce improvements in other, adjacent but not primarily targeted clinical areas as well.

Therefore, the second purpose of the follow-up study described in Paper IV was to evaluate if any effect, positive or negative, could be demonstrated for such other, adjacent clinical measures not primarily targeted in the QI intervention. The five clinical measures under scrutiny are presented in Table 5, and were pre-selected according to the study protocol.

When comparing the performance data from the baseline period (BL) with the corresponding data from Measurement period 1 (M1), we were unable to demonstrate any significant between-group differences in the changes of the five preselected clinical measures (Table 5).

Table 5 Effects on adjacent clinical measures, Baseline to M1

<table>
<thead>
<tr>
<th>Differences, Baseline to M1</th>
<th>Baseline Ctrl</th>
<th>Baseline Interv</th>
<th>M1 Ctrl</th>
<th>M1 Interv</th>
<th>Differences Ctrl</th>
<th>Differences Interv</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress test (%)</td>
<td>30.3</td>
<td>24.4</td>
<td>17.2</td>
<td>12.4</td>
<td>-13.1</td>
<td>-12.0</td>
<td>NS</td>
</tr>
<tr>
<td>Echocardiography (%)</td>
<td>59.5</td>
<td>64.8</td>
<td>59.3</td>
<td>68.6</td>
<td>-0.2</td>
<td>3.8</td>
<td>NS</td>
</tr>
<tr>
<td>Reperfusion therapy (%)</td>
<td>71.3</td>
<td>71.8</td>
<td>68.8</td>
<td>71.3</td>
<td>-2.5</td>
<td>-0.5</td>
<td>NS</td>
</tr>
<tr>
<td>Mean delay, ED to Thrombolysis (min)</td>
<td>53.8</td>
<td>65.0</td>
<td>64.8</td>
<td>57.1</td>
<td>11</td>
<td>-7.8</td>
<td>0.08</td>
</tr>
<tr>
<td>Mean length of Stay (days)</td>
<td>6.85</td>
<td>6.41</td>
<td>6.89</td>
<td>6.31</td>
<td>0.04</td>
<td>-0.1</td>
<td>NS</td>
</tr>
</tbody>
</table>

Abbreviations: ED – Emergency department

The observed decrease in the use of stress tests in both groups is explained by concurrent guideline modifications, recommending routine coronary angiography without a preceding stress test in non-ST elevation AMI.
DISCUSSIONS

The quality of care for AMI patients is continuously improving, but the improvement pace is rather slow, and the improvement potential still is considerable\(^{[41-43]}\). The knowledge on how to care for AMI patients in an optimal way builds on decades of high-quality clinical research, and has since long been compiled into evidence-based, clinical practice guidelines. However, several studies has shown that the dissemination of these guidelines often misses its target, i.e. to increase the quality of care\(^{[47-49]}\).

In Sweden, similar trends in the AMI care as described above have been shown. As a consequence, Swedish quality improvement initiatives are as needed as in the rest of the world. From our national perspective, a unique advantage when it comes to analyzing the quality of AMI care is that we have a well-established, web-based, national quality registry with an almost total coverage of all Swedish AMI patients cared for at the CCU’s. That is a definite strength in the design of our QI initiative presented herein.

Obviously, there are substantial obstacles that prevent the evidence-based, guideline-derived recommendations from being clinically implemented in an optimal way. These barriers to a proper use of the evidence-based therapies may be classified into three categories: knowledge, attitude, and behaviour\(^{[47]}\).

Discipline-specific, professional knowledge is of course a pre-requisite to proper care, but as has been shown, different forms of educational activities aiming at increasing this type of knowledge is not sufficient to improve the quality of care\(^{[48,49,53,54]}\). Without doubt, to reach break-through improvements, it is also crucial that the individual, as well as the system, also increases the improvement knowledge. In the US health care systems, significant problems related to quality and safety have been demonstrated\(^{[88,89]}\). Hence, several national committees call for a change in the education of health care workers, this to include new competencies in QI\(^{[90,91]}\). A leading role in this quest to move QI education to the foreground is taken by Case Western Reserve University, where the QI education has been a formal part of the curricula of the medical school for more than two decades\(^{[92]}\).
The attitudinal barriers may be that an individual does not believe the guideline recommendations, or that “cook-book” medicine is questioned.

The ultimate goal of the present study was to change the behaviour of the affected clinicians, this by putting the guideline recommendations and QI activities in a context where the knowledge improvement was to occur at the system level, rather than at the individual level. From this approach, knowledge would be transformed into more adequate and stable clinical processes, which in turn would improve the quality, minimize variations and make the performance less dependent on the individuals on duty. Hopefully, QI activities also lead to improvements in personal knowledge as well as attitudes, although that was outside the scope of this study to determine. However, in a review of 39 QI studies, teaching QI to clinicians did show some beneficial effects on attitudes as well as knowledge, albeit with limited evidence[93].

QI educational program (Paper I)

The QI method we designed for this study was influenced by a general and straightforward QI methodology, The Model for Improvement, described by Langley et al (1996)[24]. This model has later been adapted for implementations in the health care sector, where probably the most well-known version is that described in the Breakthrough Series by the Institute for Healthcare Improvement, IHI (Cambridge, MA, USA)[65].

The earliest implementations of the Breakthrough QI model was made in 1995, and since then, IHI states that they have sponsored over 50 collaborative projects on several dozen topics involving over 2000 teams from 1000 health care organizations[94]. The design of the model is based on a collaborative approach were multidisciplinary teams from 12 to 160 health care organizations are brought together to seek improvement in a focused topic area. The teams are to gather at learning sessions, where training is given, at the same time as interactions between the teams catalyzes wide-spread advances.

Several QI efforts based on this model has shown positive results in many areas in healthcare worldwide[77-81], and the method has been wide-spread in a multitude of health care organizations in different countries all over the world. But, to be honest, not every QI intervention based on this model has shown convincingly positive results, which has evoked some criticism about, among other things, lacking evidence for effectiveness, unproven cost effectiveness and that explicit success factors yet has to be identified[95]. To take this criticism under consideration, and to be able to make a better prediction of the chances of success of a planned QI collaborative, it is crucial to take
into consideration the core characteristics of earlier successful interventions\cite{96,97}. One key success factor that stands out is that the local organization management must be directly involved from the very beginning of a QI effort, and act as a guarantor of resources during the improvement activities. In our study, the respective organization manager was required to guarantee continuous support of the teams by signing a written contract before inclusion in the study.

One barrier to the development of improvement science in health care in general is an under-reporting of results, positive or negative, in the medical literature. At the same time, the reports that actually have been published have often been written in diverse and somewhat ineffective ways, which has been an impediment in the quest to strengthen the evidence base in QI in health care\cite{98, 99}. But, fortunately, in recent years, the possibilities to publish QI reports have increased. Some new biomedical journals dedicated to QI in different areas have been launched (e.g. *Circulation: Cardiovascular Quality and Outcomes*), and at the same time, several well-established, high-ranked journals now ask for and accept QI reports in recently defined categories (e.g. *BMJ – Quality Improvement reports*). Also, the SQUIRE project group has developed journal-independent publication guidelines aiming to stimulate publication, and also to increase the completeness, accuracy and transparency of published QI work. Our publications have been submitted to international journals with strong ambitions to advance the QI pursuit in health care.

In our QI approach, we divided the intervention group of hospitals into two subgroups, were Group A had a somewhat more resource-demanding design with more frequent learning sessions. Instead, Group B had access to a web-based portal with support facilities. When evaluating the effect of the intervention, no differences between group A and B were found. With this in mind, we feel confident to recommend the less resource-demanding model used for group B to anyone designing a QI intervention similar to ours.

**Improved adherence to AMI guidelines (Paper II)**

With what we believe to be the first controlled QI study of its kind in the AMI area, we have shown that a systematic and nationwide QI collaborative intervention can have a significant, positive impact on the treatment adherence to national AMI guidelines, and thereby lead to major improvements in acute coronary care.

When comparing with the control hospitals, significant improvements in the intervention hospitals were seen in 4 out of 5 indicators, with the 5\textsuperscript{th} (lipid-
lowering therapy) also showing an obvious trend ($p=0.065$) towards improved treatment rates.

In the control group, the improvement was poor in four of the five indicators. The only significant improvement in this group was shown for treatment with clopidogrel, which exemplifies the impact of intense marketing and updated recommendations for a newly introduced treatment. However, despite the substantial increase of clopidogrel use in the control group, an even more profound increase was seen in the QI intervention group.

As most AMI patients are subject to several treatments and evaluations in any given inpatient episode, examinations of hospital behaviour regarding combination treatments are important. Therefore, in accordance with the study protocol, we made an analysis of the aggregate use of the recommended treatments. We found that 15 out of the 19 hospitals in the QI intervention group reached adherence rates of at least 70% in four, or even all, of the five indicators, while not a single control hospital achieved this. This finding underlines the importance of simultaneously examining several aspects of the care process, and to carefully select key quality indicators so that they together cover essential aspects of the total care process.

Yet another positive effect of the QI effort is that in the intervention group of hospitals, the between-hospital, post-intervention treatment variation was substantially reduced (Fig. 7). Several international health care systems, such as the National Health Service (NHS) in the UK, now addresses and intends to reduce unwarranted clinical variation, this to improve quality of care and increase value [100]. With our intervention, we have shown that a national QI collaborative might be an effective way to reduce such unwarranted variation in clinical practice.

When comparing our results with results from other similar QI interventional studies, we can conclude that our improvements in guideline adherence are at least as good as, or better, than what have been presented before. In the Guidelines Applied in Practice (GAP) Initiative in Southeast Michigan, USA, Mehta et al [66, 67] showed significant improvements in a few quality indicators, and concluded that improvements were most obvious when different guideline-based tools such as standard admission orders, clinical pathways and AMI-specific discharge forms were used. In our study, in contrast to the findings in GAP, such tools were used very differently in interventional subgroups A and B, at the same time as the improvement rates did not differ between the subgroups. Instead, the tool we found to be very powerful, and appreciated, was the control chart function in the RIKS-HIA online registry. With this, the local teams had a very illustrative measurement and feedback tool, which motivated and promoted local improvement...
activities. This gives strength to the statement above that local, up-to-date and easily accessible measurements are a prerequisite to successful improvement efforts. Hence, it is not surprising that when the GAP study group added a real-time performance feedback functionality, further increases of adherence rates were observed\textsuperscript{[68]}. A weakness of the design of the GAP study is the fact that the conclusions were not based on comparisons with a control group, but relied on before-after, within-group comparisons. From this, it is difficult to sort out the effect of their intervention from other influences such as ongoing secular trends.

Another, still continuing QI effort in the cardiovascular field is the US-based Get With The Guidelines program. Here, LaBresh et al has combined the IHI collaborative model with a web-based Patient Management Tool, the latter used for data collection and on-line feedback. Following their intervention, the 92 intervention hospitals showed significant improvements in 10 out of 11 quality measures\textsuperscript{[72]}. As an attempt to avoid confounding of general changes over time, the group behind the Get With The Guidelines program later made a comparison with hospitals that had not been participating in the program\textsuperscript{[101]}. Here, participation in the quality improvement collaborative was shown to be independently associated with improvements in guideline adherence. However, a weakness of their comparison is that the performance data of the two hospital groups were not derived from the same source, and that vital parameters such as the number of AMI cases in the control group was not explicit, but had to be estimated indirectly by other measures. In the present study, the comparisons were more reliable since all hospitals in the two study groups entered their AMI performance data into the same registry, RIKS-HIA, where also the quality of data was routinely monitored.

Recently, results from the, European EQUIP-ACS study has been presented\textsuperscript{[102]}. Here, a cluster-randomized, collaborative QI trial aiming to improve the quality of care for patients with non-ST-elevation acute coronary syndromes has been conducted during 2008, this at 38 hospitals in France, Italy, Poland, Spain and the United Kingdom. Since two members of the EQUIP-ACS study group earlier have been central in the design and implementation of the QUICC study, it is not surprising that the experience gained from the present study has influenced the design of this European derivative. Compared to the present study, the EQUIP-ACS study had a shorter follow-up, included less patients, and lacks data about clinical outcome. Nevertheless, it is reassuring that a QI intervention so similar to the present also achieved significant and comparable improvements in guideline adherence. When analyzing eight quality indicators, the QI group of 19 hospitals had an absolute overall change of 8.5%, compared to 0.8% in the non-QI group.
Concerning the use of clopidogrel in this context, it is noteworthy that after about a decade since the first evidence of clinical benefit in patients with NSTEMI[87], and subsequent recommendations in the AMI guidelines[85], there is still a substantial underuse, and also a wide variation at the hospital level[103]. In that evaluation by Maddox and others, it was further found that the treatment performance with clopidogrel had no strong correlation with a composite measure of hospital quality. Hence, good quality in some examined areas does not guarantee good performance in each and every measure. This is yet another indication that when planning for a new QI initiative, one must make a prior assessment about which measures are in most dire need of improvement, and address only a restricted number of those specific measures.

Impact on clinical outcome (Paper III)

It is known that deviations from evidence-based recommendations in AMI guidelines have a negative effect on morbidity and mortality[10-12]. With this as a rationale, a handful of studies with different QI strategies have been designed to improve the adherence to the AMI guidelines. As described above, the results from these studies have been modest. Furthermore, an inherent problem in all of these is the fact that they have lacked proper control groups. Because of this, it has been difficult, or impossible, to distinguish between the impact of the QI intervention and concurrent secular trends. With these limitations of earlier studies in mind, we designed QUICC to be a controlled, prospective study, so that we should be able to claim that any observed positive effect on clinical outcome is indeed related to the intervention, and not a mere consequence of time.

Our results demonstrate that the QUICC hospitals, in contrast to the control hospitals, achieved significant improvements from baseline to post-intervention in the mortality, CV readmission and combined mortality/readmission endpoints. In the QUICC hospitals 2.8 lives per 100 patient years (14.2 to 11.4) and 9.3 readmissions for cardiac diagnoses per 100 patient years (49.5 to 40.2) were saved, corresponding to a 20 % and 19 % relative decrease in incidence, respectively. The magnitude of improvement in clinical outcome was in the same order as shown in earlier, comparable studies. For example, in the study by Lappe et al, a 21% decrease in 1-year-mortality was shown[13]. Similarly, in the above mentioned GAP study, a 22% decrease in 1-year-mortality was achieved[11], at the same time as a 21% decrease in the 6-months readmission rate was demonstrated[68]. Recently, a Brazilian cluster-randomized, controlled, multifaceted educational QI intervention demonstrated a similar, relative decrease of 30-day all-cause mortality with 17%[104].
Hence, as we, in contrast to the abovementioned before-after studies, included a proper control group of matched hospitals, we feel confident to claim that the improvements in clinical outcome indeed are related to our QI intervention. Also, it is most probable that the improvement in clinical outcome in the QUICC hospitals was a result of the increase in the use of evidence based treatments, and that the lack of significant improvement in the control hospitals was due to the much smaller increases in use of these treatments.

Sustainability and Diffusion of innovations (Paper IV)

In this present study we addressed important questions formulated by some leading international researchers with experience from the collaborative model of QI:

“If any improvements made are not maintained or spread after the collaborative, it is questionable whether a collaborative is worth the cost”[83].

Undoubtedly, to justify a later expansion of a time and resource demanding QI effort such as the QUICC intervention, it has to be shown that the results are maintained. Up to now, evaluations of the sustainability of the effects of QI interventions in the field of acute cardiovascular disease have been sparse.

Our findings that the initial improvements in guideline adherence were sustained over time are in accordance with the experiences gained from the follow-up study of the Get With the Guidelines-Coronary Artery Disease (GWTG-CAD) program[105], where it was shown that initial improvements in guideline adherence for six measures ( aspirin at arrival/discharge; β-blocker at arrival/discharge; ACE-I for left ventricular systolic dysfunction; smoking cessation counselling ) were sustained over three consecutive annual measurements. Moreover, our finding of a catch-up effect in the control group is also in accordance with the narrowing between the study groups that was seen in the GWTG-CAD program during their follow-up period, although the GWTG-CAD intervention hospitals maintained higher adherence rates for the entire follow-up period compared to the non-intervention hospitals [105].

A possible explanation for the pronounced improvements in the control group between the two measurement periods in the present study might be that RIKS-HIA registry data reflecting performance levels for individual hospitals were made public for the very first time at the time between the two measurements. The succeeding debate in public media concerning na-
tional inequalities of the quality of AMI care likely increased the interest of most health care providers in their own quality of care. Another possible explanation is that the QI activities during the QUICC project in the 19 intervention hospitals (involving one fourth of all Swedish hospitals managing AMI patients), as a consequence, also increased the interest in the quality of care of AMI patients in the remaining Swedish hospitals. From either of these circumstances, a spill-over effect is probable, an assumption which is in line with the experience from others, who have shown that national quality campaigns with open-access resources may have a substantial spill-over effect on non-enrolled hospitals [106].

The second important question dealt with in Paper IV was whether the QI activities targeting the five explicit quality indicators also would catalyze improvements in other guideline-derived measures. Here, it was somewhat disappointing to note that no positive effect was seen in any out of the five secondary clinical measures under scrutiny. This indicates that the quality activities in the local organizations had been confined to the five explicit quality indicators during the QI work. Unfortunately, we have no information whether the intervention hospitals initiated any new QI work after completion of the QI work mandated by the study. However, some indications that an initial QI effort may catalyze subsequent QI activities have been presented by Neily et al [107]. Here, in a one-year follow-up survey of a similar QI collaborative aiming to improve fall injury prevention, it was found that 85% (29 out of 34) of their teams reported that they had begun QI work on new topics.

Limitations

As the nature of this study made it impossible to have a fully randomized design, the intervention was made at volunteering hospitals. These hospitals might therefore, because of selection bias, be more eager to improve. However, as the baseline performance levels were no different from those at the control hospitals, that eagerness is unlikely to alone explain the improved quality of care at the QUICC hospitals. We feel that we can agree with the conclusion from the GAP study by Eagle et al [11] that “wanting to improve” is not sufficient to reach substantial improvement levels. Furthermore, as in all non-randomized studies, differences in unregistered variables between the two groups of hospitals might influence the results and are impossible to adjust for in the statistical analyses.

Even with the attempt to optimize the coverage by excluding the very eldest that commonly are cared for outside a CCU, a minor proportion of eligible
AMI patients are nevertheless cared for outside the CCU’s and hence not registered in RIKS-HIA, nor included in the study.

The concept of target patients implies that the use of a specific treatment should be measured only in those patients with indications for, and at the same time lacking contraindications against, that treatment. However, because all possible contraindications were not registered in RIKS-HIA, we could not control for those in the present analyses. Nevertheless, since the hospitals were matched, we have no reason to believe that there was any systematic difference between the two hospital groups.

Our conclusions are limited to the care of patients with acute AMI. However, given that the general methodology used in the QI programme has already been successfully used in different medical areas\cite{77-81}, it is probable that the minor modifications in our study design do not prevent the use of our model in other patient groups, as well.

The evaluation of the incidence of bleeding complications was made only on bleedings severe enough to necessitate rehospitalization. Therefore, the total number of bleeding events was quite low. The design of the study and the current version of the quality registry RIKS-HIA made it impossible to register less severe bleedings. The important findings, however, were that there was no increase in bleeding rates between the baseline and post-intervention phases at the QUICC hospitals despite a large increase in use of antithrombotic treatments; and that there in the post intervention phase were no more frequent bleedings requiring hospitalisations at the QUICC hospitals compared to at the control hospitals, this despite a higher use of antithrombotic treatments (i.e. clopidogrel).

Finally, the time span of our follow-up on guideline adherence as well as clinical outcome was rather short; it would have been advantageous with a longer follow-up period. Unfortunately, this was not feasible due to the fact that other national AMI quality improvement campaigns were launched shortly after our intervention, which would have made it very difficult to differentiate the effects of the separate interventions.
CONCLUSIONS

The quality of care for patients with AMI is continuously improving, but data from the Swedish AMI quality registry RIKS-HIA shows that the adherence to the national AMI clinical practice guidelines still is suboptimal.

The Swedish AMI quality registry RIKS-HIA (now SWEDHEART) is well-established, covers the absolute majority of Swedish hospitals with AMI care, and the quality of the data entered into the registry is high.

Before this QI initiative, the hospitals reporting to RIKS-HIA made great efforts to deliver high-quality patient data into the registry, but very few made their own data extractions. Instead, annual evaluations of the current performance were made centrally, and presented with a substantial delay.

To facilitate local QI activities, RIKS-HIA was enhanced by adding powerful functions for realtime performance feedback as well as graphic presentations of basic statistical evaluations.

In this study, multidisciplinary teams from the intervention hospitals were trained in how to use the enhanced RIKS-HIA registry to generate local performance data, and also educated in general quality improvement methodologies.

Following the educational phase, the local teams were able to use RIKS-HIA to measure their own clinical performance, and then developed local change plans with aims to improve the adherence to the national AMI guideline.

Compared to a control group of similar hospitals, the intervention hospitals had significantly higher post-intervention guideline adherence rates. This improvement in guideline adherence also had a positive correlation to clinical outcome.

In the follow-up period, a major catch-up effect was seen in the control group.
In the intervention hospitals, the improvements were sustained when the support from the study organisation was withdrawn.

No effect was seen in clinical areas other than those primarily targeted by the five explicit quality indicators used in the study.

Local changes were quite different between the hospitals, different tools were developed, and the use of the registry varied a lot, but from this, no correlation to the results was obvious. On the other hand, one key to success seems to have been a clear involvement of a local manager.

Clinical implications

The quality of clinical care is improving, not only in the clinical area addressed in this study (AMI) but in every medical discipline. This trend is driven by an ever-increasing amount of evidence-based knowledge, derived from decades of high-quality, clinical research. This knowledge is normally condensed into clinical practice guidelines, which, if regularly updated, describes the optimal care for different medical conditions.

National quality registries, provided that they have a good coverage and contain high quality clinical data, are excellent tools to follow the trends in the quality of care. In Sweden, about 70-80 national quality registries covers the most common diagnoses, such as AMI, diabetes mellitus, stroke, several cancer forms etc.

The QI initiative described in this report has been successful in improving the adherence to the national AMI guideline, as well as improving clinical outcome. Since the QI methodology used in our study is very general, and a national quality registry has been used to obtain local performance measurements, it should be very straight-forward to use a similar design as to achieve significant improvements in other clinical areas where a quality registry is at hand.

When planning for a new QI initiative, one must be careful to select which measures to address. Too many measures will probably be overwhelming to the teams, and hence contra-productive, while too few, or worse, wrong measures will not lead to clinically relevant improvements. Here, as in all improvement activities, deliberate measurements are a key to sound QI implementations.
It also is important to realize that one can not assume that one specific improvement effort will change the organizational culture, and thereby catalyze improvements in other areas. To achieve this cultural change, the role of the organisation managers can not be overemphasized. Before initiation, the managers must guarantee adequate resources; and during the QI initiative, also must be present and show that the QI initiative is important, for example by requesting regular updates of the progress. Finally, after completion of a successful QI initiative, a wise manager should soon initiate similar, local QI initiatives in adjacent areas, this when the improvement knowledge and momentum still is available.
I västvärlden utgör kranskärlssjukdom den vanligaste dödsorsaken, orsakande ungefär lika många dödsfall som alla cancerformer sammantaget. Under de senaste decennierna har dödligheten i kranskärlssjukdom minskat, detta bl a efter att evidensbaserade rekommendationer för såväl diagnostik som behandling arbetats fram och presenterats i form av nationella riktlinjer. Man har kunnat visa att en god följsamhet till dessa riktlinjer är avgörande för såväl morbiditet som mortalitet i kranskärlssjukdom.

Sedan 90-talet har svenska patienter med hjärtinfarkt registrerats i det nationella kvalitetsregistret RIKS-HIA, vilket sedan 2010 ingår i registret SWE-DEHEART. Vid uppföljningar i detta register kan man visa att kvaliteten i den svenska kranskärlsvården förvisso ökar, men tyvärr kvarstår relativt stora brister, där man också ser en påtaglig variation över såväl geografiska som tidsmässiga förhållanden.


Till detta projekt inbjöds samtliga sjukhus med vård av akut hjärtinfarkt som samtidigt registrerade data i RIKS-HIA, vilket vid den aktuella tidpunkten uppgick till 73 sjukhus. Av dessa sjukhus kom 19 stycken att ingå i studien, och dessa varierade i såväl storlek som tidigare behandlingskvalitet. Av övriga ej deltagande sjukhus utvaldes ytterligare 19 sjukhus som ovetande om detta utgjorde en kontrollgrupp. Dessa var matchade mot interventionssjukhusen med avseende på storlek och tidigare behandlingstraditioner.

Från de 19 interventionssjukhusen utsågs team av vanligen två läkare och två sköterskor med ansvar för vård av patienter med akut hjärtinfarkt. Dessa 19 team genomgick sedan en utbildningsserie på sex månader innehållande två eller fyra centralt hållna seminarier, där teamen med färre träffar istället fick ett internetbaserat stöd. Vid dessa seminarier fick teamen lära sig en grundläggande metodik för kvalitetsutveckling, vilken byggde på den så k genombrottsmetodiken och använde sig av basala verktyg som t ex PDSA-cykler och ”control-charts”. Mellan seminarietillfällena förväntades teamen att

Med hjälp av RIKS-HIA kunde mätningar av såväl interventions- som kontrollsjukhusens prestationer enkelt utföras, såväl innan som efter interventionen.

I de första två artiklarna (Paper I och II) beskrivs dels den metodik som används, och även till vilken grad interventionssjukhusen förbättrat sin följsamhet till gällande riktlinjer. För att kunna bedöma detta användes fem kvalitetsindikatorer, vilka utgjordes av behandlingar som rekommenderades i gällande riktlinjer. Vi kunde visa att de sjukhus som ingick i interventionsgruppen (jämfört med kontrollgruppen) hade en statistiskt högre ökning av följsamhet mot riktlinjerna i fyra av de fem indikatorerna.

Glädjande nog kunde vi i den tredje artikeln (Paper III) även påvisa att den ökade följsamhet till rekommendationerna i riktlinjerna även medförde positiva effekter på dödlighet och behov av återinläggning med diagnos hjärtsjukdom. En av de rekommenderade behandlingarna vi studerade var vid detta tillfälle relativt nyligen inkluderad i riktlinjerna, och då användande av denna behandling på ett inadekvat sätt riskerar att orsaka blödningar, var det tillfredsställande att kunna visa att en högre användandegrad i interventionsgruppen inte ledde till fler blödningskomplikationer.

Ett nationellt initiativ för kvalitetsutveckling inom vården i den form vi genomför tar naturligtvis en hel del resurser i form av tid och pengar. Därför är det en förutsättning att påvisade förbättringar blir bestående, och gärna också sprider sig till närliggande medicinska områden andra än de som primärt fokuserats på. I den fjärde artikeln (Paper IV) har vi visat att de förbättringar som uppnåtts också blivit bestående, även om kontrollgruppen gjort en numerärt större upphämtning under uppföljningsperioden. I absoluta mått har dock interventionsgruppens sjukhus fortsatt en högre utnyttjande grad av de rekommenderade och studerade fem behandlingarna. Däremot kunde vi inte påvisa någon positiv effekt på andra områden som t ex fördöjningstider, vårdtider, utnyttjande av arbetsprov resp. re-perfusionsterapi.

Slutsatsen blir således att man kan öka följsamheten till nationella riktlinjer genom ett nationellt och strukturerat program där upplärning av multidisciplinära team i utnyttjande av grundläggande metoder för kvalitetsutveckling.

Man bör därför innan liknande utvecklingsprojekt initieras göra noggranna utgångsmätningar och därefter välja en begränsad mängd, högprioriterade kliniska indikatorer att följa. Den metodik vi använt är till sin natur generell, och bör därför utan större besvär kunna användas inom andra kliniska områden.
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REFERENCES


40. Alfredsson J, Sederholm-Lawesson S, Stenestrand U, et al. Although women are less likely to be admitted to coronary care units, they are treated equally to men and have better outcome. A prospective cohort study in patients with non ST-elevation acute coronary syndromes. Acute Card Care. 2009; 11:173-80.


42. Eagle KA, Nallamothu BK, Mehta RH, et al. Trends in acute reperfusion therapy for ST-segment elevation myocardial infarction from 1999 to 2006: we are getting better but we have got a long way to go. Eur Heart J. 2008; 29(5):609-17.


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