Complication Registries in Orthopaedic Surgery. A Nordic Perspective

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NOF Working Groups

- Education
- Guidelines
- Complication Registry:

Frank van Ousterhout (NL)

Aare Märtson (EE)

Søren Overgaard (DK)

Ketil Holen (N)



NOF Working Groups – Complication Registry

- Present a first draft for discussion at the NOF Spring Meeting in Reykjavik May 2015
- Present a final draft at the NOF Congress in Linköping 2016
- MAIN QUESTIONS:
- Is it possible and worthwhile to establish a Nordic Complication Registry?
- If yes, how shall this registry be designed, what shall be registrated?



Some Norwegian Medical Registries

There are around 60 medical registries in Norway —



Nasionalt register for lungekreft

Publikasjoner

Sentrale helseregistre

Helseregisterprosjektet

- Genetisk masseundersøkelse av nyfødte (har ingen egen landingsside)
- Dødsårsaksregisteret
- Forsvarets helseregister (Har ikke egen nettside, kontakt Forsvarets sanitet)
- Helsearkivregisteret (har ikke egen landingsside)
- Hjerte- og karregisteret (HKR)
- Kreftregisteret (med underliggende nasjonale kvalitetsregistre)
- Medisinsk fødselsregister
- Meldingssystem for smittsomme sykdommer (MSIS)
- Nasjonalt vaksinasjonsregister (SYSVAK)
- Norsk overvåkningssystem for antibiotikaresistens hos mikrober (NORM)
- Norsk overvåkningssystem for infeksjoner i sykehustjenesten (NOIS)
- Norsk pasientregister (NPR)
- Pseudonymt register for pleie- og omsorgssektoren (IPLOS)
- Register over svangerskapsavbrudd (Abortregisteret)
- Reseptbasert legemiddelregister (Reseptregisteret)
- Resistensovervåkning av virus i Norge (RAVN)

Nyheter

Årsstatistikk Medisinsk Fødselsregister 2013 Andelen dødfødte og barn som dør innen første leveuke har aldri vært lavere. Det viser 2013-statistikken fra Medisinsk fødselsregister. Les mer på fhi.no

Årsstatistikk Hjerte- og karregisteret 2013 Hjerte- og karregisteret publiserer statistikk for alle som har vært i kontakt med spesialisthelsetjenesten for disse sykdommene. Les mer på fhi.no

Dødsårsaker 2013

Det er små endringer i forhold til tidligere år: trenden med nedgang i hjerteinfarkt og hjerneslag fortsetter. Det er ingen nedgang i lungekreft og kronisk obstruktiv lungesykdom (kols). Les mer på fhi.no

Tuberkulose – årsstatistikk for 2013
Tuberkulosestatistikken for 2013 viser
fortsatt stigning i antall sykdomstilfeller,
samtidig som forekomsten blant norskfødte
fortsatt er blant de laveste i verden. Les mer
på fhi.no

Infeksjoner etter kirurgiske inngrep, NOIS-

Dette er første gang data fra Norsk overvåkingssystem for antibiotikabruk og helsetjenesteassosierte infeksjoner (NOIS) gjennom et helt år (2013) presenteres. Les mer på fhi.no

There are many registries in cardiology





Editorial from European Heart Journal

European Heart Journal (2000) 21, 1399–1401 doi:10.1053/euhj.2000.2265, available online at http://www.idealibrary.com on IDEAL®

Are data from clinical registries of any value?

See pages 1440, 1450 and 1458 for the articles to which this Editorial refers

'The answer you get depends on the question you ask'

The question asked in the title of this editorial might be phrased differently: why bother to collect registry data at all? Is it of any use to clinicians and health care administrators/planners? Indeed, one might argue that only data from prospective, community-wide studies performed over decades such as the Framingham Heart Study are valid and therefore useful. However, my answer to these rhetorical questions is in the affirmative: collection of registry data does serve a number of useful purposes, but it is essential that we bring a critical understanding to the interpretation of such data. Let us examine the question further. I believe that registry data has at least 10 important functions:

detail in prospective, community-wide studies or by means of national health statistics.

- (2) Registries reveal the degree to which clinicians are managing a particular disease in accordance with the principles of evidence based medicine, information that is of great use to health care administrators/planners.
- (3) Registries are able to collect data on large numbers of patients rapidly and efficiently thereby producing a picture of a disease and its management at a particular moment in time. Repeated registry samples provide a dynamic estimate of changing patterns of disease demographics and therapy.
- (4) Registry data enable individual clinicians to compare their own patient population and therapeutic strategies with that of other practitioners possibly enabling these physicians to modify their practice patterns.
- (5) Registries provide insights for clinical investi-





Key suggestions for good registry design.

Alpert JS. Eur Heart J. 2000;21(17):1399-1401

- Standardize disease definitions
- Standardize sampling techniques
- Clear definition of participating hospitals
- Reporting ALL collected data
- Centralization of all data and analysis
- A professional statistician should be monitoring all data collection and analysis

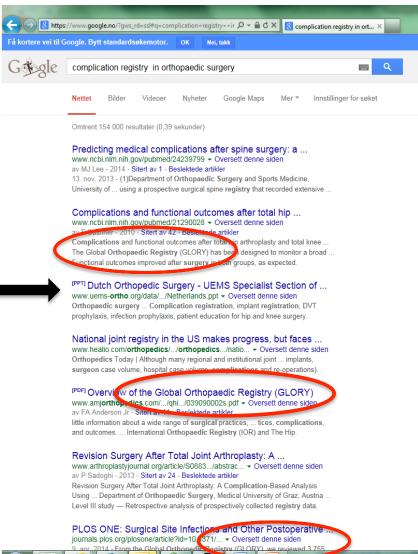


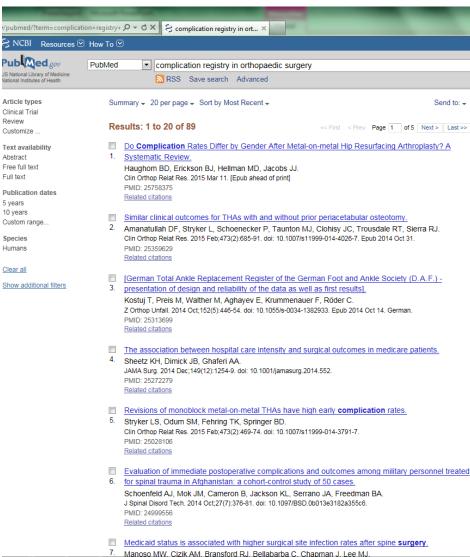
...good registry design cont.

- The accuracy and completeness of individual data sheets should be examined by a central office
- Review and approval of the registry protocol at each participating site
- Report the names of all participating investigators
- A PI or steering committee should maintain overall control of all facets of the registry's running
- Any sponsorship of the registry should be disclosed on all reports



Search on Google and PubMed:



































Registration of Complications

- Do we need a Nordic Complication Registry?
- To me, the answer is: YES
- The health authorities will soon be asking for it, and by doing this now, we can be "up front"
- What can we learn from GLORY?
- What can we learn form the Dutch Complication Registry?





The Global Orthopaedic Registry

Home
Overview
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Hospital Map
MEMBERS ROOM
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The **Global Orthopaedic Registry** is a multinational, observational database of outcomes for patients who undergo elective, primary hip and/or knee arthroplasty. **GLORY** includes over 100 hospitals in 12 countries. Participating physicians receive confidential quarterly reports showing their outcomes side-by-side with the aggregate outcomes of all participating hospitals. GLORY online Data Submissions are secured using Secure Sockets Layer (SSL) technology.

Recent Publications

- Overview of the GLOBAL Orthopaedic Registry (GLORY)
- · Complications and functional outcomes after total hip arthroplasty and total knee arthroplasty: results from the...
- · Practice patterns in the use of venous thromboembolism prophylaxis after total joint arthroplasty--insights from...
- Orthopaedic practice in total hip arthroplasty and total knee arthroplasty: results from the Global Orthopaedic...
- Lessons learned from the global orthopaedic registry: study design, current practice patterns, and future directions
- More Publications

Quick Links

 Lessons from the Global Orthopaedic Registry (GLORY) supplement to the American Journal of Orthopedics, September 2010.

GLORY is supported by a grant from Sanofi and managed by the Center for Outcomes Research, University of Massachusetts Medical School For general questions and information: GLORY@umassmed.edu • 508.856.1336 • 55 Lake Ave North S3-138, Worcester, MA 01655 Copyright 2001-2015 Center for Outcomes Research, University of Massachusetts Medical School



GLORY Hospitals

The Global Orthopaedic Registry

- GLORY HOSPITALS 115 hospitals enrolled 103 hospitals mapped
- 👩 Click on an icon to get information about a GLORY Hospital
- Ouse the controls in the upper left-hand corner of map to pan and zoom



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GLORY: Goals and Objectives

Goals and Objectives

The Global Orthopaedic Registry (GLORY) provides an opportunity to collect, analyze, and disseminate data on patients who undergo THA or TKA. Continued surveillance of the effectiveness of practices and evaluation of causes for suboptimal outcomes are critical steps toward improving health care. The goal of GLORY is to improve patient care through a better understanding of patient demographics, management, and in-hospital and post-discharge outcomes. Comparison of individual hospital data with aggregate registry data should favorably impact the quality of patient care on both a local and national scale. Once issues are identified, corrective actions can be recommended to surgeons who can implement changes and assess their impact.

The objectives of GLORY are to:

- Provide expanded data to orthopaedic surgeons to characterize existing and evolving practice patterns, delivery of care, and resource utilization in the management of THA/TKA patients
- Provide data to support internal and external standards and benchmarking of treatment patterns and patient outcomes
- Analyze data and design ancillary studies to address unanswered clinical questions
- Disseminate findings through publication in peer-reviewed scientific journals



GLORY evaluation from UMASS Center for Outcomes Research



Center for Outcomes Research

Assessing today's practices to enhance tomorrow's care.

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Euro-STAT

Glioma Outcomes

GLORY

GLOW

GRACE

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PRISM

STAT

TRACE-CORE

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Recent Publications

High-grade atrioventricular block in acute coronary syndromes: insights from the Clobal Registry of Acute Coronary Events

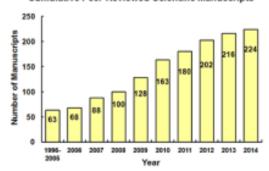
The Agency for Healthcare Research and Quality Inpatient Quality Indicator #11 overall mortality rate does not accurately assess mortality risk after ...

GRACE score predicts heart failure admission following acute coronary syndrome

Beta-blocker Use in ST-segment Elevation Myocardial Infarction in the Reperfusion Era (CRACE)

More Publications

Cumulative Peer Reviewed Scientific Manuscripts



Launched in 2001, the Global Orthopaedic Registry gathers data on demographics, diagnosis, surgical management and outcomes of patients undergoing hip or knee arthoplasty in participating hospitals in 12 countries.

For general questions and information: outcomes@umassmed.edu - 508.856,1336 - 55 Lake Ave North 53-138, Worcester, MA 01655 Copyright 2015 Center for Outcomes Research, University of Massachusetts Medical School





Publication from the Glory Registry





Surgical Site Infections and Other Postoperative Complications following Prophylactic Anticoagulation in Total Joint Arthroplasty



Zhong Wang^{1*}, Frederick A. Anderson Jr.², Michael Ward¹, Timothy Bhattacharyya¹

1 Clinical Trials and Outcomes Branch, Intramural Research Program, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, Bethesda, Maryland, 2 Center for Outcomes Research, University of Massachusetts Medical School, Worcester, Massachusetts

Abstract

Background: Anticoagulants reduce the risk of venous thromboembolism (VTE) after total joint replacement. However, concern remains that pharmacologic VTE prophylaxis can lead to bleeding, which may impact on postoperative complications such as infections and reoperations.

Methods and Findings: From the Global Orthopedic Registry (GLORY), we reviewed 3,755 patients in US who elected for primary total hip or knee arthroplasty, received either warfarin or low molecular weight heparin (LMWH) as VTE prophylactics, and had up-to-90-day follow-up after discharge. We compared incidence rates of VTE, infections and other complications between LMWH and warfarin groups, and used multivariate analyses with propensity score weighting to generate the odds ratio (OR). Patients receiving LMWH tended to be older and higher in the American Society of Anesthesiologists grade scores. In contrast, warfarin was used more frequently for hip arthroplasty with longer duration among patients with more pre-existing comorbidity (all P<0.02). A weight variable was created with propensity score to account for differences in covariate distributions. Propensity score-weighted analyses showed no differences in VTE complications. However, compared to warfactory of the propensity of the propensity score interval [CI, 204], representations (2.4% vs. 1.3%; OR = 1.77, 95% CI, 1.07 to 2.93) and infections (1.6% vs. 0.6%; OR = 2.79, 95% CI, 1.42 to 2.04), representations (2.4% vs. 1.3%; OR = 1.77, 95% CI, 1.07 to 2.93) and infections (1.6% vs. 0.6%; OR = 2.79, 95% CI, 1.42 to 2.04).



Surgical site infections and other postoperative complications following prophylactic anticoagulation in total joint arthroplasty

Zhong Wang et al. PLOS One 2014;9(4):e91755

- All results based on 3755 US-patients registrated in GLORY
- Compared to warfarin, LMWH was associated with significantly higher rates of bleeding, blood transfusions, reoperations and infections after THA/TKA



Another approach to complications in orthopaedic surgery



Avoid the complications

AAOS: "Zero in on Zero" Efforts to reduce Complications

Mark A Snyder, Cincinnati, Ohio

- How to establish a "Center of Excellence"?
- 10 targets for improvement -> eliminate the problem entirely
- For all 10 targets, contributing factors before, during and after surgery were identified
- All targets were analyzed, giving a list of best practice proposals for each target



AAOS: "Zero in on Zero" Efforts to reduce complications

Target	Starting point	Goal
Infected primary THA and TKA	As high as 3 percent in some months	0 percent—and no hospital-acquired MRSA infections
In-hospital and 30-day postoperative deaths from venous thromboembolism	Less than 0.1 percent for total joint cases	None—0 percent
Primary THA early prosthetic dislocation	Although some surgeons had rates less than 1 percent, others had rates as high as 6 percent	0 percent rate for uncomplicated primary cases
Postoperative pain management	Varying strategies, often resulting in poor pain control	100 percent of patients treated with a multimodal pain management program
Allogenic transfusions	Variable, ranging as high as 2 percent for some surgeons	0 percent in primary unilateral THA and TKA; less than 10 percent in bilateral TKA and revision surgeries
30-day readmission	Less than 2 percent	0 percent readmission for VTE, dislocation, and infected total joints; minimal cardiac event readmissions
Orthopaedic unit falls	Not known; estimated at greater than 5 percent	Eliminate entirely—achieve 0 percentate
Unsatisfied patients	Approximately 15 percent	Reduce to 0 percent
Poor discharge handoffs	Less than 5 percent	Improve to 0 percent
Catheter-associated urinary tract infections	Less than 5 percent	Eliminate entirely



Kaiser Permanente Registries

The Joint Commission Journal on Quality and Patient Safety

2012 John M. Eisenberg Patient Safety and Quality Awards

Kaiser Permanente Implant Registries Benefit Patient Safety, Quality Improvement, Cost-Effectiveness

Innovation in Patient Safety and Quality at the National Level

Elizabeth W. Paxton, MA; Mary-Lou Kiley, MBA; Rebecca Love, MPH, RN; Thomas C. Barber, MD; Tadashi T. Funahashi, MD; Maria CS Inacio, MS



From left: Tadathi Funahashi, MD, Chair, Inter-Regional Chiefy of Orthopoldi Surgery, and Assistant Regional Medical Director, Kaiseler Permanents Southern California; Mary-Lus Klay, MBd, Group Lotto, Kaiseler National Implant Registrice: Elizabeth Pacton, MA, Directo, National Implant Registrice: Elizabeth Pacton, MA, Directo, National Implant Registrice: Jed Weissberg, MD, Senior Vice Vereident, Hupitals, Quality and Care Delivery Excellence, Kaiser Foundation Health Plan and Hospitals: Thomas Barber, MD, Associate Physician in Chief, Kaiser Permanente East Bay

E ach year more than 900 implantable medical devices are approved by the US Food and Drug Administration (FDA). Medical devices are integral to patient care. It is estimated that annually 1,131,000 people in the United States receive a total joint replacement (TJR) or pacemaker and pacemaker lead implant; this figure is projected to increase significantly during the next decade. Medical device implantation accounts for a large portion of hospital costs. For example, the average cost for TJR implants is \$6,584 for total hip replacement (TKR), and \$9,547 for total knee replacement (TKR), and these procedures are responsible for the largest hospital expenditure category for Medicare of overall hospital charges. The cost of implantable devices and their related procedures is expected to reach more than \$100 billion in the United States within the next year.

Although the majority of medical devices are safe, some fail, resulting in significant pain, suffering, and even death. Between

Article-at-a-Glance

Background: In response to the increased volume, risk, and cost of medical devices, in 2001 Kaiser Permanente (KP) developed implant registries to enhance patient safety and quality, and to evaluate cost-effectiveness.

Methods: Using an integrated electronic health record system, administrative databases, and other institutional databases, orthopedic, cardiology, and vascular implant registries were developed in 2001, 2006, and 2011, respectively. These registries monitor patients, implants, clinical practices, and surgical outcomes for KP's 9 million members. Critical to registry success is surgeon leadership and engagement; each geographical region has a surgeon champion who provides feedback on registry initiatives and disseminates registry findings.

Results: The registries enhance patient safety by providing a variety of clinical decision tools such as risk calculators, quality reports, risk-adjusted medical center reports, summaries of surgeon data, and infection control reports to registry stakeholders. The registries are used to immediately identify patients with recalled devices, evaluate new and established device technology, and identify outlier implants. The registries contribute to cost-effectiveness initiative through collaboration with sourcing and contracting groups and confirming adherence to device formulary guidelines. Research studies based on registry data have directly influenced clinical best practices.

Conclusions: Registries are important tools to evaluate longitudinal device performance and safety, study the clinical indications for and outcomes of device implantation, respond promptly to recalls and advisories, and contribute to the overall high quality of care of our patients.

The Kaiser Permanente Implant Registries: Effect on Patient Safety, Quality Improvement, Cost Effectiveness, and Research Opportunities

Elizabeth W Paxton, MA; Maria CS Inacio, MS; Mary-Lou Kiley, MBA

Perm J 2012 Spring:16(2):36-44

Abstract

Introduction: Considering the high cost, volume, and patient safety issues associated with medical devices, monitoring of medical device performance is critical to ensure patient safety and quality of care. The purpose of this article is to describe the Kaiser Permanente (KP) implant registries and to highlight the benefits of these implant registries on patient safety, quality, cost effectiveness, and research.

Methods: Eight KP implant registries leverage the integrated health care system's administrative databases and electronic health records system. Registry data collected undergo quality control and validation as well as statistical analysis.

Results: Patient safety has been enhanced through identification of affected patients during major recalls, identification of risk factors associated with outcomes of interest, development of risk calculators, and surveillance programs for infections and adverse events. Effective quality improvement activities included medical center- and surgeon-specific profiles for use in benchmarking reports, and changes in practice related to registry information output. Among the cost-effectiveness strategies employed were collaborations with sourcing and contracting groups, and assistance in adherence to formulary device guidelines. Research studies using registry data included postoperative complications, resource utilization, infection risk factors, thromboembolic prophylaxis, effects of surgical delay on concurrent injuries, and sports injury patterns.

Conclusions: The unique KP implant registries provide important information and affect several areas of our organization, including patient safety, quality improve-

more costly devices are introduced into the market with little to no evidence of enhanced clinical effectiveness.

In addition, new technology sometimes fails, requiring recalls of medical devices. In 2011 a total of 41 Class 1 recalls happened in the US.º Recalls of medical devices can put patients at major risk of complications and mortality. Although some recalls require only patient consultations, others can require close monitoring of patients, and in some more serious cases a high-risk reoperation. Early identification of device failures is therefore necessary to prevent implantation of defective devices and harm to patients.

Considering the high cost, volume, and patient safety issues associated with medical devices, monitoring of medical device performance is critical to ensure patient safety and quality of care. One method for tracking these devices is the use of patient registres. A patient registress

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June 2013 Volume 39 Number 6

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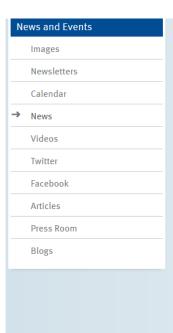
Values/benefits from registries

- Benefit patient safety
- Improve patient quality
- Improve cost-effectiveness

- Boneloc/
- Paxton EW et al. The Joint Commision 2013;
 39(6):246-52.



A Nordic Orthopaedic Complication Registry: **Something for The Nordic Council?**



Bent Høie positiv til samarbeid om høyspesialisert pasientbehandling

f 💆 in

Helseminister Bent Høie er positiv til mer omfattende nordisk samarbeid om innkjøp av legemidler, investeringer i medisinsk teknologi og klinisk forskning.

Apr 04, 2014

Under samtalen med Bo Könberg, tok helseminister Bent Høle opp viktigheten av at pasienter har muliahet til en såkalt second opinion.



Nordic health-care cooperation?

Tidligere helseminister i Sverige, Bo Könberg, har på oppdrag av Nordisk ministerråd forfattet en nordisk helseutredning som oppfordrer til samarbeid på tvers av landegrensene for å skape bedre folkehelse og videreutvikle helseomsorgen.

Les rapporten her: Det framtida nordiska hälsosamarbetet

Rapporten kommer med 14 konkrete forslag til samarbeidsområder. Et av forslagene går ut på en massiv samlet innsats med mål om å begrense bruken av antibiotika for å hindre den økende antibiotikaresistensen, som Könberg mener er vår tids største helsetrussel. Hvert år dør 25.000 mennesker i Europa pga. antibiotikaresistens

Vil ha økt samarbeid

– I Nordisk råd er vi veldig glade for at denne rapporten har kommet. Flere av forslagene om samarbeid i rapporten har allerede blitt fremmet av oss, blant annet forslag for å begrense antibiotikaresistens. Ministerne må prioritere det nordiske samarbeidet i større grad, også økonomisk, sa Sonja Mandt (Ap),parlamentariker i Nordisk råd.

Leder av Arbeiderpartiets helsefraksjon, Torgeir Micaelsen, uttrykte undring over at Norden ikke allerede har etablert et omfattende samarbeid på helseområdet, og trakk frem legemidler som et område der de nordiske land har mye å tjene på økt samarbeid.

"In The Nordic Council we are very happy for this report. Several of the suggestions about cooperation have previously been proposed by us, among others the suggestion of efforts to minimze the resistency of antibiotics. The Ministers have to give the Nordic cooperation much higher priority, also economically", said Sonja Mandt (Ap), member of The Nordic Council.

Can this information help us in "building" a Nordic Complication Registry?

- Apply for funding (from The Nordic Council?)
- Make a common sheet for registration (ref. The NOV experience), general agreement of what to register
- Establish a steering group/PI
- Start up with pilot hospitals (one in each country?)
- Pilot period: one year?
- Evaluation -> publication -> conclusion
- If positive conclusion, a common Nordic start-up?



Conclusions

- In conclusion, we have learned that registries in orthopaedics are helpful tools
- A complete Complication registry will give us a lot more data concerning all types of complications related to orthopaedic surgery
- This will improve the hospitals awareness on such complications, and probably minimize the numbers of complications -> improved healthcare



Conclusions

- The Registry have to be 100% digital, no paper accepted
- How to secure that all patients are registrated?
 - Proposal: no registration, no payment

 To achieve this, we need political support (lobbying)



So let's go for a Nordic Complication Registry in Orthopaedic Surgery

