

Overview of the Global Orthopaedic Registry (GLORY)

Frederick A. Anderson, Jr., PhD

The Global Orthopaedic Registry (GLORY) is an international registry of patients who underwent elective primary total hip arthroplasty (THA) or primary total knee arthroplasty (TKA) during the years 2000 through 2004. By providing a real-world view of practices and outcomes, its objectives are to compare practice with evidence-based standards, to identify where such standards do not exist but are needed, and ultimately to lead to hypotheses for improving research, education, and patient care that can be verified by controlled clinical trials.

Previous data on outcomes after THA or TKA have been collected from clinical trials that assess individual devices or from country-specific registries. The Swedish THA and TKA registries were among the first total joint registries established.^{1,2} A variety of country-specific registries have provided important information on both short- and long-term outcomes following THA and TKA. However, a majority of countries do not have well-established national joint arthroplasty registry programs, and both established registries and clinical trials have limitations.

Firstly, clinical trials generally assess a newly developed implant, and most registries focus on outcomes resulting from different types of implant and the factors that affect implant survival. As a result, they provide a valuable quality-improvement tool to identify superior and inferior implants at an early point following their introduction into clinical practice.^{1,3} However, they offer relatively little information about a wide range of surgical practices, postoperative complications, and functional outcomes. GLORY was designed to monitor a broad range of practices, complications, and outcomes. This approach distinguishes this registry from previous efforts directed solely at assessing implant survival.⁴

Secondly, most registries and clinical trials gather data from a single country, or even from a single hospital. As

a multinational registry, GLORY includes global, rather than solely country-specific, hospital-specific, or implant-specific, data. GLORY can thus provide unique insight into the geographical differences in THA and TKA practices and also clinically valuable data on the prevalence of postoperative complications.

This voluntary registry is physician directed and came into being by the merger of 2 preexisting registries, the International Orthopaedic Registry (IOR) and The Hip and Knee Registry (THKR), which was restricted to North America (Figure 1). THKR enrolled patients from 1995 to 2002. Results from the THKR have been published

“GLORY was designed to monitor a broad range of practices, complications, and outcomes.”

previously.⁵ THKR enrolled over 40,000 total joint procedures from more than 500 surgeons in the United States and Canada. However, its follow-up rate was only about 30%, raising concerns about the possibility of bias in the reporting of complications. In 2001 the IOR was formed and merged in 2002 with the THKR to form GLORY. The IOR case report included all variables later contained in GLORY, while the THKR only included 80% of these variables. This makes GLORY more detailed than the THKR and similar to the IOR.

Dr. Anderson is Study Coordinating Center Director, Center for Outcomes Research, University of Massachusetts Medical School, Worcester, Massachusetts.

For correspondence, contact: Frederick A. Anderson, Jr., PhD, Center for Outcomes Research, University of Massachusetts Medical School, One Innovation Drive, Suite 110, Worcester, MA 01605 (tel, 508-856-2275; fax, 508-856-5159; e-mail, Fred.Anderson@umassmed.edu).

Am J Orthop. 2010;39(9 Suppl):2-4. Copyright 2010, Quadrant HealthCom Inc. All rights reserved.

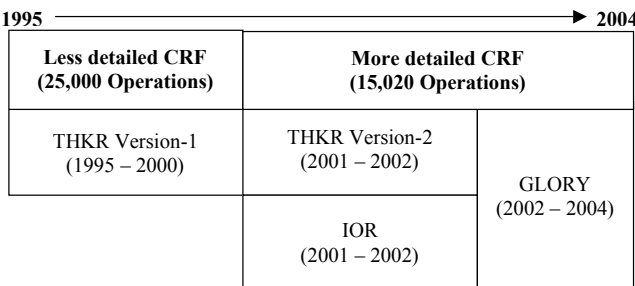


Figure 1. Understanding the evolution of The Hip and Knee Registry (THKR), International Orthopaedic Registry (IOR), and Global Orthopaedic Registry (GLORY) data sets. THKR was limited to North America-based orthopedic surgical practices. IOR included surgeons practicing outside of North America. Abbreviation: CRF, case report form.

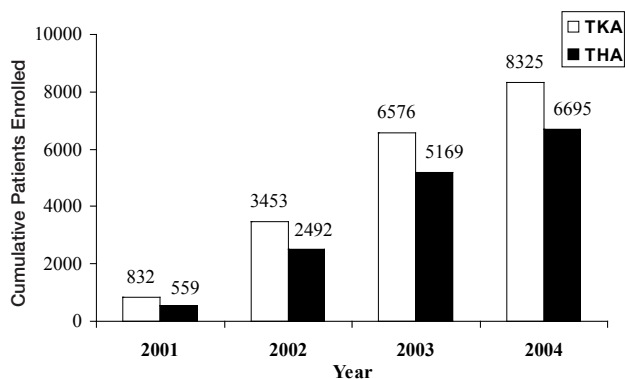


Figure 2. Cumulative patient enrollment by year. Abbreviations: THA, total hip arthroplasty; TKA, total knee arthroplasty.

STUDY DESIGN

GLORY was designed and coordinated by the Center of Outcomes Research (University of Massachusetts, USA). The registry is governed by the GLORY Scientific Advisory Board, which includes orthopedic surgeons representing each participating country and clinical scientists with experience in the design and analysis of registry data from joint arthroplasty patients.

Participating surgeons enrolled consecutive patients ≥ 18 years of age who had undergone elective primary THA or TKA. In-hospital data were collected on all patients. Wherever possible, patients were followed up at approximately 3 months and again at 12 months to collect data on selected aspects of their outpatient management and post-discharge functional outcomes. In contrast to a clinical trial, there is no imposed experimental intervention. Patient treatment is determined solely by the physicians.

One hundred hospitals participated in 13 countries worldwide: Australia, Brazil, Bulgaria, Canada, Colombia, Germany, Italy, Japan, Poland, Spain, Turkey, United Kingdom (UK), and the United States (USA). Surgeons were asked to enroll the first 10 cases of THA and the first 10 cases of TKA they see each month. For smaller centers this meant enrolling all patients who met entry criteria, while for larger centers this was an unbiased method for selecting a patient sample. The registry enrolled 15,020 patients who underwent primary elective unilateral total hip (6,695 patients) or knee replacement surgery (8,325 patients) between June 2001 and December 2004 (Figures 2 and 3). Of these patients 70% (10,490) completed either a 3-month (5,346) or 12-month follow-up (1,320) only, or both (3,824).

The scientific coordinating center ensures that the registry complies with scientific and ethical standards. Each hospital involved in GLORY received ethics committee or institutional review board approval, and, where mandated by their ethics committee, participating surgeons obtained informed consent from patients prior to their participation in the registry and for follow-up contact after discharge.

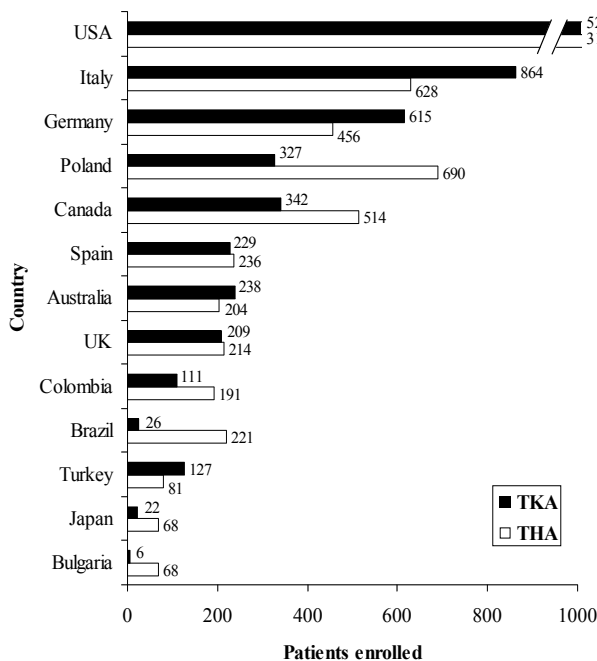


Figure 3. Patient enrollment by country. Abbreviations: THA, total hip arthroplasty; TKA, total knee arthroplasty.

DATA COLLECTION

Participating surgeons or trained study coordinators collected data on standardized case report forms. Data include patient demographics, primary diagnosis, preexisting comorbid conditions, length of hospital stay, type of anesthesia, prophylaxis for venous thromboembolism (including type and duration), in-hospital complications, discharge disposition, and patient self-reported quality of life. The completed case report forms were then sent to the scientific coordinating center for entry into the database and for analysis. Data were entered into a computer database and subsequently analyzed using a Statistical Analysis System (SAS)-PC. Data quality control was monitored using standardized query logic. Out-of-range or illogical responses were queried to the surgeon on a quarterly basis. Corrections were faxed to the scientific coordinating center.

Key outcomes include clinically recognized venous thromboembolism (VTE), postoperative bleeding, wound infection, dislocation, functional status, and death. A deep vein thrombosis (DVT) or pulmonary embolism (PE) is defined as a symptomatic event that was subsequently confirmed by diagnostic imaging techniques such as venography, ultrasound, radioisotope scanning, and 3D computed tomography scanning. Clinically important bleeding following THA/TKA is defined as “Bleeding that is recorded by the surgeon as being outside the range of typical expected levels of bleeding following THA/TKA, or bleeding that is cited as the cause of prolonged hospital stay.” Functional status was assessed through a quality-of-life self-assessment questionnaire consisting of the Short Form-8 Survey (SF-8) and the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index, completed by the patients prior to hospitalization and again at each follow-up.

Strengths of GLORY

GLORY monitors practice trends and clinical outcomes in unselected patients in a real-world routine patient care environment. These data may be more representative than data collected in the context of controlled clinical trials, in which restrictive inclusion/exclusion criteria may limit generalizability. GLORY is the only multinational orthopedic registry using standard data collection instruments, definitions, and patient selection criteria across many different healthcare systems. By monitoring what physicians are doing in the “real world,” the adoption of evidence-based practice standards can be assessed, and strategies identified to improve the quality and value of health care. Furthermore, data from GLORY can serve to plan educational programs and as a hypothesis-generating tool to plan controlled clinical trials.

Limitations of GLORY

GLORY is a voluntary registry, and as such, it is likely that many of the surgeons who agreed to provide registry data already pay special interest to evidence-based practice standards. Indeed, some differences are found in the multinational prophylaxis practices reported in this supplement compared with previous US-specific studies of orthopedic surgeons.⁶ While this may result in an overestimation of the adoption of such standards, the database nevertheless provides insights into current everyday practice and its regional variations, and it allows an appraisal of contemporary compliance with international guidelines and recommendations. As GLORY is a large-scale voluntary registry, no hospital audits were performed to check data quality. Data quality control was ensured through standardized query logic; out-of-range or illogical responses were queried to the surgeon on a quarterly basis. A voluntary registry is not a substitute for randomized clinical trials and therefore of limited value in determining the safety or efficacy of different treatment options.

GLORY Results

In this supplement, findings from GLORY will be presented and placed within the context of current knowledge regarding THA and TKA in 3 articles, dealing with orthopedic practices, thromboprophylaxis practices, and complications and outcomes consecutively. The lessons that can be learned from GLORY regarding study design and current practice patterns will be discussed in the epilogue, and future directions explored.

AUTHOR'S DISCLOSURE STATEMENT AND ACKNOWLEDGMENTS

GLORY is supported by an unrestricted educational grant from sanofi-aventis to the Center for Outcomes Research at the University of Massachusetts Medical School, Worcester, Massachusetts. The registry is overseen by an independent Scientific Advisory Committee. Additional information about this registry, including a full list of the Advisory Committee members, is available on the website at www.outcomes.org.

Dr. Anderson is a consultant for sanofi-aventis, GlaxoSmithKline, and Ortho McNeill.

REFERENCES

- 1 Robertsson O, Lewold S, Knutson K, Lidgren L. The Swedish Knee Arthroplasty Project. *Acta Orthop Scand*. 2000;71(1):7-18.
- 2 The Swedish National Hip Arthroplasty Register Annual Report 2003. Department of Orthopaedics, Sahlgrenska University Hospital, May 2004. Available at: <http://www.jru.orthop.gu.se>. Accessed August, 2005.
- 3 Havelin LI, Engesaeter LB, Espehaug B, Furnes O, Lie SA, Vollset SE. The Norwegian Arthroplasty Register: 11 years and 73,000 arthroplasties. *Acta Orthop Scand*. 2000;71(4):337-353.
- 4 The Center for Research Outcomes. The Global Orthopaedic Registry (GLORY) Available at: www.outcomes.org. Accessed August, 2005.
- 5 Anderson FA Jr, Hirsh J, White K, Fitzgerald RH Jr; Hip and Knee Registry Investigators. Temporal trends in prevention of venous thromboembolism following primary total hip or knee arthroplasty 1996-2001: findings from the Hip and Knee Registry. *Chest*. 2003;124(6 Suppl):349S-356S.
- 6 Mesko JW, Brand RA, Iorio R, et al. Venous thromboembolic disease management patterns in total hip arthroplasty and total knee arthroplasty patients: a survey of the AAHKS membership. *J Arthroplasty*. 2001;16(6):679-688.

APPENDIX

GLORY Scientific Advisory Committee

Co-chairs:

Fred Cushner, MD
New York, NY, USA

David Warwick, MD
Southampton, UK

Advisors:

Giancarlo Agnelli, MD
Perugia, Italy

John Callaghan, MD
Iowa City, IA, USA

Richard Friedman, MD
South Carolina, USA

Simon Frostick, MD
Liverpool, UK

Alexander Gallus, MD, PhD
Bedford Park, Australia

Enrique Gil-Garay, MD, PhD
Madrid, Spain

Werner Hein, MD
Halle, Germany

Kirk Johnson, MD
Worcester, MA, USA

Franco Piovela, MD
Pavia, Italy

Flavio Turibio, MD
São Paulo, Brazil

James Waddell, MD
Toronto, Canada