



National Cardiovascular Data Registry[®] (NCDR[®])

Author Guidelines

National Cardiovascular Data Registry® (NCDR®)
Author Guidelines

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OVERVIEW

The overarching goal of the NCDR research process is publication of manuscripts that utilize data from the various NCDR Registries, which offer robust platforms for a variety of research and quality improvement projects.

These Guidelines were developed in order to provide authors with an overview of the NCDR research and publications process from submission of a research proposal to generation of a manuscript. Our goal is to enhance collaborative efforts and manuscript submissions by authors who submit research proposals to the NCDR.

We request that authors adhere to these guidelines when preparing proposals, abstracts, and manuscripts.

Thank you for your interest in NCDR-based research. We look forward to helping you develop your proposal into a published manuscript.

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NCDR RESEARCH AND PUBLICATIONS TEAM CONTACT INFORMATION

For questions regarding the research and publications process, please contact the NCDR Research and Publications (R&P) team at:

Email: ncdrresearch@acc.org

Phone: (800) 257-4737

Fax: 202-375-6839

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WHERE YOU ARE IN THE NCDR RESEARCH PROCESS

As the research proposal's author, you have developed your research idea(s) with a focus on data from one of four NCDR registries cited below, alongside appropriate NCDR Trademarks:

- Acute Coronary Treatment and Intervention Outcomes Network Registry - Get With The Guidelines: **ACTION Registry®-GWTG™**
- Catheterization-and Percutaneous Coronary Intervention Registry: **CathPCI Registry®**
- Implantable Cardioverter-Defibrillator Registry: **ICD Registry™**
- Carotid Artery Revascularization and Endarterectomy (CARE) Registry: **CARE Registry®**

You have completed a Research Proposal Application (RPA) from the NCDR web site and submitted it to NCDR as the primary author.

You have been assigned a registry specific tracking number to use in all subsequent correspondence.

Your RPA has been reviewed and approved by the registry-specific Research and Publications (R&P) Subcommittee.

The assigned analytic center is reviewing your RPA. The analytic center will contact you to develop an analytic plan to conduct analysis.

STATISTICAL ANALYSIS AND DATA INTERPRETATION

Analysis of data from a specific registry is assigned to a corresponding data analytic center:

- ACTION Registry- GWTG - Duke Clinical Research Institute (DCRI)
- CathPCI - Duke Clinical Research Institute (DCRI)
- ICD - Yale Center for Outcomes Research and Evaluation (CORE)
- CARE - Mid American Heart Institute (MAHI)

After the Subcommittee approval of the Research Proposal Application (RPA), the R&P Coordinator will contact the primary author and statistician from the analytic center designated for his/her proposal. The primary author will receive a RPA Status Letter explaining the results of the vetting process that took place regarding their submitted RPA. If the RPA is scored high enough to continue through the pipeline to the analysis phase, the author will be notified in this letter.

The assigned primary statistician and analytic center clinicians will review the research proposal and contact the author to discuss a specific plan for analysis. The goal is to ensure the submission of a final manuscript to a peer-reviewed journal within 4 months of completion of the data analysis.

Analyses will be performed on a single patient population. The primary statistician will review tables and statistics and be available to assist authors as necessary. **The NCDR has contractual agreements with its participating hospitals that allow only the analytic centers to work with the NCDR data.**

REVIEW AND PREPARATION OF ABSTRACTS

It is widely accepted in the research community that manuscript publications often hinge upon the initial publication of an abstract. Therefore, after the analytic center has completed its analysis, we encourage publication of an abstract as part of the manuscript publication process.

Abstract production begins when the lead or primary author receives analysis from the NCDR analytic center. **The author and co-authors prepare an abstract draft and e-mail it to ncdrresearch@acc.org in order for the abstract to be reviewed by the appropriate NCDR[®] R&P Committee.** Comments are forwarded back to the author by the NCDR R&P team. The author then incorporates this feedback into a revised abstract before submitting the draft for possible presentation [e.g., poster, oral presentation] at a major conference or meeting. The author will submit to R&P Coordinator copies of both the initial submission and the final draft accepted to a conference or meeting. The R&P Coordinator, along with reviewers will be available to assist authors as needed during this process.

ABSTRACT APPROVAL PROCESS

- When the analysis is complete, the primary author will be responsible for informing the NCDR of the abstract status, including:
 - ✓ Conference venue or meeting
 - ✓ Type of presentation
 - ✓ Acceptance or non-acceptance
- **Abstract drafts require NCDR review and must be e-mailed to ncdrresearch@acc.org at least 2-3 weeks before a scientific meeting's abstract submission deadline.**
- The R&P reviewers will do a high-level review of the abstract and provide their comments and feedback to the NCDR[®] R&P team, which will forward comments on to authors.
- The primary statistician from the analytic center will review tables and statistics and also provide the author with comments.
- The primary author incorporates comments from the reviewers and the statistician into the final abstract and submits it to the selected scientific meeting.
- Abstracts cannot be submitted to a professional scientific meeting unless accuracy of the data is verified by the NCDR[®] R&P Committee reviewers and lead analytic center statistician.
- A copy of the final abstract must be sent to the NCDR R&P team at: ncdrresearch@acc.org .
- When abstracts are accepted as posters or talks with slides, the author is responsible for submitting posters, oral presentations, and slides in appropriate NCDR format (using NCDR[®] registry-specific slide and poster templates) to the R&P Coordinator and statistician for review one week prior to the selected meeting.
- Immediately following the conference or meeting, the lead author is responsible for forwarding the final poster or talks with slides presented at the conference or meeting, including citations, to the R&P Coordinator.

REVIEW AND PREPARATION OF MANUSCRIPTS

Manuscript production begins when authors receive completed analysis from the NCDR analytic center. Authors and co-authors prepare a manuscript draft and submit it to the R&P Coordinator, who forwards it to the same two R&P Committee reviewers who initially reviewed the proposal. The manuscript is also forwarded to the analytic center. Reviewer and statistician comments are forwarded through the R&P Coordinator to the primary or lead author, who incorporates this feedback into a revised manuscript, which is then submitted to the designated journal. The author will submit to the R&P Coordinator copies of both the initial submission and the one accepted by the journal. The R&P Coordinator, along with reviewers and analytic center staff, will be available to assist authors as needed during this process.

MANUSCRIPT APPROVAL PROCESS

- Authors are strongly encouraged to complete their manuscript and submission to a selected journal within 4 months of completion of the final data analysis.
- When the analysis is complete, the primary author will be responsible for informing the NCDR on a monthly basis of the status of the manuscript progress. The status report should be forwarded to ncdrresearch@acc.org, and include the following information:
 - ✓ Brief status report on progress in writing the manuscript
 - ✓ Expected date of completion
 - ✓ Name of journal targeted for publication
 - ✓ Date of submission (includes all dates for resubmissions to journals), acceptance, and projected date of publication [if available]
 - ✓ Final outcome.
- The author will make use of the Publications Guidelines as needed when writing the manuscript.
- The completed manuscript draft will be sent to the NCDR R&P team, which will forward it for review by the appropriate NCDR R&P Committee and analytic center statistician. Comments from the reviewers will be returned to the lead author as soon as they are received. The statistician will coordinate directly with the author regarding changes to interpretation of the analysis, tables or figures.
- Manuscripts cannot be submitted unless accuracy is verified by the analytic center staff and NCDR R&P Committee reviewers. The primary statistician will review tables and statistics and be available to assist authors in drafting statistical methods sections.
- The primary author incorporates comments from reviewers and statisticians into a final manuscript for submission to journal.
- Editorial assistance is available upon request from the NCDR R&P Team.
- If the author wishes, an NCDR R&P reviewer can suggest an initial target journal, but the final decision regarding the target journal will be left to the primary author.
- The author submits, too the NCDR R&P Team, a copy of the draft that is first submitted to a journal. S/he also submits a copy of the manuscript that is published, including citations.

Authors must not submit manuscripts to journals unless accuracy of the data is verified and reviewed by the R&P Committee and primary statistician.

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AIDS TO ABSTRACT/MANUSCRIPT PREPARATION

Authors are responsible for acquiring guidelines specific to conferences, meetings and journals selected for submission. We offer the aids listed below as a resource to authors who are preparing manuscripts for submission to the NCDR review process.

- 1) Sample Outline
- 2) Use of Standardized Language to describe the NCDR and its data
- 3) Tables and Figures
- 4) References & Citations
- 5) Definition of Variables
- 6) NCDR Registry slides and poster templates
- 7) Authorship

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Sample Outline:

I. Background

Methods

A. Data Definitions

B. Statistical Analysis

C. Study Limitations

II. Results

III. Discussion

IV. Conclusion

Use of Standardized Language to Describe the NCDR and Its Data

The following text is intended to provide examples of language that can be used in the manuscript to describe the NCDR data.

ACTION Registry[®] – GWTG[™] is a voluntary registry that receives data from ___ hundred participating hospitals. There is a standard data set with written definitions, uniform data entry and transmission requirements, and data quality checks. Details on the data collection process have previously been published. [See section 4 below on references and citations] For the purpose of this study, we examined registry patients undergoing PCI procedures from beginning month/day/year, through ending month/day/year. Patients who were undergoing PCI for ST-segment elevation acute myocardial infarction (STEMI) were excluded; all others were included.

Correct Use of NCDR[®] Trademarks

Kindly adhere to correct use of NCDR-related trademarks [shown below] when preparing your abstract and manuscript drafts. Note that logos are used stand-alone, as shown.

- Acute Coronary Treatment and Intervention Outcomes Network Registry - Get With The Guidelines: **ACTION Registry[®]-GWTG[™]**
- Catheterization-and Percutaneous Coronary Intervention Registry: **CathPCI Registry[®]**
- Implantable Cardioverter-Defibrillator Registry: **ICD Registry[™]**
- Carotid Artery Revascularization and Endarterectomy (CARE) Registry: **CARE Registry[®]**
- Improving Continuous Cardiac Care (IC³) Program[®]: **IC³ Program[®]**
- IMproving Adult and Congenital Treatments (IMPACT) Registry[™]: **IMPACT Registry[™]**
- National Cardiovascular Data Registry[®]: **NCDR[®]**

The complete name of a specific NCDR registry, including correct trademark symbols, must be written out in first use (includes in abstract/manuscript title). Thereafter, the acronym can be used, and the ® or ™ can be omitted. Example:

TITLE: Gender Differences in Short-Term Outcomes After Carotid Revascularization: Carotid Artery Revascularization and Endarterectomy (CARE) Registry (CARE Registry[®])

BODY OF ABSTRACT: Patients entered into the CARE Registry up to the first quarter of 2009 formed...

Please note we have discontinued use of the following:

ACC-NCDR®

NCDR-ACTION Registry™

NCDR-CathPCI Registry™

NCDR-CARE Registry™

NCDR-ICD Registry™

Constraints of Data

When preparing manuscripts, authors describe the constraints or limitations of NCDR data in various ways, several of which are shown below. Authors should remember that NCDR registries provide retrospective observational data. Moreover, the clinical significance of a particular study must take into account the fact that data are abstracted from a heterogeneous mixture of facilities.

- a. An unequal geographic distribution of participating hospitals leads to selection bias, which limits the proportion of the Acute Coronary Syndrome population that was evaluated during the period described by this study.
- b. NCDR-participating facilities vary in terms of the types and number of procedures they provide. This variability can impact on the data that are accrued.
- c. The extent and what types of data the NCDR collects; registries typically need more detailed data, and authors will need to address this limitation.
- d. NCDR data are collected during acute hospitalizations; the lack of longitudinal data could provide a constraint or limitation of the study.

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Tables and Figures

All tables should have a title and each descriptive row and column should be labeled appropriately. Number all tables in order of their citation in the text. Include all tables consecutively, one table per page, at the end of the manuscript.

Sample Table:

TABLE I. Percentage of Ad Hoc PCIs According to Indicators of Demographics, Comorbidity, Specific Cardiac/Lesion Issues, and Stress Test Results

	Percentage of patients undergoing ad hoc PCI with or without specific risk factors		
	Factor present	Factor absent	<i>P</i> value
Calculated high risk	58.6	63.0	<0.001
Male gender	61.0	59.9	<0.01
Age >70 ^a	58.6	62.0	<0.0001
Hypertension ^a	59.7	63.3	<0.0001
Diabetes ^a	58.8	61.8	<0.001
COPD ^a	58.0	61.0	<0.0001
History of CHF ^a	58.8	60.8	<0.01
Current CHF ^a	65.1	60.3	<0.001
CCS class II, III, IV	60.2	68.4	<0.001
Renal failure (no dialysis) ^a	50.7	60.9	<0.001
Previous PCI	59.0	61.8	<0.0001
Previous CABG ^a	56.8	61.8	<0.0001
LVEF <35% ^a	53.8	61.2	<0.0001
Triple vessel disease ^a	68.7	59.0	<0.0001
SCAI class-IV lesion ^a	62.7	60.5	<0.05
Positive stress test ^a	63.1	56.4	<0.0001

CCS, Canadian Cardiovascular Society; COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; SCAI Class IV lesion, ACC/AHA occluded class-C lesion.

^aFactors that are independently predictive of ad hoc PCI as established by inclusion in the multivariate logistic model.

Source:

Ad Hoc Percutaneous Coronary Intervention (PCI) in Patients with Stable Coronary Artery Disease—A Study of Prevalence, Safety, and Variation in Use from the American College of Cardiology—National Cardiovascular Data Registry. RJ Krone, RE Shaw, LW Klein, JC Blankenship, WS Weintraub. *Catheter Cardiovasc Interv* 2006; 68(5):696–703.

Sample Figure:

All figures should have a title and each axis should be labeled appropriately. Number all figures in order of their citation in the text. Include all figures consecutively, one figure per page, at the end of the manuscript.

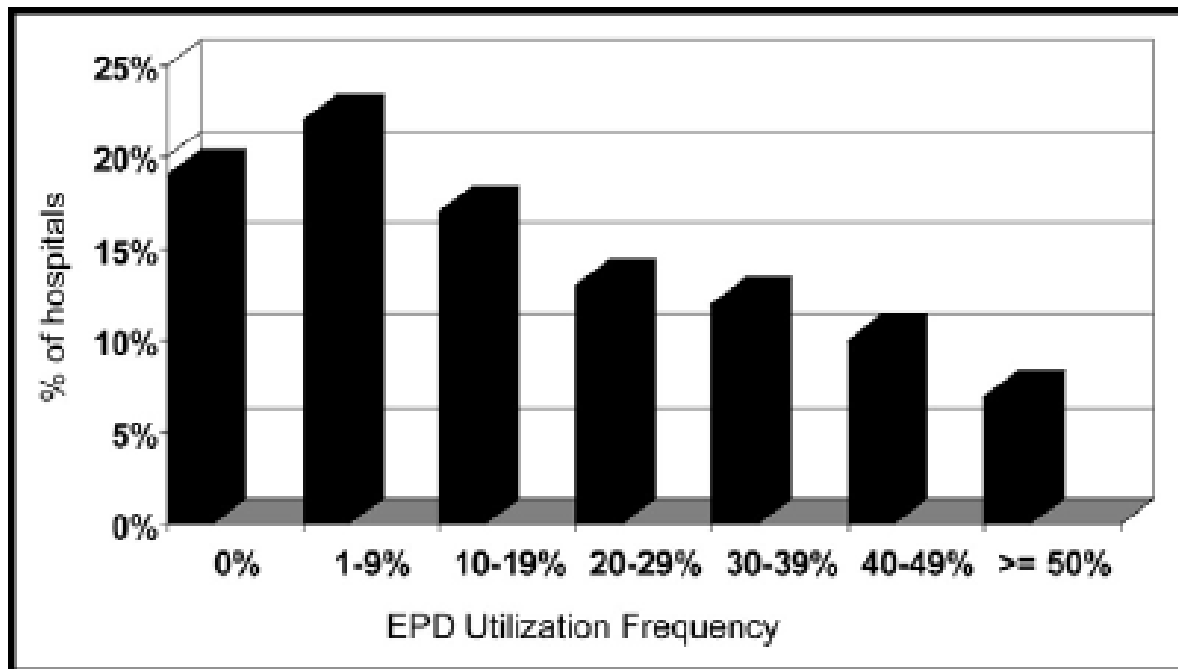


Figure 1. Hospital frequencies of EPD use.

Source:

Clinical Utilization and Efficacy of Distal Embolic Protection Devices during Saphenous Vein Graft Percutaneous Coronary Interventions. S Marso, S Mehta, et al. American Journal of Cardiology 2007; 100: 1114-1118.

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References and Citations

Ultimately, references and citations must follow a given journal's guidelines, and authors are responsible for adherence to a journal's guidelines for references. Standard citations describing NCDR-related research are included below, and provided as examples only.

Anderson HV, Shaw RE, Brindis RG, Hewitt K, Krone RJ, Block PC, McKay CR, Weintraub WS. A contemporary overview of percutaneous coronary interventions. *J Am Coll Cardiol.* 2002;39:1096 – 1103.

Shaw RE, Anderson HV, Brindis RG, Krone RJ, Klein LW, McKay CR, Block PC, Shaw LJ, Hewitt K, Weintraub WS. Development of a risk adjustment mortality model using the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) experience: 1998–2000. *J Am Coll Cardiol.* 2002;39:1104 –1112.

Shaw RE, Anderson HV, Brindis RG, Krone RJ, Klein LW, McKay CR, Block PC, Shaw LJ, Hewitt K, Weintraub WS; ACC-NCDR. Updated Risk Adjustment Mortality Model Using the Complete 1.1 Dataset from the American College of Cardiology National Cardiovascular Data Registry (ACC – NCDR). *J Invasive Cardiol.* 2003 Oct;15(10):578-80.

Shaw RE, Anderson HV, Brindis RG, Krone RJ, Klein LW, McKay CR, Block PC, Shaw LJ, Hewitt K, Weintraub WS. Updated risk adjustment mortality model using the complete 1.1 dataset from the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR). *J Invas Cardiol.* 2003;15:578 –580.

Definitions of Variables

Definitions of variables are available from the specific registry web site under the Elements/Definitions link.

NCDR Registry Slides and Poster Templates

Authors must submit abstract slides and posters in NCDR format. Templates are available from the R&P Coordinator.