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Improving publication rates in a collaborative clinical trials research network

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Abstract

Unpublished results can bias biomedical literature, favoring positive over negative findings, primary over secondary analyses, and can lead to duplicate studies that unnecessarily endanger subjects and waste resources. The Neonatal Research Network's (NRN) publication policies for approving, reviewing, and tracking abstracts and papers work to combat these problems. In 2003, the NRN restricted investigators with unfinished manuscripts from proposing new ones and in 2010, urged authors to complete long-outstanding manuscripts. Data from 1991 to 2015 were analyzed to determine effectiveness of these policy changes. The NRN has achieved an overall publication rate of 78% for abstracts. For 1990–2002, of 137 abstracts presented, 43 (31%) were published within 2 years; for 2003–2009, after the manuscript completion policy was instituted, of 140 abstracts presented, 68 (49%) were published within 2 years. Following the effort in 2010, the rate increased to 64%. The NRN surpassed reported rates by developing a comprehensive process, holding investigators accountable and tracking abstracts from presentation to publication.

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Keywords

Publication rates; Network collaboration; Authorship policies

Meta-analyses[1–3] across a broad range of biomedical specialties have estimated that only 31–52% of meeting abstracts are subsequently published as manuscripts in peer-reviewed journals. Chen et al.,[4] recently found that only 35.9% of clinical trials reported results, either in publications or on ClinicalTrials.gov, within 24 months of study completion. These low rates are the result of multiple issues from biases in journal acceptance to sustaining author's motivation through multiple revisions and journal submissions. The selection processes at both the abstract and manuscript level are biased toward studies that show statistically significant findings,[1,5,6] and favor randomized controlled, interventional trials over observational studies. The result is that "conclusions derived from systematic reviews may be biased due to lack of inclusion of not fully published or unpublished data."[3] Such biases can impact medical practice—allowing ineffective, if not unsafe, therapies to continue and impeding dissemination of more effective ones.

How to manage the manuscript process to improve publication rates is rarely discussed. This is of particular concern for collaborative research networks with large teams of investigators that need to manage the quality, quantity, and timeliness of publications.[7,8] It is complicated further for networks that conduct longitudinal studies, multiple ongoing trials, and/or undergo periodic competitive funding cycles. These networks must manage transitions across cycles, as research centers, data coordinating centers (DCCs), principal investigators (PIs), and as other staff enter and exit the team.

Over its 30-year history, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Neonatal Research Network (NRN), a collaborative research network devoted to developing evidence-based therapies for neonatal medicine, has addressed these challenges through detailed policies and procedures for proposing and selecting abstracts, reviewing manuscripts, and tracking papers through to publication. Due to its scientific productivity, the NRN has received numerous requests for its policy manual from research groups, both within and outside of neonatology. In some cases, these groups want to improve their current practices; in other cases, they are developing their own policies. The focus is to describe the NRN's publication policies and procedures and their effectiveness.

The NICHD Neonatal Research Network

Formed in 1986, the NRN is a research network of neonatal intensive care units across the United States, funded by NICHD in 5-year, competitively awarded cooperative agreements. The NRN's objective is "to facilitate the advancement of neonatal care by establishing a network of academic centers that, by rigorous patient evaluation using common protocols, can study the required numbers of patients and can provide answers more rapidly than individual centers acting alone."[9]

To fulfill this mission, the NRN conducts multiple clinical trials and observational studies simultaneously. As of March 2016, it has completed, or is currently implementing, 20 observational studies and 36 interventional trials (details are available at http://www.clinicaltrials.gov and on the NRN website at http://neonatal.rti.org). Many of these studies include primary and multiple secondary outcomes, as well as secondary protocols with additional hypotheses and data collection. Investigators are expected to publish results in peer-reviewed journals for dissemination into clinical practice. In addition, all NRN protocols, including its long-term registry, provide rich datasets for further analyses. As more data become available over time, researchers find novel ways to answer important medical and epidemiologic questions: analyzing intervention effectiveness, identifying subgroups that may benefit from or have higher risks with certain medical practices, and tracking trends in disease incidence and therapy use.

Currently, in its seventh funding cycle with 15 clinical centers and a DCC, the NRN has, over the course of its history, included 28 academic medical centers and two DCCs. Finally, the NRN has had dynamic turnover in the PIs and staff at these institutions, increasing the challenge of ensuring that research is published in a timely manner.

Methods

The NRN Steering Committee (SC), composed of the PI from each medical center and the DCC, an NICHD program scientist, and a non-affiliated chairperson, is responsible for implementing network protocols. Over time, the SC has developed a detailed Policy and Procedures Manual covering protocol development and implementation, abstract review, and publications. The SC delegates oversight of manuscripts to its Publications Subcommittee, a subset of PIs, the DCC PI, and the NICHD program scientist.

Because of the length of time from protocol development to publication, it is important to have publication and authorship expectations detailed upfront, along with a process for proposing and reviewing abstracts and papers. In addition, the network needs to strategically prioritize its limited resources and budget to conduct studies and analyze results.

All NRN protocols, both interventional and observational, undergo a thorough review and approval process prior to implementation. For each protocol, a subcommittee of PIs, coordinators, and other investigators manages study design and implementation, statistical analyses, and publication of results. The NRN's goal is to publish primary results within 1 year after all data have been collected, cleaned, and locked for analysis. The first author is expected to have a draft manuscript for subcommittee review within 3 months of data lock. Planned secondary outcomes (i.e., neurodevelopmental follow-up of subjects) and secondary protocols follow similar timetables.

Results of most main and secondary protocols are presented at the Pediatric Academic Societies (PAS) annual meeting prior to publication. Main studies are given higher priority for analytic resources than other data analyses.

NRN abstract approval process

The timeline for the NRN abstract approval process is based on the submission deadline for the PAS meetings. Proposals for secondary analyses are due 4–5 months before the deadline, to allow time for concepts to be reviewed and approved and for data analyses to be conducted. Anyone at a NRN center (e.g., PIs, site investigators, and nurse coordinators) may submit a proposal; outside investigators may partner with NRN PIs to submit proposals. The aim is not merely to present at PAS, but to generate high-quality, useful analyses that are publishable. Investigators first submit a 2–5 page concept describing their proposed hypothesis and statistical analysis plan to relevant protocol subcommittee(s) (Fig. 1). Each subcommittee reviews its concepts and can approve, disapprove, or request revisions before making a final decision.

Concepts are evaluated based on the importance of the question being addressed, quality of evidence in the existing literature, whether available NRN data will likely be able to answer the question, and whether the NRN already has plans for similar analyses. The protocol subcommittee, as the group with in-depth knowledge of the data and how they were collected is best suited to determine whether enough data exist in the appropriate format to answer each proposed hypothesis.

Approved concepts are reviewed a second time by the Abstract Review Subcommittee—the SC chairperson, DCC PI, NICHD program scientist, and the chairs of the Protocol Review, Publications, Genomics, Generic Database, and Follow-up Study Subcommittees. This group evaluates all of the approved proposals and prioritizes them. The DCC PI and program scientist use the prioritized rankings to determine how many proposals the NRN can afford to pursue in a particular year, given budget and statistician time constraints. As both levels of evaluation are done prior to conducting detailed data analyses, actual findings generally cannot bias abstract approval.

Following data analyses, the protocol subcommittees review the abstracts prior to submission to PAS. NICHD funding officials (the branch chief, deputy director, and in some cases the communications office) also review them as part of the NICHD Clearance Process. For abstracts accepted by PAS, these same groups review the presentation materials.

Following presentation, the focus turns to drafting a paper. To help ensure that this happens, the NRN policy manual states that: “Submitting an abstract implies a commitment on the part of the Study PI to draft and submit a manuscript for publication.” This expectation holds for all NRN approved abstracts, whether or not they are accepted for presentation at PAS. In addition, all primary and secondary protocols, whether submitted as abstracts or not, are expected to be published.

Authorship

For primary and secondary protocols, authors include the first author (usually the lead study investigator), members of the protocol subcommittee, the statistician(s), and one author (usually the PI) from each participating center not already represented on the subcommittee. Center authors are listed according to each center’s combined rank of number of infants

enrolled and percent of eligible infants enrolled. For secondary data analyses, authorship is determined on a case-by-case basis and generally includes the same list as above without center authors.

NRN publication process

Once drafted and reviewed by coauthors, the NRN manages manuscript quality through four reviews by the relevant protocol subcommittee(s), the Publications Subcommittee, NICHD Clearance, and the SC (Fig. 2).

First authors are responsible for drafting the manuscript and sharing it with all coauthors for their input and review. All authors complete an NRN Authorship Responsibility Form stating that they have reviewed the manuscript and detailing what substantive contributions (e.g., study design, data acquisition, analysis, interpretation, and drafting) they have made. First authors also send the final draft to the protocol subcommittee(s) for review and respond to any comments and suggestions.

Following protocol subcommittee review, the first author must submit the paper to the Publications Subcommittee for internal review. The Publications Subcommittee chair asks 4–6 investigators or topic experts at NRN sites not otherwise associated with the paper to review it within 2 weeks. At the same time, the manuscript is sent through the NICHD Clearance process and to the SC—besides providing additional layers of review, this ensures that all PIs and NICHD are aware of upcoming publications. The reviews do not use formal scoring systems, but help identify issues likely to be raised by journal editors and reviewers. Comments are returned to the first author anonymously; if requested, a reviewer can be identified in order to get clarification on suggested changes. The first author is responsible for sharing all reviews with the coauthors and deciding whether revisions are necessary. Once completed, the first author may submit the paper for journal publication.

Interventions

Over time the SC has instituted new policies and procedures to urge investigators to complete manuscripts in a timely manner. In 2003, the SC instituted a key policy that “An investigator who has an outstanding abstract—one for which he/she has not submitted a draft manuscript to the Publications Subcommittee for review—will not be allowed to submit additional proposals for abstracts or manuscripts.”

At the same time, the Publications Subcommittee developed a more robust tracking system linking abstracts with subsequent manuscripts to promote accountability. Originally a list would be distributed once a year; in 2007 the tracker was redesigned to show where items are in the process. When the tracker was redesigned, all authors and center PIs reviewed it and gave updates on their manuscripts, and many old abstracts were withdrawn. Subsequently, the NICHD Network Coordinator has requested updates, the Publications Subcommittee reviews the tracker, and results are presented at the quarterly SC meetings. If no status update for a paper is received in a 12-month period, it is administratively withdrawn, and no further NRN resources may be used to complete it without further SC approval. As a proxy for paper quality, we record the impact factor of the journals in which

the papers are published. This tracking promotes the expectation of timely publication of results and accountability for use of network resources. In February 2010, the NRN conducted an effort to complete long-outstanding manuscripts (those more than 4 years old). Authors of these manuscripts were asked to submit drafts within a month. If no draft manuscripts were submitted, the items were administratively withdrawn.

Results

During the period from 2007 to 2015 (years for which complete data were available), NRN investigators have proposed 271 concepts, recommended combining 7, and approved 189 abstracts (70%). Of the 188 abstracts submitted to annual PAS meetings (one is pending additional data collection), 177 (95%) were accepted by PAS for presentation.

Since 1990, when the first NRN studies were completed, through 2015, the NRN presented 413 abstracts from 1990 to 2015. Of these, 304 (74%) were subsequently published or in press as of March 2016. Figure 3 shows the annual number of abstracts over time and whether they were published, being drafted into papers, or withdrawn. As detailed in the Table, for 1990–2002 of the 137 abstracts presented, 97 (71%) were published, 54 (39%) within 2 years of presentation; for 2003–2009 (after institution of the “no new abstracts with any outstanding paper” policy), of the 140 abstracts presented, 116 (83%) were published or accepted for publication, 48 (34%) within 2 years. In addition for abstracts that were published, the time-to-publication decreased from an average of 3.5 years in 1990–2002 to 2.3 years in 2003–2009 to 1.1 years in 2010–2013. The number of NRN institutions increased over time—8 centers in 1987 to 12 in 1991, 14 in 1996, 16 in 2001, and 18 in 2011—which may have increased the number of abstracts presented, but would not necessarily have affected the percent of abstracts published or the time from abstract to publication. Most of the increase in publications occurred after the 2003 policy change was instituted, and when the network size was in the range of 16–18 centers.

The total number of peer-reviewed manuscripts published (or accepted for publication) for 1991–2015 is shown in Figure 4. After the institution of the manuscript completion policy in 2003, the number of publications per year increased significantly from an average of 4.6 manuscripts per year in 1990–2002 to 15.9 per year in 2003–2009. Following the 2010 campaign to complete older papers, the average increased again to 27.3 manuscripts per year.

For 1990–2002, 2.1 papers on average or 44% of all papers were published in journals with an impact factor >5 (e.g., JAMA, New England Journal of Medicine, and Pediatrics); for 2003–2010, 8.7 papers (56%) were published in high-impact journals. For 2010–2013, the number held steady at 8.5 papers published in high-impact journals.

Discussion

The key focus of the NRN publications policies was to improve the quality of the abstracts and manuscripts produced, and increase the quantity of abstracts subsequently published, thereby helping to achieve the NRN goal of advancing neonatal care.

Two large multicenter networks have published on the success of employing strict publication rules. Weiner (2010) presented an abstract at the Society for Clinical Trials about publications management practices of the NICHD Maternal-Fetal Medicine Unit Network, demonstrating improvements in its publication rate following institution of more stringent review and prioritization policies for secondary data analyses.[6] Similarly, the Gynecologic Oncology Group (GOG) published their methods and results for decreasing time-to-publication.[7] They monitored adherence to preset deadlines in the manuscript development process with the assistance of two editorial associates. The editorial associates were key to this process: formatting manuscripts according to journal requirements, incorporating revisions, and managing the submission process. The GOG's process reduced the number of days from data maturity to publication by half. Unlike with GOG, the NRN depends on the first authors to lead the publication process.

While there is no objective measure of the quality of abstracts, we speculate that NRN abstracts presented after the change in 2003 have been improved by the more stringent review process. The abstract review quality control steps, along with the high profile of its studies, are likely responsible for the NRN's high abstract acceptance rate of 95% at PAS meetings. This may also account for the increase in the percentage of abstracts that are subsequently published from 71% in 1990–2002 to 83% in 2003–2009 and the increase in the number and percentage of papers published in high-impact journals. Based on anecdotal reports, many manuscripts are submitted to multiple journals before acceptance.

The NRN Publication Subcommittee members have recently started tracking the number of journal submissions per manuscript. When data become available, it will be interesting to determine whether the abstract presentation formats (platform presentation, poster symposium, poster session, or abstract rejections) result in increased likelihood of subsequent publications, faster time-to-publication, and/or fewer journal revisions/rejections.

Conclusions

The NRN's publication policies and procedures appear to have positively impacted the percentage of abstracts proceeding to publication, the number of papers published, and the timeliness of publication. With 78% of abstracts published overall, and 81% published in recent years, the NRN has consistently surpassed the rates of 31–52% described in the biomedical literature. The timely and complete communication of study and trial results and data analyses allows us to more effectively achieve the goal of advancing neonatal care.

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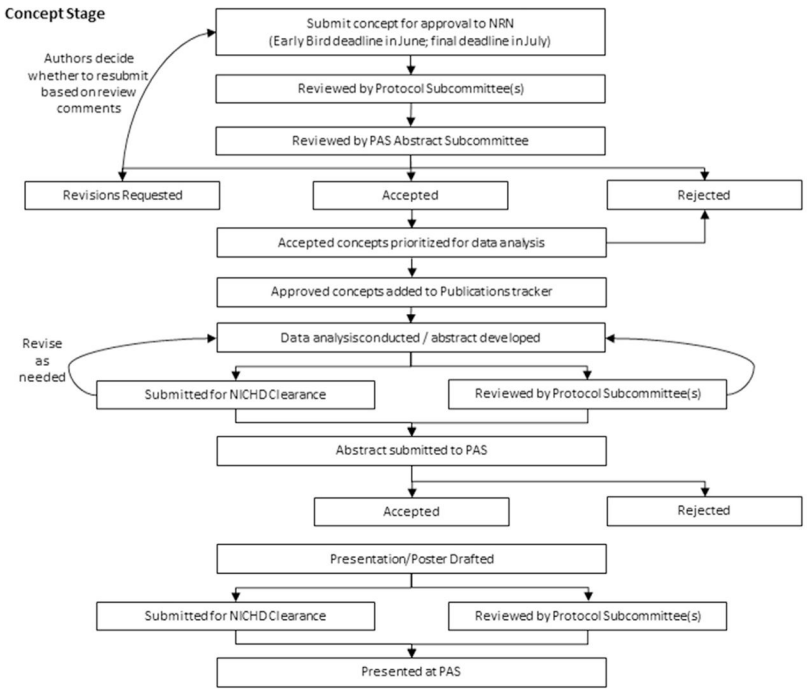

Fig. 1.

The NRN abstract review flowchart shows the review and approval process for abstract proposals to the Pediatric Academic Societies annual meeting.

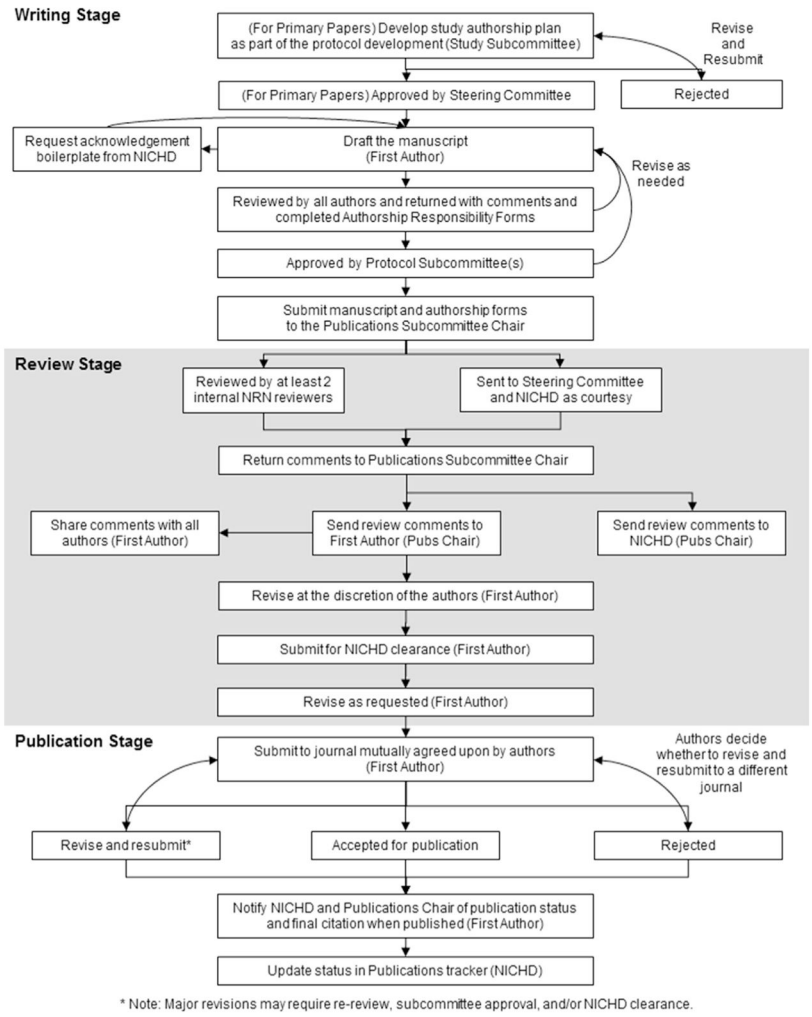

Fig. 2.

The NRN publications process flowchart outlines the writing and review process from drafting to journal submission.

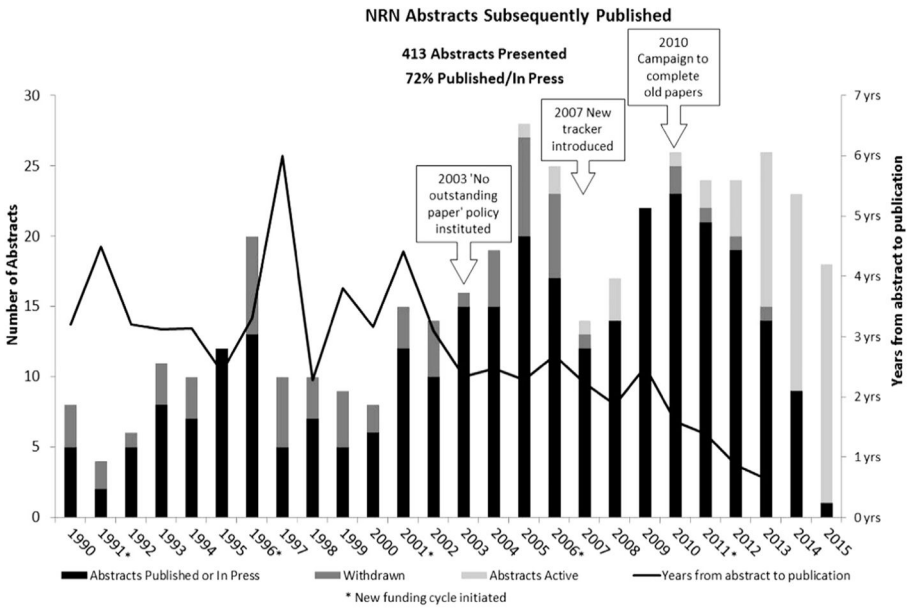

Fig. 3.

The bar graph and left axis shows the number of abstracts presented in 1990–2015 and whether they were published, withdrawn, or still being drafted. The line graph and right axis shows the number of years from presentation to publication for abstracts subsequently published. (*Note*: only published abstracts can be included in this; data for later years may be skewed by limitation of extended time to publish.)

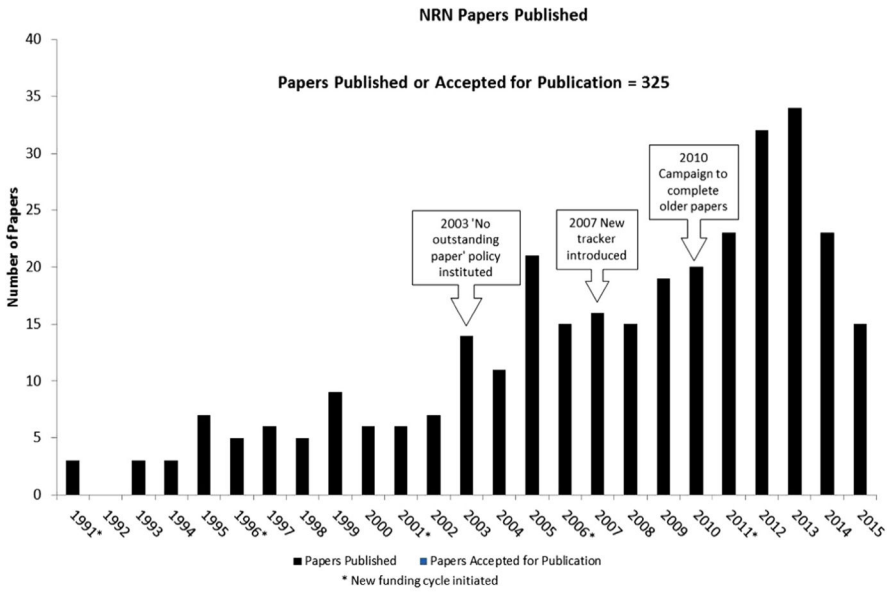

Fig. 4.

– Network papers published or accepted for publication per year from 1991 to 2013. Arrows indicate the timing of key policy interventions.

Table

NRN abstracts presented and subsequently published.

	Abstracts presented	Abstract published within 2 years of presentation		Abstract published in >2 years		Abstract not published		Abstracts published		Average number of years from abstract to publication[a]
	N	*N*	(%)	*N*	(%)	*N*	(%)	*N*	(%)	
1990–2002	137	43	31	54	39	40	29	97	71	3.5
2003–2009	140	68	49	48	34	24	17	116	83	2.3
2010–2013	97	62	64	17	18	18	19	79	81	1.1
1990–2013	374	173	46	119	32	82	22	292	78	2.6

[a]For those papers that were published.