Research Paper ■

The Columbia Registry of Information and Utilization Management Trials

E. ANDREW BALAS, MD, PhD, MARCIA G. STOCKHAM, MLS, JOYCE A. MITCHELL, PhD, SUZANNE M. AUSTIN, MHA, DAVID A. WEST, PhD, BERNARD G. EWIGMAN, MD

Abstract **Objective:** To systematically locate, register, and abstract information used in comparing effects of various information services (computerized and noncomputerized) and utilization management interventions on the process and outcome of patient care.

Design: Manual and electronic database searches located reports that met three main criteria: 1) randomized controlled trial; 2) information or utilization management intervention in the study group with no similar intervention in the control group; and 3) effect of the intervention on the process and/or outcome of patient care had been measured. Published reports were registered in the Columbia Registry.

Results: Nearly 600 reports were collected from 24 countries and 189 different publications. Frequently tested interventions included patient or physician education, telephone follow-up, patient or physician reminders, and home care services. Frequently reported effect variables included hospitalization rate, length of stay, immunization rate, and mortality rate. Standardized formal tools were developed for the separation and abstraction of practical information and methodologic details from the collected trial reports.

Conclusions: The registry provides a new source of information for meta-analyses, traditional reviews, and executive summaries of quality improvement of health services. The streamlined knowledge engineering process of quality evaluation and abstraction of critical information can generate helpful information for practitioners and researchers simultaneously.

■ JAMIA. 1995;2:307-315.

Randomized controlled clinical trials (RCTs) have achieved widespread recognition as sources of top-quality scientific evidence of the difference made by particular clinical interventions.^{1,2} If the study design, data collection, and analysis are well planned, RCTs can reduce the risks of selection bias, nonstan-

dard definitions, missing data, or multiple comparisons.³ New drugs cannot be marketed without demonstrating their efficacy and safety in such trials. Yet clinical information system developers and physician executives are often forced to make decisions affecting health services based on speculated benefits instead of high-quality scientific evidence.

Deming's theory of continuous improvement depends on understanding and revising the production processes on the basis of data about the processes themselves.⁴ Likewise, quality improvement efforts in health care depend on measurable quality objectives and appropriate interventions and changes in the process. RCTs have direct relevance to health care quality improvement as they become increasingly important sources of information about the clinical value of various interventions (e.g., physician and patient education,⁵ interventions to promote cancer screening,⁶ computerized medical records,⁷ and home care after hospital discharge.⁸).

Affiliations of the authors: Program in Health Services Management (EAB, MGS, SMA), Medical Informatics Group (EAB, JAM), School of Business (DAW), and Department of Family and Community Medicine (BGE), University of Missouri-Columbia, Columbia, MO.

Supported in part by grant HS07715 from the Agency for Health Care Policy and Research and by a grant from the University of Missouri Research Board.

Correspondence and reprints: E. Andrew Balas, MD, PhD, Program in Health Services Management, University of Missouri-Columbia, 324 Clark Hall, Columbia, MO 65211. e-mail: medinfab@mizzou1.missouri.edu

Received for publication: 3/27/95; accepted for publication: 5/22/95.

Unfortunately, searches for reports of RCTs often lead to incomplete and inconsistent results. Several studies have documented disappointingly low recall rates (the proportion of relevant items retrieved from a bibliographic database by a particular search strategy) in searches for clinical trials. For example, one study reported a 51% recall rate and another recovered only 29% of relevant trial reports stored in the MEDLINE database.^{9,10} In recent years there have been studies about improving the success rate of searches for RCTs.^{11,12} Reasons for the low recall are varied. The terminology used by investigators and National Library of Medicine indexers is continuously changing. Before 1980, the Medical Subject Headings (MeSH) term "Clinical Research" was synonymous with "Clinical Trials." In 1980, "Clinical Trials" was introduced as a MeSH term to replace "Clinical Research." In addition, there are periodicals in the medical informatics field that are not indexed in the MEDLINE database [e.g., MEDINFO proceedings and early Symposium on Computer Applications in Medical Care (SCAMC) proceedings]. Considering the significant number of computer trials in the SCAMC proceedings, the recent decision of the National Library of Medicine to index this periodical in the MEDLINE database seems to be justified and promises improved access. The addition to MeSH of publication types (e.g., randomized controlled trial) is also a potential tool for increasing access to desired trials. Despite this progress, published trials remain difficult to locate.

Various trial registries have been established in attempts to improve access to published reports. Many of these registries deal with perinatal care, management for AIDS, or cancer treatment [e.g., the Oxford Perinatal Database,¹³ the AIDS Clinical Trials Information Service, and the National Cancer Institute (NCI) Cancer Control Intervention Studies¹⁴]. Some review papers contain valuable bibliographies of clinical trials.¹⁵ However, clinical trials testing information or utilization management interventions, a broad area critical to health care quality improvement and cost control, have not been the focus of any known registry.

Once a clinical trial has been identified, the problem remains of discerning the practical message of reported results. While numerous technical details of research are necessary to ensure valid results, they can at times overwhelm the true practical message and different readers can draw different conclusions from trial reports. A recent study of the methods of randomized controlled trials¹⁶ showed that there are marked differences in several aspects of health services research compared with conventional drug trials.

Because of these differences, separating and abstracting practical information is an ongoing need of health care quality improvement.

Thus, the primary goal of establishing the Columbia Registry of Information and Utilization Management Trials was to assist practitioners, clinical researchers, computer system developers, and health care administrators in comparing the effects of various information services and utilization management interventions on the process and outcome of patient care. To accomplish this goal, the best available evidence, i.e., the results of RCTs, has been systematically collected and processed. The methods used to create the Columbia Registry are described in this paper.

Evolution of Eligibility Criteria

To make the Columbia Registry relevant to the needs of health care quality improvement, careful attention was given to the eligibility criteria applied to potential reports. Such eligibility criteria are needed to guide all literature searches and to establish relevance. Eligibility criteria were defined on the basis of designs, interventions, and effect variables of specific studies. The design requirements of RCTs are well defined and widely accepted. However, the definition of other criteria requires special considerations. Four considerations have played a large role in the evolution of the eligibility criteria used for the Columbia Registry.

Information intervention

Originally, the registry was designed to include only trials using some form of computer intervention. Once the first 100 trials had been registered, it became clear that noncomputerized information interventions can be equally valuable. For example, reminders to physicians or patients can be generated by a computer system or by office personnel and the difference in the mechanisms of action might be insignificant. Therefore, all such trials were put in the general category of information interventions, which was further divided into a computer group and a noncomputer group. Examples of these groups include a trial of computer-based instructions to patients collecting a urine specimen¹⁷ and a noncomputerized patient education encounter with new mothers to increase the pediatric immunization rate.¹⁸

Cost-benefit analysis

RCTs allow practitioners to assess potential benefits and also the costs of alternative interventions. This information can have great practical significance for health care quality improvement. For this reason, one

might consider cost analyses as one of the criteria for registration. While most researchers make efforts to follow widely accepted medical and statistical protocols, they apparently do not use standard costing procedures, making interpretation difficult or impossible. For example, in a review of 100 studies that assumed that public spending for prenatal care was justified primarily by cost savings, the authors found that only 12 specifically addressed issues of cost. Significant methodologic problems were identified in all 12 cases.¹⁹ In a study reviewing the cost-effectiveness of outpatient mental health care, a potential cost savings of \$5,500 per client was suggested. In costing the mental health care services in three assertive case management program centers, however, the authors cited costs per client that ranged from \$2,873 to \$7,201. Costs were calculated based on 6-month budgets (including indirect costs and support personnel) divided by the maximum caseload.²⁰ Essentially, the medical cost data cannot be trusted because the costing methods are not comparable. There is no consistency to costing methodology and, in many trial reports, there is no clear explanation as to how costs were computed. Checking for costing accuracy and bias would, therefore, be impossible and replicating the cost data would be difficult at best. The unreliability of cost-benefit data indicated that they could not be used as a criterion for the Columbia Registry.

Utilization

Analyses of information service trials showed that often the information intervention was part of a larger package of organizational changes (e.g., standing orders, feedback to providers, establishment of specialized units) and indicated a need for expanding the intervention criterion. Because the utilization of health care services is a critical concept for quality improvement and cost control, it seemed that utilization management should be a useful intervention criterion. Utilization management is interpreted as an activity that attempts to increase or decrease the frequency of use of a procedure already established in clinical practice (e.g., cancer screening tests, annual eye examinations for diabetic patients). For example, reminders on a patient's chart can increase the number of cancer screening tests performed by the physician.²¹ A combination of information and utilization management interventions seemed to be the best way to define health services research trials.

Process and/or outcome

It was decided that measurements of the intervention's effect on the process (utilization of procedures) or outcome (health status) of patient care are necessary for the direct applicability of clinical trial re-

sults in health care quality improvement and cost control. For example, rate of provider compliance with recommended cancer screening procedures would be a process measurement,²² while changes in patients' blood pressures or blood glucose levels would be an outcome measurement.^{23,24} Because this measurement is an important criterion, physician education trials that used only test scores, without looking at the care actually provided, were not registered. If a physician tests better at the end of an educational program, it can be assumed that the higher knowledge will translate to better patient care, but there is no evidence of the direct impact.

Current Criteria

As a result of preliminary studies, three areas have been defined and are used as criteria to determine whether published reports should be included in the registry.

The design of the potential study is the first area evaluated. The study must be a prospective, contemporaneously controlled clinical trial with random assignment of intervention. Trials using allocation systems similar to a random number table (e.g., alternating encounters, alternating days of the week) are also eligible. Reports that do not meet this basic criterion (e.g., nonrandomized trial groups, meta-analyses, review articles) are not included in the registry.

Second, there should be an information or a utilization management intervention in the study group with no similar intervention in the control group. Often, the control group simply receives the current standard of care, as compared with the experimental intervention used in the trial. For example, a trial might test community-based mental health care intervention versus standard institutionalization for the control group. Examples of trials not eligible for the registry are those that test drug efficacy, compare surgical procedures, or, in general, validate new clinical procedures.

The third criterion is that the effect of the intervention on the process and/or outcome of patient care must be measured. Planned or ongoing trials are not included in the registry because they do not meet this criterion.

Systematic Searches

Various methods were used to locate the published trials currently in the registry. Many of the trials were indexed in the National Library of Medicine's electronic databases MEDLINE, HEALTH, and HSTAR.

Table 1 ■

Example of the MEDLINE Search Strategy Used to Locate Published Reports Currently in the Columbia Registry

Study design concept

1. Random: (truncated textword)
2. Group: (truncated textword)
3. Random Allocation (textword and MeSH)
4. Randomized Controlled Trial (publication type)
5. Clinical Trial (publication type)
6. 1 or 2 or 3 or 4 or 5

Intervention or effect concept

7. Reminder systems (MeSH)
8. Appointments and schedules (MeSH)
9. Remind: (truncated textword)
10. Prompt: (truncated textword)
11. Cue: (truncated textword)
12. 7 or 8 or 9 or 10 or 11 or 12

Combination of concepts

- 6 and 12

MeSH = Medical Subject Headings.

Searches were formulated using combinations of the controlled vocabulary MeSH and textwords. Table 1 illustrates the search strategy of this project. The study design concept is the same for every search, but the second concept, intervention or effect, changes depending on specific interventions or effects. Compared with the original strategy used at the start of the registration process, the changes in design concept have been moderate (e.g., the inclusion of the new publication type Randomized Controlled Trial).²⁵ On the other hand, there have been significant changes in the variable concept of the search strategy as a result of the evolution of eligibility criteria. The original search for computer interventions has been expanded and more than 50 variations of the strategy have been developed by changing interventions or effects (e.g., feedback, checklist, home care, length of stay). For example, when searching for telephone interventions, the terms included telemedicine (MeSH and textword), telecommunications (MeSH and textword), telephone (MeSH and textword), and telephone: (truncated textword).

Other electronic databases that were searched included CINAHL (CINAHL Information Services), PsychINFO (American Psychological Association), Compendex (Engineering Index), and the Science Citation Index (Institute for Scientific Information). Searches similar to those used in MEDLINE were conducted on these databases, using the appropriate controlled vocabulary and similar textwords. Intervention-specific searches are conducted periodically to locate new trials as electronic databases are updated.

Manual searches were conducted of publications not referenced in MEDLINE (early proceedings of SCAMC, MEDINFO, etc.), and reference lists of retrieved trial reports and reviews were searched for published trials that met the criteria. Informal contacts such as telephone calls, electronic mail, and conversations at scientific meetings were used to gather additional information about trials.

Most (about 95%) of the registered trial reports could be located in the MEDLINE database, but were often found only after searches through other databases (e.g., the Science Citation Index, CINAHL, or Health Administration and Planning). Obviously, there are major overlaps and most trial reports are indexed in several databases. Frequently, searches in different databases bring the same article to the surface repeatedly.

Registration Process

The literature searches targeted a high rate of recall and, consequently, the lower precision (ratio of relevant reports to all reports retrieved) required the gatekeeper role of eligibility screening. This screening was primarily a search for reasons to exclude trials. The most frequent reasons for exclusion included: the randomization was random selection and not random allocation; the randomization used fewer than six blocks (e.g., one hospital was the study site and another the control); the same computer service was used in both the experimental group and the control group; a specific clinical procedure was evaluated and not an intervention intended to change the utilization of a clinical procedure; and the effect on physician test scores, not on the process or outcome of care, was measured.

Application of the eligibility criteria was liberal. When a potentially eligible trial was identified, a copy of the trial was obtained for eligibility screening. During this process, 17% of the reports were rejected, an amount comparable to the one-in-five rejection rate reported by the Oxford Database of Perinatal Trials.¹³ At least two people screened potential trials for eligibility criteria and admission to the registry. When there was a difference of opinion about eligibility, a consensus was formed or a third opinion was sought.

When the registration project started, a third opinion was sought for approximately 10% of the potential trials. As the eligibility criteria have been refined and as the screeners have become more experienced, the frequency of such consultations has decreased to only about 1–2% of potential trials. The eligibility check was not intended to replace the rigorous screening process required for meta-analyses. In various anal-

yses performed by our team, the interobserver agreement (Cohen's kappa) varied between 0.59 and 0.97.¹⁶

Reference Manager (Research Information Systems, Carlsbad, CA) was used to manage the Columbia Registry. Full citations plus abstracts are included in the database, and are searchable using textwords, keywords (including MeSH), authors, titles, notes, journal names, identification numbers, and years of publication. Computerization of the intervention is noted at the time of entry and included as an indexing term. We plan to add specific abstracted information from each trial (described below) to the database to further enhance retrieval of trials with specific characteristics.

To monitor progress, monthly statistics were compiled on the cumulative number of registered clinical trials. The number of trials in three main groups (computer service, noncomputerized information service, and noninformational utilization management) were counted. The sources of the trial reports were also noted so that periodicals publishing several eligible trial reports could be targeted for specialized or manual searches.

Registered Trial Reports

Currently, there are nearly 600 published trials registered in the Columbia Registry. The collection contains trials conducted in 24 different countries (Table 2). Only one published trial was found from each of ten countries.

Table 2 ■

Countries of Origin for the Nearly 600 Published Trials, Which Have Been Categorized into Three Groups, Currently in the Columbia Registry

Country	Information Trials		Utilization Trials	Total
	Computer	Non-computer		
United States	133	158	104	395
United Kingdom	14	17	34	65
Canada	12	20	18	50
Australia		6	9	15
Sweden		3	5	8
Denmark	2	3	2	7
France	2	1	3	6
Germany	4	2		6
Israel	4			4
New Zealand	3		1	4
Norway		2	1	3
Italy	2			2
Netherlands		2		2
Spain		2		2
Other	1	5	4	10

Figure 1 Years of publication and categories for published trials currently in the Columbia Registry.

There was a dramatic increase in the number of published trials beginning in 1989 (Fig. 1). The decrease in 1994 reflects the fact that there are fewer of these trials in the registry, not necessarily that there were fewer trials published in 1994. Because of the lag between publication date and appearance in the indexes, many potential trials published in 1994 are yet to be located.

Articles in the collection appeared in 189 different publications. Nearly one-third of the registered trials appeared in only seven different publications (Table 3). Publications in each category appeared most often in *Medical Care* (nearly 9% of the total collection), but other frequent sources varied by category. Reports published in the four most frequent journal sources for each category accounted for 25% of the total collection. The two journals having the most registered trials in each category accounted for approximately 15% of the total trials in each category (14–17%).

The trials in the registry tested various information or utilization management interventions. Frequently tested interventions were patient or physician education (the process of transferring information or training to patients or to health care professionals), telephone follow-up (use of the telephone as a support system or as an alternative to an office visit), patient reminders (a card or a telephone call to a patient with information about a recommended procedure such as a follow-up visit or cancer screening), physician reminders (a message about a recommended clinical action suggested at the time of decision making), and home care services. Currently, there are 62 trials testing physician reminders, 60 testing telephone follow-up or distance medicine, and 62 comparing home care services with inpatient care.

Table 3 ■

Most Frequent Sources of the Nearly 600 Published Trials, Which Have Been Categorized into Three Groups, Currently in the Columbia Registry

Journal	Information Trials		Utili- zation Trials	Total
	Com- puter	Non- computer		
<i>Medical Care</i>	19	19	13	51
<i>BMJ</i>	6	9	13	28
<i>JAMA</i>	8	8	8	24
<i>American Journal of Public Health</i>	6	12	3	21
<i>Annals of Internal Medicine</i>	6	7	5	18
<i>Journal of the Ameri- can Geriatrics Soci- ety</i>	2	5	11	18
<i>Journal of General In- ternal Medicine</i>	8	9	1	18
<i>Archives of Internal Medicine</i>	5	7	4	16
<i>New England Journal of Medicine</i>	4	3	8	15
<i>Pediatrics</i>	3	6	6	15
<i>British Journal of Psy- chiatry</i>	2	0	12	14
<i>Journal of Family Practice</i>	4	8	2	14
<i>Proceedings of the Annual Symposium on Computer Appli- cations in Medical Care</i>	12	0	0	12
<i>Canadian Medical As- sociation Journal</i>	3	3	4	10

Typical trials using these interventions are represented by the following examples: a combination of patient plus physician education resulted in physiologic improvement for diabetic patients⁵; asthma patients undergoing a self-management training program had significantly fewer asthma-related emergency visits than did the control group²⁶; reminders (particularly by telephone) improved the influenza vaccination rate for adults over age 65²⁷; and patients who used a home-monitoring blood pressure program made 1.2 fewer hypertension-related office visits than did control patients during the study year.²⁸

Effect variables reported in the trials were also varied, but frequently reported measures included hospitalization or rehospitalization rate (the number of persons hospitalized compared with the total number of persons who have the specified condition), length of stay (the number of days a person receives inpatient treatment at a health care facility), immunization rate (the number of persons immunized against a certain disease compared with the total number of persons

in the defined population), and mortality rate (the number of deaths compared with the total number of persons in the defined population). Examples of studies reporting these findings include: patients who received clinician-initiated follow-up telephone care had fewer total clinic visits, less medication use, fewer admissions, and shorter hospital stays than did the usual-care patients²⁹; a comparison of two inpatient staffing models found that patients treated by the staff service had significantly shorter hospital stays and lower total charges than did those treated by the resident service, but there was no significant difference in readmissions or mortality rates³⁰; and a significantly higher percentage of high-risk patients who received reminder postcards were immunized against influenza than were those who did not receive reminders.³¹

Abstraction of Information

The quality of the applied clinical trial methodology determines the validity of research results, particularly repeatability and generalizability. Quality evaluation of trial methodology can measure and summarize the technical aspects of the trial. A quality-evaluation tool tailored for the evaluation of health services research trials has been developed³² and validated.¹⁶ This tool consists of 20 questions assessing site/sample/randomization, process of observation, presented data, and statistical analysis.

A more structured approach to summarizing research studies has long been advocated by various authors.³³⁻³⁵ To assist practitioners and researchers, specific information needs to be abstracted, and a systematic approach was developed to do so. The standardized abstraction form shown in Figure 2 serves several purposes. First, it sets forth practical information that can be used by managers and clinicians when they are seeking evidence on which to base decisions. Second, it allows information needed for conventional reviews (site, sample, interventions, and effect variables) to be presented consistently. Third, the consistent presentation of this information allows it to be easily entered into tables used for more formal quantitative studies such as meta-analyses.

Specific information is abstracted from subsets of the registry by two research assistants working independently. The structured executive summaries include the critical information from the trial report. Data are abstracted by determining the number of clinical actions targeted to be affected by the intervention within each study and deriving the raw data from the data reported within the article. A clinical action is defined as the use of health care resources (e.g., diagnostic

tests ordered, drugs prescribed, treatments given, etc.).

Utility and reliability of abstraction can be assessed by different methods. Utility can be inferred from meeting specific needs of identified user groups. This approach was applied by Hayward et al. in devel-

oping recommendations for abstracts of clinical practice guidelines.³³ In this project, the targeted need was identified by the usual tables of meta-analytic studies.^{36,37} In research syntheses, reliability is assessed by interobserver agreement. In various analyses performed by our team, the interobserver agreement (Cohen's kappa) varied between 0.59 and 0.97.

TRIAL NUMBER

C00014

VANCOUVER REFERENCE

Chambers CV, Balaban DJ, Carlson BL, Ungemack JA, Grasberger DM. Microcomputer-generated reminders. Improving the compliance of primary care physicians with mammography screening guidelines. *J Fam Pract* 1989;29:273-80.

SETTING

Family Practice Center of the Department of Family Medicine at Thomas Jefferson University, Philadelphia.

SAMPLE (PROVIDERS)

12 full-time faculty and 18 residents.

SAMPLE (PATIENTS)

1262 female patients who visited the outpatient office and were 40 years of age or older.

INTERVENTION GROUP

The date of the last mammogram ordered and recorded in the clinical database was printed on the encounter form for each visit.

CONTROL GROUP

No information provided regarding the date of the last mammogram.

EFFECT(S)

Mammogram ordered during the study period (6 months)

Direction of effect:	Target	up
	Actual	up
Calculated P value:	=.001	
Observed ratios:	Intervention	111/580
	Control	68/563

Mammogram ordered at the completion of the study (6 months)

Direction of effect:	Target	up
	Actual	up
Calculated P value:	=.011	
Observed ratios:	Intervention	170/639
	Control	128/623

QUALITY SCORE

78 out of 100

Figure 2 An example of a standardized abstraction form used to summarize a research study. Reprinted from Chambers CV, Balaban DJ, Carlson BL, Ungemack JA, Grasberger DM. Microcomputer-generated reminders: improving the compliance of primary care physicians with mammography screening guidelines. *J Fam Pract*. 1989;29(3):273-80. Reprinted by permission of Appleton & Lange, Inc.

Discussion

The structuring of evidence is becoming an important trend in knowledge engineering. As the amount of published scientific evidence grows, finding the right report is no longer sufficient. The report has to be supplemented with the abstraction of the specific information to meet the needs of clinicians, researchers, and policy makers. Conventional abstracts by the investigators provide useful synopses, but lack detail and standardization. The Columbia Registry serves as a valuable resource for health services research by systematically collecting and rearranging the knowledge from these trials into a format that can be used by practitioners and others making health care decisions. This knowledge engineering is accomplished in several steps. First, the trials are located by using a systematic approach, which is likely to outperform conventional searches. Subsequently, critical information is abstracted from the registered trials and the practical messages of such studies are made available to those who need them. The same executive summary can be used to implement organizational changes, further health care quality improvement, conduct meta-analyses, or write literature reviews.

Several meta-analyses have already been conducted based on trials in the registry. The first assessed the clinical value of a physician reminder in increasing compliance with the preventive health care measures of cervical cancer screening and tetanus immunizations.³⁸ Results indicated that reminders are an effective intervention and can improve compliance for these procedures. A second study assessed the effectiveness of physician profiling reports in changing clinical practice patterns. A meta-analysis of trials testing home or community care versus traditional mental health hospitalization is currently underway, with preliminary results showing that community-based mental health care reduces the odds of emergency and unscheduled rehospitalization. Several other meta-analyses are in progress and it is expected that as the registry grows, more studies will be completed in various areas of interest.

An obvious limitation of this registry is that only published trial reports can be retrieved from various databases. It is well established that publication bias exists and that "negative" trials have a greater chance of not being published.^{39,40} Fortunately, there are established statistical techniques to estimate the sensitivity of meta-analytic results to unpublished negative studies.⁴¹

Information about the registered trial reports is disseminated in a variety of ways. To support improved

indexing and access in the MEDLINE database, information concerning the located trials is periodically forwarded to the National Library of Medicine. For example, information from the first 111 registered trials was used by the National Library of Medicine to modify the publication type of 23 trial reports (e.g., the publication type Randomized Controlled Trial was added to 16 citations). This project indicated that effective eligibility criteria and identification cannot be developed on a purely speculative basis, but only through the collection and analysis of a large number of clinical trial reports. Therefore, identifying trial reports meeting specific criteria eventually supports the continuous improvement of the National Library of Medicine's indexing policies. Furthermore, to facilitate practical implementation of trial results, several meta-analytic studies and reviews have been published or are in progress for various subsets of the registry. Reports resulting from such studies include bibliographies or references to the analyzed trials. Information about the registry can be obtained through the Managed Health Care Internet list (MHCARE-L@MIZZOU1.MISSOURI.EDU), which is free.

Locating and registering eligible trials is an ongoing process, so the collection continues to grow. Several studies document that, regardless of the complexity of the search process, some eligible reports will remain unretrieved.⁹⁻¹² Therefore, clinical trial registries grow not only through the inclusion of new publications, but also through the discovery of eligible studies published earlier. The developers of the Oxford Perinatal Database also noted that there is no "gold standard" available to quantify the completeness of a registry.¹³ With its growth, the Columbia Registry of Information and Utilization Management Trials aims to become an unparalleled source of high-quality clinical evidence in the areas of medical informatics and health services research.

References ■

1. Horwitz RJ. The experimental paradigm and observational studies of cause-effect relationships in clinical medicine. *J Chronic Dis.* 1987;40(1):91-9.
2. Friedman LM, Furberg CD, DeMets DL. *Fundamentals of Clinical Trials*, ed. 2. Littleton, MA: PSG Publishing, 1985.
3. Byar DP. Why data bases should not replace randomized clinical trials. *Biometrics.* 1980;36:337-42.
4. Berwick DM. Continuous improvement as an ideal in health care. *N Engl J Med.* 1989;320(1):53-6.
5. Vinicor F, Cohen SJ, Mazza SA, et al. DIABEDS: a randomized trial of the effects of physician and/or patient education on diabetes patient outcomes. *J Chronic Dis.* 1987;40:345-56.
6. McPhee SJ, Bird JA, Jenkins CN, Fordham D. Promoting can-

- cer screening: a randomized, controlled trial of three interventions. *Arch Intern Med.* 1989;149:1866-72.
7. Tape TG, Campbell JR. Computerized medical records and preventive health care: success depends on many factors. *Am J Med.* 1993;94:619-25.
8. Melin AL, Bygren LO. Efficacy of the rehabilitation of elderly primary health care patients after short-stay hospital treatment. *Med Care.* 1992;30:1004-15.
9. Poynard T, Conn HO. The retrieval of randomized clinical trials in liver disease from the medical literature: a comparison of MEDLARS and manual methods. *Control Clin Trials.* 1985;6:271-9.
10. Dickersin K, Hewitt P, Mutch L, Chalmers I, Chalmers TC. Perusing the literature: comparison of MEDLINE searching with a perinatal trials database. *Control Clin Trials.* 1985;6:306-17.
11. Jadad AR, McQuay HJ. A high-yield strategy to identify randomized controlled trials for systematic reviews. *Online J Curr Clin Trials.* 1993 (Doc. no. 33).
12. Macharia WM, Leon G, Rowe BH, Stephenson BJ, Haynes RB. An overview of interventions to improve compliance with appointment keeping for medical services. *JAMA.* 1992;267:1813-7.
13. Chalmers I, Hetherington J, Newdick M, et al. The Oxford database of perinatal trials: developing a register of published reports of controlled trials. *Control Clin Trials.* 1986;7:306-24.
14. Dickersin K. Why register clinical trials? Revisited. *Control Clin Trials.* 1992;13:170-7.
15. Davis DA, Thomson MA, Oxman AD, Haynes RB. Evidence for the effectiveness of CME: a review of 50 randomized control trials. *JAMA.* 1992;268:1111-7.
16. Balas EA, Austin SM, Ewigman BG, Brown GD, Mitchell JA. Methods of randomized controlled clinical trials in health services research. *Med Care.* 1995;33(7):687-97.
17. Fisher LA, Johnson TS, Porter D, Bleich HL, Slack WV. Collection of a clean voided urine specimen: a comparison among spoken, written, and computer-based instructions. *Am J Public Health.* 1977;67:640-4.
18. Oeffinger KC, Roaten SP, Hitchcock MA, Oeffinger PK. The effect of patient education on pediatric immunization rates. *J Fam Pract.* 1992;35:288-93.
19. Huntington J, Connell FA. For every dollar spent: the cost-savings argument for prenatal care. *N Engl J Med.* 1994;331(19):1303-7.
20. Bond GR, Miller LD, Krumwied RD, Ward RS. Assertive case management in three CMHCs: a controlled study. *Hosp Community Psychiatry.* 1988;39(4):411-8.
21. Fordham D, McPhee SJ, Bird JA, Rodnick JE, Detmer WM. The cancer prevention reminder system. *Clin Comput.* 1990;7(5):289-95.
22. Banks NJ, Palmer RH, Kane NM, Braun P, Feldstein ML, Harrington AM. Implementation and evaluation of a computerized reminder system in ambulatory care. In: *Proceedings of the Twelfth Annual Symposium on Computer Applications in Medical Care.* 1988:753-7.
23. Chiarelli F, Tumini S, Morgese G, Albisser AM. Controlled study in diabetic children comparing insulin-dosage adjustment by manual and computer algorithms. *Diabetes Care.* 1990;13:1080-4.
24. Coe FL, Norton E, Oparil S, Tatar A, Pullman TN. A prospective controlled study of hypertension treatment by computer and physician. In: *Proceedings of the Third Illinois Conference on Medical Information Systems.* 1976:206-17.
25. Balas EA, Mitchell JA, Bopp KD, Brown GD, Ewigman BG. The Columbia registry of controlled clinical computer trials. In: Frisse ME, ed. *Proceedings of the Sixteenth Annual Symposium on Computer Applications in Medical Care.* New York: McGraw-Hill, 1993:220-4.
26. Bolton MB, Tilley BC, Kuder J, Reeves T, Schultz LR. The cost and effectiveness of an education program for adults who have asthma. *J Gen Intern Med.* 1991;6:401-7.
27. McDowell I, Newell C, Rosser W. Comparison of three methods of recalling patients for influenza vaccination. *Can Med Assoc J.* 1986;135:991-7.
28. Soghikian K, Casper SM, Fireman BH, et al. Home blood pressure monitoring: effect on use of medical services and medical care costs. *Med Care.* 1992;30:855-65.
29. Wasson J, Gaudette C, Whaley F, Sauvigne A, Baribeau P, Welch HG. Telephone care as a substitute for routine clinic follow-up. *JAMA.* 1992;267:1788-93.
30. Simmer TL, Nerenz DR, Rutt WM, Newcomb CS, Benfer DW. A randomized, controlled trial of an attending staff service in general internal medicine. *Med Care.* 1991;29:J531-40.
31. Spaulding SA, Kugler JP. Influenza immunization: the impact of notifying patients of high-risk status. *J Fam Pract.* 1991;33:495-8.
32. Balas EA, Austin SM, Brown GD, Mitchell JA. Quality evaluation of controlled clinical information service trials. In: Saffran C, ed. *Proceedings of the Seventeenth Annual Symposium on Computer Applications in Medical Care.* New York: McGraw-Hill, 1994:586-90.
33. Hayward RS, Wilson MC, Tunis SR, Bass EB, Rubin HR, Haynes RB. More informative abstracts of articles describing clinical practice guidelines. *Ann Intern Med.* 1993;118:731-7.
34. Ad hoc working group for critical appraisal of the medical literature. A proposal for more informative abstracts of clinical articles. *Ann Intern Med.* 1987;106:598-604.
35. Haynes RB, Mulrow CD, Huth EJ, Altman DG, Gardner MJ. More informative abstracts revisited. *Ann Intern Med.* 1990;113:69-76.
36. Yusuf S, Peto R, Lewis J, Collins R, Sleight P. Beta blockade during and after myocardial infarction: an overview of the randomized trials. *Prog Cardiovasc Dis.* 1985;27:335-71.
37. Antiplatelet trialists' collaboration. Secondary prevention of vascular disease by prolonged antiplatelet treatment. *BMJ.* 1988;296:320-31.
38. Austin SM, Balas EA, Mitchell JA, Ewigman BG. Effect of physician reminders on preventive care: meta-analysis of randomized clinical trials. *JAMIA.* 1994 Supplement:121-4.
39. Dickersin K. The existence of publication bias and risk factors for its occurrence. *JAMA.* 1990;263:1385-9.
40. Chalmers I, Adams M, Dickersin K, et al. A cohort study of controlled trials published as short reports. *JAMA.* 1990;263:1401-5.
41. Cooper H, Hedges LV, eds. *The Handbook of Research Synthesis.* New York: Russell Sage Foundation, 1994.