

# The Clinical Value of Computerized Information Services

## A Review of 98 Randomized Clinical Trials

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**Objective:** To review all randomized clinical trials addressing the efficacy of clinical information systems and to determine the clinical settings, types of interventions, and effects studied.

**Data Sources:** Extensive and systematic MEDLINE searches were conducted using a combination of medical subject headings (MeSH) and textword terms to collect trial reports. Manual searches of books and monographs as well as informal contacts were also used.

**Study Selection:** The eligibility criteria were (1) randomized controlled clinical trial, (2) computerized information intervention in the study group, and (3) effect measured on the process or outcome of care.

**Data Extraction:** Two research assistants independently abstracted from the selected reports the following structured information: trial sites, computerized interventions, effect variables, and outcomes. Three investigators evaluated the combined list of trial features for setting, intervention, and effect. The statistical

analysis included an evaluation of agreement in developing classifications and an analysis of the ratio of positive trial outcomes.

**Data Synthesis:** Most information services were tested in outpatient care (82%), particularly in primary care (66%). The information intervention targeted the provider in 64% of the trials. The effect was primarily measured for the process of care (76%). Provider prompt/reminder, computer-assisted treatment planner, interactive patient education/therapy, and patient prompt/reminder were significantly successful interventions (sign test,  $P < .05$ ).

**Conclusions:** Randomized clinical trials confirm that four generic information interventions are active ingredients of computer systems and can make a significant difference in family medicine (physician and patient reminders, treatment planner, and patient education). To manage care and improve quality, primary care computer systems should incorporate these effective information services.

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**Editor's Note:** Computerized medical records can be very helpful in practice and are likely to become standard in the not-too-distant future. The physicians at our satellite office with access to a fully computerized medical record say that it really saves time, particularly in filing charts and writing prescriptions, and that the charts are readily accessible. They like the protocols for prevention, which are memory aids that improve compliance. Our medical records can make or break how well we provide patient care, and computers help us organize and give accessible information that improves our patient care. Apparently, some companies that provide malpractice insurance see sufficient advantage in computerized records that they give discounted insurance to physicians who use them.

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**A**LTHOUGH HEALTH care is clearly an information-intensive service, the clinical value of computer applications is often questioned because of the lack of demonstrated clinical benefits. Medical practice

involves a tremendous amount of information processing: collecting patient data, sharing information with patients, decision making in diagnostics and therapeutics, documenting care, communicating with other health care professionals, and educating patients. However, health care organizations invest on average only 2.6% of their operating budgets in information technology, a marked contrast with the average 8% to 9% in banking organizations (*Fortune.* May 17, 1993:70-75).

Few medical questions have been more controversial than the clinical application and value of computer systems. Early analyses suggested that the ability of computers to store information on pa-

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## METHODS

The systematic collection and synthesis of experimental evidence and the control of potential bias require a well-defined process. To obtain reports for the study, database searches, manual searches, and informal contacts were combined. The searches provided the initial pool of trial reports for this review. The analysis was based on independent evaluations and subsequent consensus development.

### ELIGIBILITY CRITERIA

Specific criteria were defined for the purposes of report retrieval and selection. The first criterion required that the study be a prospective, contemporaneously controlled clinical trial with random assignment of the intervention. Institutional randomization was not accepted (eg, patients of one hospital in the study group and patients of another, "randomly selected" hospital in the control group). The second criterion required that trials with a computer-assisted intervention in the study group have no similar computer assistance in the control group. The last criterion required direct observation of the quality of care through measurement of the process and/or outcome of care (eg, change in laboratory test ordering, decrease in average blood pressure).

### SEARCH FOR TRIAL REPORTS

Extensive MEDLINE searches were performed using numerous search strategies. The following medical subject heading (MeSH) terms and textwords were combined in our searches: (1) clinical trials, cohort studies, and medical informatics (MeSH, explode); (2) prospective, trial, or group (textwords); (3) random\$, comput\$, or microcomput\$ (truncated words); and (4) clinical trial (publication type). Proceedings of the meetings of the American, International, and European Medical Informatics Associations

were searched to locate results presented at leading national and international meetings. Manual searches of numerous books and monographs were performed in the area of medical informatics (eg, *Lecture Notes in Medical Informatics*, International Federation for Information Processing–International Medical Informatics Association monographs). The reference lists of retrieved reports and reviews of computer applications were also reviewed. After the initial set of trial reports was compiled, specific information interventions were identified, and additional search strategies were developed using the appropriate descriptive terms. Finally, trials were located by contacting by mail or telephone experts in the areas of medical informatics, primary health care, and health services management. Experts abroad were reached primarily by E-mail (eg, Brazilian Medical Informatics list, researchers in Australia, Japan, and European countries).

### SELECTION OF TRIALS

Following literature search and retrieval, the eligibility criteria were checked by analyzing the title, MeSH key words, abstract, and full text of the report. Once a reference to a possible computer trial had been identified, the eligibility check was primarily a search for facts that would unambiguously exclude the report from this study. This included, for example, cases in which randomization was interpreted by the authors as random sampling and not as a method of intervention allocation. When the title and abstract of a retrieved report left open the potential of eligibility, the full report was analyzed. If eligibility remained unclear, the trial investigators were contacted for definitive information. Before a study was included in the analysis, the soundness of the methods was assessed. For this task, the investigators created and validated a quality-evaluation tool specifically designed for health services research trials.<sup>11</sup> The mean total score minus 2 SDs was defined as the minimum acceptable quality score. Decisions to include or exclude studies for the analysis were based strictly on the eligibility criteria and soundness of the methods.

patient history, physical findings, and laboratory data would assist in decision making, thereby freeing the physician to focus on other aspects of clinical care.<sup>1</sup> However, enthusiasm for the potential of the computer as an intellectual tool eroded quickly. For example, some studies indicated that a computer system for diagnosing abdominal pain generates more accurate information and is associated with a reduced perforation rate,<sup>2,3</sup> while other studies concluded that the system has no useful role in this diagnosis.<sup>4,5</sup> Piantadosi and Byar<sup>6</sup> noted that, "curiously, computer algorithms are considered worthy of review and publication based largely on improvement in concept," rather than based on demonstrated practical value in improving quality.

The current debate over health system reform and the intensive search for cost-effective methods repeatedly highlight the need for adequate technology assessment of clinical information systems. Although early evaluation studies focused on the accuracy of information generated by the computer system, newer studies tend to focus on differences in the process or outcome of care because of the computer system. Randomized con-

trolled clinical trials represent the planned experimental approach in clinical medicine.<sup>7</sup> According to a consensus among practitioners and researchers, trials with positive and negative findings are equally valuable, and all evidence from randomized controlled trials should be collected and processed.<sup>8,9</sup> Randomized controlled clinical studies can provide the most valid information about the efficacy of computerized information systems in patient care.<sup>10</sup> During the last 10 years, the number of randomized controlled clinical trials testing computerized information interventions increased an average of 50% annually.<sup>10</sup>

The need for research synthesis is highlighted by the growing number of clinical trials and by troublesome gaps and controversies in the evaluation of computer systems. No comprehensive evaluation of computerized information services has been published on the basis of controlled evidence. The objectives of this study were to review all randomized controlled clinical trials that address efficacy of clinical information systems and to determine the clinical settings, types of interventions, and effects studied.

## CLASSIFICATION OF TRIAL FEATURES

Two research assistants independently abstracted information describing important characteristics of the selected reports. This information was collected into lists under three categories: trial sites, computer-assisted interventions, and effect variables. The reports' original wording was followed in composing the category lists to minimize bias during abstraction. The lists of the two research assistants were then integrated, discrepancies were resolved, and consensus was reached during meetings of the research assistants and one of the investigators.

To group related items within each list, a blinded classification method was used. Three investigators independently reviewed the three categories developed. These three investigators have experience in appropriate areas of health sciences: health services management (K.D.B.), clinical practice (B.G.E.), and medical informatics (J.A.M.). After the related items were grouped within each list, all investigators compared the proposals and developed consensus.

Two research assistants independently evaluated the outcomes of the registered trials as either positive or negative. The evaluation was based on the reported statistical comparisons of the primary effect variables. The outcome of a trial was considered positive when the null hypothesis of no difference in primary outcome as defined in the trial could be rejected and the alternative hypothesis was confirmed. Otherwise, the outcome of a trial was considered negative. In the cases of studies with more than one primary effect variable, a positive outcome for any of the variables qualified the report as positive. After this evaluation, the research assistants met to resolve discrepancies and obtain consensus.

## STATISTICAL ANALYSIS

This study compared before-consensus agreement among the three investigators regarding the independently defined categories of trial sites, computer-assisted interventions, and

effect variables. Before-consensus agreement among the three investigators was measured by the modified Mean Majority Agreement Index proposed by Armitage et al.<sup>12</sup> This index ranges from 0 for cases in which the investigators are evenly divided to +1 when the investigators are in full agreement. The modified Mean Majority Agreement Index for the trial site categories was 0.61. The Mean Majority Agreement Index for the intervention categories was 0.59. The Mean Majority Agreement Index for the effect variable categories was 0.63.

In the independent outcome evaluations, before-consensus agreement between two research assistants was measured by calculating Cohen's  $\kappa$  statistics. The Cohen's  $\kappa$  statistic measuring interobserver agreement for the overall positive/negative evaluation of the trials indicated substantial interobserver agreement based on the criteria of Landis and Koch.<sup>13</sup> The mean  $\pm$  SD Cohen's  $\kappa$  statistic was  $0.73 \pm 0.09$  for the outcome of analyzed trials.

The statistical analysis employed the vote-counting method for evaluating success rates, the ratio of positive trials.<sup>14,15</sup> The ratio of positive trials refers to the ratio formed by comparing the number of positive trials with the total number of trials in a given category. The sign test was used to test the hypothesis that the effects in the particular group of studies were randomly distributed.<sup>16</sup> The underlying hypothesis in this analysis was that the computerized intervention had a beneficial effect and that, therefore, the probability of obtaining a positive result exceeded 50%. Tolerance is the minimum number of additional but unpublished negative studies that would be needed to reduce the ratio of positive trials and reverse the conclusion of vote counting.<sup>17</sup> When the number of trials in a particular group exceeded five, tolerance was calculated using the formula,  $19s - u$ , where  $s$  and  $u$  are the numbers of positive (successful) and negative (unsuccessful) trials, respectively. The tolerance limit recommended by Rosenthal<sup>17</sup> is  $5n + 10$ , where the number of studies used in this analysis is represented by  $n$ . The tolerance limit can identify those categories for which the number of negative trials needed to reverse the conclusion is unlikely to exist.

## RESULTS

There were 100 trials included in this study, as reported in 98 articles.<sup>18-115</sup> The most prevalent sources were the journal *Medical Care* and the *Proceedings of the Annual Symposium on Computer Applications in Medical Care*, with 17 and 11 articles, respectively. Four journals—*Journal of Family Practice*, *New England Journal of Medicine*, *Annals of Internal Medicine*, and *Journal of the American Medical Association*—contributed four articles each. The mean  $\pm$  SD quality score for the 98 articles was  $55.1 \pm 12.2$ . Three of the included trials were not analyzed because their quality score was more than 2 SDs below the mean.

The classification of trials according to their experimental design, randomized units, and number of interventions is shown in **Table 1**. The trials were predominantly parallel in design. In several crossover trials, a variety of computer algorithms or protocols were tested simultaneously by permitting each provider to receive computer assistance on some protocols but not on other

protocols.<sup>54,56</sup> The crossover design can also be varied by interjecting a period of the control condition between the periods of experimental conditions.<sup>105</sup>

## SITES OF TRIALS

Results for selected trial sites indicate promising areas of computer application. Three major site groups—outpatient primary care, outpatient specialty care, and inpatient care—comprising a total of 11 site categories were defined by the investigators (**Table 2**). Some trials used more than one site,<sup>44-46,63,88</sup> and the site of one trial was unknown. Outpatient primary care sites represented the greatest percentage of trials among the three groups. University-affiliated clinic settings represented the largest percentage of reports within both the outpatient primary care and outpatient specialty care groups (39% combined).

## TESTED INTERVENTIONS AND EFFECTS

Most information interventions targeted providers, and a smaller group of interventions focused on patients

**Table 1. Protocols of Controlled Computer Trials**

	No. (%) of Trials
Design	
Parallel	88 (88)
Crossover	12 (12)
Randomized units	
Providers	32 (32)
Patients	64 (64)
Encounters	4 (4)
No. of interventions	
Study and control	71 (71)
≥3	29 (29)
<b>Total*</b>	<b>100 (100)</b>

\*Two articles reported two trials.

**Table 2. Site Categories**

	No. (%) of Reports	No. (%) Positive
Outpatient primary care group		
University-affiliated clinic	29 (30)	25 (86)
Other public or private clinic	21 (21)	16 (76)
Managed care	6 (6)	6 (100)
Residential/community-based studies	2 (2)	2 (100)
Outpatient specialty care group		
University-affiliated clinic	16 (16)	15 (94)
Emergency department	5 (5)	3 (60)
Hospital-based clinic	4 (4)	3 (75)
Other public or private clinic	5 (5)	3 (60)
Pharmacy	2 (2)	1 (50)
Inpatient care group		
Hospital ward	16 (16)	10 (63)
Intensive care unit	4 (4)	5 (100)
<b>Total*</b>	<b>98 (100)</b>	<b>83 (85)</b>

\*Some reports used more than one site. The site of one report was unknown.

**Table 3. Information Intervention Categories**

	No. (%) of Reports	No. (%) Positive
Provider focus group		
Provider prompt/reminder	19 (19)	19 (19)
Computer-assisted treatment planner	19 (19)	15 (79)
Provider feedback	19 (19)	13 (68)
Computerized medical record and information access	19 (19)	14 (74)
Prediction	6 (6)	5 (83)
Computer-assisted diagnosis	4 (4)	2 (50)
Patient focus group		
Computer-assisted interactive patient education, instruction, and therapy	19 (19)	14 (74)
Patient prompt/reminder	15 (15)	12 (80)
Patient-computer interactive information gathering	2 (2)	2 (100)
<b>Total*</b>	<b>98 (100)</b>	<b>83 (85)</b>

\*Some reports tested several interventions.

**Table 4. Primary Effect Categories**

	No. (%) of Reports	No. (%) Positive
Process group		
Diagnostic test use and preventive services	39 (39)	34 (87)
No. of drug prescriptions and dosing	23 (23)	19 (83)
Hospital and emergency department use	14 (14)	10 (71)
Outpatient care (return and follow-up visits)	11 (11)	7 (64)
Cost of health care	10 (10)	6 (60)
Outcome group		
Patient knowledge and attitudes	13 (13)	11 (85)
Morbidity, physiologic, and psychological measures	14 (14)	10 (71)
<b>Total*</b>	<b>98 (100)</b>	<b>83 (85)</b>

\*Some reports used several effect variables. One report was excluded for lack of fit.

(**Table 3**). The provider prompt/reminder intervention was typically used to improve the provision of preventive care services through computer-generated reminders to physicians<sup>18,20,22,31,61</sup> or patients.<sup>39,84,94</sup> The prediction intervention was used to forecast the outcome of tests and to assist decision making for various treatments.<sup>47,51,91</sup> The patient-computer interactive information-gathering intervention was defined as a computer application for interviewing patients to gather data relating to potentially sensitive matters (sexual history,<sup>65</sup> obtaining a urine specimen,<sup>68,111</sup> and alcohol-related illness<sup>109</sup>).

The overwhelming majority (76%) of effect variables evaluated the process of care (**Table 4**). The most commonly tested effects included cancer screening compliance rates,<sup>19,30</sup> vaccination rates,<sup>24,57,66,86</sup> blood pressure measurement,<sup>20,25,74</sup> use of laboratory tests,<sup>36,49,56,58,66</sup> prenatal screening rates,<sup>18,48</sup> and medication monitoring rates.<sup>55,81,98</sup> Only two effect variable types included outcome measures. The first category contained studies of patient knowledge and attitudes that focused on problem-solving ability,<sup>27</sup> treatment of phobias,<sup>43</sup> asthma,<sup>44</sup> and

rheumatoid arthritis.<sup>96</sup> The second category focused on the physical<sup>23,32,99,104</sup> and psychological<sup>42,72,82</sup> outcomes.

## SUCCESSFUL INFORMATION INTERVENTIONS

The association between computerized information interventions and effect variables was also evaluated (**Table 5**). The displayed fractions indicate the proportion of positive or successful trials. A significant result of the sign test indicates that the ratio of positive trials exceeds the ratio expected on the basis of random variation (0.5). In studies such as this one, a danger exists that unidentified or nonretrieved negative studies could change the statistical test results. However, our tolerance calculation indicates that none of the significant sign test results was jeopardized by unpublished negative studies.

The results of vote-counting and sensitivity analysis indicated that two active information services (provider prompt/reminder and patient prompt/reminder) and two passive services (computer-assisted patient education and computer-assisted treatment planner) were successful in a significant majority of trials. Active systems

Table 5. Evaluation of Information Interventions and Effect Variables

Intervention	Effect Variable*						
	Diagnostic Test Use and Preventive Services	Outpatient Care	Hospital and Emergency Department Use	Drug Prescription and Dosing	Cost of Health Care	Patient Knowledge and Attitudes	Morbidity, Physiologic, and Psychologic Measures
<b>Provider Focus Group</b>							
Provider prompt/reminder	16/16†‡	3/3	0/0	1/1	1/1	0/0	1/1
Computer-assisted treatment planner	4/4	1/2	1/1	10/12†§	0/0	0/1	1/2
Provider feedback	7/9	2/3	0/1	5/6	2/5	0/0	1/1
Computerized medical record and information access	6/8	1/2	5/6	0/1	2/3	2/2	2/3
Prediction	1/1	0/0	2/2	1/1	0/0	0/0	1/2
Computer-assisted diagnosis	1/2	0/0	1/1	0/0	0/0	0/0	1/2
Computer-assisted interactive patient education, instruction, and therapy	0/1	2/5	2/3	3/3	0/0	8/9†§	4/5
<b>Patient Focus Group</b>							
Patient prompt/reminder	9/9†‡	1/3	0/2	1/2	2/2	0/0	0/0
Patient-computer interactive information gathering	0/0	0/0	0/0	0/0	0/0	2/2	0/0

\*The numerator represents the number of positive reports, while the denominator represents the total number of reports.

†Tolerance limit is exceeded.

‡Results of the sign test are significant ( $P < .01$ ).

§Results of the sign test are significant ( $P < .05$ ).

generate information based on arriving data and trigger the action of the informed person without a preceding specific request. Passive systems require the user to recognize when advice would be useful and to make an explicit effort to start processing.<sup>116</sup> The following successful information interventions were analyzed:

- The provider prompt/reminder intervention was typically used to improve the provision of preventive care services through computer-generated reminders to physicians. For example, patients of physicians who received reminders on the encounter forms were significantly more likely to have a mammogram ordered.<sup>30</sup> Procedures frequently targeted by the provider prompt/reminder trials included cancer screening (stool occult blood,<sup>19,40,57,64,66,90</sup> sigmoidoscopy,<sup>40,64</sup> rectal examination,<sup>19,40,64,93</sup> mammography,<sup>30,40,57,63,66,90,93</sup> breast examination,<sup>18,19,40,64,93</sup> Papanicolaou test,\* and pelvic examination<sup>18,40,64</sup>) and vaccinations (influenza,<sup>29,57,62</sup> pneumococcal,<sup>57,90</sup> tetanus,<sup>66,93</sup> and infant<sup>86</sup> immunizations).
- The patient prompt/reminder intervention encouraged the action of patients through the use of telephone<sup>24,59,61,62</sup> or mail† reminders. The main function of the computer system was usually to identify patients and trigger the use of a particular clinical procedure. For example, in a trial testing the effect of reminders on influenza vaccination, patient reminder letters led to a significant (35.1%) improvement.<sup>59</sup> Most trials of patient prompt/reminders focused on cancer screening compliance rates (stool occult blood,<sup>40,64,66</sup> sigmoidoscopy,<sup>40,64</sup> rectal examination,<sup>40,64</sup> mammography,<sup>40,64,66</sup> breast examination,<sup>40,64</sup> Papanicolaou

test,<sup>40,61,64,66</sup> and pelvic examination<sup>40,64</sup>) and vaccination rates (influenza,<sup>24,59,62,107</sup> tetanus,<sup>66</sup> and infant<sup>86</sup> immunizations).

- A large number of studies employed computer algorithms to assist decision making concerning drug dosages (eg, aminoglycoside,<sup>21</sup> insulin,<sup>33,67,88</sup> digoxin,<sup>38,112</sup> phenytoin,<sup>69</sup> sodium nitroprusside,<sup>70</sup> lidocaine,<sup>75</sup> propranolol,<sup>105</sup> and amitriptyline<sup>105</sup>). For example, the first known computer trial compared the effect of computed digoxin dosage with the effect of digoxin dosage determined by unaided physician judgment.<sup>38</sup> The results indicated that the computer slightly outperformed the physician and that the correlation between predicted and measured serum digoxin concentrations was closer in the computer-assisted patient group.
- Interactive patient education, instruction, and therapy computer programs helped patients improve their health as well as the process through which they receive care. In this group, the interventions included computerized health promotion,<sup>31,73</sup> educational information on the management of medical conditions,<sup>44,96</sup> computerized instruction to obtain a urine specimen,<sup>68,111</sup> and computer-administered psychiatric therapy.<sup>27,43</sup>

COMMENT

This study documented the rapidly growing number of randomized controlled clinical trials of computer interventions and documented significant improvements in the process and/or outcome of care. The most frequently studied and most successful interventions included patient and physician reminders, computer-assisted patient education, and computerized treatment planners. A surprisingly high propor-

\*References 18, 19, 40, 57, 61, 64, 74, 90, 93.

†References 40, 59, 61, 62, 64, 66, 86, 107.

tion of trials were performed in outpatient facilities, particularly in primary care, while relatively few trials evaluated hospital information systems. This finding is surprising considering the large sums of money spent on information systems for inpatient care. The tested computerized interventions were collapsed into generic types by the study's independent review process. In fact, these generic information services—provider feedback, reminders—seem to be the clinically active ingredients of medical computer systems. The complex databases of many computer systems serve primarily as excipients. For these reasons, developers of systems may wish to incorporate the successful information services into future computer systems. Buyers can use the information services listed above in the specifications for medical software bids. Finally, this analysis of effect variables underscored the role of computers in changing the use of clinical procedures and other health care resources, key issues in quality improvement and cost control.

Compared with conventional review articles, the systematic and quantitative methods of this study had several advantages. This review included all known randomized controlled clinical computer trial reports available at the time of the analysis and therefore described a wide range of tested information interventions. This study's systematic collection procedures were designed to avoid the well-known deficiencies of the conventional pick-and-choose approach.<sup>117</sup> The independent review method used here led to the development of a classification system for computerized information interventions based on the results of controlled clinical experiments. Such analysis is a widely recommended safeguard against investigator bias.<sup>118</sup>

Creation of a specific type of information service intervention always raises the question of clinical efficacy. Vote counting is an established method of expressing the success rate of a particular intervention.<sup>119</sup> When the number of successful trials in a particular category is very high, then the intervention is likely to make a difference. The particular advantage of vote counting is that information on the success or failure of the intervention is available from virtually all trial reports. Obviously, vote counting does not consider the magnitude of effect. Primary research reports that do not provide enough information to calculate effect size estimates usually contain information about the direction of the effect. Future meta-analyses using the popular odds ratio methods can specify the magnitude of the effect and are likely to discover additional categories of effective interventions.

Diversity, a frequent concern in research synthesis, can be an advantage as well as a disadvantage. Pooled trials always vary somewhat in their sites, samples, interventions, and effect variables. Diverse sites and samples (within the stated pooling criteria) can help document an intervention's success under a variety of circumstances. Diverse interventions can also help to reflect the natural variability of use in different health care organizations. For example, it would be unreasonable to demand separate testing of physician reminders for every single clinical procedure. Successfully applying a particular information intervention in a variety of

settings and disease conditions increases the generalizability of results and the intervention's practical value.

This study highlighted several opportunities for improving clinical trials of computerized information services. Although clinical trials are rapidly gaining acceptance in technology assessment, the method of such trials does not seem to be common knowledge. Several techniques commonly used in drug trials are irrelevant in testing computerized information interventions (eg, blinding to the intervention, placebo), while other aspects are more critical (eg, detailed description of sites, technical specification of intervention). Another weakness of many computer trials is the lack of evaluation of patient outcome. It is understandable that many information service trials evaluate the effect on care processes. However, documenting the lack of side effects or other outcome measures, such as complication rates, would probably convince more clinicians.

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