Universidad Nacional Autónoma de México
Programa de Maestría y Doctorado en Ciencias Médicas,
Odontológicas y de la Salud

Guía de repaso de conocimientos básicos de metodología de la investigación

UNIVERSIDAD NACIONAL AUTONOMA DE MEXICO.

PROGRAMA DE MAESTRIAS Y DOCTORADOS EN CIENCIAS MEDICAS, ODONTOLOGICAS Y DE LA SALUD.

5.- EVALUACION DE LA CALIDAD DE LA ATENCIÓN MEDICA.

Objetivo:
- Repasar los criterios metodológicos mínimos requeridos en un estudio de evaluación de la calidad de la atención médica, a fin de que los resultados sean aceptados como válidos.
- Repasar los parámetros comúnmente utilizados para resumir la utilidad de la evaluación de la calidad de la atención médica.
- Aplicar los criterios y parámetros repasados a un ejemplo de la literatura médica.

Lecturas:
-Department of Clinical Epidemiology and Biostatistics, McMaster University Health Sciences Centre. How to read clinical journals: VI. To learn about the quality of clinical care. Can Med Assoc J 1981; 124:703-710.

-Starfield B, and Scheff D. Effectiveness of pediatric care: The relationship between processes and outcome. Pediatrics. 1972, 49:547-552.

Ejercicios:
En el artículo sobre la efectividad de la atención médica en pediatría, valore si se cumplen los criterios metodológicos recomendados.

Criterio metodológico.	**Valoración.**
1.- El estudio se enfoca en lo que los clínicos realmente hacen ?.	___ Sí ___ No ¿Porqué ?. _____ _____ _____ _____
2.- Los procedimientos clínicos evaluados han demostrado que producen mas beneficio que daño?	___ Sí ____ No ¿Porqué?. _____ _____ _____ _____

Criterio metodológico.	**Valoración.**
2a.- Si el proceso clínico evaluado no demostró producir mas beneficio que daño y es una investigación sobre proceso vs resultado, se debe verificar si fue un diseño de cohorte en el que se midió el porcentage de cumplimento y se registraron de todos los resultados relevantes incluyendo signos de pronostico.	___ Sí ____ No ¿Por qué? _____ _____ _____ _____
3.- Son los pacientes, los médicos y el tipo de práctica clínica similar a la suya?.	___ Sí ____ No ¿Por qué?. _____ _____ _____ _____
4.- Los procedimientos clínicos se midieron en una forma clínicamente sensible?.	___ Sí ____ No ¿Por qué?. _____ _____ _____ _____
5.- Los procedimientos clínicos midieron de manera científicamente creíble?	___ Sí _____ No ¿Por qué? _____ _____ _____ _____
6.- Se consideró tanto la significancia clínica como la significancia estadística?	___ Sí _____No ¿Por qué? _____ _____ _____ _____

How to read clinical journals: VI. To learn about the quality of clinical care*

DEPARTMENT OF CLINICAL EPIDEMIOLOGY AND BIOSTATISTICS, MCMASTER UNIVERSITY HEALTH SCIENCES CENTRE

Clinical journals are publishing increasing numbers of articles about the quality of clinical care, which we have defined as the extent to which clinical acts that do more good than harm are carried out and the extent to which those that do more harm than good are avoided.

Why should busy clinicians read such articles? First, our hospitals and professional organizations are carrying out quality-of-care studies as part of their accreditation system, and if we haven't already been the subjects of such studies we soon shall be. This being so, it's wise to understand more about how we are being judged. Second, in an effort to make quality-of-care audits more accurate, relevant and acceptable we are being asked to help carry them out, as is illustrated in the following presentation:

The head of the clinical section at your hospital has asked you to sit on the audit committee, an offer you cannot refuse. The committee is charged with carrying out at least two audits annually on the quality of care provided to inpatients on your service. Although the medical records staff have agreed to carry out the chart review, you and your colleagues have to decide what they should look for. At your first meeting you are given copies of the previous year's audit reports and a folder full of articles describing quality-of-care studies done elsewhere.

What a thankless job! Still, if it must be done it ought to be done fairly, rationally and in such a way that patients and their clinicians can benefit. Our collective experience over the last decade or so in performing and reading about quality-of-care studies has enabled us to identify some general guides for interpreting such studies. In this part of the series we discuss such a set of guides.

Guides for assessing articles about the quality of clinical care

Six guides will help the busy clinician read about the quality of care (Table I). The first guide serves as a quick screening tool that will help you toss aside many articles early.

1. *Did the study focus on what clinicians actually do?*

Evaluations of quality of care can be classified into three categories: structure, process and outcome.[1] Clinical-structure studies tally the numbers and qualifications of health professionals and describe the administrative organization and physical facilities in which they work. Clinical-process studies document health professionals' actions in patient care. These actions are often divided into technical processes (e.g., investigations, physiologic monitoring and drug prescribing) and interpersonal processes (e.g., patient education). Finally, clinical-outcome studies document the results of this care — the "proof of the pudding" — in terms of its effects on the patient's health (survival, symptoms, and physical and psychosocial function).

Articles that focus only on structural descriptions do not deserve time from a busy clinical reader. We all know that impressive diplomas and credentials cannot guarantee clinical competence and that humble, unimpressive physical facilities can be the sites of excellent clinical care. By the same token, the authors of articles that focus only on health outcomes may be fooling themselves if they think that these outcomes are the inevitable consequences of quality of care. There are three ways in which the results of such studies can be misleading:

- When unfavourable outcomes are rare, dangerous practices can appear innocuous when the study sample is small (e.g., in small studies a fatal pulmonary embolism may not occur in patients inappro-

Table I—Guides for assessing articles about the quality of clinical care

1. **Did the study focus on what clinicians actually do?**
2. **Have the clinical actions studied been shown to do more good than harm?**
   - 2a. **If the clinical actions have not been shown to do more good than harm, is the article about a process-versus-outcome study that assembled an inception cohort, ensured high rates of compliance, included all relevant outcomes and considered prognosis?**
3. **Are the clinicians, patients and type of practice similar to yours?**
4. **Were the clinical actions measured in a clinically sensible fashion?**
5. **Were the clinical actions measured in a scientifically credible fashion?**
6. **Were both clinical and statistical significance considered?**

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Reprint requests to: Dr. Peter Tugwell, McMaster University Health Sciences Centre, Rm. 2C16, 1200 Main St. W, Hamilton, Ont. L8N 3Z5

priately confined to bed after surgery,[2] or aplastic anemia may not develop in patients inappropriately treated with chloramphenicol[3]).

- When unfavourable outcomes are delayed, dangerous practices can appear innocuous when the study period is short (e.g., a brief study would miss the development of retinopathy resulting from treatment with chloroquine[4]).
- When unfavourable outcomes are determined primarily by factors other than the process of care, spurious conclusions will be made (e.g., the risk of death following a severe stroke is influenced far more by the severity of the initial brain damage than by anything clinicians do once the damage has occurred[5]).

As a result, quality-of-care studies that focus only on structure or outcomes are unlikely to provide valid information about the real quality of care being delivered, so you can pass them by. Rather, you should look for articles that focus on the process of clinical care and tell you what clinicians have actually been doing.

Given that process studies are worth reading, how do we avoid being confronted with "laundry lists" of every conceivable clinical action that the authors think should be carried out on patients with certain illnesses? One solution is for the authors to select processes that are known, from appropriately rigorous studies, to affect outcome. The use of an "indicator condition" is one such process.[6] An indicator condition is an illness, clinical situation or state of health that either evokes clinical actions known to result in more good than harm when correctly applied (e.g., treatment with high doses of acetylsalicylic acid for rheumatoid arthritis[7]) or evokes clinical actions known to result in more harm than good (e.g., treatment with chloramphenicol for self-limited upper respiratory tract infections[3]).

By selecting only articles that study clinical actions in the types of patients seen in your hospital, you will already have eliminated the large number of articles that focus only on structure and outcome or on clinical processes for conditions that are not relevant to your hospital.

2. *Have the clinical actions studied been shown to do more good than harm?*

This guide draws our attention to part 5 of this series, in which we discussed how to decide whether therapy does more good than harm.[8] The clinical actions of prime importance will be therapeutic: prescribing therapies that help and avoiding those that harm. However, other clinical actions are also important; for example, the actions of diagnosis that establish the need for therapy, those of dose-setting and monitoring, those of detection and management of noncompliance, and those of proper follow-up.

If you are confident that the clinical actions studied in the article have been shown to do more good than harm, you are ready to go on to guide 3. If, however, this is not the case, then guide 2 should be modified, as follows:

2a. *If the clinical actions have not been shown to do more good than harm, is the article about a process-versus-outcome study that assembled an inception cohort, ensured high rates of compliance, included all relevant outcomes and considered prognosis?*

This is a mouthful but is really quite straightforward. It states that you are wasting your reading time unless the article is either *about* clinical actions that do more good than harm or is *establishing whether* the clinical actions (or processes) are linked to clinical outcomes. If the article does neither of these, it should join the mass of articles that merely count patients seen, tests performed and money spent.

The actions that constitute clinical performance and thus the quality of care are only one determinant of the outcome (Fig. 1); without favourable influences from the other components the patient's health will not improve.

Because process-versus-outcome studies provide the rational basis for medical audits and contribute to the assessment of the integration of diagnosis, therapy and patient compliance, you will probably want to read them. If so, there are four special features you should look for.

First, the authors should have assembled an inception cohort of patients (consecutive patients with the target disorder identified at the first visit or at the beginning of therapy). This will ensure that patients who fail to continue attending the clinic or hospital because one of the outcomes of interest has occurred (e.g., death or severe disability) will not be lost to follow-up. Two widely quoted process-versus-outcome studies, one on myocardial infarction[9] and the other on hypertension,[10] did not use inception cohorts; rather, their inclusion criteria were that patients would be available for follow-up or would come back to the clinic. As a result, the authors were likely to miss important outcomes and thus make inaccurate conclusions.

Second, patient compliance must be taken into account in process-versus-outcome studies since it is an essential link between the actions by the health care team and the outcomes of the patients. Studies that have not considered compliance

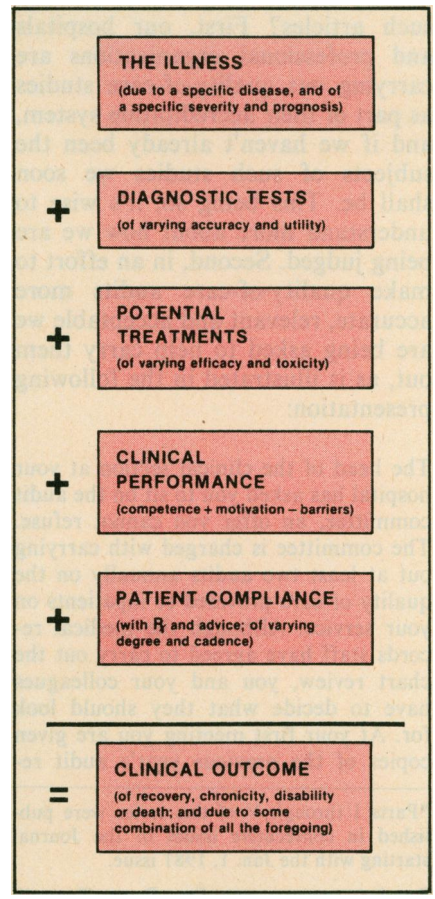

FIG. 1—Place of clinical performance as one of several components that determine clinical outcome.

have failed to demonstrate such an association.[10-14] On the other hand, studies that have considered compliance have documented strong links between the clinical process and the outcome of care in patients with urinary tract infections, hypertension, iron-deficiency anemia and other conditions.[15-17] Before stating that there is no relation between process and outcome the authors should provide evidence that the lack of such an association was not merely due to low rates of compliance.

Third, a process-versus-outcome study must examine all clinically relevant outcomes. These might include death, improvement or deterioration in physical, emotional or social function, or even in the physiologic control of a risk factor for a disease (when it is justified to substitute alterations in such risk factors for death or disability, as in hypertension[18]), patient satisfaction and the side effects of therapy. The methods for assessing these outcomes should be accurate and, to minimize bias, should have been used by an assessor who was blind to the details of the patients' management.

Finally, to isolate the effects of the clinical processes from those of other determinants of outcome, process-versus-outcome studies must control for the other determinants. Because patients with more severe disorders usually need more extensive assessment, monitoring and intervention but will tend to have poor outcomes irrespective of the quality of care provided, a study that failed to control for the severity of illness would conclude that the greater the number of processes carried out, the worse the outcome!

Once you are satisfied that there is indeed a link between the clinical process and outcome, you are ready to apply the next guide.

3. *Are the clinicians, patients and type of practice similar to yours?*

Information on the clinicians' training, certification, years of experience and workload, on the source and types of patients, and on the type of practice (primary, secondary or tertiary care) in an article will help you decide whether the results of the study will apply to you and your patients. Moreover, the methods used to select the clinicians and patients should be described in the article so that you can judge whether the individuals are likely to be representative of a particular population. For example, if only the clinicians who volunteered for the study were included, and they accounted for less than 80% of clinicians who were eligible for the study, it would not be wise to apply the results to those who did not volunteer or to clinicians in general.

Finally, the rules for what constitutes a "case" should be realistic. For example, eligibility for inclusion in a study of an indicator condition should be based on the presence of an illness or complaint (e.g., sleep disturbance) rather than on the presence of disease (e.g., depression), since the latter assumes a correct diagnostic process and therefore excludes patients in whom the indicator condition was present but not diagnosed. Similarly, except for discrete emergencies, the definition of a case should allow the assessment of episodes of care, including follow-up visits when appropriate.

Since it is unlikely that any study setting will exactly replicate your practice, you should ask yourself Are the clinicians and their practices *so different* from those in the area in which I am interested that I could *not* apply the study results?

4. *Were the clinical actions measured in a clinically sensible fashion?*

The rules for measuring the clinical actions must be explicit, comprehensive and flexible. First, the measurement criteria should be explicitly stated so that you can see if they make sense. This means that the actual criteria used in the study must be available or, ideally, mentioned in the article.

Second, the process criteria should be comprehensive. That is, they should include all the clinically important aspects of care (e.g., history-taking, physical examination, laboratory tests, therapy, patient education, consultation etc.), and they should have been applied to all the patients (e.g., in different age groups and different socioeconomic groups). You cannot assume that a clinician who complied with the defined standards for history-taking, physical examination and laboratory investigation also complied with the standards for drug therapy, patient education and follow-up. Moreover, because of conflicting evidence as to whether a clinician's actions for one type of problem are representative of his or her actions for other types of problems,[19,20] the authors should have evaluated all the conditions for which they drew conclusions. However, a sizeable proportion of most practices can be represented by a small selection of health problems. Therefore, by covering just these, you can obtain a reasonable overview of a clinician's quality of care.[21]

Finally, it is important to consider whether the process criteria were flexible enough to allow for appropriate changes in management according to variations in diagnosis, severity of disease and complications. In many situations this is not necessary, so it would be acceptable to apply identical criteria to all the patients (e.g., a criterion for all children to have been fully immunized by a certain age would be appropriate). On the other hand, you should demand more sophisticated assessment methods when patients present with complex problems (e.g., pleuritic chest pain). Similarly, flexible process criteria are appropriate for assessing the management of patients with different complications or degrees of severity of disease (e.g., those with chest pain due to acute myocardial infarction). All too often, long and invariant "laundry" lists are applied to heterogeneous groups of patients. On the other hand, Sibley and colleagues' indicator-condition approach,[6] which stratifies patients according to severity of disease, and Greenfield and associates' criteria-mapping method,[22] which uses branching criteria to reflect sequential judgements, are two ways of addressing this issue; authors should therefore have incorporated such methods when they were needed.

5. *Were the clinical actions measured in a scientifically credible fashion?*

The method used to decide whether specific clinical actions were carried out must be both accurate and

precise. Accuracy means that the method should have revealed the clinically important deficits or differences in the clinical process, and precision means that different examiners applying the same method to the same cases should have come to the same conclusions about whether specific clinical processes were carried out.

A major limitation to the accuracy of measuring clinical processes by methods that rely on medical records is the inconsistency with which different physicians record their clinical actions.[23] As a result it may be difficult or impossible to distinguish clinical actions that were not performed from those that were performed but not recorded. On the other hand, it can be argued that good clinical care necessitates good record keeping; important actions have to be recorded for recall, for communication with others and for minimizing the clinical errors that result from recording only the conclusions and management decisions and not the observations that led to them. Surprisingly, despite the faults of clinical records, several studies have shown that they can provide accurate, adequate data for a wide range of clinical processes; however, this accuracy is usually achieved when explicit criteria have been restricted to the essentials.[6,22] When one relies only on implicit clinical judgements about quality there is often a lack of consistency, even among "experts".[11] To achieve precision, therefore, the criteria for acceptable quality of care must be explicit. Moreover, there should be a high degree of interobserver agreement in the application of the criteria.

Finally, the information should have been collected in a blind fashion to avoid bias due to the expectations of the abstractor, who knows the patient, the clinician or the outcome. When logistics have made this difficult, a sample of the observations should have been assessed in a blind fashion to obtain a measure of the bias.

6. *Were both clinical and statistical significance considered?*

The analysis must be clinically sensible, and its results must be applicable in routine clinical care. Beware of "scores" and analyses that have simply added up the number of "right" actions, for such analyses can generate ludicrous conclusions. For example, a clinician caring for a patient who is vomiting blood could take a thorough history (worth lots of points), flawlessly execute a series of diagnostic tests (worth lots more points) and end up with a reasonably high score while the patient continues to lose blood for want of proper therapy. In fact, actions related to correct management constituted only 1% to 16% of the scores assigned in widely quoted quality-of-care studies.[9,10,24]

Appropriate analyses are of two sorts. The first simply comprises a table that lists each action and the proportion of cases in which it was carried out. This descriptive analysis permits you to draw your own conclusions as well as to study those of the authors. The second establishes a minimum set of actions, *all* of which must be carried out for a case to have been handled with adequate quality of care.

Finally, any conclusions about the quality of care provided in such articles should be backed up by tests of statistical significance. These were discussed in part V of this series; to recap, you should ask yourself the following questions:

- If the difference in quality of care is statistically significant, is it also clinically significant?
- If the difference is not statistically significant, was the study sample large enough to enable detection of clinically significant differences in the quality of care if there were any?

Conclusion

The readers' guides in this paper can serve many purposes. The first guide (Did the study focus on what clinicians actually do?) can help you choose the few studies that are most likely to be both valid and useful. Moreover, the use of all the guides can help you not only to understand the studies done by others but also to design your own studies. The application of previously described guides on how to select accurate diagnostic tests[25] and efficacious treatments[8] will help you decide which clinical processes you should include in your studies. The results of your study can then become the basis for a grand rounds or the starting point for clinical research.

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℞DESYREL*
(trazodone HCl)

A REMARKABLE ADVANCE IN THE TREATMENT OF DEPRESSION.

ACTION
Trazodone hydrochloride is a psychoactive compound with sedative and antidepressant properties. Its mechanism of action in humans is not clear. Trazodone hydrochloride is well absorbed after oral administration with peak plasma levels obtained within one-half to two hours after ingestion. Absorption is somewhat delayed and enhanced by food. The mean plasma elimination half-life is 4.4 hours for the period from 3 to 10 hours after dosing, and 7 to 8 hours for the period from 10 to 34 hours. The drug is extensively metabolized with 3 or 4 major metabolites having been identified in man. Approximately 60-70% of ^{14}C-labelled trazodone was found to be excreted in the urine within two days and 9-29% in feces over 60-100 hours. Trazodone is 89-95% protein bound in vitro at concentrations obtained with therapeutic doses.

INDICATIONS AND CLINICAL USE
DESYREL (trazodone hydrochloride) is of value in the symptomatic relief of depressive illness.

CONTRAINDICATIONS
Known hypersensitivity to trazodone.

WARNINGS
Recent clinical studies in patients with pre-existing cardiac disease indicate that DESYREL (trazodone hydrochloride) may be arrhythmogenic in some patients in that population. Arrhythmias identified include isolated PVC's, ventricular couplets, and in two patients short episodes (3-4 beats) of ventricular tachycardia. There have also been several post-marketing reports of arrhythmias in DESYREL-treated patients who had pre-existing cardiac disease. Until the results of prospective studies are available, patients with pre-existing cardiac disease should be closely monitored, particularly for cardiac arrhythmias. DESYREL is not recommended for use during the initial recovery phase of myocardial infarction.

PRECAUTIONS
General: The possibility of suicide in depressed patients remains during treatment and until significant remission occurs. Therefore, the number of tablets prescribed at any one time should take into account this possibility, and patients with suicide ideation should never have access to large quantities of trazodone.
Safety of Driving: Since DESYREL (trazodone hydrochloride) may impair the mental and/or physical abilities required for performance of potentially hazardous tasks, such as operating an automobile or machinery, the patient should be cautioned not to engage in such activities while impaired.
Interactions: Trazodone may enhance the response to alcohol and the effects of barbiturates and other CNS depressants and patients should be cautioned accordingly.
Because it is not known whether an interaction will occur between DESYREL and MAO inhibitors, administration of DESYREL should be initiated very cautiously with gradual increase in doses as required, if an MAO inhibitor is given concomitantly or has been discontinued shortly before medication with DESYREL is instituted.
DESYREL may cause hypotension; caution is required if it is given to patients receiving antihypertensive drugs and an adjustment in the dose in the antihypertensive medication may be required.
Because of the absence of experience, concurrent administration of electro-shock therapy should be avoided.
Use in Pregnancy and Nursing Mothers: Since the safety and use of DESYREL in pregnant women has not been established, it should not be used in women of childbearing potential unless in the opinion of the physician the expected benefits justify the potential risk to the fetus. Since DESYREL and/or its metabolites have been detected in the milk of lactating animals, it should not be administered to nursing mothers unless the potential benefits justify the possible risks to the child.
Use in Children: The safety and effectiveness of DESYREL in children below age of 18 have not been established.
Laboratory Tests: It is recommended that white blood cell and differential counts should be performed in patients who develop sore throat, fever, or other signs of infection or blood dyscrasia and DESYREL should be discontinued if the white blood cell or absolute neutrophil count falls below normal.
Hyperprolactinemia and Breast Tumors: There is sufficient experimental evidence to conclude that chronic administration of those psychotropic drugs, such as trazodone, which increase prolactin secretion has the potential to induce mammary neoplasms in rodents under appropriate conditions. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with a previously detected breast cancer. Although disturbances such as galactorrhea, amenorrhea, gynecomastia and impotence have been reported, the clinical significance of elevated serum prolactin levels or increased secretion and turnover are unknown for most patients. Neither clinical studies or epidemiological studies conducted to date, however, have shown an association between administration of these drugs and mammary tumorgenesis; available evidence is considered too limited to be conclusive at this time.

ADVERSE REACTIONS
The most common adverse reactions encountered are drowsiness and dry mouth. Adverse reactions reported include the following:
Behavioral: drowsiness, fatigue, lightheadedness, dizziness, difficulty in concentration, mild confusion, lethargy, retardation, forgetfulness, disorientation, excitement, agitation, insomnia, anxiety, tension, nightmares, hostility and, rarely, hypomania, delusions and hallucinations.
Neurologic: tremor, headache, ataxia, akathisia, muscle stiffness, slurred speech, retarded speech, vertigo, tinnitus, tingling of extremities, paresthesia and, rarely, impaired speech, muscle twitching and numbness.
Autonomic: nasal congestion, blurred vision, constipation, sweating, urinary retention and incontinence.
Cardiovascular: orthostatic hypotension, hypertension, tachycardia, palpitations, shortness of breath, syncope and arrhythmias.
Gastrointestinal: nausea, vomiting, diarrhea, gastrointestinal discomfort, anorexia, increased appetite.
Endocrine: decrease and, more rarely, increase in libido, weight gain and loss and, rarely, menstrual irregularities and retrograde ejaculation.
Miscellaneous: skin rash, itching, edema, aching joints and muscles, peculiar taste, hypersalivation, anemia, chest pain and hematuria.

SYMPTOMS AND TREATMENT OF OVERDOSAGE
Overdosage of DESYREL (trazodone hydrochloride) may cause an increase in incidence or severity of any of the reported adverse reactions, e.g. hypotension and excessive sedation. In one known suicide attempt, the patient presented with symptoms of drowsiness and weakness three hours after ingesting 7.5 grams (12.5 times the maximum daily dose) of trazodone hydrochloride. Recovery was uneventful. Death by deliberate or accidental overdosage has not been reported. There is no specific antidote for trazodone hydrochloride. Management of overdosage should, therefore, be symptomatic and supportive. Any patient suspected of having taken an overdosage should be admitted to hospital as soon as possible and the stomach emptied by gastric lavage. Forced diuresis may be useful in facilitating elimination of the drug.

DOSAGE AND ADMINISTRATION
Dosage should be initiated at a low level and increased gradually noting carefully the clinical response and any evidence of intolerance. It should be kept in mind that there may be a lag in the therapeutic response. Increasing the dosage rapidly does not normally shorten this latent period and may increase the incidence of side effects.
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EFFECTIVENESS OF PEDIATRIC CARE: THE RELATIONSHIP BETWEEN PROCESSES AND OUTCOME

Barbara Starfield, M.D., M.P.H., and David Scheff, M.D.

From the Department of Pediatrics, The Johns Hopkins University School of Medicine and the School of Hygiene and Public Health (Department of Medical Care and Hospitals), The Johns Hopkins University, Baltimore, Maryland

ABSTRACT. The effectiveness of patient care was assessed by determining the adequacy of various steps in the care process and relating them to its outcome. Fifty-three children attending either of two university hospital clinics and having newly discovered low hemoglobins were randomly chosen. Review of medical records and home interviews showed that only 14 of the 53 low hemoglobin values were recognized, diagnosed, treated, and followed-up. In 39 children, the low hemoglobin value was unrecognized in 24, recognized but undiagnosed in six, diagnosed but untreated in one, and treated but not scheduled for follow-up in four; for four children the follow-up appointment was not kept. Mothers of 7 of the 22 children for whom treatment was prescribed denied receiving any therapy. Outcome in terms of eventual hemoglobin level was significantly related to the adequacy of the processes of care and especially to whether or not the patient received therapy. Major problems with record keeping also were apparent. The model used here is useful in evaluating the effectiveness of medical care because it relates specific activities of physicians, other health workers, and patients to outcome. *Pediatrics*, 49:547, 1972, PATIENT CARE.

THE end result of medical care often does not live up to the expectations of its practitioners. In this study, half of the children with low hemoglobin values still had low hemoglobin 6 months later. What aspects of medical care process are related to this poor outcome?

This study, which was conducted in two large primary care facilities for children, employed a model[1] using diagnostic and therapeutic processes and outcome to assess the care of children with a common medical problem and to relate specific processes of care to outcome as measured by improvement of the condition. Brook and Stevenson,[2] using a similar format to assess the care provided in an emergency room, showed that medical management led to effective care in only 27% of adult patients.

METHOD

All outpatient reports in the pediatric hematology laboratory files for July-September 1969 with a recording of a hemoglobin under 10 gm/100 ml of blood were collected. Medical records of the 138 children so identified were examined to eliminate children younger than 6 months and those already under care for anemia. The remaining reports were for children 6 months and older with newly found low hemoglobin levels. These patients were attending one of two facilities located in a university medical center: a clinic, staffed by fellows in ambulatory care, for children residing in a particular geographic area, and a clinic staffed by interns and residents who provide care for children living in the inner city but not in that particular area. Other than their place of residence, the children attending the two clinics were of similar backgrounds.

In order to complete the study in the available time, half (53) of the eligible children were randomly selected for the study. Letters were sent informing the

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ADDRESS FOR REPRINTS: (B.S.) The Johns Hopkins Hospital, 601 North Broadway, Baltimore, Maryland 21205.

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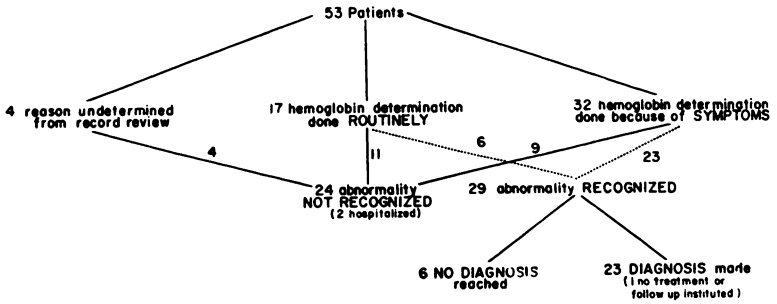

FIG. 1. Evaluation of diagnostic outcomes.

mother that a physician would come to the home, at a time appropriate for her, to repeat the previous "blood" test. At that visit a questionnaire which ascertained the mother's knowledge of the previously low hemoglobin and her recall of instituted therapy was administered. Using capillary blood, hemoglobins were determined in duplicate by the cyanmethemoglobin method[3] and hematocrits by microcapillary centrifugation.

Each medical record was searched to determine the reason why the initial hemoglobin was ordered and for evidence that (1) the low hemoglobin had been noticed by a physician, (2) appropriate diagnostic procedures were instituted and a diagnosis was made, (3) appropriate therapy and follow-up were initiated, and (4) the follow-up appointment had been kept by each of the patients.

STUDY POPULATION

Almost half (47%) of the children were between 1 and 2 years old. One-third were over the age of 2 and the remainder were between 6 and 12 months old. The distribution of ages was similar for the two clinics. Thirty-three of the 35 children in the clinic staffed by the fellows and 13 of 18 in the housestaff clinic were Negro.

Over 20% of the patients had moved in the 6 months between their initial hemoglobin assessment and the follow-up study. Despite this, all but two patients were eventually traced, and one mother refused the visit. In a fourth child, no hemoglobin was obtained although the mother was interviewed. Therefore, the overall completion rate for the study was 94% for interviews and 92% for the hemoglobin determinations.

RESULTS

1. Diagnostic Processes and Outcomes

Figure 1 shows that the lab result indicating low hemoglobin was apparently not recognized in 24 (45%) of the children. Where the hemoglobin had been ordered as a result of the presence of some symptom or because the child had a past history of anemia, 72% of the low values were recognized. In contrast, where the hemoglobin had been done in the course of a routine checkup, only 35% were recognized. Age of the child was related to recognition of the low value. Although only one-third of the children were over 2, almost half (46%) of the unrecognized low hemoglobin values were in children in this age group. This phenomenon was not related to the reason for which the hemoglobin had been done; in fact, more of the unrecognized older children had their hemoglobins ordered because of symptoms than was the case for the younger children. When the hemoglobin values were categorized as 9.5 or more, 9 to 9.4, and less than 9 gm/100 ml of blood, lower hemoglobin values were more likely to be recognized than higher ones only in those children for whom the hemoglobin had been ordered because of symptoms or past history. Where the hemoglobin was done routinely, values under 9 were no

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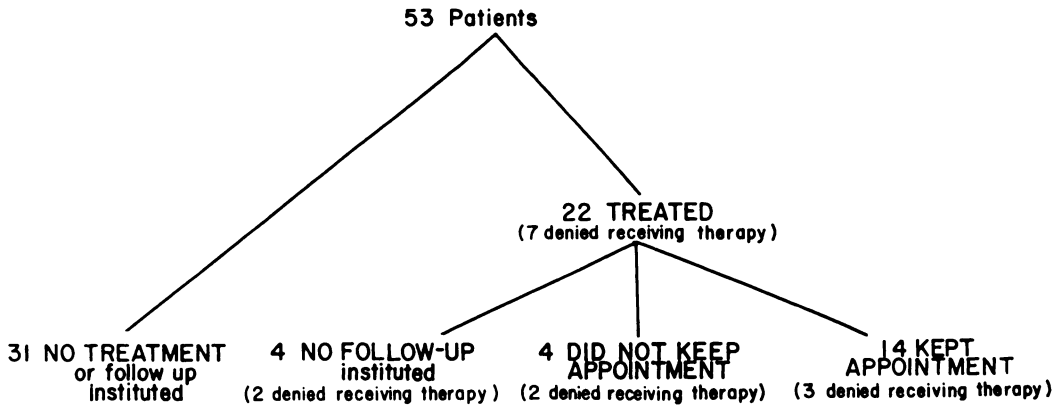

FIG. 2. Therapeutic processes.

more likely to be recognized than those over 9.

A tentative or a final diagnosis was reached for only 23 (44%) of the children. All 23 children had a hematocrit determined at the same time as the hemoglobin. Sixteen had at least one other procedure: three a blood cell smear; three a smear and reticulocyte count; four a smear and sickle cell preparation; three a smear, sickle cell preparation, and reticulocyte count; two a reticulocyte count (17%) only; and one a sickle cell preparation only. One patient had a stool examination for occult blood loss. The

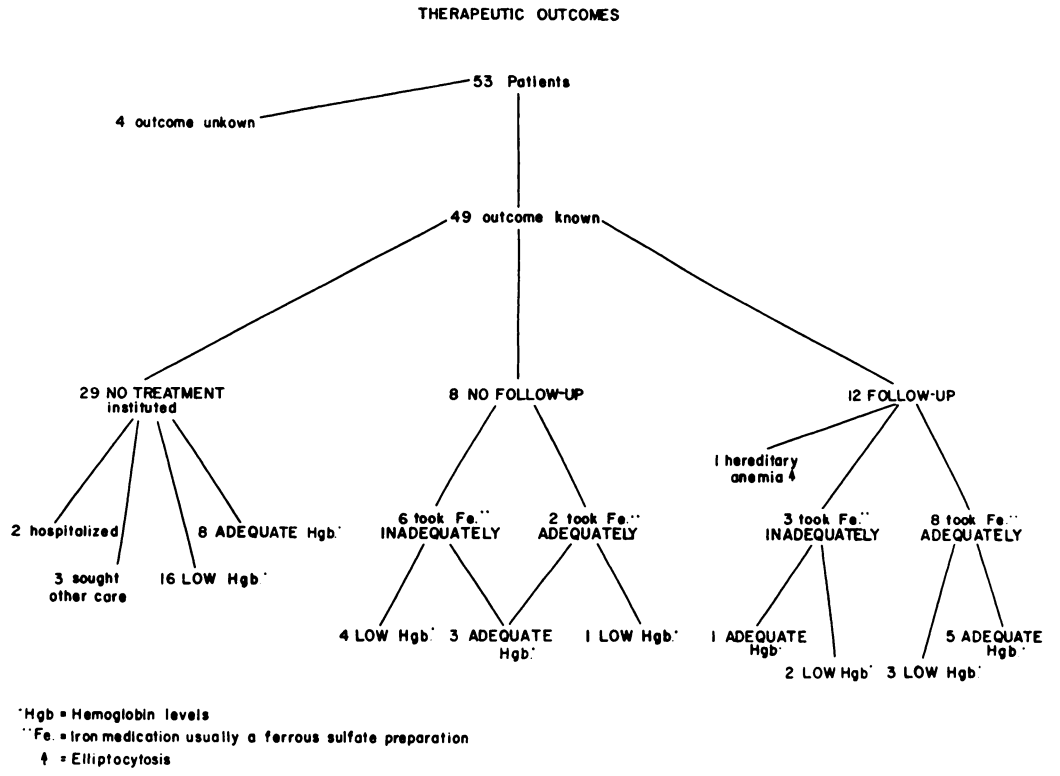

FIG. 3. Therapeutic outcomes.

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TABLE I

TREATMENT AND OUTCOME OF CARE IN CHILDREN WITH IRON DEFICIENCY ANEMIA

	Treatment Instituted		*Treatment not Instituted*	
	(A) Medication Adequately Taken	*(B) Medication Inadequately Taken*	*(C) Received Medication Elsewhere**	*(D) Received no Medication*
Hemoglobin adequate	6	3	3	8
Hemoglobin low	4	6	0	16

The difference between A+C and B+D (Chi-Square test 4.86) is significant with p less than .05.

* All three patients took medication adequately.

performance of additional procedures was related to the reason the hemoglobin had been done: of the 16 children with symptoms for whom a diagnosis was made, 15 had one or more further procedures. In contrast, only one of seven children whose hemoglobin was done routinely had any further procedures to arrive at the diagnosis. The initial diagnosis on all patients for whom a diagnosis was recorded was iron deficiency anemia, but one of these patients was later found to have hereditary elliptocytosis. Two children whose low hemoglobin values were unrecognized subsequently appeared with other types of anemia: one had a sickle cell crisis requiring hospitalization; another had both a previous and a subsequent hospitalization for a bleeding ulcer.

2. Therapeutic Process

Figure 2 shows that 7 of the 22 patients who had treatment instituted denied receiving any therapy. Of the 22, four (18%) had no plan for follow-up recorded. Of the 18 children for whom there was mention of arrangement for follow-up, over three-fourths (78%) actually kept that appointment.

Overall, only 14 (26%) of 53 patients with hemoglobin values under 10 gm/100 ml of blood were recognized, diagnosed, treated, and reassessed. Although the differences were not large enough to be statistically significant, patients attending the clinic staffed by fellows were more likely to have had their low hemoglobins recognized, and to have had a diagnosis, therapy, and successful follow-up (7 of 16 symptomatic patients and 3 of 16 routine care patients) than patients in the housestaff clinic (4 of 16 symptomatic patients and 0 of the 1 routine care patient). In addition to the different type of physicians in the two clinics, there were also differences in other staffing patterns; the clinic in which the fellows worked had considerably more paramedical personnel. However, in both clinics a lack of physicians' awareness of the abnormal laboratory result was the most important contributor to patient loss, even for those children who had symptoms prompting the test. For the total group, over half, both in the symptomatic and routine groups, had no plans made for reassessment of the low value.

3. Therapeutic Outcomes

Figure 3 combines the results of the hemoglobin determination and interview at the study visit. The hemoglobin was considered "adequate" if it was 10 gm/100 ml of blood or higher. Therapy was considered adequate if it was taken for at least 1 month, but of the nine who took medication inadequately, five did not take it at all. With these criteria, it is evident that the hemoglobin level is related to the provision of diagnostic and therapeutic services. Of all the diagnostic and therapeutic maneuvers (recognition of the low laboratory value, recording of a diagnosis, institution of therapy, and follow-up), the one most closely associated with good outcome of care is therapy. Table I shows that there is a significant relationship between effective treatment and the adequacy of the eventual hemoglobin. Although the number of children is very small, the findings suggest that, if treatment is instituted, the process of follow-up may also be related to a good outcome: 6 of 11 children followed had adequate hemoglobin levels as contrasted with three of eight children not followed.

The adequacy of the eventual hemoglo-

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bin was unrelated to the reason for which the original test had been done and whether or not a diagnosis had been reached (in the absence of the therapy). For those patients who received iron therapy, there was no difference between the clinics in the adequacy of the final hemoglobin.

There was no clear relationship between age and final hemoglobin, but children over the age of 2 were somewhat more likely to have adequate levels than younger children. This was not a result of better treatment, as five of the eight children over 2 with adequate hemoglobins were untreated. Although older children would normally be expected to have slightly higher hemoglobins than younger ones, explanations for this phenomenon might also be found in nonmedical factors which vary with the age of the child. For example, it is possible that diets of older children were more likely to result in improvement of anemia, even without specific therapy, than the diets of younger children. Variations in the reliability of the initial hemoglobin could conceivably account for the differences. Even though the oxyhemoglobin method[4] (the method by which the original hemoglobin was determined) is considered an excellent one, it may be that its reliability varies with the age or size of the child. In no instance where the low hemoglobin was recognized was the test repeated to determine its accuracy.

As a result of this study, the four children who were said to have received adequate therapy but still had low hemoglobin values were brought under further care, retreated, and followed until hematologic indices were within normal limits.

4. Technical Difficulties in Carrying Out the Study

Apart from the expected problem of tracing patients who had moved during the 6-month period, the major difficulty was finding and auditing the medical records. Although most charts are kept in a central hospital record facility, many are stored in individual record rooms maintained by separate clinics. In order to avoid undercounting the recognition, diagnosis, and treatment of low hemoglobins, each investigator independently sought and audited the charts. The initial sample consisted of 60 children who were thought to be eligible for the study. In seven instances, an additional chart which indicated that the hemoglobin determination had been a follow-up of a previously diagnosed anemia was subsequently found; these children had to be withdrawn from the study. In 16 other cases, two or more charts were found for each child. The extent to which portions of children's records were found in different locations in the hospital was the same for both clinics: 7 of 19 in the housestaff clinic and 16 of 41 in the clinic staffed by fellows. The incompleteness of the chart was not always evident; if duplicate record reviews had not been carried out, the information obtained by the two investigators would have differed significantly for 12 of those children and would have indicated a much greater patient loss in various stages of the medical care process than was actually the case. In both clinics, the physician is informed of all laboratory findings by receiving a copy of the official report for all of his patients at the end of the work day, although the results of tests may also be obtained by telephoning or visiting the laboratory at any time. A clerk is responsible for inserting the official report in the chart; slippage in this mechanism is indicated by absence of the official report in records of 10 of 53 children.

The results of this study were presented to the administrators of the clinics and changes in procedures and record keeping are presently underway.

DISCUSSION

Outcome of care,[5] as measured by death, degree of morbidity, disability, discomfort or dissatisfaction, is the critical indicator of the utility of health services. But it may often be an inappropriate measure because of the influence on health of many factors out-

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side the realm of medical care. Therefore, most attempts to evaluate medical care concentrate on the activities or processes of management;[5] in the absence of information to the contrary, processes such as the adequacy of diagnosis, continuity of care, or compliance with care have been assumed to be worthwhile objectives.[6] They, at least, can be more directly related to medical care.

Little is known about the relationship of these processes, or "inputs," to the health of patients.[7] One would feel more comfortable with the use of these measures of effectiveness if they were consistently shown to be related to outcome of care. In this study, we were able to show that prescription of therapy is one process that is related to good outcome, and that follow-up of patients may also be.

It may be tempting to judge as unsatisfactory the overall performance of the two clinics in this study. Without evaluations of other conditions and of other facilities, such an assessment is unwarranted. However, this type of study is useful in indicating the existence and importance of specific medical care functions which are performed poorly, and which are associated with poor patient outcome. To facilitate needed changes, those physicians and other health personnel who are being studied will have to be involved in establishing the criteria for adequate performance and outcome. This will assure that the standards being used are reasonable, achievable, and acceptable to those who will have to meet them.[8]

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