

lines. HIMA has objected to the proposal on the basis that manufacturers' oversight of physicians' use of their products is inappropriate; because the proposed requirements would require lengthy and expensive testing of single-use products that ESRD facilities are reprocessing; because the FDA's current workload delays approvals for 400 days, and the addition of new applications for already-approved dialyzers would significantly lengthen the delay for all devices; and because the FDA may not have the authority to force compliance with the guidelines.

FROM: *AAMI News* February 1994.

### **Penicillin Tolerated by Majority of Patients with History of Allergy**

Dr. Gadde and colleagues in Baltimore found that 97% of study patients with a history of penicillin allergy and negative skin tests were able to tolerate treatment with penicillin. In a 5-year surveillance program for penicillin allergies in an STD clinic, 8.3% of the 9,313 subjects enrolled reported a previous adverse reaction to penicillin. These reactions varied from anaphylaxis, urticaria, or exanthematous rashes to uncertain histories. All subjects with histories of penicillin allergy were skin-tested, and approximately 50% of the subjects without this history also were skin-tested. Penicillin skin-testing was performed in duplicate with

benzyl penicilloyl polylysine (PPL), which is the major determinant, and a minor determinant mixture (MDM). Subjects who were positive to the MDM also were skin-tested with its individual constituents. All subjects with negative skin tests in both groups were treated with penicillin.

Of the 776 history-positive subjects who were skin tested, 7.1% reacted to either PPL or MDM or both, and 2.7% had equivocal reactions. Of the 4,287 subjects without a history of penicillin allergy who were skin-tested, significantly fewer (1.7%) had positive reactions and 0.3% had equivocal reactions. Of all the subjects with positive skin tests, 75% reacted to PPL alone, 10.2% to MDM alone, and 14.8% to both PPL and MDM. Of the subjects with equivocal reactions, 82% were retested later, and all were found to have negative skin tests.

The reactions were classified according to the type of prior reaction. Positive skin tests occurred in 17.3% of patients with a history of anaphylaxis, 12.4% of patients with a history of urticaria, 4% of patients with a history of exanthematous rash, and 1.7% of patients with an uncertain history.

This study confirms the need for penicillin skin testing to verify or exclude the diagnosis of penicillin allergy

FROM: Gadde J, et al. *JAMA* 1993;270:2456-2463.

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# Information for Authors

Manuscripts should consist of new material based on hospital epidemiologic or infection control activities, from the United States or abroad. The Journal welcomes submissions that involve the use of epidemiologic principles and methods to evaluate or improve the delivery of care within healthcare institutions or that address the transmission of infection. Examples of appropriate material include rates, distributions, preventive measures, or cost benefit studies of infections or other adverse events in patients; surveillance; occupational health issues affecting healthcare workers; pertinent regulatory actions; and analyses of resource utilization.

Manuscripts should be accompanied by a cover letter that includes the title of the manuscript and the name, address, telephone, and (if available) fax number of the corresponding author. If blinded review is desired, the cover letter should so request. All manuscripts should be submitted in triplicate (with three copies of figures and tables), typewritten on one side of 8½ × 11-inch paper, double-spaced, and with generous margins. Pages should be numbered consecutively beginning with the title page. The author should keep a complete copy of the manuscript, as submitted manuscripts will not normally be returned (however, original figures, photographs, or other artwork will always be returned).

The organization of the paper should be as follows: title page; abstract; introduction; methods; results; discussion; acknowledgments; references; tables; figures; and figure legends. The main sections and subdivisions should be indicated by side headlines flush with the left margin and two lines above the text. The Arabic numbering system should be used.

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The Editor requests that authors reporting the results of clinical trials describe clearly the following: 1) eligibility criteria; 2) whether or not subjects were admitted before allocation to one of the study groups; 3) the method of randomization; 4) whether the study was "masked," what specific information was masked and whether subjects, clinicians, and evaluators were all masked; 5) the method used to identify treatment complications; 6) an explanation and analysis of subjects lost to follow-up; 7) statistical methods employed; 8) information that led to the determination of the size of the study groups and the expected differences between groups; and 9) indications that studies involving human subjects have been reviewed and approved by their institutional review board.

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Brief communications are encouraged of approximately four to six typewritten pages containing information that does not represent a formal study. They may summarize unusual experiences or reflect opinions, hypotheses, or impressions related to infection control or hospital epidemiology.

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A separate title page should include the following: title of manuscript; author(s); laboratory or institution of origin with city and state; acknowledgment of grant support; name, address, and telephone number of the corresponding author; and (if different) address to be used for reprint requests. An abbreviated title, to be used as a running head, should be included. This should not exceed four words. A preliminary report or abstract should be credited by use of a footnote to the title. Provide three to six key words (MESH terms are preferred) appropriate for indexing the manuscript. If blinded review was requested, include a second title page that contains only the full and abbreviated titles.

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Authors submitting manuscripts reporting the results of clinical investigations should prepare an abstract of no more than 250 words under the following headings: Objective, Design, Setting, Patients (or Participants), Interventions

(if any), Results, and Conclusions. The content following each heading should be as follows:

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The abstract should begin with a clear statement of the precise objective or question addressed in the report. If more than one objective is addressed, the main objective should be indicated and only key secondary objectives stated. If an a priori hypothesis was tested, it should be stated.

### 2. Design

The basic design of the study should be described. The duration of follow-up, if any, should be stated. As many of the following terms as apply should be used.

a. Intervention studies: randomized control trial; nonrandomized control trial; double-blind; placebo control; crossover trial; before/after trial.

b. For studies of screening and diagnostic tests: criterion standard (ie, a widely accepted standard with which a new or alternative test is being compared; this term is preferred to "gold standard"); blinded or masked comparison.

c. For studies of prognosis: inception cohort (subjects assembled at a similar and early time in the course of the disorder and followed thereafter); cohort (subjects followed forward in time, but not necessarily from a common starting point); validation cohort or validation sample if the study involves the modeling of clinical predictions.

d. For studies of causation: randomized control trial; cohort; case-control; survey (preferred to "cross-sectional study").

e. For descriptions of the clinical features of medical disorders: survey; case series.

f. For studies that include a formal economic evaluation: cost-effectiveness analysis; cost-utility analysis; cost-benefit analysis. For new analyses of existing data sets, the data set should be named and the basic study design disclosed.

### 3. Setting

To assist readers in determining the applicability of the report to their own clinical circumstances, the study setting(s) should be described. Of particular importance is whether the setting is the general community, a primary care or referral center, private or institutional practice, ambulatory, or hospitalized care.

### 4. Patients or Other Participants

The clinical disorders, important eligibility criteria, and key sociodemographic features of patients and how they were selected should be provided, including the number of otherwise eligible subjects who were approached but refused. If matching is used for comparison groups, characteristics that are matched should be specified. In follow-up studies, the proportion of participants who completed the study must be indicated. In intervention studies, the number of patients withdrawn for adverse effects should be given.

For selection procedures, these terms should be used, if appropriate: random sample (here "random" refers to a formal, randomized selection in which all eligible subjects have a fixed and usually equal chance of selection); population-based sample; referred sample; consecutive sample; volunteer sample; convenience sample. These terms assist the reader to determine an important element of the generalizability of the study. They also supplement (rather than duplicate) the terms used by professional indexers when articles are entered into computerized databases.

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The essential features of any interventions should be described, including their method and duration of administration. The intervention should be named by its most common clinical name (eg, the generic term "chlorthalidone"). Common synonyms should be given as well to facilitate electronic textword searching. This would include the brand name of a drug, if a specific product was studied.

### 6. Results

The main results of the study should be given. Measurements that require explanation for the expected audience of the article should be defined. Important measurements not included in the presentation of results should be declared. As relevant, it should be indicated whether observers were blinded to patient grouping, particularly for subjective measurements. Due to the current limitations of retrieval from electronic databases, results must be given in narrative or point form rather than tabular form. If possible, the results should be accompanied by confidence intervals (eg,

95%) and the exact level of statistical significance. For comparative studies, confidence intervals should relate to the differences between groups. For nonsignificant differences for the major study outcome measure(s), the clinically important difference sought should be stated and the confidence interval for the difference between the groups should be given. When risk changes or effect sizes are given, absolute values should be indicated so that the reader can determine the absolute as well as relative impact of the finding. Approaches such as "number needed to treat" to achieve a unit of benefit are encouraged when appropriate; reporting of relative differences alone is usually inappropriate. If appropriate, studies of screening and diagnostic tests should use the terms sensitivity, specificity and likelihood ratio. If predictive values or accuracy are given, prevalence or pretest likelihood should be given as well. No data should be reported in the abstract that do not appear in the rest of the article.

#### 7. Conclusion(s)

Only those conclusions of the study that are directly supported by the evidence reported should be given, along with the clinical application (avoiding speculation and over-generalization); indicate whether additional study is required before the information should be used in normal clinical settings. Equal emphasis must be given to positive and negative findings of equal scientific merit.

To permit quick and selective scanning, the headlines outlined above should be included in the abstract. For brevity, parts of the abstract can be written in phrases rather than complete sentences (eg, 2. *Design. Double-blind randomized trial*, rather than 2. *Design. The study was conducted as a double-blind, randomized trial.*) This technique may make reading less smooth but facilitates selection scanning and allows more information to be conveyed per unit of space.

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#### 1. Articles

Annunziato D, Goldblum LM. Staphylococcal scalded skin syndrome: a complication of circumcision. *Am J Dis Child*. 1978;132:1187- 1188.

#### 2. Books

Heoprich PD. *Infectious Diseases*. 2nd ed. New York, NY Harper & Row Pubs Inc; 1977:169.

#### 3. Contributions to Books

Schaffner W. Psittacosis: ornithosis, parrot fever. In: Beeson PB, McDermott W, Wyngaarden JB. eds. *Cecil Textbook of Medicine*. 15th ed. Philadelphia, Pa: WB Saunders Co; 1979:336338.

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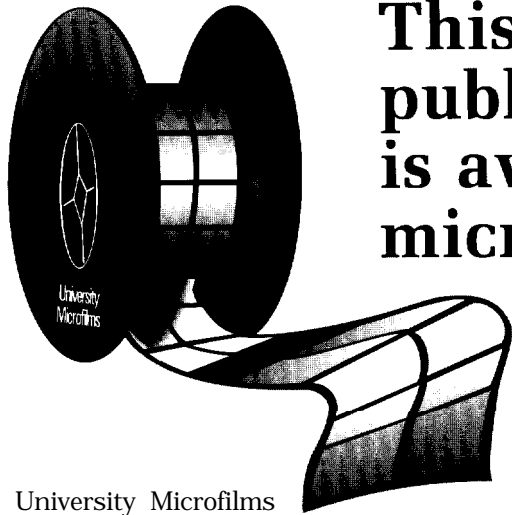
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