INTRODUCTION

Policymakers, payers, and health care providers are responsible for deciding which health services should be provided to whom to help reduce the burden of disease, disability and death. To achieve this goal, evidence-based information is required to make the precise decisions. Since health service resources need to be spent efficiently, steps in health information inquiries have been proposed. These steps are shown as the Technology Assessment Iterative Loop (TAIL) as discussed in the Introduction. In this chapter, we will focus on the community effectiveness, which is the third step in the TAIL.

The rationale of community effectiveness is to determine how well an intervention with the potential for reducing burden will work when applied in the community. Community effectiveness may be considered as the 'real world' efficacy of an intervention since it is affected by certain external elements. Community effectiveness is determined by five factors: efficacy, screening and diagnostic accuracy, health provider compliance, patient compliance, and coverage.

EFFICACY

Efficacy is defined as the extent to which a specific health intervention does more good than harm to patients who are diagnosed correctly and appropriately cared for and who fully comply with the recommendations or treatment. In brief, it asks the question, Can it work? The evaluation of efficacy assumes optimal diagnostic accuracy, heath provider compliance, and patient compliance. When estimating the benefit of interventions applied in a community setting, efficacy acts as the 'anchor point' and it quantifies the maximum benefit that can be achieved. Efficacy is regarded to be more stable and less liable to fluctuation in different circumstances than the other four factors of community effectiveness.

To assess the efficacy of therapeutic or preventive health interventions from studies, methodological standards are needed. These standards include seven guidelines and are summarized in Table 1.

Table 1. Methodological Standards for Studies of the Efficacy of Therapeutic or Preventive Health Interventions

1. Is the research design appropriate?

    a. Were the major sources of bias avoided or, if present, measured?
    b. Were the methods used for sampling, assessment of exposure, and analysis acceptable?

2. Were all relevant outcomes reported?

3. Were the study patients or population recognizably similar to your own?

4. Were both clinical-community and statistical significance considered?

5. Is the therapeutic manoeuvre feasible in your setting?

6. Were all patients who entered the study accounted for at its conclusion?

7. Are the study results consistent with those of the others?

1. Is the research design appropriate?

The strongest evidence of efficacy is provided by a well-executed randomized controlled trial. In any disease that is not uniformly fatal, improvement unrelated to the intervention can be taken into account by identifying and following a control group of patients who are similar in as many ways as possible to those receiving the intervention.

The best way of achieving comparability between the treatment and control groups is to assure that every patient entering the study has the same probability of receiving one or the other of the treatment being compared. If this is done, it should be stated as the key terms of randomized trial or random allocation in the abstract, the method section, or even the titles of such studies. Random allocation eliminates many of the biases that lead to false results and conclusions in non-randomized trials. For example, the claims of the efficacy of polio immunization (Francis et al 1955) and anti-microbial prophylaxis in the secondary prevention of acute rheumatic fever (Evans 1950) arise from randomized, double-blind, placebo controlled trials.

Non-experimental evidence from the cohort, before-after, case-control, and case series designs can provide important information about etiology and the adverse effects of therapy. However, they are not suitable for the demonstration of efficacy. This leads to the requirements for experimental validation of new drugs, new surgical procedures, or even health services.

There are three exceptions to this requirement for experimental evidence. First, when a disorder is associated with a uniformly fatal outcome, any intervention that saves lives is efficacious, and no randomized trial is necessary. An example is the efficacy of oral rehydration salts (ORS) in severely ill cholera patients; a dramatic reduction in case-fatality rate was shown (Levine 1985, Mahalanabis et al 1973). Secondly, when a disorder producing substantial mortality rates is

uniformly cured, a controlled trial is also unnecessary. Thirdly, the experimental evidence is not required when the intervention is judged unethical or would be politically unacceptable. This exception depends on geography and local practice.

Although random allocation is the method most likely to produce comparable study groups, this method does not guarantee similarity of groups with respect to all-important variables. The use of prognostic stratification prior to randomization is one way to ensure that study groups are comparable with respect to known prognostic factors.

2. Were all relevant outcomes reported?

The outcomes assessed should include all potential components of health status relevant to the intervention being assessed, including quality of life and patient preference. The measurable terms of health include death, disease, distress, discomfort, disability, dysfunction, disharmony (family impact), dissatisfaction, disposition (risk factors) and debt. Increasing attention is being directed toward the importance of including an assessment of the impact of the intervention on the patient's quality of life, i.e. health status, functional abilities, and patient preferences.

Another important issue regarding relevant outcomes is the demonstration of explicit, objective outcome criteria. Outcome criteria should be reproducibly defined. For each outcome, the following factors should be considered when deciding whether the results are likely to be meaningful:

1. Credibility of the assessment method used: This refers to the extent to which the method appears to measure what it is intended to measure and the results are therefore acceptable to be used.
2. Reproducibility: This concerns the extent to which the measurement instrument produces the same result on repeated applications.
3. Assessment of results by blind observers: This is required to minimize the likelihood of bias.
4. Responsiveness to change: This refers to evidence that the instrument used can detect a change in outcome when a change is known to exist by other assessment methods.

3. Were the study patients or population recognizably similar to your own?

This criterion has two elements. First, the study patients must be recognizable, i.e. how they were selected, what diagnostic criteria were used, and the patients' clinical and socio-demographic criteria status must be described in sufficient detail for you to be able to recognize the similarity between the study patients and your own patients. Second, the study patients must be similar to patients in your practice or community. If the patients are recognizable and similar, you will be able to predict the outcomes to be expected from the application of the specific therapy or program to specific patients or populations.

4. Were both clinical-community and statistical significances considered?

Clinical-community significance refers to the importance of a difference in health outcomes between treated and control patients. This difference is considered clinically significant to the community when it leads to a change in health care practice or community behavior. Statistical significance simply indicates whether a difference is likely to be real, not whether it is importance or large. It tells us about the likelihood that this difference is due to chance alone.

Clinically significant changes are reported in the terms of relative risk reduction and absolute risk reduction. Relative risk reduction is defined as the reduction of the risk in the treatment group in proportion to that of the control group, while absolute risk reduction is the difference in the risks between the control and treatment groups. Clinically significant changes are also reported as the number needed to treat (NNT), which is the reciprocal of the absolute risk reduction. Important differences in the quality of life are significant clinically and to the community from the patient's perspective. Utility measurement techniques, which quantify the strength of an individual's preference for alternative health outcomes or interventions is an approach that has been used to address this issue in a number of diseases.

The determinants of clinical and community significance are therefore the determinants of change in clinical and community action while the determinants of the statistical significance of any given result rises (i.e., the p value falls) when the number of subjects in the study is increased, when the health outcomes show less fluctuation from day to day or from patient to patient, and when the measurement of this health outcome is both accurate and reproducible.

Thus, certain issues should be considered when reading clinical studies. First, is the reported difference of clinical or community significance? Readers must examine the difference in clinical outcomes in the studies to see whether they are of potential significance. If so, is the difference statistically significant - if yes, then the results are both real and worthy of implementation.

Second, if the difference is not statistically significant, is the number of patients large enough to show a significant difference clinically or in the community if it should occur? If a study is huge, the difference in health outcomes can be statistically significant even when its magnitude is not clinically significant. On the other hand, if a study is too small, even large differences of enormous potential clinical or community significance may not be statistically significant.

5. Is the manoeuvre or health intervention feasible in your setting?

The health care manoeuvre or intervention has to be described in sufficient detail for readers to replicate it with precision. This issue represents special problems in trials evaluating the impact of a 'package' of interventions. For example, in the community-based trial comparing the efficacy of direct, observed treatment with antituberculosis drugs to that of self-supervised treatment, (Kamolratanakul et al 1999) the intervention consisted not only of anti-TB drugs but also of the availability of treatment supervisors and appropriate follow-up schedules required for maximum compliance.

The description of the manoeuvre or intervention in a published report should also indicate whether or not the authors avoided two specific biases in its application. These biases are contamination and co-intervention. Contamination is defined as the control patients accidentally receiving the experimental treatment - this results in a spurious reduction in the difference in outcomes between the treatment and control groups. Cointervention is the differential application of additional diagnostic or therapeutic acts to either treatment or control patients that could influence clinical outcomes and thereby bias the magnitude of difference observed between the two groups. Double-blinding (study patients and clinicians) can be used to prevent cointervention.

6. Were all patients who entered the study accounted for at its conclusion?

The number of patients entering the study and finishing the study should be provided in the report. In case the outcomes are not reported for missing subjects, one approach is to arbitrarily assign a bad outcome to all missing members of the group with the most favorable outcomes. If this manoeuvre fails to shift the statistical or clinical significance of the results across the decision point, the study's conclusion can be accepted.

7. Are the study results consistent with those of others?

This step concerns whether or not the study results agree with those of others. Different results can often be explained by the strength of the research method used.

With these seven guidelines, both health care policymakers and providers should be able to critically assess and judge the validity, applicability, and gaps in the knowledge about the efficacy of a specific health intervention.

SCREENING AND DIAGNOSTIC ACCURACY

Information on diagnostic accuracy can be obtained from studies where patients with the condition of interest are correctly discriminated from those without the condition. This is applicable for the accuracy of clinical signs or other para-clinical investigations (laboratory, X-ray, etc.) Detection or screening of patients with remedial health needs is necessary to establish the denominator of the population at risk. However, unavoidable health needs, those for which no therapy is currently available, should not be the focus of screening, not only because of the expense, but also because of the negative health consequences of the 'labeling' that results.

EVALUATION OF HEALTH PROVIDER COMPLIANCE

Health provider compliance is assessed by whether the appropriate diagnostic and management actions (prevention, therapy, and rehabilitation) are performed by the health provider. These actions are known as 'clinical processes'. Studies of health provider compliance should be restricted to situations in which the causal relationship between the process of care and patient outcome is established (i.e., there is a demonstration of efficacy).

Information from evaluations of the ability of different health professionals to apply efficacious interventions is also included in this category. An example of this type of evaluation is a study conducted in Thailand to compare the health care and outcomes of women receiving postpartum tubal ligations by either specially trained nurse midwives or doctors (Dusitsin et al 1980).

EVALUATION OF PATIENT COMPLIANCE

Patient compliance is determined by whether the patients follow the health provider's recommendations and treatment. A good example is the effectiveness of artesunate treatment for uncomplicated malaria in a field trial in Thailand (Fungladda et al 1998). Patient compliance and cure rate in the artesunate treated group were significantly higher than those in the quinine and tetracycline treated group. The strategy to improve patient compliance, and thus effectiveness, is to use a short-course, once daily regimen with minimal adverse effects.

EVALUATION OF COVERAGE

Coverage refers to the proportion of the target population in need of a specific, efficacious intervention and who could potentially have access to it. It describes whether or not an individual in need of a specific health intervention makes contact with the health professional. Because coverage estimates do not represent the proportion of all patients in need who are effectively treated, they do not take into account the other components of community effectiveness.

Coverage evaluation requires that the use of health services be related to the need for them in a defined population during a specific time period. It should be differentiated from utilization of services, which describes the form of activity-to-population ratios. Since utilization of services fails to incorporate information about need, it is not as accurate as a measure of availability.

Availability and Acceptability of Effective Health Services

Availability concerns whether efficacious health services are accessible to those in need and whether the population is aware of services being available. Accessibility can be measured by estimating the supply of services and by taking into account the distribution. Awareness of the availability of these services by those in need is also relevant. This component is important in screening studies to ensure that there is appropriate linkage of identified patients with the condition of interest to the health provider, so that they get treated rather than just 'labeled'. For example, a promotional campaign on the use of oral rehydration salts (ORS) is required to enhance awareness and the level of coverage.

Quantification of acceptability can be best obtained from surveys and should not be confined to users of health services. Measurement of acceptability can be divided into the patients' perceptions of (1) the resources or facilities, (2) the behavior of health professionals and their staff, and (3) the benefits expected from the health service.

Prediction of the Magnitude of Community Effectiveness

It is important to be able to estimate the impact of specific treatment interventions when assessing whether a program is achieving its full potential, when assessing the economic efficiency of the whole program or when looking at alternatives for improving the program. Almost all of the economic evaluations require an estimate of community effectiveness. The lack of valid evidence on clinical-community effectiveness limits the validity of economic evaluations.

The relationship among the five factors that determine community effectiveness is most accurately estimated by using a multiplicative conditional probabilities model. However, the necessary information on conditional probabilities is rarely available. Thus, an acceptable alternative is to use a simple multiplication formula, which assumes that all factors are independent. Both models are shown in Table 2.

An example of community effectiveness calculations is given in Table 3. This shows the effect on the efficacy estimates of the other factors that influence community effectiveness. The efficacy estimates were obtained under ideal circumstances. These calculations serve as the 'best estimates' based on currently available evidence, which might be subject to error. However, they identify the relative magnitude of the difference between efficacy estimates for an intervention and its impact when implemented under community conditions. In addition, by

examining each of the individual components of community effectiveness, the ones that would have the greatest impact on the change of community effectiveness will be identified.

Several approaches for deriving best estimates based on the results of multiple studies are suggested. These include voting (based on a tabulation of study results and assessment of study quality), delphi and nominal group techniques, consensus, and statistical approaches (meta-analysis, overview analysis) for combining results from two or more studies. Where applicable, meta-analysis is the approach of choice, as it would provide the best estimate based on the currently available evidence in the literature. A major resource of metaanalyses is the Cochrane Database of Systematic Reviews, which is produced by the Cochrane Collaboration. (Detailed information regarding the Cochrane Collaboration is given later in this chapter and in Appendix 1.) However, if the result from meta-analysis is not available, the best estimates would come from the result of the study with the strongest methodological quality.

From Table 3, the efficacy of ORS for acute diarrhea of childhood under ideal conditions is at least 95 percent. Estimates of community effectiveness and other components of the equation are based on community-based field trials of ORS and studies targeting the specific individual components. For others interested in deriving estimates for use in their own setting, it would be worthwhile to carry out local investigations on compliance and coverage to assure accuracy. The overall impact of ORS on a community may depend upon the proportion of acute watery diarrhea compared to dysentery or chronic diarrhea for which the effectiveness of ORS is not yet established.

The best evidence of ORS efficacy comes from the trial by Rahaman in Bangladesh (Rahaman et al 1979). The results of this community-based trial suggest that a 79 percent reduction in diarrhea case fatality rates is expected with the implementation of health center-based distribution programs. The magnitude of the impact observed in this study should be interpreted with caution since this study represents an exceptionally intensive community-based effort that may not be easily replicated in other settings. Moreover, the comprehensive review of the literature reveals an extremely wide range of results suggesting that the impact of ORS programs can vary significantly. It should be noted that patient compliance and coverage can have a major impact, causing sub-optimal levels of community effectiveness. Patient compliance, especially the attitudes and behaviors of the mother towards ORS, is the most likely source of this loss of efficacy. If patient compliance and coverage can be raised to a more optimal level (around 90 percent for each), community effectiveness can be improved to 66 or 70 percent of the maximum possible impact based on efficacy estimates.

Another issue to be noted is that the iatrogenic complications of ORS therapy are ignored in this example for simplicity. Although the risk of complications from ORS is considered small, ORS, when inappropriately administered, can result in severe electrolyte imbalances.

These estimates do not predict to what extent the community as a whole would be better off if an intervention is implemented. The reduction in the overall burden of illness experienced by the community will depend on two factors. First, the proportion of the total burden accounted for by a specific disorder will determine the overall community impact of interventions targeted at this disorder. Second, the effect of competing risks will determine the overall influence on the health of the community.

Table 2. The Relationship Between the Five Factors that Determined Community Effectiveness

The multiplicative conditional probabilities:
The chance of two events x and y, both happening is P(x and y) = P(x)P(y), if both are independent.

If y is dependent upon x, P(x and y) = P(y/x)P(x)

Thus, Community Effectiveness = P(coverage)

(or probability of benefit) x P(diagnostic accuracy/coverage)

x P(health provider compliance/coverage and diagnostic accuracy)

x P(efficacy of treatment/coverage and diagnostic accuracy and health provider compliance)

x P(patient compliance/coverage and diagnostic accuracy and health provider compliance and efficacy of treatment)

The simple multiplicative formula:

Community Effectiveness	= Efficacy x	diagnostic x accuracy	health provider x compliance	patient compliance x	coverage

Table 3. Sample Calculations for Community Effectiveness: Oral Rehydration Salts

Type of estimate	Efficacy	Diagnostic accuracy	Provider compliance	Patient compliance	Coverage	Community effictiveness (reduction in case fatality rate)	Percent of efficacy achieved in community
'Best evidence' estimate	79% reduction in case fatality rate					79% drop	79/95 = 83%
Range of evidence estimate	56-79% reduction in case fatality rate					56-79% drop	59-83%
	N/A	N/A	N/A	N/A	N/A	N/A	N/A

a. From studies combining all components b. Fromt studies of individual components	95-100% drop in case fatality rate	95-100%	87-100%	59.5-80%	60-70%	28-56%	30-59%
Under improved conditions of provider and coverage (Potential/theoretical)	95	95	90	90	90	66	66/95 = 70%

The Cochrane Collaboration

The Cochrane Collaboration is an international organization that aims to help people make well informed decisions about health care by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of health care interventions.

The foundation of the Cochrane Collaboration was based on the idea of Dr. Archie Cochrane, a British epidemiologist, in 1993. As Cochrane had emphasized, reviews of research evidence must be prepared systematically and they must be kept up-to-date to take account of new evidence. If this is not done, important effects of health care (good and bad) will not be identified promptly, and people using the health services will be ill served as a result. In addition, without systematic, up-to-date reviews of previous research, plans for new research will not be well informed. As a result, researchers and funding bodies will miss promising leads, and embark on studies asking questions that have already been answered (Antman et al 1992).

The goals of the Cochrane Collaboration include:

1. To ensure high quality, up-to-date systematic reviews are available across a broad range of health care topics
2. To promote access to Cochrane Reviews
3. To develop an efficient, transparent organizational structure and management system for the Cochrane Collaboration
4. To achieve sustainability of the Cochrane Collaboration.

The Cochrane Database of Systematic Reviews, the principal output of the Cochrane Collaboration, is published electronically in four successive issues per year. The Cochrane Database of Systematic Reviews summarizes the evidence for efficacy and effectiveness of health care interventions. Preparation and maintenance of the Cochrane reviews is the responsibility of international collaborative review groups that cover most of the important areas of health care. At the present time, the number of the Cochrane Collaborative Review Groups is 49. The members of these groups - researchers, health care professionals, consumers, and others - share an interest in generating reliable, up-to-date evidence relevant to the prevention, treatment and rehabilitation of particular health problems or groups of problems.

The Cochrane reviews and information about the collaborative review groups, together with modules from all the other groupings registered as contributors to the Collaboration are submitted at intervals to the Collaboration's Parent Database. It is from this continuously updated Parent Database that Cochrane reviews and information about the Cochrane Collaboration is derived for electronic publication in The Cochrane Library.

Several databases are included in The Cochrane Library. They are The Cochrane Database of Systematic Reviews, which contains Cochrane reviews; The Cochrane Controlled Trials Register, which is a bibliographic database of controlled trials; The Database of Abstracts of Reviews of Effectiveness (DARE), which includes structured abstracts of systematic reviews that have been critically appraised; and The Cochrane Review Methodology Database, which is a bibliography of articles on the science of research synthesis.

Conclusions

Community effectiveness is the efficacy of an intervention to reduce the burden of illness when applied in the community. It is required for health economic evaluation and health policy-making. It is determined by five factors: efficacy, screening and diagnostic accuracy, health provider compliance, patient compliance, and coverage. Individual factors may impact on community effectiveness to a different extent depending on the intervention and outcome of interest. Community effectiveness can be calculated from the efficacy estimates, which can be best obtained from meta-analyses. An example of community effectiveness estimates of oral rehydration salts calculated from efficacy estimates provided in clinical trials has been given in this chapter. Community effectiveness provides health care providers and policymakers important information for health services decision-making.

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