

DEVELOPING THERAPEUTICAL GUIDELINES

RESEARCH DOCTOR PHARMA

Introduction

•**Therapeutic Guidelines** are clinical practice based guidelines written principally for prescribers (general practitioners and trainee physicians in particular) to provide clear, practical and up-to-date therapeutic information, for the management of patients with specific conditions.

The need for guidelines

- The government agencies and professional organisations have focused on improving the quality of patient care through the quality of establishment of therapeutic guidelines.
- Guidelines are also necessary to control healthcare costs. This is especially important in developing countries, where available funding sources for the healthcare system are often insufficient and conflict of interest exist due to ownership of equipment by healthcare providers.
- Lastly guidelines are necessary to increase consistency of recommendations and treatment by practitioners.

Examples of guidelines

•The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure was developed by an executive committee, multidisciplinary healthcare team representing the fields of medicine, nursing, nutrition, pharmacy, public health and staff at the National Heart, Lung and Blood Institute. •The first guidelines to be formulated by an expert body of Indian doctors were hypertension guidelines endorsed jointly by the Cardiology Society of India, the Hypertension Society of India, the Indian College of Physicians and the Association of Physicians of India in 2001.

Development of guidelines

•Steps in guideline development includes:

1. Identify group members for guideline development.
2. Identify & refine the problem focusing on the disease and published literature.
3. Review the literature, organisational recommendations & internet resources to determine the present standard of care
4. Obtain opinions from experts in the field
5. Begin the information feedback process.
6. Coordinate resources to avoid duplication of resources and time.
7. Access the quality, relevance, variability and strength of the information.

8. Synthesise the information.

9. Summarise and disseminate the information, focussing on measurable outcomes.

1. Identify group members for guideline development.

- When developing the recommendations in the guideline, it is always advisable to have a multidisciplinary groups.
- The ideal number of people involved in such a group is at least 6 but no more than 15 members; too few members limits adequate discussion and too many members makes effective functioning of the team difficult.
- The choice of medical specialists in the development group depends on the drug or disease being targeted.
- Healthcare professionals (up to five general practitioners, up to two hospital consultants, a healthy authority medical adviser, and a pharmacist); specialists (an epidemiologist and a health economist); and a specialist in guideline methodology and in leading small groups.

2. Identify & refine the problem focusing on the disease and published literature.

- Guidelines can be developed for a wide range of subjects.
- Potential area can be identified based on the major causes of morbidity and mortality for a given population, uncertainty about the appropriateness of drug therapy or about the evidence for improving patient outcomes.
- For example, the first step for preparing a treatment guideline in a hospital is to select a drug/disease for guideline development and then analyse the utilisation trends of the drug in the hospital to assess the significance of the selection.
- After identification of the topic for guideline development, it has to be refined before the evidence can be assessed in order to answer exact questions. The usual way of refining a topic is by having a dialogue among the potential users or evaluators of the guideline.

3. Review the literature, organisational recommendations & internet resources to determine the present standard of care.

- Identification & assessment of the evidence is best done by performance of a systematic review. The purpose of a systematic review is to collect all available evidences, assess its potential applicability to the clinical question under consideration, inspect the evidence for susceptibility to bias, and extract and summarise the findings.
- Methods of identifying and synthesising evidence include expert opinion, unsystematic literature review, graded systematic review, and formal meta-analysis.
- To ensure validity and reliability. The guidelines should be based on high quality research studies.

4. Obtain opinions from experts in the field

- Opinions of experts should be used to interpret evidence and to derive recommendations in the absence of evidence.
- Recommendations based solely on clinical judgment and experiences are likely to be more susceptible to bias and self-interest. Therefore, after deciding what role an expert opinion is to play, the next step is deciding how to collect and assess the expert opinion.

5. Begin the information feedback process

- Information feedback refers to the provision of health data information which may allow clinicians to compare their own practice with the practice of their colleagues or other hospitals.

6. Coordinate resources to avoid duplication of resources and time

- Judgments about whether the costs of tests or treatments are reasonable depend on how cost effectiveness is defined and calculated, and on the resource constraints of the healthcare system.
- Comparative studies conclude that internal guidelines are less likely to be scientifically valid because local groups require greater resources and lack the clinical, managerial and technical skills, needed to develop guidelines.
- Therefore, the most attractive way for a local group to develop a guideline is to adapt published guidelines for local use.

7. Access the quality, relevance, variability and strength of the information

- Summarized evidence is categorised to reflect its susceptibility to bias.
- This is a shorthand method of conveying specific aspects of the evidence to a reader of the guideline

8. Synthesise the information

- Synthesis of study results is the most subjective area of guideline developments and impacts on the presentation, acceptability and dissemination of results.

9. Summarise and disseminate the information, focussing on measurable outcomes

- The way in which guideline is presented will determine how well it is accepted.

Guidelines can be presented as the full version, summary sheets of all or part of the guideline, or reminder sheets in patient records.

- ‘Plan, do, study, act’ cycle is necessary to determine the effect of practice guidelines and to close the gap between practice and treatment.

- Evaluation of the failures in the present system is important to improve practitioner acceptance and utilisation.

FACTORS AFFECTING IMPLEMENTATION OF GUIDELINE OR POTENTIAL LIMITATIONS OF GUIDELINES.

- Although most guidelines are useful tools to provide the busy clinician with up-to-date information, physicians may regard guidelines to be unrealistic, and some may even consider guidelines to be a challenge to their autonomy.

a) Complexity

- Studies indicated that when a guideline can be relatively easily understood and tried out, the chance is greater that the guideline will be used. It is important therefore for guideline developers to take into account the complexity of the guidelines. Particularly for developers of multi-disciplinary guidelines directed at several target groups with varying educational levels and backgrounds (e.g. physicians, nurses, patients), it is a challenge to describe recommendations that are understandable and usable for all target groups.

b) Organizational and resource related factors

- Effective organizational structure with strong leadership and a powerful learning culture were found to be important facilitating factors in implementing guidelines
- Lack of financial resources was also raised as an essential issue that prevents the progress of implementation work.

c)Physicians related factors

- Studies found that knowledge, attitude and behaviour are considered the main factors that affect physicians' adherence

Knowledge: Knowledge such as lack of familiarity and awareness, volume overload, time needed to stay informed and guideline accessibility are important in modifying physician practice patterns.

Attitude: Physician attitude about practice guideline is another barrier to guideline adherence. Lack of agreement and confidence with specific

guidelines, that explain that most individual doctors may not agree with guidelines issued by their own peers, leading them to choose a different course of treatment, however, many doctors have seen that a specific guideline may be too rigid to apply.

- Therapeutic guidelines are useful only when the prescribers are not clear about appropriate practice or evidence-based practice. Guidelines may not be useful when the practitioners are aware of the information contained in it.

d) Characteristics of patients

- Characteristics of patients, too, appear to exert influence: for instance, co-morbidity in a patient appears to reduce the chance that guidelines are followed. Other limitations include:

- The guidelines were too time-consuming

- Too cumbersome

- Difficult to understand and/or did not leave room for personal experience and clinical judgment. Physicians preferred review articles compared to guidelines.

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