

General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine



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Foreword

During the last decade, use of traditional medicine has expanded globally and has gained popularity. It has not only continued to be used for primary health care of the poor in developing countries, but has also been used in countries where conventional medicine is predominant in the national health care system.

With the tremendous expansion in the use of traditional medicine worldwide, safety and efficacy as well as quality control of herbal medicines and traditional procedure-based therapies have become important concerns for both health authorities and the public.

Various practices of traditional medicine have been developed in different cultures in different regions without a parallel development of international standards and appropriate methods for evaluating traditional medicine.

The challenge now is to ensure that traditional medicine is used properly and to determine how research and evaluation of traditional medicine should be carried out. Governments and researchers, among others, are increasingly requesting WHO to provide standards, technical guidance and information on these issues.

Since 1991, WHO has developed and issued a series of technical guidelines such as *Guidelines for the assessment of herbal medicines*; *Research guidelines for evaluating the safety and efficacy of herbal medicines*; and *Guidelines for clinical research on acupuncture*. However, these guidelines are still not sufficient to cover the many challenging issues in the research and evaluation of traditional medicine.

In 1997, with the support of the National Center of Complementary and Alternative Medicine, National Institutes of Health, Bethesda, MD, USA, a WHO informal discussion developed draft guidelines for methodology on research and evaluation of traditional medicine. Since then, the draft has been revised four times. The guidelines were finalized at a WHO consultation in April 2000, in Hong Kong, China, with the support of the Government of Hong Kong SAR.

The guidelines focus on the current major debates on safety and efficacy of traditional medicine, and are intended to raise and answer some challenging questions concerning the evidence base. They also clarify certain commonly used but unclear definitions. The guidelines present some national regulations for the evaluation of herbal medicine, and also recommend new approaches for carrying out clinical research, for example, using the WHO *QOL user manual*. The quality of life (QOL) manual was developed by the WHO Programme on Mental Health, and may also be used to evaluate the results of clinical research in traditional medicine.

Although the guidelines have been carefully developed and modified, based on comments received from various experts and national health authorities across the world, there still may be other issues and views that, unintentionally, have

not been included. Unfortunately, it is possible that some experts in the field may not have been consulted, due to WHO's limited budget and time for preparation.

There can be no doubt that the guidelines will achieve their purpose of improving the quality and value of research in traditional medicine. It is anticipated that the guidelines will be revised again in the near future, in response to developments in research in traditional medicine. We therefore welcome all comments and views at any time.

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Introduction

Definitions

Traditional medicine

Traditional medicine has a long history. It is the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses. The terms complementary/alternative/non-conventional medicine are used interchangeably with traditional medicine in some countries^a.

General considerations

Practices of traditional medicine vary greatly from country to country, and from region to region, as they are influenced by factors such as culture, history, personal attitudes and philosophy. In many cases, their theory and application are quite different from those of conventional medicine. Long historical use of many practices of traditional medicine, including experience passed on from generation to generation, has demonstrated the safety and efficacy of traditional medicine. However, scientific research is needed to provide additional evidence of its safety and efficacy. In conducting research and evaluating traditional medicine, knowledge and experience obtained through the long history of established practices should be respected.

Despite its existence and continued use over many centuries, and its popularity and extensive use during the last decade, traditional medicine has not been officially recognized in most countries. Consequently, education, training and research in this area have not been accorded due attention and support. The quantity and quality of the safety and efficacy data on traditional medicine are far from sufficient to meet the criteria needed to support its use worldwide. The reasons for the lack of research data are due not only to health care policies, but also to a lack of adequate or accepted research methodology for evaluating traditional medicine. It should also be noted that there are published and unpublished data on research in traditional medicine in various countries, but further research in safety and efficacy should be promoted, and the quality of the research should be improved.

^a The term complementary and alternative medicine is used in some countries to refer to a broad set of health care practices that are not part of the country's own tradition and are not integrated into the dominant health care system.

The methodologies for research and evaluation of traditional medicine should be based on the following basic principles. On the one hand, the methodologies should guarantee the safety and efficacy of herbal medicines and traditional procedure-based therapies. On the other hand, however, they should not become obstacles to the application and development of traditional medicine. This complex issue has been a concern for national health authorities and scientists in recent years.

The discussion of methodologies for research and evaluation of traditional medicine is divided into two parts: herbal medicines and traditional procedure-based therapies. However, successful treatment is often the consequence of both types of treatment acting synergistically. Thus, the efficacy of traditional medicine has to be evaluated in an integrated manner, taking into account both treatment types. Consequently, efficacy assessment of traditional medicine may be quite different to that of conventional medicine. As traditional medicine relies on a holistic approach, conventional efficacy assessment measures may not be adequate.

Purpose of the guidelines

These guidelines have been developed to improve the situation described above, and to promote the proper use and development of traditional medicine. The specific objectives of the guidelines are to:

- ◆ harmonize the use of certain accepted and important terms in traditional medicine;
- ◆ summarize key issues for developing methodologies for research and evaluation of traditional medicine;
- ◆ improve the quality and value of research in traditional medicine; and
- ◆ provide appropriate evaluation methods to facilitate the development of regulation and registration in traditional medicine.

Use of the guidelines

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