

UNPROVEN THERAPIES

Preamble

All physicians must meet the same standards of practice and any medical act must meet the following criteria:

- The context within which it is performed has the informed consent of the patient or appropriate legal authority;
- the medical act is carried out in a manner reasonably consistent with the standards recognized by the profession.

Evidence-based medicine is the foundation of medical practice. Today some physicians are asking for better direction regarding the criteria which must be met in those areas of medical practice which are not evidence-based. Questions arise such as – *What activities may be considered unacceptable? Are there any specific requirements with respect to patient consent?* This paper is intended to answer such questions and provide some guidance to physicians who wish to introduce unproven activities into their practice.

Definitions

The word “unproven” is used in preference to “alternative” or “complementary” because it implies that the processes lack scientific basis and are adjuncts, rather than replacements, for orthodox processes.

Unproven therapy refers to those processes and interventions used for diagnosis, prevention, therapy, or rehabilitation for which there is no *scientific* evidence of efficacy, reproducibility, and reliability. Some of these activities have become accepted by the medical community over the years, despite no evidence to support them.

Orthodox medicine consists of evidence-based knowledge and also those unproven concepts which have become commonly accepted by the medical community. New activities or concepts which are shown to be “evidence-based” become part of orthodox medicine. Activities which are discredited by scientific evidence cease to be acceptable and are unorthodox.

Diagnosis

Only diagnostic tests acceptable to orthodox medicine will be used to determine a patient’s biochemical, physiological, anatomical, or psychological status.

Requirements Relative to Unproven Therapies

- Unproven therapies are to be practised as adjuncts to evidence-based medicine, and not as alternatives. The physician may also use unproven therapies where no evidence-based alternative is available.
- The patient has a right to seek health care from any provider even if the health service provided is unproven. If the therapy is known to be harmful, then the physician must inform the patient.
- A physician must review the scientific literature in order to assess a theory before using it in patient care.
- The nature of the unproven therapy being provided by a physician must be explained to the patient with regard to the quality of research relative to efficacy, reliability, reproducibility, and risk.
- If the unproven therapy may cause harm, the potential for this harm must be fully explained.
- The physician must not provide a service when harm significantly exceeds that of orthodox medicine, or where there is no reasonable expectation of offsetting benefit.
- Physicians must be aware of the economic well-being of their patients, and advise regarding cost/benefit of any unproven therapy they may propose.
- Where physicians may personally profit from the sale of any device, service, or product associated with the unproven therapy service, they must comply with conflict of interest guidelines.

The overriding principle of all medical practice, “Remember first the well-being of the patient.” All of medical practice must adhere to the same standards.