NEUROLOGY 2006;66:966–967

Editorial

Practice Parameters for Parkinson disease

Signposts for clinical research

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> Let us be partners in confusion and one day we may be brothers in understanding.
>
> —James Fenimore Cooper

Physicians strive to practice medicine in a manner that optimizes outcomes for patients. This demands both thoughtful individualization of care and application of the best knowledge relevant to the clinical problem at hand. In recent years, the evidence-based medicine movement has attempted to raise the standards of clinical practice by bringing the methods of clinical epidemiology and clinical research into day to day practice.[1] In an effort to present scientifically sound guidelines to aid the practice of neurology, the Quality Standards Subcommittee (QSS) of the American Academy of Neurology sponsors a series of Practice Parameters relevant to different neurology subspecialties. The recent development of a series of Practice Parameters regarding the treatment of Parkinson disease (PD) demonstrates the strengths and limitations of this approach.[2-5]

Development of Practice Parameters is a rigorous, transparent process aimed at important, clearly stated clinical questions, using prespecified criteria for evaluation of evidence and articulation of recommendations. Under the auspices of the QSS, important questions are posed and a panel of specialists on the clinical problem and general neurologists experienced in evidence-based reviews are assembled. Using large databases like MEDLINE, searches are conducted for relevant literature. Articles identified through these searches are reviewed for relevance. Secondary searches based on bibliographies of relevant articles are used to expand the literature search. Articles in the final list are evaluated and classified according to the quality of the research (Class I–IV). For example, a Class I study of a diagnostic method requires a prospective cohort of a broad spectrum of individuals with the suspected condition, reference standards for diagnosis, blinded evaluation, and appropriate tests of diagnostic accuracy. A Class IV study lacks these features, lacks independent assignment of diagnosis, or is based on expert opinion alone or uncontrolled descriptive case series. Based on the accrued and classified studies, recommendations are made with the strength or level (A, B, C, U) of the recommendation based on the quality of the evidence. A Level A recommendation makes a definite statement about effectiveness and requires at least two concordant Class I studies. Levels B (probably effective, ineffective, or harmful) and C (possibly effective, ineffective, or harmful) reflect poorer evidence, and Level U reflects inadequate data.

The success of this process depends on two factors: the quality of the reviews per se, and the quality of the evidence. In the recent PD-related Practice Parameters, there can be little doubt about quality of the reviews. All these Parameters are based on careful evaluation of the literature and we owe the review panels thanks for undertaking these time-consuming activities. In addition to being aids to clinical practice, these Practice Parameters are excellent, critical reviews of the literature relevant to the questions posed.

The success of the Parameters as guides to practice, however, rests also on the nature of the underlying evidence. Consonant with the notorious GIGO (garbage in, garbage out) principle, no amount of thoughtful analysis can overcome deficits in basic knowledge. This fact is illustrated well by these Practice Parameters. Out of over 20 different recommendations, there is one Level A recommendation, about one third are Level B recommendations, and the remainder are Level C and Level U recommenda-

See also pages 968, 976, 983, and 996

This article was previously published in electronic format as an Expedited E-Pub at www.neurology.org.
Supported by NS15655 and AG08671.
Disclosure: The author reports no conflicts of interest.

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tions. Examination of the one Level A recommendation reveals additional questions about the knowledge base on which this recommendation is based.[5] This Level A recommendation is that the COMT inhibitor entacapone and the MAO-B inhibitor rasagiline be offered to reduce "off" time. The same Parameter includes a Level C recommendation that sustained release carbidopa/levodopa may be disregarded as a treatment to reduce "off" time. The idea that extended release carbidopa/levodopa is ineffective in reducing "off" time flies in the face of considerable clinical experience. The different levels of the recommendations are a function of the available clinical trial data. The entacapone and rasagiline recommendations are based on the existence of replicated successful Class I trials for these agents. There have been no Class I or II trials of the efficacy of extended release carbidopa/levodopa in reducing "off" time. This evidentiary discrepancy probably reflects the fact that entacapone and rasagiline are novel entities, not adaptations of an existing agent. As recently developed agents, they faced greater scrutiny from regulators and from the movement disorders community than did extended release carbidopa/levodopa. In addition, we do not know the best approach for reducing "off" time. This review panel was unable to issue a strong recommendation because of inadequate comparative data.

The lack of adequate data for formulating strong recommendations is not unique to the treatment of PD. Does this mean that these, and by implication other, Practice Parameters are fruitless? Absolutely not. Even if the Practice Parameter process does not lead to a large number of strong recommendations for clinical practice, these exercises point out crucial directions for clinical research. The Practice Parameter process requires the identification of important issues in clinical practice. This is an important end in its own right. The Practice Parameter process also identifies major knowledge gaps, crucial for future progress in improving care for our patients. While the immediate impact of these Practice Parameters may be modest, they will influence our clinical research agenda and are likely to have significant long-term consequences.

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Neurology 2006;66;966-967 Published Online before print April 2, 2006
DOI 10.1212/01.wnl.0000214662.19840.ea