

## EDITORIAL

# Modern Education, Modern Media

Patient Empowerment in Today's Medicine

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Editorial to accompany the article "Educating orally anticoagulated patients in drug safety—a cluster randomized study in general practice," by Vormfelde et al., in this issue of *Deutsches Ärzteblatt International*

**P**atient empowerment, in other words letting patients take charge of managing their own illnesses, is fortunately being taken ever more seriously. This is not just reflected in increased patient autonomy and individual maturity; it also improves treatment outcomes in a major way. The efficacy of patient education has already been demonstrated for a variety of indications, including asthma (1), diabetes (2), and other chronic diseases. The merit of the trial by Stefan Viktor Vormfelde and coauthors that appears in this issue of *Deutsches Ärzteblatt International* is to have extended our knowledge that patient education does, in fact, work to the area of therapeutic anticoagulation with phenprocoumon—and to have done so with an innovative, interactive study design that was directly implemented in general practitioners' practices (3). Many patients are still being treated with phenprocoumon, and, in view of the current debate about the safety of the newer anticoagulant drugs (4), permanent anticoagulation with phenprocoumon will likely continue to play an important role in patient care (5). Thus, the method of patient education used in this trial will continue to be important.

## Cluster randomized controlled trials

Adequate patient education about the risks and side effects of treatment, and the necessity of adapting one's lifestyle to it, is of special importance in the case of oral anticoagulation. The effectiveness of patient education can be markedly increased by the method of Vormfelde et al., as this randomized controlled trial (RCT) demonstrates (3). Trials in which medical practices, rather than patients, are randomized are the gold standard for the demonstration of a benefit of an intervention in routine outpatient care in private practice. In classic RCTs, patients are randomized to the intervention arm or the control arm of the trial before the treatment begins. But an RCT of this type is hard to carry out in general practice, as the individual general practitioner and his or her practice team will surely find it difficult to switch back and forth from an old to a new method of treatment from one patient to the next, depending on the random allocation of each. This is unrealistic for practical reasons; it would also tend to water down the observed difference between treatment methods, as the participating physicians would probably optimize their control treatments while

participating in the trial (gradual contamination).

It follows that randomization on the patient level is not implementable, and that entire practices should be randomized instead (cluster randomization, as this is called). The efficacy of the intervention is then compared with that of usual care in the control practices (6). Cluster randomized controlled trials (cRCTs) are the most informative type of RCT for routine clinical practice. They are, however, very demanding for the participating practices, which must change their mode of operation. cRCTs also present a special challenge in the computation of requisite case numbers (power analysis), because, if a cRCT is to bring a truly existing benefit to light, it must include more patients than a traditional RCT to enable controlling for the potential effect of the individual practices (6).

The present trial included 319 patients and is thus the largest trial ever conducted anywhere in the world on this topic. The number of patients may have been too small nonetheless: the amount of time spent in the target range of the international normalized ratio (INR) in the six months after patient education was 71% in the intervention group and 64% in the control group, but this difference narrowly missed being statistically significant ( $p = 0.11$ ). As the authors correctly state, the lack of significance may be due not only to inadequate case numbers, but also, in part, to insufficient standardization of the individual discussion each patient held with a practice nurse after watching the informational video. In any case, the primary endpoint of the trial was the patients' knowledge, and the trial indeed succeeded in demonstrating that the patients who underwent the intervention (patient education) knew more about therapeutic anticoagulation six months later than those in the control arm, who were only given a brochure. A positive effect of self-management can be assumed.

## Self-management

Self-management is an important underpinning of patient empowerment. It enables patients to talk with us physicians at eye level and to make decisions for themselves (7). They can take their fate in their own hands, at least in part. This improves not just treatment outcomes, but also the quality of life of persons suffering from many different kinds of chronic disease. These are worthy objectives, and more clinical

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trials of self-management in general practice would be highly desirable. The imperative to advocate for patient empowerment comes from the principles that underpin the global health promotion charters, initiated by the Alma-Ata in 1978 (8). Health is reaffirmed as a human right in this charter. Primary health care is seen as a promoter for patient participation and addresses health problems in the community. Thus, the comprehensive care of patients with their own active participation is a major objective of general practice. The concept of patient empowerment has, accordingly, been incorporated into the European definition of general practice and family medicine (9). It is fortunate that this important principle is now being served by the modern concept of “blended learning” for patients; it is particularly fortunate that the educational materials, including the video presentation, have been made freely available on the Internet, so that they can help as many patients as possible (3).

### Overview

Nor should we neglect to mention here that self-management is most effective when combined with self-measurement. This combination has been shown to lessen the incidence of thrombotic events and death (10). Its broad implementation has been hampered, however, by the high cost of measuring devices—which we ought to consider in the context of the newer anticoagulant drugs recently brought onto the market: these cost about 1000 euros per year of treatment and are thus even more expensive.

#### Conflict of interest statement

The author declares that no conflict of interest exists.

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