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# *98 – New Era for Clinical Research in Primary Care*

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Primary care is the cornerstone of the health services in many countries. Nevertheless, most of the knowledge that we base our practice on is derived from a secondary or tertiary care setting. The need for more research performed in primary care is urgent. It is essential to establish an infrastructure for independent research that is relevant to general practitioners (GPs), their patients and to the community. Such an infrastructure was set up years ago in the form of primary care research networks in the UK, Netherlands and the US (1-3), and there are new initiatives elsewhere, for instance in Ireland (4) and Norway (5).

Clinical trials in primary care have almost been synonymous with pharmaceutical trials. These trials have to go through an extensive process to ensure patient safety and scientific quality, and the pharmaceutical companies provide an infrastructure that secures that the involved practices will deliver what is demanded and adhere to protocol. The requirements that have to be met call for resources that most academic institutions cannot even dream of, and participation in such trials gives GPs the possibility to take part in research of high quality.

Participation in pharmaceutical trials offers many advantages, but there are also uncertainties and pitfalls, for both physicians and patients. One task of the GP in clinical practice is to balance pros and cons in a long line of different encounters every day, and sometimes to assist her patients in living with the necessary compromises and consequences. How to relate to the pharmaceutical industry is yet another area where these skills are needed as there are common, but also potentially conflicting, interests.

The industry itself is eager to point out the benefits for the physicians: Professional development and recognition, taking part in the evolution of medicine, and the opportunity for additional income (6). There should be no misunderstanding about the fact that there is a lot of money involved in recruiting patients for pharmaceutical trials. How much the GP should receive for his/her effort is always debatable, but the compensation should at least reflect the actual work involved. On the other hand the amount should not seduce GPs into taking part in bad science.

There are studies that will gain new knowledge or improve treatment options, but there is also a risk that some are just as much aimed at prolonging patent rights or strengthen market position. A thorough evaluation of proposed projects may be difficult, beyond the capacity of the average GP, and there should be a process for systematic assessment of protocols for studies aimed at primary care.

Participation in trials is often considered beneficial by patients that are included. Several studies have shown that other benefits than physical improvement is of importance to the patients. The combined perceived advantage of additional monitoring, the opportunity for assessment by a specialist and an altruistic motivation to help others is a consistent finding across several studies.

The assertion that patients will receive better follow up by participating in trials, with improved clinical outcomes from study participation itself as an effect, is uncertain. The conclusion of summarized research on comparing the outcome of patients within or outside clinical trials is that there is no clear evidence of such an effect (7). There is a risk that the inclusion and exclusion criteria might bias the study population towards someone with a better prognosis, and other forms of bias can also influence the results. This has been most extensively studied in cancer research, but there is no reason that it should be different in primary care studies. A possible effect of this kind of bias is that the generalizability of the studies may be questionable, and assessing this is important to GPs who see a cross section of the general population.

The challenges introduced by current changes in demography cannot be met with yesterday's solutions. Technological development paves the way for innovations in primary care, and we already see the possibilities for data gathering and disease monitoring by the use of patients' home devices. This opens exciting possibilities for improved care and improved research, and family doctors should be at the forefront of this development and help secure that new ideas are introduced and properly tested.

We know that a large proportion of patients are willing to participate in clinical trials (8). We also know that GPs will benefit from taking part in studies, and participation in research should be considered an integrated part of primary care, not different from secondary care. This is not the case today. Therefore attitudes must change and sufficient resources, both time and money, must be allocated. This cannot just be the responsibility of the pharmaceutical industry and there must be an alternative based on existing health services and the academic institutions. Lessons from the UK and the Netherlands have taught us that establishing comprehensive public research networks is an efficient and cost-effective strategy to support high quality research in primary care.

Primary care research networks tie a number of general practices together under the common umbrella of a coordinating organisation based inside or outside the academic institutions. The infrastructure should be robust and sustainable, and the network must be able to deliver services essential to both researchers and participating GPs:

1. Recruit a sufficient number of GPs and practices capable of delivering patients to clinical trials.
2. Provide tools for extracting data from electronic patient records.
3. Assess practices and certify those ready for research.
4. Evaluate feasibility of proposed projects.
5. Estimate fair compensation for participating doctors, based on actual cost and time required.
6. Support inclusion of patients into clinical trials, and secure data from these patients.
7. Promote implementation of research based knowledge into clinical practice and health policy.

A primary care research network is the laboratory where we all need to bridge the current gap between clinical work and academic general practice in many countries. It will be the place where we can study research questions important to GPs, our patients and the community.

## *Take home messages*

- Changes in demography call for innovations in both research and care.
- Practice based research in primary care is urgently needed.
- A permanent infrastructure is essential to secure that feasible projects are completed as planned.
- Primary care research networks are a well documented foundation for high quality research.

## *Original abstract*

http://www.woncaeurope.org/content/3870-clinical-trial-primary-care-physicians-it-beneficial

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