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Feature article

# General practitioners who do not adhere to guidelines – do they have valid reasons?

Clinical guidelines for prevention of cardiovascular disease have been developed and implementation of them attempted since the 1980s. Although the guidelines have been especially tailored to general practice, studies have shown that general practitioners tend not to adhere to them although they emphasise the importance of guidelines in general. A recent, prestigious Norwegian study supports these findings. We claim that an explanation for this lack of concordance is a want of thorough questioning and discussion of the theoretical basis for the guidelines, rather than negligence from the doctors.

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Disease prevention is an important part of the health services' mandate. In this feature article, we question the relevance of preventive measures for cardiovascular disease based solely on «biological risk factors» in the subjectively healthy part of the population. The story of tracking and treating high blood pressure in general practice in Norway forms the basis for the article. With an emphasis on recent implementation research we claim the time has come to reassess the knowledge basis for current handling of high blood pressure in general practice.

## High blood pressure – the beginning of it all

High blood pressure was the first risk factor for potential disease to be subject to extensive medical treatment. The advent of new antihypertensives, documented to be well tolerated and safe, contributed to great treatment optimism among doctors in the 1980s. Recommended thresholds for intervention have been steadily reduced ever since and new, usually more expensive drugs have been taken into use (1).

Several parties have affected this development. Various *groups of doctors* have provided the premises in their roles as researchers and clinical opinion leaders. The *pharmaceutical industry* has played a key role by financing the largest studies, and therefore has had substantial influence on the professional debate in Norway, as in other countries (2). The *authorities* have, to a large degree, left the professional and health economic assessments to professional groups and information about drugs to the industry, at the same time as they have committed themselves to pay the bill – over the social security budget (1). The *patients* have, however, not had possibilities to independently assess whether they wish medical treatment of their high blood pressure or not – therefore they have had little influence on this development (1).

## Clinical guidelines – an historical retrospect

The Unit for Health Services Research at the Norwegian General Scientific Research Council (the Unit is currently part of the Norwegian Institute of Public Health) proposed guidelines for a «blood pressure reduction programme» as early as 1978. Subsequent clinical guidelines for prevention of cardiovascular disease have been further developed over the years in order to quality assure recommended preventive actions. In 1980, more than 70 % of doctors in the county of North-Trøndelag stated that they wanted guidelines for treatment of hypertension, and thereby empirically confirmed that an action programme for this type of treatment was needed. A detailed action programme was sent to the general practitioners (GPs) and to both hospitals in the county. An evaluation three years later showed that the action programme still had massive support (3).

A cross-disciplinary group developed the first national action programme in 1986. The group consisted of health service researchers, health economists, epidemiologists, blood pressure researchers, hospital doctors and the reference group for hypertension in the Norwegian College for General Practice (NCGP). The programme (revised in 1993) suggested higher thresholds for blood pressure treatment than corresponding guidelines in other countries; a discrepancy that caused debate. Hospital-based opinion leaders were especially critical; the Norwegian Society of Cardiology quickly released other guidelines that recommended lower and age-independent thresholds for intervention. Critics of the higher thresholds proposed by NCGP, claimed that the prevalence of stroke was likely to become higher in Norway than in other European countries (1). Nevertheless, it did not occur (4). The programmes from 1986 and 1993 were both printed in stocks of about 20 000 and distributed freely to the two levels of health care in the Norwegian health care services (primary health care and secondary specialist health care services).

This time-period was characterised by a firm belief in that development and distribution of clinical guidelines would automatically ensure the quality of preventive measures in medicine. In 1994, however, a summary of international literature in the field gave the impression that this was not quite as simple (5). It was therefore recommended that various strategies should be used to actively implement guidelines (5).

In 1991, a Norwegian study showed that eight of ten doctors considered guidelines for hypertension and diabetes mellitus to be useful, and that nine of ten doctors wished to receive revised versions. Nevertheless, when the degree to which guidelines affected clinical practice was assessed, one found a large discrepancy between their positive attitude towards guidelines and what they actually did in clinical practice. This concerned both patients with hypertension and patients with diabetes mellitus (6). Even a multifactorial implementation strategy did not improve adherence to guidelines to any significant degree (6). At the time it seemed most appropriate to conclude that lack of implementation partly concerned difficulties with prioritising the large population in question, even though the thresholds for intervention were set higher than in other countries. It also became clear that the recommended «theo-


*Illustration Katrine Kalleklev*

retical» approach was not that easy to implement into clinical practice. As several of the doctors said: «Guidelines are fine, but they are not really suitable for my patients» (6).

When the time had come to revise the guidelines from 1993, it was not possible for NCGP's reference group to provide financing, despite contacting all public sources that had contributed to the 1993 programme. A stock of 22 000 booklet, with a short version of the guidelines to put on the desk, was budgeted to cost 600 000 NOK. NCGP's professional work was meant to be unpaid. The reference group, which consisted of GPs with clinical and academic competence, found that the two previous programmes had involved extensive professional compromising, and that public health aspects had not been sufficiently emphasised. All these issues caused the group to publish the guidelines for primary care in the Journal of the Norwegian Medical Association. Four articles were published; two covered general challenges concerning generation and implementation of new knowledge in general practice, one concerned advice on lifestyle and one was on medical preventive measures.

## «Evidence-based medicine» raises hope

The notion of basing clinical recommendations on systematic research with outcome measures of clinical importance became increasingly emphasised (7, 8), and in the end of the 1990s the health authorities provided funding to the Norwegian Institute of Public Health with the following aim: to improve treatment of hypertension and hypercholesterolaemia through development and implementation of clinical guidelines in accordance with evidence-based medicine (8–10). The Norwegian Knowledge Centre for the Health Services continued this work. They initiated the study «Rational Prescribing in Primary Care» (RaPP), with an explicit intention of providing the health authorities with evidence-based advice (7).

A systematic literature review prior to the study, led the RaPP researchers to conclude that they were not completely content with any of the available guidelines for implementation of preventive actions (7). Therefore, they developed new guidelines themselves based on the literature they considered to be of relevance (8–10). Their recommendations were thereafter thoroughly reviewed. NCGP's reference group made the following two comments in the subsequent hearing round: Firstly, the RaPP guidelines did not present clearly enough that the thresholds for intervention (20 % 10-year risk for disease) (8) and treatment goals for lowering of blood pressure (< 140/90 mm Hg) (9) and cholesterol (< 5 mmol/L) (10) were based on consensus and should therefore be interpreted as «value choices», i.e. normative reasons for action. Secondly, the group stated that providing guidelines for every risk factor (9, 10) would not help doctors understand and explain the effect of multiregimes in the prevention of cardiovascular disease. These valid and important scientific comments were not taken into account.

## Optimal conditions – still a minimal effect

The RaPP study was carried out according to an impeccable methodology; a randomised study design was used and 146 doctors' offices were involved. The implementation strategy was comprehensive. Before the study started, the researchers tried to identify and reduce all potential hindrances for success; e.g. lack of knowledge, software for risk calculation, patient information materials, or others. Study implementation comprised practice visits, feedback to individual doctors about their practice and organising of «study reminders» on doctors' screens during consultations.

Because the RaPP study was so well planned and organised, the results should be considered carefully. The result of the intervention was surprising: only a small effect was shown on prescription frequency of thiazides as first choice, which the guidelines recommended (increase from 6 % to 17 % in the intervention group and from 9 % to 11 % in the control group, relative risk 1.9; 95 % CI 1.5–2.5). The researchers regarded this to be a «notable effect on prescription practice» (7). This is perhaps true in statistical terms, but from a clinical point of view we believe that a «small effect» would be a more appropriate conclusion. The intervention had no effect on the other endpoints. One endpoint was to achieve recommended treatment goals for blood pressure, which was achieved for a third of the patients, but the effect of the intervention was small and similar in both groups (2.7 % versus 2.9 %, p = 0.3). The other goal that was not achieved was to increase the frequency of cardiovascular total risk assessments before the start of treatment (17.2 % versus 14.6 %, p = 0.9). However, 62 % of doctors claimed they had done such an assessment (7), which is in line with findings in other studies; what doctors actually do is often different from what they say they do (6).

After the interventional part of the RaPP study, the researchers evaluated the process thoroughly, hoping to improve their understanding of the results. The evaluation did not provide good explanations to the lack of adherence to recommendations or to the large diversity between doctors' practices (7) – a diversity that had been recognised previously (6). Our view is that results from the RaPP study show that systematic development and implementation of guidelines for prevention of cardiovascular disease *still* does not seem to work, even when all is done according to evidence- based medicine (11).

## Guidance taken seriously

When an intervention in medicine does not work, it is common practice to start the reconstruction of a new one. But, the high quality of the RaPP study give reasons to stop and think. The scientific approach to the challenge in question was close to optimal and large resources were invested. In our opinion, the study adhered so strictly with rules for evidence-based medicine and was conducted in such a stringent and transparent manner that it is difficult to see how it could have been improved. The scientific output from the study was impressive: guidelines, a PhD thesis with five articles (7) and 9 additional articles (8–10). The fact that doctors were thereafter instructed to prescribe thiazides as their first choice does not free the researchers and professional groups from the challenging task to provide health authorities with solid advice, which was the RaPP study's main objective.

For many, a lack of effect from the RaPP intervention is almost incomprehensible. Nevertheless, the finding is in concordance with those in other implementation studies (6). It is therefore logical, not to say adamant, to ask what reasons there were to believe that explicitly «evidence-based» guidelines would be easier to implement than the action programmes that preceded them. The lack of compatibility between the scientific basis for the RaPP study and clinical reality – as the NCGP's reference group had claimed – may be part of the problem.

## A need for radical reconsideration

Blood pressure and cholesterol are considered to be important, causal risk factors for cardiovascular disease. Nevertheless they represent *only two* of a rapidly increasing number of such «factors». Frequent redefining of thresholds for intervention implies a need for intervention in a rising proportion of the population. Intervention often means drug treatment, and this development may open up for comprehensive commercial exploitation of the human body, which the medical profession seems to «fragment» in the name of science. It should be discussed to what extent treatment of all these risk factors is compatible with sustainable and effective preventive medical practice (12).

What can we learn from the fact that ambitious and systematic preventive actions aimed at two of the most established medical risk factors (7) seem to be relatively unsuccessful? What is the consequence of the existence of other «causal factors» that may be causal on a more existential level than the biological ones, and how do we relate to all the GPs who may acknowledge this? Associations between physiological pressure in blood vessels and other organs and human existential conditions are increasingly documented (13) and must be part of such an analysis.

The discord between GP's acknowledgement of the importance of evidence-based guidelines and their lack of adherence to them in their clinical practice, provokes a discussion based on the following questions:

- How should we interpret the fact that motivated and strongly governed GPs do not act according to what is considered to be the most updated knowledge within evidence- based medicine in a central field?
- Could there be something fundamentally wrong with the structure and content of the guidelines despite of their accordance with how guidelines should be developed (11)?
- Is there so to say a fallible theoretical rationale behind the guidelines, which renders them suboptimal as guidance for treatment of human beings? May this contribute to a kind of «civil disobedience», even among ambitious doctors with the best of intentions?
- Could it therefore be that doctors involved in the RaPP study- at least in part- act on the basis of a professional rationale that is not yet identified, described and understood- and that formal arguments presenting their stance in relation to the official guidelines have not yet been formulated?
- In brief: Could it be that the scientific rationale for prevention of cardiovascular disease in clinical practice is based on a view of human beings, disease and doctors that is too restrictive?

The prestigious RaPP study should not pass into medical history with the conclusion that «stronger measures than volunteering are needed to change doctors' practice» (14), as the researchers wrote in their presentation of the thesis (7). A view mainly focusing on practicing doctors having laid-back attitudes or not following up properly in general (15), may leave this deeply needed professional revision with misleading conclusions. The suggested «alkali treatment» of practicing doctors may in the worst case, as we see it, contribute to dehumanisation of medicine. We consider the roots of the problem to be much deeper than previously acknowledged and that the phenomenon does not only affect GPs but the medical profession itself (12, 13).

A theoretical approach to disease and associated risk, which is limited to biological aspects of the human organism, is far too narrow. It implies a scientific simplification and thereby a degradation of humanity as such. This simplification may affect both the person in the patient role and the one in the role of the treatment provider. From such a perspective we dare say that lack of goal attainment, as it was documented in the RaPP study, should not mainly be attributed to the participating doctors. We believe the lack of success is implicit in the traditional biomedical model where people are considered advanced biological clock-works. In another article in this issue of the Journal we have attempted to document that human beings are so very different and so much more than machines (13).

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