Health Policy 107 (2012) 105–107

Contents lists available at SciVerse ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Editorial

Dealing with chronic disease – The role of structured programmes and guidelines

Ageing populations and advances in medical technologies together create a situation in which chronic diseases are increasingly impacting on health systems in Europe and globally. Chronic diseases – such as diabetes, chronic heart failure, coronary artery disease, asthma, COPD, depression or certain types of cancer – require a long-term perspective, first in tackling their determinants and so preventing them from occurring, but also in developing often complex "disease management" programmes needed to manage them, in which different health professionals intervene both simultaneously and consecutively. Such programmes are increasingly implemented in healthcare systems worldwide in order to enhance quality and continuity of care for the chronically ill, whilst making efficient use of healthcare resources.

International debate has initially rightly focused on the question whether such programmes are effective in improving processes (both clinical processes and patient behaviour), disease control (*i.e.* changes in intermediate measures) and outcomes (both clinical as well as patient-focused such as quality of life or satisfaction). While evidence on clinical processes, disease control and, to a lesser degree, patient-focused outcomes is growing, evidence on the improvement of clinical outcomes is still scarce.

Whether the assumption that disease management programmes reduce healthcare costs (at least in the long run) is really true was not very well evaluated for a long time as well. In 2011, a systematic review analysing 31 papers on 21 studies showed a wide range of savings and incremental costs. Substantial variation was found between studies in terms of study design, number and combination of components of disease management programs, interventions within components, and characteristics of economic evaluations. The authors came to the conclusion "that evidence for this claim is still inconclusive. . . . To support well-considered decision-making in this field, well-designed economic evaluations should be stimulated [1]."

In this issue the same group of authors address another open question in regard to structured programmes for chronically ill, namely whether and how the concept of structured programmes designed around one chronic illness can be expanded to care for patients with multiple chronic conditions. They identified 42 publications describing 33 studies evaluating 28 comprehensive care programmes for multimorbid patients. They find moderate evidence for beneficial effects on inpatient healthcare utilization, healthcare costs, patient health behaviour, perceived quality of care, and satisfaction of patients and caregivers. However, they find insufficient evidence for beneficial effects on health-related quality of life in terms of mental functioning, medication use, outpatient healthcare utilization and healthcare costs – and even no evidence for beneficial effects on outcomes such as cognitive functioning, depressive symptoms, functional status, mortality, quality of life in terms of physical functioning, and caregiver burden. They rightly conclude that "more rigorous evaluation studies are necessary to determine what constitutes best care for the increasing number of people with multiple chronic conditions [2]." *Health Policy* continues to seek to publish such well-designed and well-reported evaluation studies!

As the improvement of clinical processes is a crucial component to improve disease control, which in turn will (hopefully) improve clinical outcomes, clinical guidelines are a central component of activities dealing with the challenges presented by chronic diseases. This is why the European Union, in its role of encouraging exchange of information in support of public health, and therefore facilitating concerted action to optimize responses to the challenges of chronic diseases, is also interested in gathering knowledge on how clinical guidelines for chronic disease prevention and treatment have been developed and implemented in the different Member States. To this end, the European Commission's Directorate–General for Health & Consumers in early 2011 asked the European Observatory on Health Systems and Policies to prepare a

0168-8510/$ – see front matter
http://dx.doi.org/10.1016/j.healthpol.2012.08.019

report exploring the various national practices on clinical guidelines as well as their impact on processes of care and patients' outcomes.

This report sought to understand the definitions used for clinical guidelines relevant to chronic diseases and their relationship with related strategies to improve care for chronically ill patients; the regulatory basis for, actors involved and processes used in developing clinical guidelines across the European Union and the quality thereof; the strategies used to disseminate and implement clinical guidelines in countries and what is known about their effectiveness; and whether clinical guidelines actually have an impact on processes of care and patients' health outcomes.

In this issue of *Health Policy*, updated results of the three core parts of the report are published. The first one provides an in-depth summary of clinical guidelines experience in all European countries. This analysis was conducted according to an agreed conceptual framework designed to assess systematically the landscape for clinical guidelines in the EU. It consists of five dimensions: regulatory basis, development, quality control, implementation and evaluation of clinical guidelines [3]. This is followed by two systematic reviews, one on the methodological quality of clinical guideline development along the dimensions of the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument [4] and one on the effectiveness of strategies to implement clinical guidelines [5].

The "mapping exercise" shows that most European Union countries have an established national, regional or local clinical guideline programme, and a substantial proportion have developed guidelines on the prevention and management of chronic diseases. However, they find only few examples of formal evaluations of the development, quality, implementation and use of guidelines [3]. While one could say that the divergent practices regarding the development, dissemination and implementation of clinical guidelines simply reflect the different stages of development of quality assurance mechanisms in European health systems, the report goes one step further and suggest that a similar initiative to the one promoting the optimization of HTA methodology (the EUnetHTA programme) would not only greatly benefit those many countries where guideline development and application are still in their infancy and support the establishment or amelioration of quality assurance practices – but also help those where clinical guidelines are more advanced. The challenge of a severe lack of standardized guideline terminology and accessibility as well as rigorous studies to evaluate the relationship between different ways to develop guidelines and their methodological quality, between their quality and the actual implementation and usage, and finally between implementation and health outcomes clearly affects all countries – within the EU and beyond.

In contrast to other reviews on clinical guidelines' quality and effectiveness [6–9], the two systematic reviews in this issue focus on European clinical guidelines only, thus avoiding the usual problem that most studies are conducted in other countries (often in the U.S.) and that their applicability and transferability is therefore questionable.

Nine studies analysed the methodological quality of 28 European clinical guidelines which focused on chronic diseases, using the AGREE appraisal instrument. The findings confirmed conclusions of other studies that there was considerable variation in quality. This indicates a lack of consistency in relation to some aspects of the information provided to clinicians across Europe. Inconsistencies in the quality of guidelines may have an impact on the quality of recommendations made and therefore on quality of care provided to patients. Moreover the findings consistently showed that the least well addressed AGREE domains were rigour of development, stakeholder involvement, applicability and, with the lowest score, editorial independence. There is thus "considerable scope for improvement in the methods used to develop clinical guidelines for the prevention, management and treatment of chronic diseases in Europe [4]."

For the systematic review on the effectiveness of the implementation strategy, a total of 21 studies were found. Overall only four studies found that the implementation or impact of guidelines was effective, eight studies showed partial effectiveness and nine studies did not demonstrate any effectiveness. However the results and the size effect varied across the included studies. The evaluation of the different implementation strategies showed that multifaceted implementation strategies are only slightly more effective than single intervention. Only four studies reported any data on the cost of the implementation but none undertook a cost-effectiveness analysis. Only one study presented data on the barriers to the implementation of guidelines, noting a lack of awareness and agreement about clinical guidelines. These results reveal once more that there are only a few rigorous studies which assess the effectiveness of a strategy to implement clinical guidelines in Europe. Therefore, "further research is needed to develop more rigorous studies to evaluate health outcomes associated with the implementation of clinical guidelines; to assess the cost-effectiveness of implementing clinical guidelines; and to investigate the perspective of service users and health service staff [5]." Needless to say that these issues fit the scope of *Health Policy* very well – so we are looking forward to receiving manuscripts helping to close the gap for evidence-based health policy-making in the area of tackling chronic disease.

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