Influencing physician prescribing in an international context
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Introduction
Chapter 1

General introduction

Relevance of “Rational Drug Use” in primary care

Drug therapy constitutes a central component of health care in Western countries:
In most developed countries, the share of drug expenditure of total health care costs is increasing over the last decades. In European countries, between 60% and 95% of physician consultations result in prescriptions, most of them in primary care. For instance in the UK about 80% of all prescriptions are issued in primary care. As a consequence, prescription costs in primary care often consume over 50% of the total budget. Therefore good prescribing is central for quality of care as well as for cost containment.

Quality and cost of prescribing
Quality of prescribing has been an increasing concern due to the fact that evidence as reflected in guideline recommendations is not taken up to the degree expected. This was often more pronounced in primary care. For instance CHF patients in Europe who are mainly treated in primary care, were prescribed the first line drug (ACE-inhibitors) between 48% -76%.

In addition, there is mounting evidence of variation in prescribing between individual physicians, settings and countries, raising additional concerns about quality and use of up-to-date evidence.

The need for efficient resource utilization on the other hand causes most Western countries to continuously adapt and reform their health care systems. Therefore policymakers are in need of evidence about treatment quality and costs and effects of regulatory and organizational measures. However, scientific evaluations about those are still sparse and evaluations of policy interventions are mostly national, often cross-sectional or narrative. Many methodological questions remain unsolved with policies, unlike scientific trials, being introduced within a constantly changing environment.

Descriptive versus evidence based methods in comparative health care research
Consequently, as Marmor and Okma put it: “As there is no realistic laboratory for experiments in major welfare state programs, nations understandably turn to the experiences of others when seeking solutions for their policy problems.”. This growing comparative research builds
mostly on qualitative policy analysis, but quantitative efforts to compare performance and assess effects of interventions between countries are applied increasingly.

Also in clinical research interest in comparative studies is increasing. In chronic heart failure for instance international initiatives are looking at risk factors\textsuperscript{17,18}, quality of prescribing\textsuperscript{19-22}, uptake and effects of new technologies\textsuperscript{23} and the organization of care\textsuperscript{24}. The importance of the health care setting for clinical performance is recognized increasingly. This is for example reflected in the updated European guideline for chronic heart failure: ‘Depending on the local health care system, it seems important to determine which health care provider is the most appropriate to participate in various components\textsuperscript{25}.

At the same time, a more evidence based approach is reflected in growing efforts to make policy evidence-based\textsuperscript{26}. Corresponding to the systematic reviews performed by the Cochrane collaboration in clinical medicine, the Cochrane Effective Practice and Organisation of Care Group (EPOC) as a part of the Cochrane collaboration aims to add evidence for policy makers with systematic reviews, applying defined criteria of study-design and grading of evidence. The scope covers “educational, behavioural, financial, organisational and regulatory interventions designed to improve health, professional practice and the organisation of health care services”\textsuperscript{27}.

\textbf{Quality assessment in clinical medicine}

Once the concept of EBM was established, good quality was defined based on the evidence and therefore measurable. Accountability of health care performance gained importance for clinicians and policy makers alike and promoted quality improvement efforts in medical care over the last decades\textsuperscript{28,29}.

Physician centered instruments to improve quality of prescribing include educational initiatives such as continuous medical education, clinical guidelines\textsuperscript{30}, organizational measures such as interdisciplinary care structures (e.g. disease management programs) as well as the introduction of quality management systems. These quality systems usually include audits, benchmarks and feedback\textsuperscript{31} and therefore require performance assessment. As a consequence, methods to measure quality had to be refined and performance indicators are developed not only for research, but also for benchmarking prescribers\textsuperscript{32-35}. Increasingly performance indicators are also used as a base for financial and contractual arrangements\textsuperscript{36-38}. Therefore, professional interventions to increase prescribing quality on the one hand and regulatory measures to enhance cost effectiveness on the other are more and more overlapping and have to be considered in the light of the health care setting\textsuperscript{39-41}.
Chapter 1

Scope of the thesis

This thesis is aiming to increase the understanding of factors influencing prescribing in an international context and with a focus on the health care setting. Two approaches are used to tackle that issue:

**Part 1: Cross sectional analysis using the example of heart failure:**

In part one, cross-sectional analysis was applied as a methodological approach to explain international variation in prescribing. Prescribing for chronic heart failure in European primary care is used as a case study. Treatment of chronic diseases in old age such as heart failure is of especially high relevance for health care.

Heart failure poses a major burden to Western societies with supposedly 10 million people in Europe\(^42\) or about 2% of the population affected\(^43,44\). Prevalence of chronic heart failure will further increase due to ageing societies, being a disease of older age and due to vastly improved treatment options\(^45-48\). However, chronic heart failure is still a highly malignant and debilitating disease with high mortality\(^49\). Its treatment consumes up to 2% of the HC budget. While being highly malignant, heart failure prognosis can be vastly influenced by effective treatment.

Drugs form the most important part of CHF treatment and innovations mostly resulted in additions of newer drugs rather than replacements of older drugs. Since the beginning of the 1990ies, a heart failure patient should always receive an ACE-inhibitor as first line drug (Trials e.g. SOLVD\(^50\), consensus\(^51\), ELITE)\(^52\). Beta-blockers, after being obsolete in impaired cardiac function until the mid-nineties, should now as well be considered in all symptomatic patients (Merit-HF, CIBIS-II)\(^53\). In severe heart failure, additionally aldosterone antagonists are increasingly recommended since the RALES study\(^54\). Alternatively or in addition, there are traditional drugs such as glycosides without proven beneficial effects for patients without atrial fibrillation as well as newer angiotensin-II antagonists and selective RAAS inhibitors. Patients usually will also be treated symptomatically with diuretics, and frequently with anti-arrhythmics and anti-thrombotic agents\(^55\).

To firstly understand how much of the international variation of heart failure drug therapy can be explained by differences in patient populations, the relevance of co-morbidities and other patient characteristics for treatment quality was assessed in Chapter 2, using multivariate analysis.
The example of heart failure prescribing was also used to further investigate reasons for variation at a national level in Chapters 3 to 5. Next to focusing on knowledge centered factors responsible for physician decision-making, the role of the care environment, of organizational, legal and financial factors is increasingly getting in focus.

In Chapter 3 the focus is on one of the most commonly used policy option addressing prescribers directly, i.e. guidelines. National guideline recommendations for chronic heart failure across Europe were compared and related to clinical prescribing data. The hypothesis was, that significant differences in national recommendations should be reflected in national prescribing patterns.

The relevance of the country’s health care setting as a statistical determinant for prescribing in addition to patient characteristics was assessed in Chapter 4.

To further illuminate the role of individual settings within European primary care a multilevel analysis was used in Chapter 5 to test the impact of individual primary care structures on prescribing for heart failure in Europe.

**Part 2: Systematic Reviews:**
In the second part we present two examples applying the strict methods of systematic Cochrane reviews to evaluate effects of pharmaceutical policies on rational drug use. These reviews are part of a series of systematic Cochrane reviews on pharmaceutical policies, investigating their effect on either drug or health care utilization, costs or health outcomes. Pharmaceutical regulations can generally target all players in the health care field. In Chapter 6 the effects of pricing (e.g. reference pricing) and purchasing policies are evaluated, providing an example of policies which do not directly address physicians, however nevertheless are intended to influence drug utilization and expenditure.

In Chapter 7 pharmaceutical policies using financial incentives for prescribers are assessed. This is an example for policy interventions directly addressing prescribers. The general trend to introduce market elements in health care during the last decades or so also induced arrangements which made prescribers increasingly accountable for resource use induced by their treatment, including prescribing. This review deals mainly with budgetary policies including fundholding in the UK and drug budgets in Germany.
In Chapter 8 we summarize the main findings and discuss their wider implications for research and practice.

References


