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The international generalisability of evidence for health policy: A cross country comparison of medication adherence following policy change

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ABSTRACT

Copayments for prescriptions may increase morbidity and mortality via reductions in adherence to medications. Relevant data can inform policy to minimise such unintended effects. We explored the generalisability of evidence for copayments by comparing two international copayment polices, one in Massachusetts and one in Ireland, to assess whether effects on medication adherence were comparable. We used national prescription data for public health insurance programmes in Ireland and Medicaid data in the U.S. New users of oral anti-hypertensive, anti-hyperlipidaemic and diabetic drugs were included (total n = 14,259 in U.S. and n = 43,843 in Ireland). We examined changes in adherence in intervention and comparator groups in each setting using segmented linear regression with generalised estimating equations.

In Massachusetts, a gradual decrease in adherence to anti-hypertensive medications of −1% per month following the policy occurred. In contrast, the response in Ireland was confined to a −2.9% decrease in adherence immediately following the policy, with no further decrease over the 8 month follow-up. Reductions in adherence to oral diabetes drugs were larger in the U.S. group in comparison to the Irish group. No difference in adherence changes between the two settings for anti-hyperlipidaemic drugs occurred.

Evidence on cost-sharing for prescription medicines is not 'one size fits all'. Time since policy implementation and structural differences between health systems may influence the differential impact of copayment policies in international settings.

1. Introduction

Health policy interventions such as copayments for prescription drugs aim to control third party payer costs. Despite their rational underpinning, a large body of research has accumulated over the past four decades detailing the negative impact of prescription copayments on prescription drug use and subsequent health outcomes [1–3]. Most studies have found that as the price of the copayment increases, patients reduce their adherence to essential life-prolonging drugs that are used in the treatment of chronic disease [1,4,5]. In this way, copayments for prescription drugs are associated with increased morbidity, mortality and increased health care costs [3,6–8].

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While the results of previous research on copayments are mostly consistent, the majority of studies included in existing systematic reviews have been conducted in the U.S. and Canada [1,2,5,9–11]. For example, all studies included in a review by Gibson et al. were from the U.S. or Canada, 54 out 65 studies in a review by Goldman et al. were from North America or Canada and so were 18 out of the 21 studies in a Cochrane review on the same topic [1,2,9]. The limited geographic diversity of the available evidence raises questions about the generalisability of results to European health care systems with dissimilar financing, organisation and delivery of pharmaceutical care [12]. Given that the development of evidence-based policy is contingent upon the availability of valid, reliable evidence pertinent to the health system of interest, this issue of uncertain generalisability may hinder international policymakers seeking to design prescription drug cost-sharing policies in their unique regional settings [13,14]. For example, when policymakers in countries outside of the U.S. and Canada are planning their own prescription copayment policies, they will turn to the extant body of systematic reviews and primary research for guidance on the effectiveness of these policies. The challenge they face in this task is assessing how this evidence applies to their own local setting [13,15].

Cross country comparisons of drug adherence related to cost have been carried out in the past [16,17]. However, these studies were not focused on analysing the impact of a policy intervention, rather they reported on prevalence of existing self-reported non-adherence. Thus, these results are not useful in providing context for developing copayment policies [18], or in anticipating potential patient behaviours resulting from such policies.

To formally address this question of potential international heterogeneity, we designed a case study to compare the effects of similar changes in prescription copayment policies, one in Massachusetts and one in Ireland, on subsequent adherence. By comparing analogous policy changes, we assessed whether changes in adherence behaviours, in response to pharmaceutical policy intervention, were broadly generalisable across these two health systems. We discuss our findings using the framework suggested by Lavis et al. to demonstrate how international evidence should typically be assessed for local applicability [13].

2. Methods

2.1. Ethics

Ethical approval was granted by the Clinical Research Committee of the Cork Teaching Hospitals, Ireland and the Institutional Review Board at Brigham and Women's Hospital, Boston, MA, USA.

2.2. The General Medical Services scheme and Medicaid

The General Medical Services (GMS) scheme is the national tax-funded public health insurance program in Ireland for people on low incomes and people aged ≥70yrs. It provided hospital services and primary health care, including general practitioner visits and prescription drugs, to approximately 40% of the population (1.85 million people) in 2013 [19]. In the U.S., Medicaid is the main public health insurance programme for low-income parents and children, caregivers, pregnant women, disabled adults and low income seniors [20]. In 2011, Medicaid provided healthcare for 41 million people across the U.S. including 864,500 people in Massachusetts (∼13%) and 1.6 million people in Pennsylvania (∼13%) [21].

2.3. Policy interventions

In January 2013, individuals on the GMS scheme were required to pay a €1.50 copayment per prescription dispensed, an increase of €1 from the previous charge of 50c. Beginning January 2003, Medicaid beneficiaries in Massachusetts were required to pay a $2 copayment per prescription, an increase of $1.50 from the previous charge of 50c.

2.4. Patient populations and data sources

The GMS population comprised the Irish intervention group. The comparator group included patients in the publicly funded Long Term Illness (LTI) scheme, because there was no policy change on this scheme throughout the study period. LTI coverage provides free prescriptions only and is provided to approximately 60,000 individuals who have been diagnosed with one of 16 chronic conditions e.g., diabetes or epilepsy, regardless of their income [22]. If an individual has a long term illness, but is also low-income, he/she will qualify for the GMS. Person level pharmacy claims data for the GMS and LTI schemes were retrieved from the Health Service Executive Primary Care Reimbursement Services (HSE-PCRS) national database years 2012–2013.

In the U.S., the Massachusetts Medicaid population comprised the intervention group. The comparator group included Pennsylvania Medicaid beneficiaries because the copayment in this state remained static ($1/item) throughout the study period. We used person level pharmacy claims data for Massachusetts and Pennsylvania Medicaid beneficiaries in the U.S. Medicaid Analytic Extract database (MAX), 2002–2004. Both MAX and PCRS databases have been shown to accurately reflect medication use [23,24].

Eligible patients were 21–65 years and had continuous eligibility on their respective insurance schemes for the study period.

2.5. Study design

We employed a repeated measures retrospective study. We included new users (no drug claim in that medication group in the previous 6 months) of an oral drug for hypertension, hyperlipidaemia and/or diabetes in the 6 months prior to policy initiation [25,26]. Follow up ran from cohort entry until 8 months after policy implementation (Supplementary information 1). New users of chronic disease drugs follow a well-defined pattern of adherence, with typically 50% of new users remaining adherent 6 months post initiation [27–29]. Our study design allowed new user adherence patterns to occur as expected, but allowed anal-