



The role of physicians in prescribing irrational fixed-dose combination medicines in India



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ABSTRACT

Many irrational fixed-dose combination (FDC) medicines have been approved by the state and central regulatory authorities in India and their use is promoted extensively by pharmaceutical firms. In this study, we examine the previously-neglected role of physicians in India, as their prescriptions are essential for the continued proliferation of FDCs. Primarily using longitudinal data on prescriptions by 4600 physicians spanning 19 disciplinary categories for 48 months between 2008 and 2011 provided by IMS Medical Audit, we study 201 medicines in the cardiovascular and oral-antidiabetic markets. We find that 129.6 million (8.1%) prescriptions for irrational FDCs were written by the sample of physicians in India during the study period, half of which were written by cardiologists and consulting physicians. A further analysis of the regional markets reveals that cardiologists prescribe more irrational FDCs in the richer, metropolitan cities of western India. We also document the role of medical practitioners without an undergraduate degree in medicine in generating prescriptions for irrational FDCs. Our results suggest that an effective government strategy to curb irrational FDCs must recognize that spreading greater awareness about the perils of irrational FDCs is at best an incomplete solution to the problem in India as many who prescribe them are specialists. Organizations such as the Indian Medical Association must develop clear guidelines to stop prescribing such FDCs.

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1. Introduction

Several recent studies have highlighted the proliferation of irrational fixed-dose combination (FDC) medicines in India (e.g., Evans and Pollock, 2015; Gautam and Saha, 2008). FDCs refer to medicines containing two or more plain molecules. For example, Atorvastatin and Aspirin—two plain molecule medicines of independent therapeutic value—are combined and sold in a single tablet form, often under a separate brand name. Many FDCs, including the combination of Atorvastatin and Aspirin, are rational as they improve patient adherence to the medicine regimen and provide added therapeutic value (e.g., Nakamura et al., 2006). Indeed many FDCs are listed in the World Health Organization's model list of essential medicines, including antiretroviral drugs (WHO, 2013). Yet some FDCs can have negative consequences. They may lead to adverse drug reactions and to the growth of resistance to medicines such as antibiotics (Kotwani and Holloway, 2014).

Even when the combination is harmless, it is often unnecessary rendering the combination medicine more expensive for the patient compared to the plain medicine alternative. While the use of irrational combinations is not limited to India, it has become a particularly troubling trend in the recent years, causing the Indian government to discuss ways to contain their continued proliferation and for scholars to study the factors behind their diffusion (Parliament of India, 2014). The Indian government recently imposed a ban on 344 FDCs in March 2016 (Indian Express, 2016) but what has driven their diffusion remains understudied in prior work.

Prior studies have expressed alarm at the presence of some irrational combinations and their unabated introduction into the Indian market. For example, Chakrabarti (2007) studies a sample of 2163 physicians in India and finds that 59 percent of their prescriptions for diarrhoea included an irrational combination of an antiprotozoal and an antibacterial medicine, whereas the condition can only be caused by one of the two factors but not by both simultaneously in a patient. Another type of irrational combination is Glimepiride and Metformin, which outsells Metformin in India but there are no scientific studies to suggest the added beneficial

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health effects of the combination (Bhaskarabhatla et al., 2016; Evans and Pollock, 2015). Yet another type of irrational combination medicines arises when the two drug components have no adverse interactions and may be prescribed as separate medicines but cannot be taken together as a combination medicine. For example, Diclofenac and Omeprazole fixed dose combination medicine is irrational as one is to be taken on an empty stomach and the other not. Prior studies have generally implicated poor training and targeted promotional activities by pharmaceutical firms for such prescription patterns (Narendran and Narendranathan, 2013). That said, previous studies have not examined the type of physicians that contribute to the continued growth of FDCs after their introduction.

2. The role of the regulator, pharmaceutical firms, and the physicians in India

In this study, we ask which type of physician is behind the proliferation of irrational combination medicines in India. As documented by Evans and Pollock (2015) and an Indian parliamentary committee examining the issue, the regulatory body named the CDSCO (Central Drugs Standard Control Organization) entrusted with the job “to protect and promote public health” in India continued to allow the introduction of irrational combinations (CDSCO 1961–2013). The CDSCO has appointed an expert committee to evaluate FDCs approved by some individual states but not by the central regulator. In recent years, Indian pharmaceutical firms have introduced FDCs—including the irrational ones—excessively as a strategy to build newer brands. Such brand proliferation is known to deter entry by other firms (e.g., Schmalensee, 1978). It is estimated that the CDSCO's expert panel received 5000 applications for FDC approval, which is nearly two times the number of medicines—plain and combinations—sold currently in India (PharmaBiz, 2014). In the area of cardiovascular and oral-antidiabetic medicines we study, nearly 40 percent of the medicines as well as brands are FDCs. Therefore, beyond the obvious role played by the regulatory authority and the pharmaceutical firms in introducing them, what role do physicians and other health care professionals play in the subsequent diffusion of irrational combination brands in India?

In this paper, we focus particularly on the type of physicians generating prescriptions for irrational combinations in India. Those who prescribe medicines in India are composed of physicians, non-physician clinicians, and other healthcare professionals empowered by the Government in India. For example, to meet its public health challenges, India expanded its rural health infrastructure and brought in many individuals untrained in a medical school (Sachan, 2013; Times of India, 2013a). Not surprisingly, prior studies have found that their prescriptions are generally inappropriate (Banerjee and Bhaduri, 2014; Gopalakrishnan et al., 2013). Others prescribing medicines include practitioners of traditional Indian medicine such as ayurveda and other practices such as homeopathy, which are growing in prevalence (Prasad, 2007). Recent studies have found the prescription patterns of such non-medical professionals to be inappropriate as well (Rao et al., 2013). In addition, the Indian Medical Association has recently expressed concern that students in medical schools without yet receiving a formal degree are posing as doctors and prescribing medicines. For example, in the therapeutic area of diabetes, there have been concerns that self-styled diabetologists have surfaced, whereas such degrees are not awarded by any educational institution (Times of India, 2013b).

Many scholars have called for programs to spread greater awareness about the negative effects of irrational combinations. Underlying such a policy recommendation is the assumption that it is predominantly the untrained intruders into the health care

system writing unscrupulous prescriptions that sustain the growth of irrational combinations in India. In addition, it is assumed that such unqualified prescribers of medicines are driving prescriptions uniformly across all regions in India including the metropolitan cities and non-metropolitan cities and towns. We challenge such assumptions because the growth reflects a wider participation of general physicians and specialist doctors in driving prescriptions. We quantitatively examine the relative contribution of prescriptions to irrational combination medicines by several categories of physicians.

2.1. Aims & research question

To summarize and reemphasize, our baseline research question is as follows. Beyond the obvious role played by the regulatory authority and the pharmaceutical firms in introducing them, what role do physicians and other health care professionals play in the subsequent diffusion of irrational FDCs in India? In addition, we aim to investigate in this study the relative contribution of prescriptions to irrational FDCs by several categories of physicians, the key pharmaceutical firms who are significant manufacturers of such medicines in India and the sub-national heterogeneity in prescribing behaviour by various physicians for these medicines in the country.

2.2. Data and methodology

Evans and Pollock (2015) highlight the problem of irrational FDCs using the example of Metformin, an oral-antidiabetic medicine used commonly as a first line of treatment. In building on their work, we focus on all 201 cardiovascular and oral-antidiabetic (OAD) medicinal molecules sold in India, as they represent one of the rapidly growing public health challenges in India, described by some experts as a ticking time bomb and by the International Diabetes Federation as the diabetes capital of the world (Shetty, 2012). We exploit two datasets compiled by IMS Health India for the period 2008 to 2011, which have been used before by Dutta (2011) and Chatterjee et al. (2015). First, we use IMS Medical Audit dataset, which is based on a panel of 4600 physicians across India disaggregated into 19 different general and specialist categories. Second, we use data on the sales of medicines, which is based on a sales audit of nearly 55000 retailers across India. The datasets are a monthly time series panel spanning 48 months. The data span 9369 brands and 224 firms and is structured at the brand-physician cohort-region-month level for the 201 molecules in our sample. We observe how many prescriptions of various brands are written by all our cohorts of physicians, in various regions of India in each of our 48 months between 2008 and 2011. The data are further disaggregated at the level metropolitan and non-metropolitan cities of Northern, Western, Eastern and Southern India.

In order to investigate whether various types of physicians are more or less likely to prescribe irrational medicines, we conduct a multivariate regression analysis. We estimate an ordinary least squares model as follows:

$$\log(1 + \text{prescriptions}_{ijft}) = \alpha + \beta \cdot \text{physiciantype}_{ijft} + \gamma \cdot \text{physiciantype}_{ijft} * \text{irrationalmedicine}_j + \delta_j + \omega_t + \kappa_f + \varepsilon_{ijft} \quad (1)$$

where prescriptions refers to the number of prescriptions written by cohort of physicians i in medicine (or molecule) market j for

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