Social Science & Medicine 72 (2011) 202–205

Contents lists available at ScienceDirect

Social Science & Medicine

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

The antagonism of push and pull strategies, and the current funding campaigns to fight orphan diseases

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ARTICLE INFO

Article history:
Available online 25 November 2010

Keywords:
Push and pull mechanisms
Orphan diseases
Optimal policies
Developing countries
Public good

ABSTRACT

We argue that an increase in investments in R&D for innovative treatments to eradicate neglected diseases in developing countries leads to a rational decrease in investments in available treatment technologies. In a formal model where the government of a developing country seeks to optimally allocate public resources, we show that the higher the odds of appearance of an innovative treatment, as occurring when investments in R&D increase, the lower the optimal provision of current treatments and other health expenditures. We also show that this phenomenon is aggravated when the opportunity cost of investments in current treatments increases. This implies that welfare in developing countries deteriorates as innovative treatments are more likely to become available. We also describe an insurance scheme that remedies these issues, and that leads to Pareto-optimal allocations regardless of the investment level in R&D for innovative treatments.

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Introduction

Many diseases such as HIV/AIDS, malaria and tuberculosis have a high prevalence in poor countries. Treatments exist for many of them, but their cost is prohibitive and their effectiveness can largely be improved. Despite large international aid, most of the cost of eradicating these pandemic with available treatments remain on poor countries (see UNAIDS, 2005). In a broader context, Philipson, Jena, and Mechoulan (2010) argues that the world's willingness to pay for better global health in developing countries is as much as 2 percent of total domestic health spending in these countries.

Large financial efforts are nonetheless allocated in developed countries to make available innovative and cheaper treatments for these diseases; in particular, Push and Pull Mechanisms described later aim at restoring incentives for private pharmaceutical companies to initiate R&D in innovative treatments. A typical example is the worldwide effort to develop a therapeutic vaccine against HIV/AIDS (see Klausner et al., 2003).

We argue that these mechanisms alone, and without an insurance mechanism described here, are antagonistic with the current campaigns in developing countries aimed at fostering the delivery of available treatments. In particular, we show that an increase in investments in Push/Pull Mechanisms leads to a temporary decrease in welfare in developing countries because of a resulting rational reduction in patients' coverage. Moreover, we show that this paradoxical reduction increases as the opportunity cost of current investments increases, as it is typical with severe budget shortfalls. The availability of securities as in Leoni and Luchini (in press), for instance, restores incentives to invest in available treatments, regardless of the financial efforts put into Push/Pull Mechanisms.

On top of describing these securities, Leoni and Luchini (in press) analyze the welfare improvement in developing countries resulting from their availability, regardless of the odds of appearance of innovative treatments. We extend this analysis by pointing out that optimal investments in available treatments are strongly decreasing in investments in Push/Pull Mechanisms, and that opportunity costs of current investments is an aggravating factor to this phenomenon. Therefore, we argue that the availability of the insurance scheme above becomes increasingly important to compensate for welfare losses as the obsolescence of current investments becomes more imminent and budget shortfalls increase. These findings are consistent with standard results in optimal investments as in Dixit and Pindyck (1994, Chap. 1–7).

The fact that a likely rapid obsolescence leads to lower health investments is consistent with some recent observations in the case of HIV/AIDS, even if a direct causality is not yet established. In 2005 for instance, UNAIDS (2005) p.11 reports that some Sub-Saharan countries were in measure to rationally increase their AIDS-related expenditures but failed to do so despite high prevalence; these sovereign decisions occurred during the R&D phases of a therapeutic vaccine both by Merck and the Pasteur Institute. No such behavior was reported after the failure of these two ventures, even if we strongly emphasize that many other explanations are possible.

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doi:10.1016/j.socscimed.2010.10.031

The paper is organized as follows. We first give concrete examples of Push/Pull Mechanisms and an overview of current funding campaigns worldwide with available treatments; we then explain and document the antagonism created by these efforts; concluding remarks are then presented; finally, the formal model and the proofs are given in the Appendix.

Push/Pull Mechanisms and international aid

There are specific deterrents for a private pharmaceutical company to invest in R&D for diseases found in developing countries. The risk of failure is high in many cases (a therapeutic AIDS vaccine for instance), the market is not profitable enough because most of the infections are in poor countries, and there is a history of breaking patents at least for HIV/AIDS. At the same time, innovative treatments are critically needed in developing countries to contain and then to eradicate these diseases, and private companies are the most likely to develop them (Webber & Kremer, 2001). In the case of HIV/AIDS, the new technology capable of challenging the many drugs patents already in place is a therapeutic vaccine, which could delay the need for current treatments such as ARV drugs for several years at a low cost (see Klausner et al., 2003, and Wei et al., 2004).

There are difficult medical challenges to overcome when developing such innovative treatments. *Push Mechanisms* tackle these pitfalls, by reducing the cost of R&D failure and facilitating widespread dissemination of scientific knowledge. Push Mechanisms have in part focused on developing research grants to universities and on increasing knowledge transfer at international level. A typical example is the International AIDS Vaccine Initiative (IAVI, 2004), which has already worked with academia and industry to launch 4 vaccine development partnerships in Sub-Saharan Africa. Other examples of push strategies involve tax credits to commercial companies seriously undertaking vaccine development, whose purpose is to transfer the cost of failure to society as a whole.

Pull Mechanisms foster the commercialization phase, which is deficient because of low market return and high risk of loosing patent's rights. The most common pull mechanism in the U.S. is a tax credit on sales to organizations officially designated for the delivery to patients in developing countries. Another particularly promising pull mechanism is an *Advance Market Commitment* (or AMC), as described in Berndt et al. (2007) and Towse and Kettler (2005) for instance. Other interesting attempts are transferable patent extensions, which allow an extension on another existing patent when the current patent is broken, and a transferable priority regulatory review with direct consequence to speed access to highly valued treatments (see Ridley, Grabowski, & Moe, 2006).

Independently of these initiatives, there are many programs at international level aimed at fostering investments in current treatment technologies. Among these initiatives, we point out the '3 by 5' initiative that was an ambitious project launched in 2003 by UNAIDS. The GFATM also received U.S.$ 9 billion in 2001 to coordinate prevention, care and treatment worldwide mostly against HIV/AIDS but also against other orphan diseases (in a broad sense, which a strong emphasis in diseases with high incidence in developing countries). Roughly U.S.$ 2.5 billion have been invested in HIV programs, and treated 220,000 patients between 2001 and 2005 (Lamptey, Johnson, & Khan, 2006). A third major initiative was the launch in 2003 of the U.S. President's Emergency Plan For AIDS Relief. This plan spanned 5 years and was endowed with U.S.$ 15 billion to fight HIV/AIDS beyond U.S. borders.

The relative importance of this foreign aid may have significant spill-over effects on domestic expenditures, such as fungibility and crowding-out effects. Feyzioglu, Swaroop, and Zhu (2005) and Agosin and Machado (2005) report no significant empirical evidence of these effects at macro-economic level in developing and emerging countries, both for direct aid and foreign investment. A similar study for health expenditures is nonetheless missing.

The antagonism and a solution

The identification of the antagonism between Push/Pull Mechanisms and these funding campaigns, and a possible solution to remedy it, is a central element of optimal public policies in developing countries affected by widespread pandemic. The main reason is that current campaigns targeted at delivering available treatments are funded both by international agencies, developed countries, and also foremost by developing countries. UNAIDS (2005) reports that, during the period 2004–2007, roughly one-third of the overall burden worldwide to treat HIV-patients with available treatments was born by some of the poorest countries in the world. In particular, Hickley (2003) argues that slightly less than 1% of overall national expenditures of South Africa in 2005 was allocated to HIV/AIDS only. The basic insight of the antagonism is described next, whereas the formal point is developed in the Appendix.

Consider a government in developing countries, facing the decision of investing large amount of resources to treat a particular disease with available treatments in a situation of major budget shortfalls. A critical aspect of these investments is that a significant part will be foregone when an upgrade occurs because of the introduction of an innovative treatment, as documented next for the case of HIV/AIDS.

Managerial costs, also called *Program Level Costs*, are the most natural sunk costs and clearly lost when upgrading. These costs include monitoring and evaluation of current delivery policies, staff training, supervision of personnel and patients tracking. United Nations estimates assert that such costs amounted to US$ 1.236 billion in 2006, US$ 1.095 billion in 2007 and US$ 1.281 billion for all 135 low and middle income countries (UNAIDS, 2005). In South Africa for instance, these costs roughly amount to 8% of the global investment in ARV treatment program (Cleary et al., 2005). Even if these losses are not direct monetary losses, the opportunity cost they trigger is enormous for developing countries in situation of severe budget shortfalls, and this must be encompassed in any optimal public policy.

Other severe losses when upgrading are on the drug production side. ARV drugs are often produced in developing countries, for instance in Brazil and India, where the patents have been broken. The nature of ARV treatments makes any reshuffling of these plants too expensive because of rigid manufacturing plans and costly regulatory requirements (Shah, 2004).

The risk faced by developing countries is about the date of obsolescence of these current investments. The longer the current investments remain in place, the higher the return and benefits to society as a whole. We next see how the uncertainty about the time these losses occur distorts optimal decisions to invest now in available treatments technologies.

The optimal decision of investing now in current treatment technologies is based on the comparison between the return of the investments on the one hand, and the overall social cost of the investments on the other. The social costs of these investments ought to include the opportunity cost of money; that is, the cost of not using this money for other necessary social needs such as building schools and roads. The decision to invest now is optimal when the expected social benefits exceed the expected social costs, where the expectation encompasses the random time of obsolescence of current investments. This method is standard in Economics, and it is studied in related setting in Dixit and Pindyck (1994).

Since the time of appearance is random, it is rational to use the expected time of appearance when making the above comparison. When better information becomes available over time, the estimator of the expected appearance time becomes more accurate, leading in turn to more reliable risk assessment. In our setting, the efficiency of

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