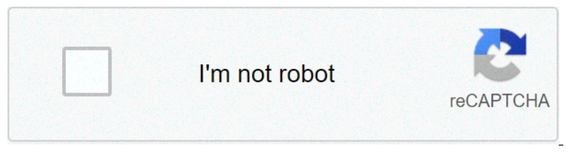

Continue

How to paint background trees

Modern medicine relies on effective antibacterial drugs, vaccines, and rapid diagnostic tools, collectively referred to as “antibacterial products” hereinafter, for the prevention, detection, and treatment of bacterial infections. Since antibacterial drugs first came into use in the 1940s, they have transformed mankind’s ability to combat deadly microorganisms and saved innumerable lives. However, use of these drugs is not without consequences. The mutations and natural selection processes that occur when an antibacterial drug is utilized can lead to the selection of strains of bacteria that are resistant to antibacterial drug or drugs. Many such strains (e.g., methicillin-resistant Staphylococcus aureus) are now quite common throughout the U.S. and the world. Today, the rapid rate of increase in antibacterial drug resistant bacteria combined with a weak pipeline for new antibacterial drugs threatens to create a public health crisis in which we are no longer able to effectively treat common infections (Kesselheim & Outterson, 2010; Laxminarayan & Malani, 2007; Infectious Diseases Society of America , 2004; Smith & Coast, 2013). Drug resistance problems are compounded by the misuse of existing antibacterial drugs. Antibacterial drugs are commonly overused by physicians and patients; for example, they may be prescribed to treat conditions caused by viral pathogens, which will not respond to antibacterial treatment, or for infections that will resolve quickly on their own. Additionally, under-treatment through inadequate dosage or inappropriate treatment duration can also give rise to resistant bacterial strains (Laxminarayan & Malani, 2007; Kesselheim & Outterson, 2010; Levy, 1992). Appropriate use of existing diagnostic tests and/or the development of new tests could help relieve selective pressure resulting from unnecessary or inappropriate antibacterial use. By identifying the etiologic causes of infections, diagnostic tools can help physicians determine an appropriate course of treatment for their patients. Unfortunately, many existing tests are too slow to provide results, too invasive or uncomfortable for patients, or too expensive to be practical (Laxminarayan & Malani, 2007). An alternative mechanism for reducing antibacterial drug demand is infection prevention, which might be achieved in part through more widespread vaccination, the development of additional vaccines, and more effective infection control, especially in health care facilities. Plus, there are likely to be spillover benefits from vaccination of part of the population to unvaccinated individuals. Nevertheless, the cost and voluntary nature of vaccinations hinder their uptake, and vaccines for some common infections, such as a vaccine to prevent infections caused by Staphylococcus aureus, are not yet available (Laxminarayan & Malani, 2007). Despite the potential of new antibacterial products to reduce the social burden associated with resistant infections, some of the large companies have been exiting the markets for antibacterial drugs and vaccines in recent years and have also not responded to the possible social value of opportunities in production of rapid diagnostic products. These market exits have been driven by the most basic of reasons: insufficient return to capital invested in development of these products. Commentators have identified a number of factors limiting markets for some new antibacterial products, including short treatment durations, an absence of market mechanisms to capture social benefits, challenges of conducting clinical trials, use of single-purchaser government power to limit payments for final products, and the availability of cheap generic drugs to treat most infections. However, empirical evidence is lacking to evaluate the relative impact of these factors (Kesselheim & Outterson, 2010; Mossialos, et al., 2010). Furthermore, there remain a number of participants in, as well as, new entrants to these markets and there are opportunities for novel products despite the exits of many large companies (Usdin, 2012). Current antibacterial product development efforts are directed primarily towards addressing the treatment of acute bacterial skin and skin structure infections including infections caused by methicillin-resistant Staphylococcus aureus (MRSA), Clostridium difficile associated diarrhea, and some infections caused by drug-resistant gram-negative pathogens. Given the potentially sizable social benefits of new antibacterial products, governments have been considering a number of alternative policies to foster development. While many approaches have been proposed, the path for policymakers to succeed in accelerating antibacterial product development is not well established. Further, a rigorous transparent analytical framework that can be used to systematically examine the effects of different policy alternatives is currently lacking. This study is therefore intended to fill that void by developing an analytical framework to evaluate the economics (private and social value) of development of antibacterial products that can aid in considering potential strategies designed to incentivize these antibacterial products. Page 2 Modern medicine relies on effective antibacterial drugs, vaccines, and rapid diagnostic tools, collectively referred to as “antibacterial products” hereinafter, for the prevention, detection, and treatment of bacterial infections. Since antibacterial drugs first came into use in the 1940s, they have transformed mankind’s ability to combat deadly microorganisms and saved innumerable lives. However, use of these drugs is not without consequences. The mutations and natural selection processes that occur when an antibacterial drug is utilized can lead to the selection of strains of bacteria that are resistant to antibacterial drug or drugs. Many such strains (e.g., methicillin-resistant Staphylococcus aureus) are now quite common throughout the U.S. and the world. Today, the rapid rate of increase in antibacterial drug resistant bacteria combined with a weak pipeline for new antibacterial drugs threatens to create a public health crisis in which we are no longer able to effectively treat common infections (Kesselheim & Outterson, 2010; Laxminarayan & Malani, 2007; Infectious Diseases Society of America , 2004; Smith & Coast, 2013). Drug resistance problems are compounded by the misuse of existing antibacterial drugs. Antibacterial drugs are commonly overused by physicians and patients; for example, they may be prescribed to treat conditions caused by viral pathogens, which will not respond to antibacterial treatment, or for infections that will resolve quickly on their own. Additionally, under-treatment through inadequate dosage or inappropriate treatment duration can also give rise to resistant bacterial strains (Laxminarayan & Malani, 2007; Kesselheim & Outterson, 2010; Levy, 1992). Appropriate use of existing diagnostic tests and/or the development of new tests could help relieve selective pressure resulting from unnecessary or inappropriate antibacterial use. By identifying the etiologic causes of infections, diagnostic tools can help physicians determine an appropriate course of treatment for their patients. Unfortunately, many existing tests are too slow to provide results, too invasive or uncomfortable for patients, or too expensive to be practical (Laxminarayan & Malani, 2007). An alternative mechanism for reducing antibacterial drug demand is infection prevention, which might be achieved in part through more widespread vaccination, the development of additional vaccines, and more effective infection control, especially in health care facilities. Plus, there are likely to be spillover benefits from vaccination of part of the population to unvaccinated individuals. Nevertheless, the cost and voluntary nature of vaccinations hinder their uptake, and vaccines for some common infections, such as a vaccine to prevent infections caused by Staphylococcus aureus, are not yet available (Laxminarayan & Malani, 2007). Despite the potential of new antibacterial products to reduce the social burden associated with resistant infections, some of the large companies have been exiting the markets for antibacterial drugs and vaccines in recent years and have also not responded to the possible social value of opportunities in production of rapid diagnostic products. These market exits have been driven by the most basic of reasons: insufficient return to capital invested in development of these products. Commentators have identified a number of factors limiting markets for some new antibacterial products, including short treatment durations, an absence of market mechanisms to capture social benefits, challenges of conducting clinical trials, use of single-purchaser government power to limit payments for final products, and the availability of cheap generic drugs to treat most infections. However, empirical evidence is lacking to evaluate the relative impact of these factors (Kesselheim & Outterson, 2010; Mossialos, et al., 2010). Furthermore, there remain a number of participants in, as well as, new entrants to these markets and there are opportunities for novel products despite the exits of many large companies (Usdin, 2012). Current antibacterial product development efforts are directed primarily towards addressing the treatment of acute bacterial skin and skin structure infections including infections caused by methicillin-resistant Staphylococcus aureus (MRSA), Clostridium difficile associated diarrhea, and some infections caused by drug-resistant gram-negative pathogens. Given the potentially sizable social benefits of new antibacterial products, governments have been considering a number of alternative policies to foster development. While many approaches have been proposed, the path for policymakers to succeed in accelerating antibacterial product development is not well established. Further, a rigorous transparent analytical framework that can be used to systematically examine the effects of different policy alternatives is currently lacking. This study is therefore intended to fill that void by developing an analytical framework to evaluate the economics (private and social value) of development of antibacterial products that can aid in considering potential strategies designed to incentivize these antibacterial products. MMEs must meet the eligibility requirements of both Medicare and Medicaid. At a high level, Medicare beneficiaries become eligible for Medicaid through one of three ways: having low income and few resources, incurring high medical expenses, or requiring institutional level of care (for a more complete description, see the companion study by Borck et al. (2013)).2 The transition from Medicare-only to MME status is of particular policy interest as it may represent a transition to impoverishment or a transition based on a need for more resource-intensive LTC services.3 Of particular policy concern are transitions that occur after an individual has become dependent upon institutional care and impoverished when those outcomes could have been prevented by early access to community-based services and supports. States and the Medicare program have little information at their disposal to design coverage in a way that will limit the number of Medicare beneficiaries becoming impoverished or unnecessarily reliant on institutional care, and thereby qualifying for Medicaid (Woodcock et al. 2011). The available literature suggests several characteristics that may be associated with the transition from Medicare-only enrollment to MME status, but many of these provide limited information to policymakers on how to target interventions to reduce unnecessary transitions to MME status. The likelihood of transitioning to MME status increases with age or as health declines, as measured by self-reported health status, the number of co-morbidities, and functional limitations (Pezzin and Kasper 2002, Shin and Moon 2005). Other characteristics linked to becoming MMEs include being female, having low educational attainment, living in the west or in rural areas, and residing in a LTC facility (Stuart and Singhal 2006). Recent studies of Medicare beneficiaries who transitioned to MME status offer more detailed insights about the population of the new MMEs. Borck et al. (2013) find that nationally, only about 2 percent of Medicare-only beneficiaries became dually eligible for Medicare and Medicaid in 2009, but this transition rate varied considerably by age group and across states. Nationally, most new MMEs live in the community, but transitions to MME status are much more common among those residing in nursing homes (Borck et al. 2013). A study based on beneficiaries living in Maryland finds patterns that are consistent with what is seen at the national level. About half of those transitioning from Medicare-only to MME status in Maryland became eligible due to establishing eligibility for Supplemental Security Income benefits or because they had too few resources to cover institutional care (Johnson, Folkemer, and Stockwell 2012). About 31 percent of new MMEs in Maryland used nursing facility services in the year prior to transition and almost half (48 percent) used inpatient services. The Maryland study also indicated that about 80 percent of the new MMEs in that state had Medicare claims for chronic conditions in the year prior to their transition and more than 60 percent had two or more chronic conditions, with an average of three co-occurring conditions per beneficiary (Stockwell, Trippe, and Folkemer 2012). Compared to the Maryland-based studies, which compare the characteristics of those who recently transitioned from Medicare-only to MME status to those who recently transitioned from Medicaid-only to MME status, this study focuses on predictive characteristics by comparing Medicare-only individuals who transitioned to MME status to Medicare-only individuals who did not. This type of ex-ante comparison can highlight patient characteristics and patterns of prior service utilization to give policymakers insights into the populations of Medicare beneficiaries who might be more likely to transition to MME status, and also potentially identify interventions that could either delay the transition or hasten it. Among these predictors, the link between nursing home care and transition to MME status has been documented (Woodcock et al. 2011), but other patterns may also exist. One possibility, for example, is that high costs related to emergency rooms (ERs) and inpatient hospitalizations may result in medical spending that causes an individual to become eligible for Medicaid. Given our finding in this report that nursing home use is a significant predictor of MME status, relevant predictors for nursing home entry are also potentially informative. For example, previous research suggests that dementia and the number of prescription drugs are significant predictors of institutionalization (Bharucha et al. 2004). Other characteristics include dependencies in three or more activities of daily living, cognitive impairment, and prior nursing home use (Gaugler et al. 2007). These possible causes for transition from Medicare-only to MME status raise important questions for policymakers: To what extent do service utilization patterns and beneficiary characteristics predict whether a Medicare beneficiary will become Medicaid eligible? Given the likely influence of nursing home use on becoming Medicaid eligible, what service utilization patterns predict entry into (non-skilled nursing facility) nursing home care? To what extent is the presence of certain chronic conditions associated with becoming dually eligible and entering a nursing home?