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Prevalence-Based Economic Evaluation

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ABSTRACT

Objective. Researchers have often stated that economic evaluations of new drugs have rarely been used to inform healthcare decisions, despite the large volume of published studies. In this paper, a new categorization for economic evaluations of new drugs is proposed: incidence-based and prevalence-based. This categorization is designed to increase the likelihood that decision-makers are given more complete and useable economic information about new treatments.

Results. Incidence-based evaluations (such as cost-effectiveness analysis) focus on the impact of a new treatment on a health condition from onset until cure or death. Prevalence-based evaluations focus on the impact of a new treatment on a health condition during a 1-year period. An incidence-based evaluation may focus either on a representative individual or on a specific disease cohort. A prevalence-based evaluation generally focuses on a specific population. Incidence-based evaluations measure the value of the new treatment compared to alternative treatments for the same health conditions and compared to commonly used treatments for other health conditions. Prevalence-based evaluations measure the impact of introducing the new treatment on annual healthcare budgets and population health.

Conclusion. Both types of evaluation provide important information when a new treatment is introduced to a population.

Healthcare costs in the United States continue to receive intense scrutiny as government and corporate budgets are increasingly constrained. Decisions about the total amount to spend on healthcare and the allocation of these resources are made by many different providers of medical care in a healthcare system. These decision-makers are responsible for containing costs and insuring that the resources available are used to provide more and better healthcare. In the United States these decision-makers include: healthcare policy-makers; administrators of managed care organizations; administrators of government healthcare programs such as Medicaid, Medicare, and the Veterans Administration; pharmacists; prescribing physicians; health insurance administrators; and employers who pay for much of their employees' health insurance premiums. All of these groups have a need for information on the economic value of alternative healthcare interventions if they are to make truly informed decisions about how much to spend on healthcare and how to spend that amount most efficiently.

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Recently, in a paper presenting a methodological approach for performing cost-effectiveness analyses (CEAs), Russell et al. [1] stated that "CEA is rarely used to inform decisions about health services in the United States." Sloan and Conover [2] make a similar statement: "Cost-benefit/cost-effectiveness analyses are rarely used in benefits coverage decisions." Davies et al. [3] noted the same lack of impact of CEA in the results of a survey in Europe that indicated that economic evaluation has had a relatively low impact on healthcare policy or healthcare decision-making despite the large volume of research studies that have been published. These findings raise a question about the usefulness of the product that the research community is delivering. Economic evaluations may not be useful because the information presented is not in a format that is useable and/or understandable by non-economists. Or it may be that researchers are providing data that answer questions from a perspective different from that of the decision-maker in terms of the range of outcomes included, the time horizon considered, and the population included.

Many published economic evaluations have as their goal the estimation of a cost-effectiveness ratio, computed as the incremental cost with the new treatment compared to the current therapy, divided by the incremental benefits with the new treatment

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for a typical patient. This cost-effectiveness ratio can be compared to a generally accepted value (e.g., $50,000 per life-year gained) to determine whether or not the new treatment for the specific disease is a good value for the money. This type of value measure is also very useful if decision-makers are trying to determine the best way to allocate healthcare funds between alternative uses. Thus, if they have a fixed healthcare budget and want to get the best value from that budget, they should allocate the funds to the uses that give the most return for each dollar spent. That is, they should allocate funds first to the uses with the lowest cost-effectiveness ratios.

In addition to a measure of drug value, such as that given by the cost-effectiveness ratio, decision-makers need to know by how much their annual budget is likely to increase or decrease in year 1, 2, and so on, after its introduction, if the new drug is added to the formulary. They also need to know what annual health benefits are likely to be associated with this budget increase or decrease. The need for this type of information has been stated recently by Foundation Health Corporation (FHC) in its 1996 guidelines for formulary submission [4]. However, there are very few published economic evaluations that give this type of information, although it is clearly of great relevance for decision-makers. In addition, this type of analysis is not generally included in methodological guides to economic evaluation such as Gold et al. [5].

In order to begin to fill this methodological gap, this paper presents a new categorization for economic evaluations for new drugs: *incidence-based* and *prevalence-based*, and describes general guidelines for performing each type of evaluation. The paper also illustrates, with examples, the value of prevalence-based estimates for different types of treatments. The routine completion by researchers of both types of economic evaluation for new drugs will insure that healthcare decision-makers have access to economic data in a format that is useful to them.

A New Categorization for Economic Evaluations of New Drugs

In their landmark study entitled "The Incidence and Economic Costs of Major Health Impairments," [6] Hartunian et al. distinguished between two analytic approaches for estimating the economic costs of illness. These are an incidence-based approach and a prevalence-based approach. The incidence-based approach estimates lifetime costs of health impairments that are incident (first occur) in the population in a given year. For each incident case, the total discounted costs attributable to that impairment are estimated regardless of whether those costs occur during the incident year or in subsequent years. Hartunian et al. used this approach to estimate the costs of major illness or accidents in the United States in 1975 [6]. By contrast, the prevalence-based approach estimates the costs attributable to all in the population with a specific health impairment during a specified year, irrespective of how long they have had the impairment. This approach was used by Cooper and Rice to estimate the costs of major illness in the United States in 1972 [7].

Although there is a long tradition of distinguishing between incidence-based and prevalence-based approaches for estimating total costs associated with specific health conditions [6], this distinction has not been applied to estimations of the impact of new drugs on healthcare costs and health and other outcomes. Table 1 summarizes the key attributes of the incidence-based and prevalence-based approaches when applied to economic evaluation of new drugs. The incidence-based approach estimates the impact of the new drug on expected lifetime costs and health and other outcomes for a disease cohort (all persons newly diagnosed with the disease in a given year) or for a representative person with the disease of interest. The prevalence-based approach estimates the impact of the new drug on healthcare budgets, population health, and other outcomes for years 1, 2, and so on, after the introduction of the new treatment into a specific population. Estimates using the incidence-based approach are useful to decision-makers for allocating a fixed budget among alternative healthcare interventions. Estimates using the prevalence-based approach are useful for decision-makers for budget planning and for understanding population health impacts. Recently, the distinction between the incidence-based and prevalence-based approaches for economic evaluations of new drugs was made by Mauskopf and Simpson [8] in a poster presentation entitled "The Costs and Benefits of Alternative Drug Treatment Regimens for HIV Patients," and the distinction is also made in the FHC guidelines [4].

Incidence-Based Approach

The incidence-based approach to economic evaluation is the traditional approach used by most analysts. Examples of analyses that follow this approach include cost consequence analysis, cost-effectiveness analysis, cost-utility analysis, and cost benefit analy-

Table I A new characterization of economic evaluations of new drugs

Analysis approach	Population studied	Time span	Example outcome measures	Value to decision-makers
Incidence-based	One-year incidence cohort or representative individual	Disease duration	Incremental lifetime costs Incremental life-years Cost per life-year gained	Budget allocation decisions among different treatments
Prevalence-based	All people with disease in 1-year period	One year	Annual change in healthcare costs Annual change in mortality or morbidity	Budget planning Reaching target health outcomes

sis [5]. In this approach, the impact of the new treatment on healthcare costs and health and other outcomes for the complete duration of the disease are estimated. These estimates may then be used to compute incremental cost-effectiveness or cost-utility ratios, comparing the new treatment with current treatments. Detailed descriptions of how to perform incidence-based economic evaluations are presented in several publications [1,5,9–11].

The outcomes generally included in these analyses include the impact of the new treatment on: direct healthcare service use and costs such as hospital care, outpatient visits, home healthcare, and drugs; direct nonhealthcare services such as transportation, medical devices, and paid caregiver time; indirect costs such as lost productivity; and health outcomes such as mortality rates and changes in functional status and quality of life. The outcomes included in a particular analysis depend on the perspective chosen. Gold et al. [5] recommend that a societal perspective, including all the outcomes listed above, should be used to compute a cost-effectiveness ratio for the reference case. Alternatively, if a health system or other perspective is taken, only a subset of these outcomes would need to be included in the analysis.

The recommended procedure in Gold et al. [5], for the societal perspective, is to look at only the impact of the new treatment on the outcomes associated with the disease of interest. For example, if people are prevented from dying prematurely because of a new treatment, the extra medical care costs for other diseases that they now live long enough to experience are not typically included in the analysis. If a health system or other perspective were taken, however, it might be appropriate to include these additional healthcare expenses.

The appropriate time horizon for these analyses depends on the disease. For an acute disease, the time horizon would be for as long as the complete episode of the disease. This may be 5–10 days for influenza or common bacterial infections, or it may be between 14 days and 2 years for a disease like zoster. For a chronic disease, the appropriate time horizon is the patient's remaining lifetime. For diseases lasting more than 1 year, future treatment costs and benefits are discounted back to the initial year at a recommended rate of 3% [5].

Sources of data for incidence-based analyses include clinical trial data, observational databases, and expert opinion. The impact of the new treatment on clinical endpoints will generally be derived from clinical trial data. The impact on healthcare service use may also come from clinical trial data or may be obtained using observational databases or expert opinion. Data from clinical trials for long-lasting acute illness and for chronic illness will not generally extend for the complete time horizon. They may need to be extrapolated to the full time horizon using observational databases and expert opinion. For example, if we are interested in a cost-effectiveness analysis for cholesterol-lowering drugs, clinical trials may only last for a period of 1 year. If the key outcome is the reduced risk of coronary events or stroke, this will not occur until many years into the future. Only if the clinical trial is an extended one (such as the Scandinavian Simvastatin Survival Study [4S] [12]), will the trial data be able to be used for direct estimates of the reduced risk of these longer-term outcomes.

The focus of incidence-based economic evaluations is generally the individual patient. The impact of the new treatment on lifetime costs and health benefits for a representative patient are estimated. The impact of the new drug may be different for different types of patients, either those with different disease severity or those with different demographic characteristics. It is important that incidence-based approaches recognize the differences in the value of new treatments for different population subgroups, though this is not frequently attempted. Published examples of analyses that estimate the impact of a new treatment on different subpopulations include: 1) estimates of the impact of neonatal surfactant rescue treatment for respiratory distress syndrome subdivided according to size of the premature infant [13,14]; and 2) estimates of the impact of tissue-type plasminogen activator

(t-PA) compared to streptokinase for treating post–myocardial infarction patients subdivided according to subsets of patients defined by age and location of the myocardial infarction [15]. In both examples, the cost-effectiveness of the new treatment was very different for different patient subgroups.

Prevalence-Based Approach

The second approach to economic evaluation is the prevalence-based approach, where the impact of the new treatment on annual costs, annual health, and other outcomes in the population of interest is estimated. Impacts on annual costs, health, and other outcomes should be estimated both for the first year that the new treatment is used as well as projected out for future time periods.

A broad range of outcomes should be included in the analysis if the societal perspective is taken. For example, the outcomes impacted by a new treatment might include annual research and prevention costs, annual treatment costs and productivity losses, and annual deaths and nonfatal health events. There might also be changes in disease incidence and prevalence attributable to the new treatment, changes in the distribution of disease severity within the prevalent population, and even changes in the proportion of people with the disease who access and receive treatment. If a health system or other perspective is taken, only the relevant subset of these outcomes would need to be included in the analysis.

As with the incidence-based approach, the perspective of the analysis is important in determining whether or not to include additional costs from unrelated diseases. Although it is recommended [5] that estimates taking a societal perspective and using the incidence-based approach ignore additional costs from other diseases when a new treatment reduces the risk of premature death from the disease being treated, this might not be the appropriate standard for a prevalence-based approach for either the societal or health system perspective. The extra costs of treating additional survivors are real costs to society and decision-makers. The costs need to be included in the analysis for the analysis to be useful for their decision-making. These extra costs can be determined by estimating the increased size of the prevalent population as a result of the life saving treatment and estimating the total expected healthcare costs for these people. For example, drug prophylaxis for preventing pneumocystis carinii pneumonia (PCP) infection in persons with AIDS reduces the risk of death from PCP and thus increases overall life expectancy for persons with AIDS. If the number of newly diagnosed patients with AIDS stays constant, the size of the AIDS population alive at any time in a healthcare plan will increase as each patient lives for a longer time period after diagnosis. The additional healthcare costs because of the longer life expectancy should be included in prevalence-based economic evaluations whatever the perspective.

When looking at the impact of a new treatment from the prevalence perspective, additional data are needed beyond those needed for the incidence-based approach including estimates of the size, distribution of disease severity, and demographic characteristics of the population of interest. Epidemiology studies of the disease of interest will generally provide these data at the societal level. For example, natural history data for the disease (e.g., sex-, race-, and age-specific incidence rates, life expectancy with the disease, and typical disease course) can be used to categorize the prevalent population in terms of number of people at each level of disease severity. These data can be used in combination with the results of the incidence-based analyses to compute estimates of the annual budget and health impacts of the new treatment. For example, prevalence-based cost and health outcomes estimates for a short acute nonfatal illness will equal the incidence-based cost and health outcomes estimates times the number of cases in the population of interest. This relationship will be more complex for acute illness with a nonzero fatality rate (i.e., acute illness that may last for an extended period of time) or for chronic illnesses.

Populations are likely to include people with a mix of ages, sexes, and disease severity. This complexity must be addressed explicitly for the prevalence-based approach to estimate the impact of the new treatment on the specified population. Frequently, the data available are sufficient only to estimate the impact of new treatments on one or two population subgroups. In this case, extrapolation from these subgroups to other subgroups in the population of interest will be required, using observational databases or expert opinion.

The Value of the Prevalence-Based Approach

Estimates of the effect of a new drug on cost, health, and other outcomes can be generated using a prevalence-based approach and either a societal, health system, or other perspective. These estimates would be very valuable in giving policy-makers an understanding of the likely impact of a new drug on the annual burden of the disease for the economy or for their covered population. These esti-

mates would allow the healthcare decision-maker to evaluate the health benefits expected in the population for which they are responsible, as well as to insure that their budgets are sufficient to allow them to add the new drug.

Frequently, retrospective studies have demonstrated the impact of new drugs on population healthcare costs and population health. For example, a study of surfactant therapy for neonatal respiratory distress syndrome showed that, after its introduction, both mortality rates and hospital costs for premature infants declined [16]. Another study of an antidepressant drug showed that the increased acquisition costs for the new drug were completely offset by savings in other healthcare costs for the depressed population [17]. These studies, however, were not undertaken until the drug had been in use for several years. Examples are presented below of acute, chronic, and preventive treatments for which prevalence-based analyses at the time of new drug approval would provide useful information for healthcare decision-makers.

Community Acquired Pneumonia

Community acquired pneumonia is a good example of an acute illness for which both incidence- and prevalence-based estimates have been computed [18,19]. These two studies demonstrated similar efficacy (cure rates) for alternative times to switch from IV to oral antibiotic therapy and lower healthcare costs for those patients switched to oral treatment more rapidly. Individual patient estimates of healthcare cost savings (incidence-based estimates) are easily converted into estimates for a population of patients (prevalence-based estimates) by multiplying them by the total number of patients in the population. In this way, estimates can be obtained of the possible savings from early switching to oral therapy for a covered population. If the benefits of early switching vary according to the bacterial cause of the pneumonia and the extent to which the bacteria are drug resistant, prevalence estimates would take into account the relative prevalence of the different bacteria in the population of interest to convert incidence-based estimates into population estimates. In this way, a decision-maker can determine the impact of earlier switching to oral therapy for their own population.

Human Immunodeficiency Virus Infection

Another chronic illness, for which both incidence- and prevalence-based estimates are needed, is HIV infection. HIV is now a chronic disease whose sufferers experience episodes of acute illness alternating with periods of relatively healthy life. There are several published estimates of cost-effectiveness for new therapies estimated using incidence-based Markov models [20–25]. These estimates present the incremental lifetime costs per life-year saved for new HIV treatments using health event data from clinical trials combined with data from standard treatment algorithms based on observational data and expert opinion. Most of these estimates indicate that new treatments for HIV are cost-effective relative to treatments for other diseases (see Table 2). For example, because of its favorable cost-effectiveness ratio, triple combination antiretroviral therapy is the standard of care in the United States [23]. In contrast, ganciclovir prophylaxis for cytomegalovirus disease in persons with AIDS, which has a much more unfavorable cost-effectiveness ratio, is not standard therapy [26].

The impact of a new drug for HIV infection can be estimated as its incremental cost per life-year gained (an incidence-based estimate) or as its impact on the annual budget and patient outcomes (a prevalence-based estimate). While the incidence-based estimates are constant over time, prevalence-based cost and health outcomes will change over time after the introduction of a new treatment, being different in year 1, 2 and so on, until a new steady state is reached. This variability over time is due to changes in the population size and CD4 cell count distribution each year after introduction of the new drug and depends on the magnitude of the effect of the new drug on life expectancy. For example, combination antiretroviral therapy, by increas-

Table 2 Cost-effectiveness ratios for antiretroviral treatment for HIV infection

CD4 cell count	Intervention	Cost per life-year gained
200–500	ZDV vs ZDV+3TC [24]	$12,600
200–500	ZDV vs ZDV+3TC+indivinavir [23]	$10,000–$18,000
200–500	ZDV+3TC vs indinavir [31]	<$10,000
200–500	ZDV+3TC vs ZDV+3TC+indinavir [31]	$30,000
<200	ZDV vs no antiretroviral treatment [32]	$34,600

3TC, lamivudine; ZDV, zidovudine.

ing life expectancy in the HIV-positive population, will lead to higher prevalence of disease but at a CD4 cell count distribution shifted towards higher cell counts (i.e., less severe disease). Information on the impacts for each year after the new therapy is introduced is critical for decision-makers who have to manage healthcare budgets.

There have been only two conference presentations on the impact of alternative HIV treatment patterns on annual healthcare budgets and health outcomes [8,27]. In these studies annual outpatient drug costs and total health system costs and health outcomes were estimated based on the CD4 cell count distribution of the population, incidence rates of opportunistic diseases at different CD4 cell counts, and treatment decisions. Table 3 presents the results of the Mauskopf and Simpson study [8]. Table 3 presents the budget and health impacts of going from a treatment regimen that includes only monotherapy with antiretrovirals and treatment, as needed, of opportunistic diseases to a more comprehensive treatment regimen that includes prophylaxis for PCP and mycobacterium avium complex (MAC), and chronic suppression for genital herpes.

Estimates of the impacts of new therapies on annual healthcare budgets are critical for planning by healthcare decision-makers in charge of AIDS drug assistance programs (ADAPs) or Medicaid programs. The Mauskopf and Simpson model [8] was used in 1994 by the North Carolina AIDS Drug Assistance Program (ADAP) to estimate the amount of additional funding needed to move from a formulary providing only antiretroviral monotherapy to one providing prophylaxis and treatment for opportunistic infections as well. The model was also used by the North Carolina ADAP to show the value of the more comprehensive formulary in terms of the health benefits to the ADAP enrollees and offsetting cost savings in other parts of the health system.

A budget model, derived from the Mauskopf and Simpson model [8], was designed to help ADAP administrators when combination antiretroviral therapy became the US standard. In this model, the impact of triple combination therapy on annual costs and patient outcomes is assumed to depend on: 1) the starting CD4 cell count distribution within the population of interest; 2) when in the disease progression the combination treatment is given; and 3) its efficacy, measured as an increase in CD4 cell count. The results from this model are currently being used by ADAP administrators to support their requests to federal and state governments for additional funds to pay for the new protease inhibitors, as well as to help them make decisions about how to allocate the new treatments among their program participants [27].

Hepatitis B Vaccine

The third treatment example that illustrates the value to a decision-maker of prevalence-based estimates is the hepatitis B vaccine. The majority of the costs associated with hepatitis B occur many years after the initial acute episode. These costs arise in a subset of those with acute disease who go on to have chronic disease and a subset of these who end up with either liver cancer or cirrhosis after a time period of approximately 20 years. Vaccination stops acute episodes immediately, but much of the cost savings associated with a vaccine program will be experienced only many years after the start of the program, when the number of cases of liver

Table 3 Formulary comparisons: annual cases of opportunistic diseases (ODs) and healthcare costs per 100 HIV-positive persons

	Antiretrovirals and no prophylaxis	Antiretrovirals and prophylaxis for PCP and HSV	Antiretrovirals and prophylaxis for PCP, MAC, HSV
Opportunistic diseases (no. cases)			
PCP	6.86	4.08	4.08
MAC	1.89	4.66	1.54
Other	13.70	19.29	19.29
Total	22.45	28.03	24.91
Genital herpes (HSV)			
Episodes	92	58.8*	58.8*
Costs			
Outpatient durgs	$361,469	$417,276	$459,471
Total outpatient	$434,781	$527,011	$565,339
Total inpatient	$180,908	$211,420	$199,627
Total medical treatment costs	$615,690	$738,430	$764,962

*Assuming only 33% of HSV positive population on chronic suppression.
HSV, herpes simplex virus; MAC, mycobacterium avium complex; PCP, pneumocystis carinii pneumonia.

cancer or cirrhosis declines. Most estimates of the cost-effectiveness of a vaccine program have taken an incidence-based perspective and estimated the incremental costs for the vaccine per case of hepatitis avoided or per life-year gained [28]. Costs savings in the future are discounted back to the current time period. These estimates are helpful in understanding the value of introducing hepatitis B vaccine for different population subgroups.

Incidence-based estimates are less helpful to budget holders in understanding how much money they will have to spend on hepatitis B each year over, for example, the next 20 years. Table 4 illustrates the costs and benefits over time from the start of the vaccine program. In the first year of a vaccine program, the budget will have to cover the program's cost, as well as the costs of treating chronic and end-stage hepatitis B from those who acquired the disease before the vaccine was available. The cost of the vaccine program in the first year is also larger than in subsequent years because of start-up costs and the cost of vaccinating all of those who would have been eligible in previous years had the vaccine been available. The only offsetting cost saving the first year will be from reduced expenditures for acute initial episodes of hepatitis B. Thus, total expenditures on the vaccine and disease treatment are likely to be much higher the first year of the program than either before the vaccine was available or in subsequent years. The vaccine program costs will fall to a steady state level sometime after the first year, once all catch-up vaccinations are complete. Annual expenditures for hepatitis B treatment will gradually fall after the first year, as there are fewer cases of chronic hepatitis requiring treatment as well as fewer acute episodes. Hepatitis B expenditures, however, will not start the decline to their final very low levels until 10–20 years after the introduction of the vaccine, at which point the incidences of end-stage hepatitis B, cirrhosis and liver cancer, begin to decline. A study by Hamilton [29] shows the annual costs after starting a hepatitis B vaccination program in a teaching hospital. He estimates the costs and benefits of the vaccination program over the first 10 years of implementation. He shows that costs are initially high; they break even after 7 years; and there are cost savings after 10 years.

Prevalence-based impacts of vaccination for chicken pox are simpler to estimate, because chicken pox is primarily an acute illness. In the Lieu et al. study of chicken pox vaccination [30], they present annual estimates of the costs and benefits of a vaccine program averaged over the first 10 years of the program. This analysis was used as one input into the Centers for Disease Control decision to recommend this vaccination for all children.

Discussion

The lack of widespread use of the documented results of economic evaluations for new interventions by US and European decision-makers is not surprising. Prevalence-based and incidence-based estimates of economic outcomes from societal and health system and other perspectives are necessary for a comprehensive view of the value of a new treatment and for the economic evaluation to be of maximum use to healthcare decision-makers. An incidence-based cost-consequence estimate from the patient perspective is useful for an individual physician and/or patient as they choose between alternative treatments for a specific condition. Also, incremental cost-effectiveness ratios for a new treatment for different patient subpopulations, from a societal or health system perspective, are critical measures of the value of the new treatment, which can be used by decision-makers responsible for allocating healthcare budgets across all types of healthcare interventions. The cost-effectiveness ratio can be compared with the values for other currently used therapies. Healthcare decision-makers managing the health and healthcare budgets for defined populations, however, have critical additional information needs

Table 4 Hepatitis B vaccine program costs and benefits over time*

	Year 1	Year 2 (year 3, etc.)	Year 20
Disease treatment costs	No acute Chronic (−1 to −18) Cirrhosis and cancer (−19)	No acute Chronic (−1 to −17) Cirrhosis and cancer (−18)	No acute No chronic No cirrhosis and cancer
Vaccine program costs	Catch-up costs New cohort	New cohort	New cohort
Total annual costs			
Total annual benefits			

*Assuming the vaccine is completely effective, all vaccine catch-up costs occur during the first year, cirrhosis and cancer occur after 20 years with chronic disease.

from the health system perspective about how the new drug is going to change their annual budgets and the annual health and other outcomes for their populations.

Despite the seeming value of prevalence-based estimates to decision-makers, the majority of the published economic evaluations take an incidence-based approach. There are several possible reasons for this. First, prevalence-based estimates are population-specific, depending on the size and case-mix of the population. This increases the data needs and the complexity of performing the analyses. Second, there is a tradition of performing prevalence-based analyses retrospectively (by using large databases) rather than at the time the new drug is first introduced. Third, since most new drugs improve health and increase total healthcare costs, there may be a reluctance on the part of the drug manufacturers to quantify this increase prospectively. For example, prevalence-based estimates found in the literature are often performed for programs where the government has a large stake, or where they are funded by the government [30].

The fear that analyses showing increased healthcare costs with a new drug would be detrimental to the sales of the new drug may not be accurate. Decision-makers are willing to pay more for improved health, as recent changes in HIV treatments have shown. However, in these circumstances, decision-makers can really benefit from estimates of the budget impacts for planning purposes. The Canadian guidelines for cost-effectiveness analyses and the FHC formulary submission guidelines both request this sort of information for healthcare costs, but not for health benefits. It seems a more balanced approach for analysts to take a prevalence-based approach to economic evaluation, where annual costs, population health, and other outcomes are presented together.

Incidence-based estimates are useful for determining the overall value of the new treatment. If efficiency is our goal, we would want to construct a healthcare system in which we allocate all available funds to different uses based on cost-effectiveness of the treatment [2]. If a new drug reduces overall costs, then we would always want to add that drug to the formulary. However, in this type of healthcare system, every time a new drug comes along that increases overall costs but is more cost-effective than at least one existing treatment, some older, less cost-effective treatment—perhaps one designed for a different condition—could no longer be used if total costs are to remain unchanged. This is a difficult type of system to implement on a day-to-day basis. It is more likely that healthcare budgets will continue to increase as new drugs that increase health at an acceptable cost continue to become available. If this is the case, it is important that researchers performing economic evaluations for new products provide estimates to decision-makers of these budget increases, the associated health benefits, and the timing of these changes after introduction of the new drug, so that decision-makers can justify additional budget requests or make plans to lower other costs.

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