AIDS Care

Psychological and Socio-medical Aspects of AIDS/HIV

ISSN: 0954-0121 (Print) 1360-0451 (Online) Journal homepage: http://www.tandfonline.com/loi/caic20

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To cite this article: J. Reyes-Urueña, C. Campbell, E. Diez, V. Ortún & J. Casabona (2017): Can we afford to offer pre-exposure prophylaxis to MSM in Catalonia? Cost-effectiveness analysis and budget impact assessment, AIDS Care, DOI: 10.1080/09540121.2017.1417528

To link to this article: https://doi.org/10.1080/09540121.2017.1417528

Published online: 20 Dec 2017.

AIDS CARE, 2017
https://doi.org/10.1080/09540121.2017.1417528

Routledge
Taylor & Francis Group

Can we afford to offer pre-exposure prophylaxis to MSM in Catalonia? Cost-effectiveness analysis and budget impact assessment

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ABSTRACT

Pre-exposure prophylaxis (PrEP) effectiveness has been well established. This study aims to assess the cost-effectiveness of providing PrEP, estimate the number of eligible MSM, and its budget impact in Catalonia. Cost-effectiveness analysis compared costs of on daily basis and "on demand" PrEP to prevent one infection with lifetime costs of one HIV infection. We estimated the total cost of providing PrEP by estimating number of eligible MSM, and included in the budget impact assessment antiretroviral and laboratory costs. Costs were lower for the on-demand PrEP group by €64015.1 and the incremental benefit was nearly 15 life-years and 17 quality-adjusted life-years gained. The incremental cost-effectiveness ratio (ICER) was cost-effective at €6281.62 when undiscounted PrEP was given daily. On-demand PrEP can be considered cost-saving in 20 years if the price is reduced by 90%. The number of eligible MSM in Catalonia ranges from 5,989 to 10,972. At current antiretroviral costs, the annual cost would range between €25.3–46.7 million/year (on demand PrEP), and €42.9–78.7 million/year (daily basis PrEP). PrEP is most cost-effective if targeted towards groups with high incidence rates of over 3%/year. Beneficial ICER depends on reducing the current price of Truvada® and ensuring that effectiveness is maintained at high levels.

ARTICLE HISTORY
Received 12 April 2017
Accepted 19 November 2017

KEYWORDS
HIV; cost-effectiveness; pre-exposure prophylaxis; budget impact assessment; Spain

Introduction

Despite concerted efforts at prevention of HIV over the course of the epidemic, the incidence remains stubbornly high in Spain as in many other countries in Europe (European Centre for Disease Prevention and Control, 2015). Furthermore, Spain is one of the countries showing least improvement in its response to HIV by 2015 (Lim et al., 2016). Although there have been successes in reducing incidence in e.g., injecting drug users, through the implementation of needle exchange programmes, both the incidence and prevalence among men who have sex with men (MSM) in Spain remain worryingly high (Centre d'Estudis Epidemiològics sobre les Infeccions de Transmissió Sexual i Sida de Catalunya, 2015; Ferrer et al., 2015). The number of new infections among MSM, in Spain and elsewhere in the EU has increased by over 30% in the last decade, despite the availability and promotion of condom use, HIV testing and treatment (European Centre for Disease Prevention and Control, 2015).

In addition to classical condom promotions and risk reduction strategies, several biomedical interventions have recently been proven to be effective at reducing incidence of HIV, including treatment as prevention (TasP) (Forsyth & Valdiserri, 2012) and pre exposure prophylaxis (PrEP) (Punyacharoensin et al., 2016). Although TasP is effective in reducing onward transmission by driving down viral load to undetectable levels, a high proportion of people infected with HIV are diagnosed late. Even in MSM, who have the highest testing rates (Dowson, Kober, Perry, Fisher, & Richardson, 2012), there is a considerable lag between infection and diagnosis (Ndawinz, Costagliola, & Supervie, 2011; van Sighem et al., 2015). For TasP to be effective, early HIV diagnosis is crucial (Sorensen et al., 2012). Moreover, the promising results from PrEP efficacy and effectiveness trials (Grant et al., 2010; McCormack et al., 2016; Molina et al., 2015) has ensured that PrEP is firmly on the agenda for prevention of HIV in people at high risk, albeit as part of a well planned and executed comprehensive programme of

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HIV prevention. Given that PrEP is assuming and is likely to continue having a greater role in the prevention armoury, policy makers need to think about its role, implementation, impact, side effects and budget impact (Hankins, Macklin, & Warren, 2015).

The effectiveness of PrEP in preventing the acquisition of HIV in MSM has been well established (Cairns, McCormack, & Molina, 2016; Gomez et al., 2012; Paltiel et al., 2009) and efficacy of PrEP with Truvada has ranged from 64% to 96% in those with good adherence (Alistar et al., 2014). The ability of PrEP to deliver reductions in incidence has been estimated in the UK (Punyacharoensin et al., 2016) and compared to other interventions such as TasP, concluding that PrEP could have a significant impact on incidence within the context of improved combination prevention (Ratmann et al., 2016).

Many cost effectiveness studies on PrEP have been carried out in countries with differing epidemics, from Kenya and South Africa to the US, UK and Netherlands (Punyacharoensin et al., 2014). The general outcome of these analyses is that PrEP is cost effective if directed at key populations with an HIV incidence over 2%, adherence is maintained at high levels and the cost of the medication decreases substantially. It may not be simple, however, to access these key populations and subgroups and it is unlikely that the price will decrease in the short term (Cambiano, Miners, & Phillips, 2016).

Efficacy would be preferably demonstrated in real world scenarios rather than clinical studies such as, which was conducted within sexually transmitted infections (STI) clinics was able to demonstrate an effectiveness of 86%, high enough that it was considered unethical to continue the study and it was stopped early (McCormack et al., 2016).

Prior to incorporating an intervention like PrEP into national prevention strategies two key questions need to be answered; firstly whether the intervention is effective and cost-effective; that is, are the benefits of the intervention deliverable at a price that society is willing to pay? And the second question is whether the intervention is affordable even if it has been shown to be cost-effective. Also implicit in decisions on new interventions is the concept of opportunity cost, what (if any) other intervention in health service delivery will be affected by our adoption of this new intervention, if no extra funds are available?

In order to help inform these decisions, in this paper, we look at the cost-effectiveness of providing PrEP in Catalonia, we undertake a sensitivity analysis of the factors most likely to have an impact on the cost effectiveness of PrEP, we estimate the numbers of MSM who would likely be include in such a programme and estimate the budget impact that this would have in the medium term.

Methods

Cost of HIV

To model the costs of HIV infections, an inventory of all health care inputs consumed during the course of HIV disease was created (Table 1). Direct annual medical costs for outpatient (initial and follow-up) care, emergency visits, primary care visits, hospitalisation and laboratory were included and derived from the study of costs and cost-efficacy analysis of the 2016 GESIDA/Spanish AIDS National Plan recommended guidelines for initial antiretroviral (laboratory testing included complete blood count, CD4 count, viral load, lipid profile, kidney and liver function tests and blood glucose test (Rivero et al., 2016). Cost of antiretroviral therapy (ART) included only drug costs and was informed by the Servei Català de la Salut (CatSalut) (Generalitat de Catalunya, n.d.). The indirect cost of HIV infection included only annual occupational losses, measured as the average of different estimates of the loss of working time due to HIV in Spain, and it was extracted from a systematic review of the impact of HIV/AIDS in five European countries including Spain (Trapero-Bertran & Oliva-Moreno, 2014).

Costs of PrEP

To model the costs of the PrEP, we used the annual cost of daily dosing and "on demand" regimens, the later estimated as half that of daily dosing (Table 1) (Molina et al., 2015). We assumed that those on PrEP would have six

Table 1. Annual costs of HIV infection per patient and annual costs pre exposure prophylaxis (PrEP) strategy per person selected.

	HIV costs	PrEP costs	
		On demand	Daily
Outpatient (initial +follow-up)	230.95[a]	490[b]	490[b]
Emergency visits	189.7[a]		
Primary care visits	50[a]		
Hospitalisation	551.74[a]		
ART	6586[b]	2936.9[b]	5873.9[b]
Laboratory	212.4[a]	276.7[b]	276.7[b]
Assumed annual salary losses		536[c]	536[c]
Average annual productivity cost due to HIV	5661.18[d]		
Total costs	**13481.97**	**4239.6**	**7176.54**

ART: antiretroviral therapy; **PrEP:** pre exposure prophylaxis.

[a]Costs of resources were extracted from the study of costs and cost-efficacy analysis of the 2016 GESIDA/Spanish AIDS National Plan recommended guidelines for initial antiretroviral (Rivero et al., 2016).

[b]Source of costs: Servei Català de la Salut (CatSalut) (Generalitat de Catalunya, n.d.).

[c]he assumed annual salary loss was calculated assuming four days of work absenteeism annually and a cost per working day in Catalonia of 134€. Published cost, price or reimbursement tariff from the National Statistics Institute, INE by its acronym in Spanish.

[d]Annual occupational losses due to HIV due to HIV was extracted from a systematic review of the impact of HIV/AIDS in five European countries including Spain (Trapero-Bertran & Oliva-Moreno, 2014).

outpatient visits per year and incur laboratory costs. These testing costs (fourth generation rapid test) were provided by the Servei Català de la Salut (CatSalut) (Generalitat de Catalunya, n.d.). Drug costs were calculated using the 2016 price listing for Truvada® in Spain (244.75€ for 15 tablets and 30 tablets 489.49€ a month). For the indirect costs, we assumed four days of work absenteeism annually. The cost per working day in Catalonia was 134€, the cost, price or reimbursement tariff published in Catalonia by the National Statistics Institute (INE).

Cost of preventing one infection

The cost of preventing one infection reflects the average annual cost of either "on demand" PrEP intervention or daily PrEP required to avert one infection. This average annual cost is proportional to the number of participants of the different PrEP interventions needed to prevent one infection. In order to calculate the cost of preventing a single HIV infection we multiplied the annualised cost of each intervention by the number needed to treat (NNT). The NNT, in turn, was determined by the assumed effectiveness (86% in the baseline model and varied for the sensitivity analysis) and the baseline incidence in the group to be targeted (2% and again varied in the sensitivity analysis). Baseline NNT was calculated to be 58.1 in the baseline cost-effectiveness (CE) analysis (1/ absolute risk difference). The analysis compares two scenarios, the most expensive one when the strategy used is Truvada® on a daily basis and the least expensive one with the used of Truvada® on demand.

Cost-effectiveness analysis

In our CE analysis we followed the approach suggested by the Centers for Disease Control and Prevention (CDC; Georgia, USA) guidelines (Centers for Disease Control and Prevention (CDC), 2015) as implemented by Ouellet, Durand, Guertin, LeLorier, and Tremblay (2015) in which we compare the cost of preventing one HIV infection with the lifetime cost of treating a single HIV infection (Table 2). Given that the median age at diagnosis in Catalonia is similar to that described by Ouellet et al, we also undertook the CE for an individual diagnosed at 30 years of age and applied the survival at this age derived from the ART-CC cohort collaboration (Antiretroviral Therapy Cohort Collaboration, 2008), especially as ART-CC also uses data from HIV infected people under follow-up in Catalonia.

Benefits in the CE analysis are presented in life-years and in quality-adjusted life-years (QALY), using the reduction in QALY in asymptomatic HIV infection described by Tengs and Lin (2002) of 0.94, varying this in the sensitivity analysis (SE) to 0.81. In line with recommendations on undertaking CE analysis, we present the results undiscounted and discounted at 3% and 5% and following Ouellet et al present only the undiscounted costs of PrEP as these are incurred only over a single year.

In the sensitivity analysis, our baseline scenario assumed an HIV incidence of 2% per year, effectiveness of 86%, Truvada drug costs 100% of the 2016 price in Spain and a QALY in an HIV infected person to be 0.94 (Tengs & Lin, 2002). We adjusted baseline incidence in the target group between 1% and 5%, examined variations in effectiveness between 44% and 96%, looked at price reductions of up to 90% over 2016 prices and estimated the impact of reducing the QALY in an HIV infected person HIV from 0.94 to 0.84. This one-way sensitivity analysis of the incremental cost-effectiveness of PrEP is represented in a tornado diagram summarising the results of multiple 1-way sensitivity analysis on the incremental cost-effectiveness of PrEP.

Table 2. Cost-effectiveness analysis for prevention of an HIV infection acquired at 30 years of age (at 2015 €) comparing least expensive ("On demand" PrEP intervention) and most expensive (On daily basis PrEP intervention) scenarios.

	Undiscounted		Discounted 3%		Discounted 5%	
	Least expensive	Most expensive	Least expensive	Most expensive	Least expensive	Most expensive
Costs						
PrEP for 1st year	246,488.4	417,240.7	246,488.4	417,240.7	246,488.4	417,240.7
HIV Infection	310,503.4	310,503.4	176,428.2	176,428.2	144,438.7	144,438.7
Incremental cost	−64,015.1	106,737.3	70,060.1	240,812.5	102,049.6	272,802.0
Benefits life years						
PrEP	50.1	50.1	24.3	24.3	19.2	19.2
HIV Infection	35.2	35.2	20.8	20.8	17.2	17.2
Incremental benefit	14.9	14.9	3.5	3.5	1.9	1.9
Benefits QALY						
PrEP	50.08	50.08	24.3	24.3	19.2	19.2
HIV Infection	33.09	33.09	20.1	20.1	16.8	16.8
Incremental benefit	16.99	16.99	4.19	4.19	2.36	2.36
ICER	**−3,767.36** €	**6,281.62** €	**16,706.73** €	**57,424.80** €	**43,329.57** €	**115,829.82** €

PrEP: pre exposure prophylaxis; **QALY:** Quality-adjusted life-years; **ICER:** Incremental cost-effectiveness ratio.

Budget impact analysis

In order to estimate the number of MSM in Catalonia who might use PrEP, we based the population denominator on the 2013 mid-year estimates produced by the Catalan Statistics Institute, Idescat (http://www.idescat.cat/). We estimated both upper and lower estimates of the proportion of MSM aged 18–59; the upper value (3.4%) was estimated using the proportion of male population who reported in a national survey of sexual health having had receptive anal intercourse in the previous 12 months (Ministerio de Sanidad Servicios Sociales e Igualdad, 2009), whereas the lower value (1.86%) is derived from the survey-surveillance discrepancy method described by Marcus, Hickson, Weatherburn, and Schmidt (2013). We then subtracted 11.2% of MSM who were estimated to be already HIV positive (Ministerio de Sanidad Servicios Sociales e Igualdad, 2014), and calculated, using the answers provided in the EMIS (Weatherburn et al., 2013) questionnaire for Spanish respondents that of these, 29.4% would meet EACS criteria (European AIDS Clinical Society (EACS), 2015) for PrEP (HIV-negative MSM and transgender individuals who are inconsistent in their use of condoms with casual partners or with HIV-positive partners who are not on treatment). We assumed, using data from a local survey, that 58% of these men would be willing to use PrEP (Ferrer et al., 2016). Transgender population was not considered as a part of the MSM population.

We estimated the total cost of providing PrEP to the estimated number of eligible men aged 18–59 who would be willing to use it. We included in the calculation the costs of Truvada® at 2016 prices in Spain as well as the laboratory costs associated with follow-up according to current draft guidelines for PrEP in Spain (Grupo de Estudio de Sida de la SEIMC (GeSIDA), 2016). Indirect costs and additional staffing costs associated with PrEP counselling, prescribing and medical follow-up were not included. PrEP promotion and marketing was not included as well.

Results

Cost-effectiveness

Annual costs of both HIV infection and PrEP can be seen in Table 1. The total annual cost of an HIV infection was estimated to be €13481.97 whereas the annual cost of 15 Truvada® tablets was €4103 and of 30 Truvada® tablets was €7176.54, including laboratory costs. Given a NNT of 58 at an effectiveness of 86% and incidence in the target group of 2% per year, the cost to prevent a single HIV infection was estimated to be €246488,4 when PrEP was "On demand" and to be €417240.7 when PrEP is used on a daily basis.

The results of the cost-effectiveness analysis can be seen in Table 2. Undiscounted lifetime costs were lower for the on-demand PrEP group by €64015.1 and the incremental benefit was nearly 15 life years and 17 QALYs gained in the PrEP group on this intervention. The undiscounted lifetime incremental cost-effectiveness ratio (ICER) was cost-saving when the intervention used was on-demand, and was cost-effective at €6281.62 when undiscounted PrEP was given daily and was €16706.73 when discounted at 3% per QALY gained with on-demand PrEP.

In the sensitivity analysis (Figure 1), the ICER was highly dependent on input assumptions and on the type of intervention chosen. PrEP on-demand would be cost effective in 50 years at current ARV costs or in 20 years if the cost of ARVs falls by 60%. Daily PrEP can be considered cost-saving if the price of PrEP is reduce by 80%, and on-demand PrEP can be considered cost-saving in 20 years if the price is reduced by 90%.

Our one-way sensitive analysis (Figure 2), highlights that cost effectiveness of PrEP in Catalonia can be reached when the effectiveness of PrEP is above 90%, the incidence of HIV in the selected group of MSM is above 3% and the price of ART is reduced more than 10% of its actual price.

Budget impact

We estimated that the total number of MSM in Catalonia who would be willing to use PrEP would range between 5,989 (1.86% of the male population aged 18–59) and 10,972 (3.4%), using the assumptions described in the methods (Figure 3). At current Truvada® costs, the total annual cost (including laboratory costs but excluding overheads and staffing) would range between €25.3 and €46.7 million a year if the intervention chosen is on demand, or between €42.9 and €78.7 million a year if the intervention is on a daily basis.

Discussion

Now that PrEP has been demonstrated to be effective in preventing HIV infection in HIV negative MSM, and the European Medicines Agency has recommended granting a marketing authorisation for Truvada in Europe (Committee for Medicinal Products for Human Use (CHMP) European Medicines Agency, 2016), it is only a matter of time before it becomes a standard part of the arsenal in combination HIV prevention programmes along with increased testing. In order to ensure the proportion of MSM with viral suppression increases towards 90%, substantial increases in testing would be required (Phillips et al., 2015) and simultaneous use of

1a.		Time in years						
		5	10	20	30	40	50	Lifetime
Percent reduction in Truvada price	Current Price	565517	211176	72732	37809	23809	16827	16707
	10%	520412	191074	63525	31650	26517	12726	12635
	20%	475308	170972	54318	25492	14158	8625	8563
	30%	430203	150870	45111	19334	9333	4524	4491
	40%	385099	130768	35905	13176	4507	423	420
	50%	392650	136250	39658	16248	7216	-3678	-3652
	60%	294890	90564	17491	860	-5144	-7779	-7724
	70%	249785	70463	8284	-5298	-9969	-11881	-11796
	80%	204680	50361	-923	-11456	-14795	-15982	-15868
	90%	159576	30259	-10130	-17615	-19620	-20083	-19940

1b.		Time in years						
		5	10	20	30	40	50	Lifetime
Percent reduction in Truvada price	Current Price	1016563	412194	164802	99390	72063	57837	57425
	10%	926354	371990	146388	87074	62412	49635	49281
	20%	836144	331787	127974	74757	52761	41433	41138
	30%	745935	291583	45111	62441	43111	33231	32994
	40%	655726	251379	35905	50125	33460	25029	24850
	50%	565517	211176	72732	37809	23809	16827	16707
	60%	475308	170972	54318	25492	14158	8625	8563
	70%	385099	70463	130768	13176	4507	423	420
	80%	294890	90564	17491	860	-5144	-7779	-7724
	90%	204680	50361	-923	-11456	-14795	-15982	-15868

Figure 1. Cost effectiveness of pre-exposure prophylaxis (PrEP) intervention on the Catalan HIV epidemic among men who have sex with men (MSM) with a progressive reduction in Truvada® price and timeframe. **1A.** ICER (per QALY gained) with a discount of 3% when the intervention on PrEP used is on Demand, and **1B.** ICER (per QALY gained) with a discount of 3% when PrEP is based on a daily intervention. ▫ Cost-saving (leading to a health benefit and saving in cost); ▫ Cost-effective (ICER below €20,000 / QALY gained); ▫ Border-line cost-effective (ICER between €20,000 and €30,000 / QALY gained); ▫ Not cost-effective (ICER above €30,000 / QALY gained).

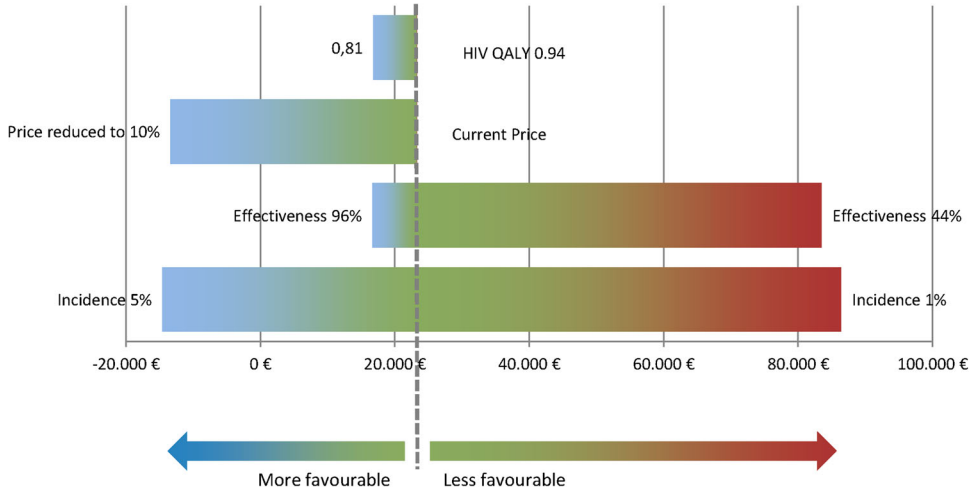

Figure 2. One-way sensitive analysis of the incremental cost-effectiveness of pre-exposure prophylaxis (PrEP). Bars show the change in the incremental cost-effectiveness ratios if the value of a key parameter is changed between the number at the left of the bar and the number at the right of the bar. Each horizontal bar represents the range of incremental cost-effectiveness ratios (ICERs) resulting from variations of a given model parameter across its plausible range, as indicated at opposite ends of each bar. The range for each bar is reported in the direction of the ICER for that bar. The doted vertical line indicates the base case ICER (20.000€ per year of life saved). A bar reaching −20.000€ on the left would indicate cost saving.

PrEP in a comprehensive strategy could have the greatest impact on HIV incidence (Punyacharoensin et al., 2016). In addition, many community organisations and professionals consider that there is an urgent need to make PrEP available within such a comprehensive prevention package (Cairns et al., 2016; Gomez et al.,

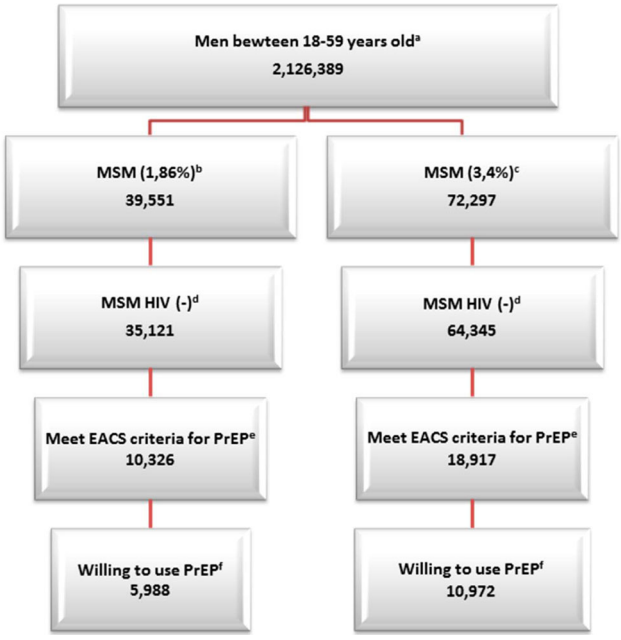

Figure 3. Estimation of the number of men who have sex with men that can be susceptible to be selected for pre-exposure prophylaxis (PrEP) in Catalonia. **MSM:** Men who have sex with men; **EACS:** European AIDS Clinical Society; **PrEP:** pre-exposure prophylaxis. [a]Population denominator based on the 2013 mid-year estimates produced by the Catalan Statistics Institute, Idescat (http://www.idescat.cat/). [b]The upper value (3.4%) was estimated using the proportion of male population reported by a national survey of sexual health: men who have had receptive anal intercourse in the previous 12 months (Ministerio de Sanidad Servicios Sociales e Igualdad, 2009). [c]Lower value (1.86%) was derived from the survey-surveillance discrepancy method described by Marcus et. (Marcus et al., 2013). [d]Percentage 11.2% were subtracted from the number of MSM who were estimated to be HIV positive (Plan Nacional sobre el Sida S.G. de Promoción de la Salud y Epidemiología/Centro Nacional de Epidemiología-ISCII, 2016). [e]Number of MSM who meet criteria for PrEP was calculated using the answers provided in the EMIS (Weatherburn et al., 2013) questionnaire for Spanish respondents that of these, 29.4% would meet EACS criteria (European AIDS Clinical Society (EACS), 2015) for PrEP (HIV negative MSM and transgender individuals who are inconsistent in their use of condoms with casual partners or with HIV-positive partners who are not on treatment). [f]Number of MSM willing to sued PrEP was subtracted from a local survey, 58% of these men would be willing to use PrEP (Ferrer et al., 2016).

2013). It is therefore up to the scientific and public health community support decision-makers with evidence of the costs and benefits to inform the implementation of PrEP. We are not aware of any other studies estimating cost-effectiveness of PrEP in Spain and this study is a response both to the need to stimulate local debate and to a recommendation made by the Spanish Society for Public Health and Health Management, SESPAS in 2016 for economic analysis of PrEP to be undertaken in Spain.

Our CE findings are broadly in line with those of other recent CE studies, in which our estimate of the undiscounted lifetime costs of an HIV infection of €310,503 is lower than that of the Ouellet et al and broadly similar to estimates of CE from the UK (Nakagawa et al., 2015) and most of this cost derives from antiretroviral drugs and accounts for the high impact of price on the CE of PrEP. As also reported in other studies, the ICER is highly sensitive to PrEP price, effectiveness and baseline incidence of HIV (Drabo, Hay, Vardavas, Wagner, & Sood, 2016; Ong et al., 2015).

This study does have some limitations, particularly in the large uncertainty in the local costs associated with HIV infection. These HIV costs are likely to be an under-estimate which would make the CE results less favourable than they would otherwise be. Staffing costs are not calculated for PrEP, which leads to overestimating the CE of the intervention and underestimating the budget impact of introducing PrEP. Neither have we considered the potential impact on the analysis of drug resistance, although there is little evidence that this is likely to be a major concern (Cambiano et al., 2016). A further consideration that will impact upon the implementation of a programme and is not considered here, is the need to consider initial capital outlays and recruitment and training needs in order to implement an effective PrEP programme. This initial investment will need to be costed and planned prior to roll-out.

Although the annualised costs of PrEP may be underestimated by not factoring in staff costs, it remains clear that the budget impact of widespread PrEP introduction would be considerable, amounting to up to 15% of the total current ART expenditure for Catalonia in 2015 (€152 million). Our estimates of the potential costs of a PrEP programme in Catalonia cannot be considered to be a formal and comprehensive budget impact analysis as described by Trueman et. al. (Trueman, Drummond, & Hutton, 2001) and suggested by Cambiano for PrEP (Cambiano et al., 2016); nevertheless, they do provide an idea of potential laboratory and drug costs at current prices and highlight the need for a further formal analysis of the budget impact of a PrEP programme. A key consideration in implementing a new intervention is ensuring that funding it does not carry excessive opportunity costs by diverting funds from other essential and effective public health programmes, whether in sexual health or in other specialties. Therefore, sound planning should take into consideration budget impact, affordability and opportunity costs. Pressure exerted by different stakeholders may attempt to downplay the medium and long-term opportunity costs as has occurred in other scenarios where the soaring costs of an increasing number of new drugs has threatened to

exceed the capacity of societies to absorb the cost (Campillo-Artero, Garcia-Armesto, & Bernal-Delgado, 2016).

Finally, any PrEP programme needs to ensure that the target community are fully aware, engaged and that comprehensive support is available when PrEP is introduced equitably across the various communities who will be using it (Frankis, Young, Flowers, McDaid, & Dezzutti, 2016). In order to improve the targeting of key populations and subgroups most likely to benefit, targeting tools have been developed in order to better direct the cost effective use of PrEP to those MSM who could most benefit, including tools to clinically determine PrEP eligibility using the HIV Incidence Risk Index for MSM (HIRI-MSM) (Ross, Cinti, & Hutton, 2016).

To conclude, the CE analysis suggests that although PrEP is cost-effective over a lifetime, it is most cost effective if targeted towards groups with high incidence rates of over 3% per year, and the beneficial ICER depends heavily on reducing the current price of Truvada® and ensuring that effectiveness is maintained at very high levels. Despite the likelihood of PrEP being cost-effective given these requirements, any PrEP programme implemented will necessarily be a compromise between the number of HIV infections potentially prevented and the affordability of doing so; it is up to policy makers, in consultation with professionals and civil society organisations, to decide where that compromise should be. Any programme implemented will need to include monitoring and evaluation systems to assess its impact and determine the STI services required to deal with a potential increase in STI and will require the collaboration of Public Health specialists, clinicians and NGOs.

Disclosure statement

No potential conflict of interest was reported by the authors.

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