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ORIGINAL PAPER

HIV Rapid Testing Programs in Non-Clinical Settings have the Potential to Constitute a Major Diagnostic Option for MSM in Spain

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Abstract We analyze the impact of HIV rapid testing (RT) programs in non-clinical settings (NCS) by evaluating their contribution to new diagnoses reported to the Spanish HIV Surveillance System (SINIVIH) from 2007 to 2012. We estimate the proportion of new diagnoses reported to SINIVIH attributable to them and the maximum annual contribution (MAC). Of 95.575 rapid tests conducted, 2061 were reactive; 1582 in men who have sex with men (MSM). The contribution of RT in NCS increased from 3.4% in 2007 to 11.0% in 2012 (8.1%–16.6% in MSM). RT programs contributed 25.3% of the new diagnoses reported in Catalonia (MAC:30.6%), 15% in the Canary Islands (MAC:16.2%) and 13.7% in the Basque Country (MAC:21.0%). Among MSM, contribution was of 45.2% in Catalonia (MAC:60.7%), 20.2% in the Canary Islands (MAC:21.3%) and 16.6% in the Basque country (MAC:20.9%). Especially among MSM, RT in NCS contributed a large proportion of the new HIV cases diagnosed in regions with a very high HIV incidence.

Resumen Analizamos el impacto de los programas que ofertan la prueba rápida del VIH en entornos no clínicos (ENC) a través de su contribución a los nuevos diagnósticos notificados al sistema de información sobre nuevos diagnósticos de VIH en España (SINIVIH) en el periodo 2007–2012. Se estima la proporción de nuevos diagnósticos notificados al SINIVIH atribuibles a este tipo de programas y la contribución máxima anual (CMA). De 95.575 prueba rápidas, 2061 fueron reactivas (1582 en hombres que tienen sexo con hombres (HSH)). La contribución de los programas de prueba rápida en ENC creció

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desde el 3.4% en 2007 hasta el 11.0% en 2012 (8.1%–16.6% en HSH). Estos programas contribuyeron con el 25.3% de los nuevos diagnósticos notificados en Cataluña (CMA:30.6%), 15% en las Islas Canarias (CMA:16.2%) y 13.7% en el País Vasco (CMA:21.0%). Entre los HSH, la contribución fue del 45.2% en Cataluña (CMA:60.7%), 20.2% en las Islas Canarias y 16.6% en el País Vasco (CMA:20.9%). Especialmente entre los HSH, los programas de pruebas rápidas en ENC contribuyeron con una elevada proporción de los nuevos diagnósticos de VIH notificados en regiones de muy alta incidencia.

Keywords HIV infection · Diagnosis · Public health · Epidemiology

Introduction

Approximately 29% of the HIV-infected population in Spain remains unaware of their infection [1]. HIV diagnosis is the gateway to treatment, which reduces morbidity and mortality [2, 3] and offers important benefits for public health since it makes seropositive individuals less infectious [4]. Furthermore, diagnosis also offers individuals the opportunity to adopt safer sex strategies to protect their partners [5]. In 2003, the United States Centers for Disease Control and Prevention (CDC) proposed taking HIV testing to non-clinical settings (NCS) in order to promote timely diagnosis and reduce the undiagnosed HIV epidemic. By using rapid testing (RT) kits (approved by the Food and Drug Administration in 2002), this strategy aimed to facilitate testing for certain groups disproportionately affected by the epidemic who faced barriers to access the health system [6].

Since then, this strategy has been included in both national and international guidelines and recommendations [7–10]. It is very heterogeneous in terms of the target population, requirement for appointment, duration of counselling and type of rapid test used.

There is a relatively wide body of literature that evaluates programs of this nature. In the European context, evaluations come mostly from the United Kingdom (UK) and Spain [11–14]. Some of these studies have reported that such programs were able to identify a large number of previously undiagnosed individuals and were responsible for a substantial proportion of the new diagnoses reported to their regional or city-level surveillance systems [13, 15–17]. However, they are all evaluations of individual programs and the extent to which RT programs in NCS are contributing at a population level remains unknown.

In Spain, programs working in NCS began operating in the late nineties. However, it was the approval of RT kits in 2006 that led to the expansion of this strategy. More than 10 years later; we still lack an evaluation at country level that allows us to better understand the role of this strategy in the context of countries with multiple diagnostic options. The main goal of this study is to fill the gaps of knowledge in the literature and to try to understand how the introduction of these programs in Spain is helping to uncover the undiagnosed fraction of the epidemic. To do so, we assess the impact that the introduction of RT in NCS in Spain by analyzing its contribution to the new diagnoses reported in Spain during the 6 years following the approval of RT kits and by analyzing its potential as a core testing option.

Methods

The data we analyze represent the activity of virtually all the RT programs conducted in NCS in Spain from 2007 to 2012. This strategy has been incorporated at a different pace in Spain's various regions. Some began in 2007 while others still had no programs running in 2012. Thus, we analyze data from a 6 year period of operation in the regions of Catalonia, Madrid, Extremadura, the Basque country and Ceuta (2007–2012), a 5-year period in the Balearic Islands, Valencia, Aragón, Galicia (2008–2012); 3-year period in Castile and Leon, Andalusia and the Canary Islands (2009–2012), 2-year period in Cantabria, and La Rioja (2011–2012), and 1-year period in Navarre (2012). To our knowledge, no RT programs were conducted in the remaining four regions (Asturias, Melilla, Castile-La Mancha and Murcia) between 2007 and 2012. We include data from 86 programs.

Almost all the programs were run by Non-Governmental Organizations (NGO). The only exceptions were the three community pharmacy based programs launched in the Basque country, Catalonia and Castile and Leon as a partnership between the Regional Ministries of Health and the regional Councils of Professional Associations of Pharmacists, and a program carried out in Barcelona run by the city's public health agency.

All programs operated in a single region, with two exceptions: a multicenter program run by "Médicos del Mundo" (MdM), which offered RT in several Spanish regions and a program run by the NGO "Madrid Positivo" which operated mainly in the city of Madrid but also performed outreach activities in other regions in certain years. Details on both programs can be found elsewhere [11, 12].

When possible, data were obtained by individually contacting the organizations that ran the programs. However, in some regions aggregated data were provided directly by the HIV-AIDS regional plan (Extremadura, Andalusia, Galicia, Canary Islands, La Rioja and Ceuta). Either way, the responsible persons were asked to fill out a brief datasheet that included information about the number

of tests and reactive results by year and sex-sexual behavior (women, MSM and heterosexual men). In order to be as inclusive as possible, if this stratification was not available, they were asked to provide data by year and sex and if this was not possible either, by year.

The Spanish information system on new HIV diagnoses (SINIVIH in its Spanish acronym) provided us with data for the annual new diagnoses reported in each region by transmission category: women, heterosexual men and MSM updated to June 2014. Missing information on the most probable route of transmission was adjusted by applying the proportional distribution of each known exposure group to the total number of new diagnoses in each year.

Statistical Analysis

We present the trend of the overall number of rapid tests conducted in NCS from 2007 to 2012 as well as those conducted in men, women and MSM. We estimate the prevalence of reactive tests by year both overall and for the MSM group. The precision of the estimates for HIV prevalence were analyzed by calculating the 95% confidence interval (95% CI). Prevalence changes over time were assessed using Chi square tests for linear and non-linear trends.

The impact of RT programs in NCS was assessed in two ways:

1. The impact in the 6 years following the approval of RT in Spain was assessed by estimating the proportion of new diagnoses reported to SINIVIH attributable to RT programs during the period 2007–2012. In Spain, epidemiological surveillance on HIV did not include data from all regions until 2013. For regions and years with no data available, we assumed the number of new diagnoses reported in the following year with available data. SINIVIH had no data available for Andalusia in 2007–2012. The denominator for this region was calculated based on an incidence rate of 7.1 new diagnoses per 100.000 inhabitants (unpublished data, based on personal communication). Changes over time were assessed using Chi square tests for linear and non-linear trends.
2. To assess the potential of RT programs in NCS as a major diagnostic option, we focused our analysis on the regions and periods in which programs offered RT. We estimated the proportion of new diagnoses reported in each region attributable to RT programs in NCS, considering only the data for the period during which programs were operating. We also estimated the year of maximum contribution.

Results

Trends in Number of Tests and Proportion of Reactive Results

Overall, 95.575 rapid tests were conducted in NCS from 2007 to 2012 [average tests per year (avg): 15.929]. The number of annual tests increased from 6.690 in 2007 to 23.283 in 2011 and decreased slightly in 2012 (22.619). This increase was observed in men (average tests per year: 10.515; range: 4.633–14.857) and women (avg: 3.464; range: 1.858–4.972) as well as in MSM (avg: 6.292; range 1.890–9.435) (Fig. 1).

Of the rapid tests conducted 2.062 were reactive, 1.884 in men (91.4%), 1582 of whom were MSM (76.7% of all reactive tests), and 149 (7.2%) in women. The sex of the other 29 individuals (1.4%) who obtained a reactive result is unknown. The overall prevalence was 2.2% (95% CI 2.06–2.25) and remained stable throughout the study period. The highest prevalence was observed in the MSM group among whom 4.2% (CI 95% 4.0–4.4) of the tests performed resulted in a reactive result. The prevalence in this group was 7.1% (CI 95%:5.9–8.3) in 2007 but decreased significantly to 3.3% (CI 95% 2.9–3.6%) in 2012 [Chi square for slope (linear trend) = 55.9; $p < 0.001$] (Fig. 2).

Contribution Made by RT Programs in NCS to the New Diagnoses Reported to SINIVIH 2007–2012

Reactive rapid tests detected in NCS represent 7.7% of all the new diagnoses reported in Spain from 2007 to 2012. Contribution in this 6-year period was notably lower in women (3.2%) than in men (9.5%) and was highest in the MSM group (13.3%). We observed an overall increase of the annual contribution: from 3.4% in 2007 to 11.0% in 2012 (Fig. 1) [Chi square for slope (linear trend) = 304.4; $p < 0.001$]. This increase was also observed in women: 0.6% in 2007 to 7.6% in 2012 [Chi square for slope (linear trend) = 72.7; $p < 0.001$]. In men, it increased from 4.6% in 2007 to 13.2% in 2011 but dropped slightly to 12.5% in 2012. Likewise, in the MSM group it increased from 8.1% in 2007 to 16.6% in 2011 to drop again in 2012 to 14.9% [Chi square for slope (linear trend) = 63.7; $p < 0.001$].

Contribution During Years of Operation: Differences by Region

When focusing on the regions and years in which RT in NCS was being offered, it was the Catalonian programs that contributed the most with 25.3% of the total new

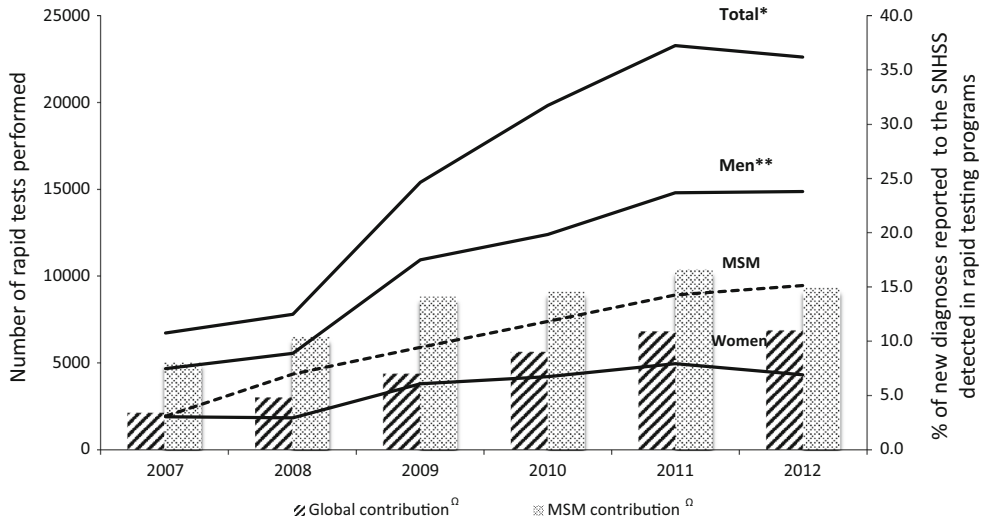

Fig. 1 Number of rapid tests and contribution of rapid testing programs in non clinical settings to new diagnoses reported to the Spanish National HIV Surveillance System (SNHSS) (2007–2012). *Tests in Andalusia are represented only in the total line as their distribution by sex is unknown. **Tests in men in Cantabria, Aragon, Extremadura and in the multicenter program "Médicos del Mundo" are not available by sexual behavior and are represented only in the *line* for men. $^{\Omega}$ Chi square test for slope (*linear trend*) for global contribution = 304.4; $p < 0.001$. Chi square test for slope (*linear trend*) for contribution in MSM = 63.7 ($p < 0.001$)

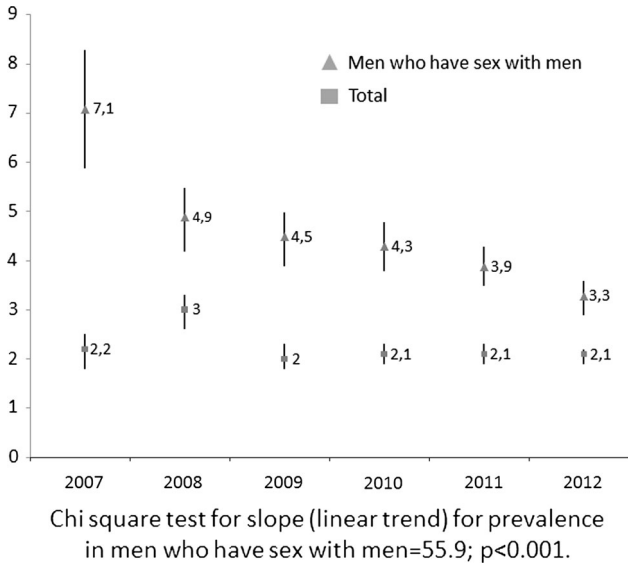

Fig. 2 Prevalence of reactive tests in non clinical settings in Spain (2007–2012). Chi square test for slope (linear trend) for prevalence in men who have sex with men = 55.9; $p < 0.001$

diagnoses reported in Catalonia attributable to them. The programs in the Canary Islands, the Basque country, and Andalusia all contributed more than 10% of the new diagnoses reported in their respective regions, whereas those operating in Madrid, the Balearic Islands, Valencia, and Galicia contributed <5% of the new diagnoses reported in these regions. Programs in La Rioja and Ceuta did not detect any reactive results (Table 1).

Regarding the MSM group, Catalonian programs were responsible for almost half (45.2%) of the new diagnoses reported in the region. In Navarre the contribution was 32.3% although the number of reactive tests was very small (n = 2). Programs in the Balearic Islands (6.3%), Madrid (5.7%) and Valencia (4.0%) presented the lowest contributions (Table 1).

Although the impact of RT was highest in the MSM group, in some regions it also revealed a substantial proportion of previously undiagnosed women. Thus, in Cantabria 18.8% of the new diagnoses among women reported in the region were attributable to programs in NCS operating in the region. In the Canary Islands, programs were behind 11.7% of the new diagnoses and in the Basque country of 11.8% (Table 1).

Maximum Annual Contribution (MAC) by Region

Overall, MAC was highest in Catalonia where it reached 30.6% in 2009, whereas in the Basque country, programs reached their MAC (21%) in 2012. In the Canary Islands the MAC reached 16.2% in 2011; in Extremadura, 15.8% in 2011; in Cantabria, 13.2% in 2012; in Andalusia 12.5%; in 2012 and in Aragon, 10.5% in 2012. In the rest of the regions, the MAC was below 10% (Table 1).

Regarding the MSM group, the Catalonian programs contributed with 60.7% of the new diagnoses reported in 2009, and in Navarre they contributed 33.3% of those reported in 2012 (their only year of operation). In the Canary Islands, the MAC was reached in 2012 and was 21.3%, whereas in the Basque country it reached 20.9% also in 2012. The regions with the lowest MACs were

Table 1 Contribution of rapid test programs to the total new diagnoses reported to the Regional Surveillance Systems by region and gender-sexual behavior

	Madrid (2007–2012)	Catalonia (2007–2012)	Basque Country (2007–2012)	Extremadura (2007–2012)	Balearic Islands (2008–2012)	Aragon (2008–2012)	Valencia (2008–2012)[a]	Galicia (2008–2012)	Canary Islands (2010–2012)	Andalusia (2010–2012)[a]	Castile and Leon (2010–2012)	Cantabria (2011–2012)	Navarre (2012)
Number of overall new diagnoses reported to surveillance systems	6973	4566	982	307	827	540	2165	989	493	1800	296	81	32
Number of reactives in rapid test programs	293	1157	135	29	29	20	52	23	74	195	23	7	2
% of total new diagnoses attributable to rapid tests programs	4.2	25.3	13.7	9.4	3.5	9.9	2.4	2.3	15.0	10.8	7.8	8.6	6.3
Maximum annual contribution	5.5	30.6	21.0	15.8	9.2	10.5	3.7	6.4	16.2	12.5	9.6	13.2	6.3
% by gender-sexual behavior men (overall)	5.0	33.9	16.2	n/a	3.9	3.9	2.6	2.4	16.3	11.2	9.4	7.1	22.2
Maximum annual contribution	6.3	45.5	23.0		11.0	10.0	5.0	6.1	17.3	12.4	13.1	11.5	22.2
MSM	5.7	45.2	16.6	n/a	6.3	n/a	4.0	7.1	20.2	n/a	10.0	n/a	33.3
Maximum annual contribution	7.2	60.7	20.9		12.5		6.9	9.1	21.3		13.1		33.3
Women	1.5	5.1	11.8	n/a	3.2	4.3	2.1	3.4	11.7	9.2	2.3	18.8	0.0
Maximum annual contribution	3.2	15.9	20.7		7.7	16.7	6.3	11.5	20.7	13.3	4.5	40.0	0.0

La Rioja (in 2012) and Ceuta (from 2007 to 2012) had rapid testing programs in NCS running during the study period but had no reactive rapid tests

Asturias, Melilla, Castile-La Mancha and Murcia had no rapid testing programs from 2007 to 2012

n/a data not available

[a] The number of new diagnoses reported to surveillance systems is based on estimations

Galicia (9.1% in 2011) Madrid (7.2% in 2012) and the Valencia (6.9% in 2011) (Table 1).

Among women, the programs in Cantabria reached their MAC in 2012, where they were responsible for 40% of the women diagnosed with HIV during that year. The MAC reached 20.7% in the Basque country in 2012 and 20.7% in the Canary Islands in 2011. The MAC was above 10% in Aragón (16.7% in 2012), Andalusia (13.3% in 2012), and Galicia (11.5% in 2012). The MACs in women were lower in the Balearic Islands where they reached 7.7% in 2009, Valencia (6.3% in 2008) and Madrid (3.2% in 2010) (Table 1).

Discussion

Programs offering rapid tests in NCS have gradually increased their relevance as a diagnostic option in Spain. The number of tests and reactive results has grown significantly since 2007 as has their contribution to the new diagnoses reported to SINIVIH. The contribution differed substantially by region and was surprisingly low in some areas with very high HIV incidence. These programs contributed the most in the MSM group. In some regions however, programs in NCS were responsible for a substantial proportion of the new diagnoses reported among women.

This is the first study to evaluate the impact of RT in NCS at a national level. In Catalonia, the sole introduction of this new technology, resulted in a 102% increase of tests conducted in these settings [18]. In Spain, the number of rapid tests conducted in 2012 is 3.5 times higher than in 2007. This increase has been spurred by the growing number of programs created throughout the country. However, the number of tests decreased in 2012 which may partly be due, to the public funding cutbacks that NGOs have faced since 2008 [19].

Although the number of reactive tests has increased over time, the overall prevalence of HIV has remained stable. This tendency has also been described in Catalonia [20]. In the MSM group, we observed a continuous decrease in prevalence: from 7.0% in 2007—similar to that found in HIV counseling and testing clinics in Spain (8.0%) [11]—to less than half that amount in 2012 (3.3%). This reduction in prevalence can be explained by the expansion of the programs to regions less affected by the epidemic. In 2007 programs were conducted only in Madrid and Catalonia, the regions with the first and third highest incidence rates in Spain, respectively, and which represent approximately half of the newly diagnosed MSM reported annually in Spain. As a result of the gradual incorporation of programs conducted in regions with lower rates of HIV, the prevalence has dropped. Nevertheless, it is still well above the cost-effectiveness thresholds established by different organizations [7, 9, 21].

When assessing the public health impact of RT in NCS, we found that the percentage of new diagnoses reported in Spain from 2007 to 2012 attributable to these type of programs did not reach 10%. Although this might seem a modest figure, it should be noted that these programs conducted approximately 16.000 tests per year. The remaining 90% of new diagnoses were probably detected using conventional tests, about 1.2 million of which are conducted annually in Spain [19].

The overall contribution of RT programs in NCS grew substantially until 2011 but stalled in 2012, mirroring the same pattern observed in the MSM group where the majority of the reactive rapid tests were reported. Whether this reduction is anecdotic or is the beginning of a downward trend remains to be seen. MSM were the population in which these programs reached their peak contribution. RT in NCS has proven to be an effective way of revealing undiagnosed infections especially in this key population [22], so this is not a surprising result. In fact, BCN checkpoint, a community-based program in Barcelona (Catalonia) for the detection of HIV and other sexually transmitted infections, and the largest program included in this analysis, focuses specifically on the MSM population and has already proven its capacity to reach and diagnose a large number of MSM [16]. Furthermore, other programs focusing on the general population have also proven effective in detecting previously undiagnosed infections among MSM [11, 13, 15, 23].

Women, however, are the only group in which the contribution of these programs has increased continuously throughout the whole period. Outcomes achieved in women in certain regions such as the Basque country or Catalonia are heavily influenced by pharmacy based testing programs which were able to diagnose a considerably large number of women [15]. Other programs have also been able to attract high-risk women such as sex workers and migrants from sub-Saharan Africa [12], contributing to the overall figures in women.

To assess the potential for programs in NCS to constitute a major diagnostic option, we performed an analysis by region limited to the years in which these programs actually operated. This analysis showed profound differences by region. The results for Catalonia were especially remarkable. The programs in this region contributed a large proportion of the new diagnoses reported, especially in MSM, in whom they accounted for half of all new diagnoses.

These results are largely due to BCN Checkpoint, which is responsible for 60% of the reactive tests found in NCS in Catalonian programs [16]. Since they started to offer RT, the number of tests and infections detect at their center has risen continuously year after year.

Programs in other regions such as the Basque country, the Canary Islands and Andalusia also contributed substantially to the new diagnoses reported in their territory. The contributions in these and most other regions tend to be higher in the later years. This is an obvious result of the incorporation of new programs but is also due to a necessary period of consolidation in which programs need to adjust their protocols and become known to their potential users. In contrast with the aforementioned result, the contribution in other regions has been surprisingly low. Madrid, the Balearic Islands and Valencia were the regions with the first, third and fourth highest incidence rates, respectively, in Spain in 2012. The strikingly low contribution achieved in these regions could indicate the need to expand this strategy to help detect undiagnosed infections.

The reasons that underlie the profound differences found by region merit further studies. At least partially, they could stem from the decentralized organization of the Spanish health system, with regional health ministries responsible for managing health services. Political willingness to allow and promote this type of initiatives, could also play a role in explaining the regional variations. Thus, some regions could have decided to promote different diagnostic strategies that focus similar populations [24]. Regional variations could also be explained by the capacity of certain programs to attract funding and increase testing in spite of the economic recession. Nevertheless, in order to explore these hypotheses, we would need to perform a different analysis and take into account regulatory, budgetary and policy related variables that are far away from the initial scope of the present work.

It is difficult to say if the regional contributions described in this study are high or low since we have found no studies that assess this aspect. However, a large scale study conducted in the United States (US) by the CDC showed that 37.9% of the 17.426 newly diagnosed infections seen during 2013 in the 61 health departments and 151 community-based organizations funded by the organization were carried out in non-health care settings [25]. Nevertheless, the social and health contexts in Europe and the US are different and difficult to compare.

This study originally aimed to assess the capacity of RT in NCS to promote early diagnosis and to link those diagnosed with HIV to care, but very few organizations had follow up data. Such data are critically needed in the near future to evaluate whether these types of programs are achieving one of the objectives of offering HIV testing in NCS: the promotion of timely diagnosis and treatment by facilitating access to HIV testing for populations with difficult access to the health system and enabling more frequent testing in target groups. Several studies [11, 17, 23] have concluded that programs of this nature can promote early diagnosis but whether if this can be generalized at country level remains unknown.

Our results have several limitations. In some regions the number of new diagnoses was not available for the entire 2007–2012 period. In such cases, we assumed the number of new diagnoses of the closest year with available information. This limitation affects especially data from Andalusia, which first reported data to SINIVIH in 2013 and from the region of Valencia which had data only for 2012. Our estimates for MSM take into account only the 11 regions that provided data on MSM. However, these regions account for more than 90% of the new diagnoses reported to SINIVH in this group. Due to limited availability of follow up data, we do not know how many reactive tests were actually false positives. This is especially relevant in programs that used oral based RT [26]. Some of the reactive tests might not have been counted as new diagnoses in SINIVIH since they could have been made in foreigners temporarily residing in Spain who chose to confirm their result in their country of origin, thus they would be counted as a new case of HIV in their national HIV surveillance systems. Similarly, regional contributions can be affected by individuals choosing to attend RT in NCS in programs outside of their region of residence. This could be especially true during 2007 when few regions offered RT in NCS. Contributions during the latter years might be overestimated since data from SINIVIH is affected by reporting delays. However, the latest surveillance data used in this analysis for 2012, and the latest report [27] presents data for 2013. Given that some of the organizations offering RT are very small and difficult to identify and contact, we cannot assure that all programs offering RT have been included in the analysis. However we believe that the 86 programs that were included capture the majority of the rapid tests conducted in Spain in NCS.

This is the first study to quantify the impact of RT in NCS in a national surveillance system. The contribution of these programs in Spain has risen notably since 2007, reaching its peak in MSM, a key vulnerable population. Given the results in some regions, such programs may potentially constitute a core diagnostic strategy, especially for this group. We have identified several regions with high HIV incidence that could clearly benefit from the introduction of a testing option that would facilitate testing of individuals who find it difficult to access the health system or increase testing regularity in those populations in the need of it. We have also identified the need of improving monitoring of follow-up data without, which it is not possible to evaluate the extent to which RT programs in NCS contribute to the reduction in delayed diagnoses and the undiagnosed fraction of the HIV epidemic.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval This is a retrospective study. For this type of study formal consent is not required. Only aggregated data was used in the analysis and no identifying information whatsoever was given by the organizations that run the programmes.

Informed Consent Informed consent was obtained from all the programme attendees included in the study.

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