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Health literacy and breast cancer screening adherence: results from the population of Tuscany, Italy

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Abstract

Mammographic screening can reduce breast cancer (BC) mortality in women. In Italy, although attendance rates increased recently, they are still far from the recommended levels internationally. Inadequate health literacy (HL) may be a reason for poor awareness and/or knowledge about the importance of completing cancer screening. This study examined the relationship between HL, other sociodemographic determinants, and their influence on participation in both opportunistic and organized BC screenings among women aged 50–69 in Tuscany. The study analyzed 2017–2019 data from the Tuscan population subsample in the Italian Behavioral Risk Factor Surveillance System PASSI (Progressi delle Aziende Sanitarie per la Salute in Italia). HL was assessed using the Italian version of the six-item European Health Literacy Survey Questionnaire (HLS-EU-Q6). Among the 2250 interviewees, 75.3% underwent the organized BC screening and 9.4% on voluntary basis. Although to a different extent, HL was significantly associated to compliance rates with both opportunistic and organized screenings. Among sociodemographic factors, only occupational status was associated with opportunistic screening attendance rates. As expected, being invited by letter resulted to be strongly associated with participation to organized screening programs and the medical advice predicts for participating to both opportunistic and organized screening. This study highlights the relevant role that HL plays in BC, opportunistic and organized, screening adherence in a universal healthcare system. To increase BC screening participation rates, healthcare systems would benefit by implementing interventions for improved HL at population level or within healthcare organizations.

Keywords: health literacy, screening, breast screening, prevention, social determinants of health

INTRODUCTION

Female breast cancer (BC) is the most frequently diagnosed malignant tumor in women (representing 25% of all cancers) and accounts for 15.5% of cancer deaths globally (Globocan, 2020).

Mammographic screening for women over 50 years old significantly reduces BC mortality, with estimates suggesting a 48% decrease in mortality among

screened individuals (Independent UK Panel, 2012; Broeders *et al.*, 2018).

Many countries offer a population-based mammographic screening program, defined as organized BC screening program. In Italy, the BC screening is free to all women between 50 and 69 years (age range 45–74 in some regions), provided at regional level and implemented by local health units. It is performed through

Contribution to Health Promotion

- This study examined the role of health literacy and other sociodemographic factors on adherence both opportunistic and organized breast cancer screening among Tuscan women in Italy.
- Health literacy significantly influences breast cancer screening adherence, encompassing both opportunistic and organized screening.
- Occupational status is associated with opportunistic screening participation, while organized screening attendance heavily relied on invitation letters.
- Medical advice significantly influenced women's decisions to participate in both types of screening.
- Healthcare systems should implement literacy initiatives at both the population and healthcare institution levels to enhance screening participation.

mammography every 2 years, which allows to find different types of lesions and early diagnosis of BC. Usually, screening invitations are sent by letter to the eligible target population (ONS, 2019). Additionally, opportunistic BC screening, that is the screening uptake on voluntary basis, significantly contributes to overall adherence (Carrozzi *et al.*, 2015), probably because of the low cost of the test and the reduced waiting times. Women's attendance is promoted also before the age of 50 in case of a specific recommendation by a healthcare professional (such as family BC, for example) or as a woman's own choice; in these cases, the exam is generally at the women's own expense (Pelullo *et al.*, 2021).

In Italy, although participation rates generally increased in recent years, they are substantially lower than those recommended by international guidelines (Arbyn *et al.*, 2010). In 2018, participation in organized public screening programs was 54% for BC (ONS, 2019), which is far from the goal of 70% fixed by the European guideline (Arbyn *et al.*, 2010; Damiani *et al.*, 2012).

Particularly, literature reported that specific populations, such as minorities and low socioeconomic status (SES) groups mostly, do not equally benefit from cancer screening and continue to suffer from high cancer mortality rates (Smith *et al.*, 2012). Inadequate health literacy (HL) may be a reason for the lack of awareness and/or knowledge about the importance of taking cancer screening tests and may be a contributing factor to

cancer screening disparities (Davis *et al.*, 2002; Oldach and Katz, 2014; Baccolini *et al.*, 2022).

HL has been defined as "the combination of personal competencies and situational resources needed for people to access, understand, appraise, and use information and services to make decisions about health, which includes the capacity to communicate, assert, and act upon these decisions" (Bröder *et al.*, 2018). Literature showed that low HL levels are associated with less healthy behaviors and lifestyle, worse self-management skills with related poorer health outcomes and poorer use of health care services (van der Gaag *et al.*, 2022). Berkamn *et al.* (2011) showed how inadequate HL implies a series of heavy consequences on people's health: more hospitalizations, a greater use of emergency care, a lower engagement in mammography screening, a poorer ability to demonstrate taking medications appropriately as well as to interpret labels and health messages, and, among elderly persons, a poorer overall health status and higher mortality rates. Furthermore, patients with low HL levels showed difficulties in understanding and managing complex health care processes, such as programs of oncological screenings, and had a low propensity to seek clarification or help from physicians and healthcare professionals (Kugbey *et al.*, 2019; Tayakoly *et al.*, 2020).

Therefore, in the last decade, scientific research has been showing great interest in HL not only from an individual perspective but also at the organizational level. Health-literate healthcare organizations (HLHOs) has been defined as organizations enabling people to navigate, understand, and apply information and services to take care of their health (Farmanova *et al.*, 2018). Indeed, HLHOs need consistent and robust data to assess progress toward the goal of aligning skills and abilities with demands and complexities, which has not yet been fully implemented to date.

To better explore these difficulties, in 2017, in the Italian Region Tuscany, an additional module to measure HL has been added to the core of the questionnaire of the Behavioural Risk Factor Surveillance System (BRFSS) PASSI (Progressi delle Aziende Sanitarie per la Salute in Italia—Progress by local health units toward a healthier Italy). PASSI is an ongoing nationwide surveillance system, which, since 2008, several modifiable health-related risk factors in the adult population living in Italy, including compliant behaviors with preventive measures, among which opportunistic and organized cancer screenings (Epicentro, 2023).

In recent years, many studies have investigated the relationship between HL and BC screening attendance, mainly focusing on the US and population minorities or individuals from specific socioeconomic settings, so limiting the generalizability of their findings (Baccolini *et al.*, 2022). Furthermore, to the best of our

knowledge, there are no studies investigating the association between HL and adherence to BC screening considering both the public program and the voluntary exams, as women's personal choice or on medical prescription. Opportunistic screening often involves individuals taking the initiative to seek screening independently, which may require a higher level of HL to navigate and comprehend available information, leading to a potentially more substantial role for HL in this context. In contrast, organized screening, characterized by systematic invitations and structured programs, might diminish the relative impact of individual HL, as the initiative for participation primarily relies on the receipt of invitations and established healthcare procedures. Therefore, the present research aims to fill this gap investigating the potential impact of HL and other sociodemographic determinants on both opportunistic and organized BC screening uptake among Tuscan women aged 50–69 years.

METHODS

Study population, sampling criteria and data collection

The present study includes data from 10 734 individuals who were part of the regional representative sample of Tuscan residents aged 18–69, interviewed between 2017 and 2019 through the Italian BRFSS (PASSI). We analyzed data from a specific subset of female respondents aged 50–69 (2250 participants, accounting for 21.5% of the total sample), which served as a representative sample of the Tuscan population targeted by the regional BC screening program. We chose not to include data beyond 2019 due to the disruptions caused by the COVID-19 pandemic, which may have had consequences both on healthcare services and on people's health behaviors.

PASSI collects information on significant behavioral risk factors (i.e. smoking habits, alcohol consumption, physical activity, and diet and nutritional status), the implementation of preventive healthcare services and adherence to crucial preventive measures such as oncological screenings and vaccinations in the adult population aged 18–69 residing in Italy. Trained personnel from the public health departments of each LHM interviewed respondents using a standardized questionnaire carried out by telephone. The core questionnaire comprises 114 questions grouped in 12 modules. In Tuscany, an additional module aimed at investigating HL has been developed and administered from 2017 onward (Zanobini *et al.*, 2021, 2022). Additional information about the survey, sampling methods and PASSI questionnaire items is available elsewhere (Baldissera *et al.*, 2011, 2014).

Measures

Sociodemographic characteristics included in this analysis were age (grouped in 50–59 or 60–69 years age groups), educational level (coded as 'low' for secondary school or lower; 'high' for high school diploma or higher), occupational status (employed, not employed and retired) and nationality (Italian or foreign). Lastly, financial status was assessed asking if the respondents experience financial difficulties in getting at the end of the month with their available resources. The question posed was, 'With the financial resources at your disposal - from your own or family income - how do you get to the end of the month?'. There were four possible answers, categorized for analytical purposes into 'very easily' and 'quite easily' (coded together as 'good'), 'with some difficulties' and 'with many difficulties' (coded as 'poor').

HL level was assessed using the Italian version of the 6-items European Health Literacy Survey Questionnaire (HLS-EU-Q6) (Lorini *et al.*, 2017, 2019), which is a self-reported tool with Likert-type responses ('very easy', 'fairly easy', 'fairly difficult', 'very difficult') designed for the general populations. The numeric values assigned to the response categories were as follows: 'very easy' = 4; 'fairly easy' = 3; 'fairly difficult' = 2; 'very difficult' = 1; and 'don't know/refusal' was considered as missing. The index score was computed by summing the obtained values and dividing the sum by the number of items for which responses were provided, requiring a minimum of five of the six items to have valid responses (Pelikan *et al.*, 2014). According to the final score (x), three possible levels of HL could result: inadequate HL ($1 \leq x \leq 2$); problematic HL ($2 < x < 3$); sufficient HL ($3 \leq x \leq 4$). In this study, HL was treated as a dichotomous variable, grouping together problematic and inadequate HL results (problematic/inadequate HL).

Adherence to BC screening was assessed by asking respondents if they had undergone mammography screening in the 2 years preceding the interview. To distinguish between organized and opportunistic screening, respondents were asked if they had paid for the exam (opportunistic screening) or not (organized screening). Lastly, they were asked if they had received information related to mammographic screening (either the letter of invitation for screening participation, a physician's advice to undergo screening or both).

Statistical analysis

The data were expressed as percentages along with standard deviations, and the Taylor series method was employed to estimate variances. Weighted percentage estimates were computed, with each record assigned a probability weight equivalent to the reciprocal of

Table 1: Descriptive analysis of collected variables (total sample; not screened omen in the last 2 years preceding the interview; voluntarily participated; participated within organized programs)

Variables		Total	Breast cancer screening			P ^a
			Not screened	Opportunistic	Organized	
		% (N = 2250)	% (N = 344)	% (N = 212)	% (N = 1694)	
Age	50–59	52.7 [50.6, 54.8]	51 [45.6, 56.4]	63.6 [56.8, 69.9]	51.7 [49.3, 54.1]	0.005
	60–69	47.3 [45.2, 49.5]	49 [43.7, 54.4]	36.4 [30.1, 43.2]	48.3 [45.9, 50.8]	
Educational level	High	59.4 [57.4, 61.5]	49.3 [44.0, 54.7]	76.2 [69.8, 81.6]	59.4 [57.0, 61.8]	<0.001
	Low	40.6 [38.5, 42.6]	50.7 [45.3, 56.0]	23.8 [18.4, 30.2]	40.6 [38.2, 43.0]	
Occupation	Employed	49.4 [47.3, 51.5]	44.0 [38.8, 49.4]	59.8 [52.9, 66.3]	49.2 [46.8, 51.6]	0.004
	Not employed	3.3 [2.7, 4.2]	4.7 [2.9, 7.7]	0.9 [0.2, 3.6]	3.4 [2.6, 4.4]	
	Retired	47.2 [45.2, 49.4]	51.3 [45.9, 56.6]	39.3 [32.9, 46.2]	47.4 [45.0, 49.8]	
Financial Status	Good	54.5 [52.4, 56.7]	45.1 [39.7, 50.5]	62.7 [55.9, 69.0]	55.4 [53.0, 57.8]	<0.001
	Poor	45.5 [43.4, 47.6]	54.9 [49.5, 60.3]	37.3 [31.0, 44.1]	44.6 [42.2, 47.1]	
Nationality	Italian	94.8 [93.8, 95.7]	91.8 [88.2, 94.4]	96.3 [92.6, 98.1]	95.3 [94.1, 96.2]	0.022
	Foreign	5.2 [4.3, 6.2]	8.2 [5.6, 11.8]	3.8 [1.9, 7.4]	4.7 [3.79, 5.92]	
HL level	Sufficient	59.4 [57.2, 61.6]	46.3 [40.7, 52.0]	71.5 [64.7, 77.4]	60.5 [57.9, 62.9]	<0.001
	Problematic/inadequate	40.6 [38.4, 42.8]	53.7 [48.0, 59.4]	28.5 [22.6, 35.3]	39.6 [37.1, 42.1]	
Information receipt	None	3.0 [2.3, 3.8]	14.1 [10.7, 18.3]	4.0 [2.0, 7.7]	0.6 [0.3, 1.2]	<0.001
	Letter only	24.5 [22.8, 26.4]	23.8 [19.6, 12.5]	10.3 [6.8, 15.3]	26.4 [24.4, 2.6]	
	Medical advice only	4.1 [3.4, 5.1]	9.0 [6.4, 12.5]	29.6 [15.6, 26.7]	1.2 [0.7, 1.9]	
	Letter + medical advice	68.3 [66.4, 70.3]	53.0 [47.6, 58.4]	65.2 [58.4, 71.4]	71.8 [69.6, 73.9]	

^aChi-squared test.

the sampling fraction within each LHU stratum, following the methodology outlined by [Baldissera et al. \(2014\)](#). Bivariate associations between participation in BC screening and sociodemographic factors were examined using the chi-squared test. A multinomial logistic regression model was adopted to assess the association between sociodemographic factors (independent variables) and BC screening uptake (dependent variable, coded as ‘no screening’, ‘yes, organized’ or ‘yes, opportunistic’, considering ‘no’ as the reference category). The regression coefficients are expressed as relative risk ratio (RRR).

All confidence intervals (CI) are calculated taking 95% as the confidence level and an alpha level of 0.05 was considered as significant.

Statistical analyses were performed using Stata 18.0 (STATA Corp LLC, College Station, TX, USA).

RESULTS

Among the total sample of 10 734 interviewees, 2250 women belonged to the 50–69 years group (mean 59.2 SD ± 5.7) and were included in the analysis. Among them, 75.3% underwent BC screening as part of the regional organized program, 9.4% on voluntary basis

(opportunistic), while 15.3% did not undergo mammography. Moreover, 59.43% had a high education level, 49.4% were employed, 54.5% reported a good financial status and 52.1% had a sufficient HL. Finally, 92.9% received an invitation letter and 72.5% were advised by a physician to undergo screening. HL and all the sociodemographic variables were significantly associated with the screening behaviors. A descriptive analysis of the collected data is presented in [Table 1](#).

According to the multinomial logistic regression, HL level was associated with both opportunistic and organized screening compared with nonattendance. In particular, having a sufficient HL level increases the RRR of both opportunistic (RRR 3.23 95% CI 2.01–5.18; $P < 0.001$) and organized (RRR 1.63 95% CI 1.18–2.24; $P = 0.003$) screening attendance. Being unemployed reduce the RRR of opportunistic screening attendance (RRR 0.10 95% CI 0.01–0.89; $P = 0.039$),

Having received information (either an invitation letter, medical advice or both) increases the likelihood of participating in organized screening (RRR 19.49 95% CI 8.24–46.11, RRR 2.96 95% CI 1.03–8.46, RRR 18.88 95% CI 8.20–43.51, respectively). Having received only medical advice to undergo screening was also associated with attendance to

Table 2: Multinomial logistic regression analysis: association of breast cancer screening attendance with sociodemographic factors, health literacy levels and the receipt of invitation letter

Variables	Opportunistic vs no screening			Organized vs no screening		
	RRR	P	95% CI	RRR	P	95% CI
HL level						
Problematic/inadequate ^a	—	—	—	—	—	—
Sufficient	3.23	<0.001	2.01–5.18	1.63	0.003	1.18–2.24
Age						
50–59 ^a	—	—	—	—	—	—
60–69	0.80	0.396	0.48–1.34	1.02	0.901	0.71–1.46
Education level						
Low ^a	—	—	—	—	—	—
High	1.79	0.073	0.96–2.70	1.05	0.756	0.75–1.47
Occupation						
Employed ^a	—	—	—	—	—	—
Not employed	0.10	0.039	0.01–0.89	0.79	0.539	0.38–1.66
Retired	0.82	0.465	0.47–1.41	1.01	0.959	0.69–1.47
Financial status						
Good ^a	—	—	—	—	—	—
Poor	0.65	0.073	0.41–1.04	0.72	0.051	0.51–1.00
Nationality						
Italian ^a	—	—	—	—	—	—
Foreign	0.99	0.448	0.36–2.73	1.20	0.594	0.62–2.33
Information receipt						
None ^a	—	—	—	—	—	—
Letter only	1.37	0.574	0.46–4.07	19.49	<0.001	8.24–27.76
Medical advice only	6.39	0.002	2.01–20.31	2.96	0.042	1.04–8.46
Letter + Medical advice	2.65	0.055	0.98–7.15	18.88	<0.001	8.20–43.51

^aReference group.

opportunistic screening (RRR 6.39 95% CI 2.01–20.31) (Table 2).

DISCUSSION

Our study investigates the impact of HL and sociodemographic factors on the participation in opportunistic and organized BC screenings among women aged 50–69 in Tuscany. We utilize data from the national surveillance system PASSI, which provides a large sample of 2250 women in this age group and residing in the region, representing the target population for BC screening programs. In the investigated sample, 75.3% undergo the BC screening as part of the regional organized program and 9.4% on voluntary basis. We found that HL was significantly associated with both opportunistic and organized screening attendance rates, although to a different extent. Among socio-demographic factors, only occupational status was

associated with opportunistic screening attendance rates. As expected, the receipt of invitation letter, either alone or in combination with the doctor's advice, seems to have a strong association with organized screening programs, while the receipt of only medical advice predicts for participating to both opportunistic and organized screening.

According to our study, only a minority, albeit a significant one, of the population underwent opportunistic screening. Organized screening campaigns have several advantages over opportunistic screening they are free for patients, provide simplified access to high-quality screening and treatment services, and invitation letters reach almost all the population (93% of the target Tuscan population according to our data). Our results suggest that the invitation letter plays the most significant role in motivating women to participate in an organized screening campaign. As a side note, it should be highlighted that the effect of the invitation letter alone is substantially similar to that of

the letter combined with medical advice. On the other hand, among those who did not receive the invitation letter, the receipt of medical advice appears to have a positive influence, prompting women to actively seek inclusion in the organized screening campaign.

Moreover, medical advice seems to have a significant association with attendance to opportunistic screening. The medical recommendation could be the result of a diagnostic doubt which needs to be clarified with a mammography outside of the organized campaign. In accordance with our findings, [Chamot et al. \(2007\)](#) showed that women undergoing opportunistic screening had more contacts with a gynecologist or a general practitioner and therefore are more likely to receive medical advice.

Concerning SES, in our study, only being unemployed reduces the RRR of attendance to opportunistic screening. On the other hand, according to previous research, certain populations, mainly minorities and low SES groups, do not benefit equally from cancer screening ([Smith et al., 2012](#)). Specifically, lower levels of education, lower income and unemployment appear to have a negative impact on participation in BC screening rates ([Duport et al., 2008](#); [Damiani et al., 2012](#); [Nuche-Berenguer and Sakellariou, 2019](#)). However, it is important to note that our study is set in Italy where there is a universal health system, and this may help in reducing SES inequalities. As a general consideration, participants in organized screening programs are almost evenly distributed in all the educational levels. The importance of a universal coverage is testified also by the fact that foreign people, often the most deprived part of the population, participate almost as much as Italians. Embracing a diverse range of individuals, including foreign people, promotes equity and inclusivity within healthcare initiatives. This approach not only benefits the health and well-being of the entire population but also enhances the resilience and cohesion of both society and the healthcare system overall ([Cawcutt and Wilson, 2016](#)).

These results support the hypothesis that screening programs may be an equitable vehicle for prevention ([Chamot et al., 2007](#); [Peisl et al., 2019](#)), but HL still plays a fundamental role in the participation, as testified by other studies that showed that a limited or inadequate level of HL may influence cancer screening participation ([Berkman et al., 2011](#); [Oldach and Katz, 2014](#); [Baccolini et al., 2022](#)). HL, by enabling individuals to gain insight into the potential benefits, risks, alternative options and uncertainties related to undergoing a recommended cancer screening test, holds crucial meaning while making informed decisions about cancer screening. Moreover, it helps individuals in comprehending the importance of early detection and diseases prevention ([Damiani et al., 2012](#)). Concerning

attendance to opportunistic screening, a sufficient HL enables individuals to understand and engage in a shared decision-making process with their doctor ([Damiani et al., 2012](#)). On the other hand, considering attendance to organized screening programs, HL plays a crucial role in the effectiveness of screening campaign invitation letters as it may help individuals to understand the purpose of screening campaigns, so facilitating adherence. Furthermore, an adequate HL allows individuals to understand and follow instructions accurately, increasing their chances of successful participation.

Therefore, in order to increase breast screening participation rates, health care systems should implement interventions at the population level or within healthcare organizations, particularly by the development of HLHOs, which can be clear in the information offered and simple to be navigated. Population-level interventions should aim to enhance HL levels by addressing the SES or through educational and informative reinforcement interventions toward groups with low HL ([Barry et al., 2013](#); [Jacobs et al., 2016](#); [Heine et al., 2021](#)). At the same time, the HLHOs should ensure the dissemination of invitation letters to the target population as widespread and precise as possible, as well as promote the effectiveness of screening for people's health by using clear and plain language, visual aids and a system for timely follow-up and reminders to ensure that individuals receive and act upon the invitation letters ([Brouwers et al., 2011](#); [Cox et al., 2011](#); [Brach et al., 2012](#); [Houston et al., 2021](#)). To reduce inequalities and warrant a universal coverage upon mammography, the objective should be focused on the implementation of an organized screening campaign not influenced by the participants' HL level.

To the best of our knowledge, this is the first study that try to investigate the role of HL in participation to BC screening both on a voluntary basis and as part of public health screening programs in a large representative sample of the general population. The use of a multinomial logistic regression analysis allowed us to distinguish the different relationships that may exist between the participation to both opportunistic and organized BC screening and sociodemographic factors, particularly HL.

However, our work presents some limitations. First, foreign citizens in PASSI may not be representative of the nonresident foreign population, as participating in the PASSI interview requires being enrolled in the healthcare lists and being able to speak Italian. Therefore, some temporary or nonresident foreigners, such as asylum seekers and recent arrivals, might be excluded from being surveyed through the PASSI system. Moreover, self-reported questionnaires may

have led to an overestimation of screening procedures. However, the data on the adherence to BC screening in PASSI are consistent with those of the universal survey of the Italian National Screening Observatory (ONS, 2019).

Another limitation is due to the estimation of coverage within and outside organized screening programs that was carried out using a proxy indicator based on whether the mammography was paid for or not. The use of this indicator may slightly overestimate the coverage within the organized screening programs for two main reasons: (i) some women undergo the test free of charge even outside organized screening programs (e.g. benefiting from health insurance coverage that includes mammography) and (ii) some women do not remember the exact date of the test and do not remember if they paid for it or not.

It is important to note that our study did not encompass certain relevant determinants that may impact participation in BC screening, such as attitudes toward screening, perceptions about engagement, satisfaction derived from previous BC screening experiences and broader aspects related to the health system.

Furthermore, this study encountered the possible limitations of a cross-sectional design when examining associations, as it assesses both exposure and outcomes concurrently, making it impossible to establish the temporal sequence of events. To gain deeper insights into the connection between sociodemographic factors, HL and participation in BC screening, longitudinal investigations are essential. Lastly, it is important to highlight that our study is based on data collected up to 2019. This means we lack information about potential changes that might have occurred in recent years, particularly in light of the COVID-19 pandemic.

CONCLUSION

This study demonstrates the significant role played by HL in BC screening adherence in a universal healthcare system for both opportunistic and organized screening. In order to increase breast screening participation rates, health care systems should implement HL interventions at population level or within healthcare organizations. The final goal of HLHOs, which we wish to develop in order to remove the obstacles that restrict the use of health services offered by the public system, should reduce the impact of low HL through tailored interventions, aiming to eliminate health inequalities within the population. Future research should try to investigate whether the role of HL still remains relevant also after COVID-19 pandemic and the subsequent changes intervened in the management of healthcare services.

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CONFLICT OF INTEREST

The authors have no interests to declare.

ETHICS AND DATA

The research adhered to the principles outlined in the Declaration of Helsinki and was carried out as a component of the Italian healthcare surveillance system PASSI (Progressi delle Aziende Sanitarie per la Salute in Italia). The Ethics Committee of the Italian National Institute of Health (Istituto Superiore di Sanità) provided a favorable ethical evaluation for the Italian behavioral surveillance system PASSI, which includes this study. The final opinion was assigned the protocol number CE-ISS 06/158, dated 8 March 2007.

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