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Full Length Research Paper

Piloting second generation HIV surveillance in Berlin, Germany, 2005 - 2007: Risk profile of recently acquired HIV infections in MSM

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Men having sex with men (MSM) are by far the transmission-risk-category most affected by HIV in Berlin and were investigated in this pilot-study with the aim to identify detailed risk- and prevention-behaviours in recently infected persons. From November, 2005 - February, 2007, venous blood samples were taken from patients in Berlin aged ≥18 years within 3 months after diagnosis of HIV-infection and tested with BED IgG-capture-ELISA (BED-CEIA) to differentiate between longstanding and recent HIV-infections dating back no longer than 140 days from blood sampling. Data on knowledge, attitudes, behaviour and practices ("KABP-survey") relating to HIV/AIDS, were collected anonymously by structured patients' questionnaires, accomplished by demographic data via additional questionnaires filled by the physicians. SPSS 15.0 was used for data analysis. This sub-analysis includes 37 MSM with confirmed recently acquired HIV infection. Mean age was 34 years (20 - 53). Good knowledge on HIV/AIDS in Germany and transmission risks was present in most cases; nevertheless unprotected sexual contacts were indicated by 90% of recently HIV-infected MSM (independent from type of intercourse and partners' sero-status) with 64% reporting unprotected anal intercourse. Unprotected anal intercourse with a person they knew to be infected with HIV was stated by 19% of cases. In 5% drugs/alcohol and in 48% (n = 18/37) uncertain HIV-related knowledge, hope and beliefs about transmission risks were stated as reasons for unprotected sex. Almost half of recently infected MSM in this pilot-study were infected because hope and beliefs on HIV-transmission-risks had guided their personal decisions on HIV-prevention efforts. Limitations due to a small study population, lack of HIV-negative-tested controls and selection bias should be optimised in future studies; however, the findings have strong implications for amending prevention messages in Germany addressing MSM.

Key words: KABP-survey, HIV, BED-CEIA, second-generation HIV surveillance, recency of infection.

INTRODUCTION

HIV/AIDS surveillance in Germany is based on obligatory anonymous reporting of newly diagnosed HIV infections from laboratories diagnosing HIV infections in blood samples, whereas AIDS cases and HIV/AIDS-related mortality are reported voluntarily to the Robert Koch-Institute (RKI) from treating physicians. HIV case reporting is mandatory since 1987 in Germany. Since 2001 HIV surveillance in Germany is legally regulated through of the national *Protection against Infection Act* (*Infektionsschutzgesetz*; IfSG). HIV case reporting includes a case-related coding with the aim to identify double or multiple case reports thus improving data quality considerably without allowing at the same time to make individuals identifiable (Hamouda, 2003). HIV surveillance in Germany observed a steady decline of reported newly diagnosed HIV cases since the mid 19-nineties with the lowest annual number of 1,443 cases reported in 2001. Thereafter Germany faced a considera-

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ble resurgence of newly diagnosed cases by more than 90% until 2007 when 2,752 annual cases were reported. This increase was primarily related to the transmission risk category men having sex with men (MSM) (Hamouda et al., 2007; RKI, 2008). The rise observed in MSM, however, is not yet fully understood since traditional surveillance data only allow limited risk analyses. First data from HIV recency testing in Germany suggest that this increase is not only due to more frequent HIV diagnoses, but rather new infections actually happen more often, especially in the age group 20 - 29 years (Bätzing-Feigenbaum et al., 2009). An internet survey in 2006 addressing MSM in Germany found indicators for sexual behaviour implying increasing risk to acquire HIV (Schmidt et al., 2007).

It is the specific nature of HIV, its natural course of infection and its particular epidemiology which implicate limitations with regards to the interpretation of traditional surveillance data. One limitation is that the newly diagnosed HIV cases represent only part of the actually newly acquired, incident infections, because not all new HIV infections are diagnosed immediately. The main reasons are the frequent lack of symptoms during acute HIV infection, the unspecific character of symptoms, and the extreme variability of the asymptomatic period until symptoms are observed which can last up to many years (Kahn and Walker, 1998). Another limitation is that the available tools for routine HIV diagnosis only allow to confirming diagnosis, but for the most part not to deciding when the infection actually happened. Only under the rare condition that the infection is diagnosed during acute infection presenting markers for acute seroconversion the time of infection can be determined with some accuracy (Daar et al., 2001).

It was a diagnostic cornerstone when in 1998 a serology-based algorithm was described that was able to discriminate between recent and longstanding HIV infections (Janssen et al., 1998). Since then the methodology was further developed and amended by a number of working groups with test systems based on various approaches and algorithms (Suligoi et al., 2003; Murphy et al., 2003; Dobbs et al., 2004; Barin et al., 2005; Martro et al., 2005; Parekh and McDougal, 2005; Schüpbach et al., 2007). Due to the relatively low specificity and sensitivity of all methods published until today, these tests are approved for epidemiological research only and not for individual diagnosis. In a pilot study between 2005 and 2007 in Berlin the methodology was used for the first time in Germany. In the first phase we compared two distinct methods using a sample of 148 HIV seroconverters from the German HIV Seroconverter Cohort with well defined dates of seroconversion (Loschen et al., 2008). Both, the BED IgG-capture ELISA (BED-CEIA) and the Avidity-Test proved competent to differentiate between recent HIV infections dating back no longer than 140 days from blood sampling and longstanding infections. In the second phase we tested the BED-CEIA in the field by implementing a pilot study with cross-sectional recruitment of patients with newly diagnosed HIV infections in Berlin.

In the Berlin pilot study the proportion of recently acquired HIV infections in the study population of overall 51% (Bätzing-Feigenbaum at al., 2009) was high compared with findings from other studies in neighbouring countries, where proportions of 27% in Austria, 36% in Switzerland, and 25% in France were found (Puchlhammer-Stockl et al., 2005; Gebhardt et al., 2007; Lot et al., 2004). But the results referring to MSM in the French national HIV surveillance indicating a proportion of 46% (Semaille et al., 2007) were comparable with the corresponding proportion found in the Berlin study (54%). The low proportion of recent infections in persons with HIV transmission risks other than MSM of 16% in the pilot study corresponded well with the findings from France were 18% of cases with heterosexual transmission risk and 10% of persons originating from HIV high prevalence countries (HPC) in sub-Saharan Africa were found to have recent HIV infections (Semaille et al., 2007). The World Health Organisation (WHO) and the United Nations Programme on HIV/AIDS (UNAIDS) define HPC with an HIV prevalence higher than 1% in the general population (UNAIDS and WHO, 2008; UNAIDS, 2007).

Methods to estimate recency or incidence of HIV infections are currently used as routine HIV surveillance instrument in some federal states and regions of the United States of America (CDC, 2006; Hall et al., 2008) and in the national HIV surveillance systems of France (Lot et al., 2004; Semaille et al., 2007) and Switzerland (Gebhardt et al., 2007).

Since 2002 WHO and UNAIDS have advocated to supplement the traditional HIV core surveillance focusing on epidemiological and demographic data with the collection of data on knowledge, attitudes, behaviour and practices in the context of HIV/AIDS (“KABP”-survey), also referred to as “second generation surveillance” (WHO and UNAIDS, 2002). The aim of collecting such data is on the one hand to characterize sexual behaviour and practices including risks to acquire HIV infection, on the other hand to identify possible protective factors. Due to the constraints for HIV surveillance described above the realization of HIV second generation surveillance in Germany is limited and more or less restricted to sentinel surveillance sites or to selected study populations at increased risk for HIV.

However, simple serological methods to identify the actual time window for recent HIV infections could open up new vistas on second generation surveillance. Thus case-related behavioural data can be correlated exactly to the individuals who recently acquired their HIV infection. To our knowledge KABP-data correlated with HIV recency test results were only used in the national HIV surveillance in Switzerland (Gebhardt et al., 2007).

In Germany estimations of HIV incidence up to now have been limited to the back-calculation modelling HIV

case reports and prevalence data collected through the national HIV surveillance instruments (Hamouda et al., 2007; RKI, 2008). There are currently no instruments of second generation HIV surveillance routinely implemented in Germany as recommended by the WHO and UNAIDS (WHO and UNAIDS, 2002).

The aims and objectives of this study were to pilot the following questions: (i) to evaluate and establish serology-based algorithms for HIV recency testing in Germany (published elsewhere; Loschen et al., 2008); (ii) to judge feasibility and applicability of the method in the context of German HIV surveillance (published elsewhere; Bätzing-Feigenbaum et al., 2008; Bätzing-Feigenbaum et al. 2009); (iii) to assess the relevance of the results for amending the German national HIV/AIDS surveillance in accordance with WHO standards (published elsewhere; Bätzing-Feigenbaum et al. 2008); (iv) to assess the collection of KABP-data related to HIV/AIDS and correlate these data with core epidemiological information sampled from men having sex with men (MSM) recently infected with HIV ("second generation surveillance" in its strict sense according to WHO and UNAIDS).

In this paper we address the last of the above mentioned aims. For several reasons we included only MSM with recently acquired HIV infection in the analysis. One reason is that the number of patients with other HIV transmission risk categories in this pilot study, were by far too small for sound analyses (13 of 132 patients recruited; Bätzing-Feigenbaum et al., 2009). This fact reflects on the other hand the situation in the Federal Land of Berlin, where MSM are the most affected transmission risk category for acquiring HIV infection. In 2007 MSM constituted 77% of all new HIV diagnoses in Berlin compared with 56% in Germany country-wide (RKI, 2008). The focus on MSM is furthermore relevant from the Public Health point of view, since in contrast to all other transmission risk categories the number of reported new diagnoses in MSM is increasing steadily in Germany since 2001.

METHODS

Venous blood samples (VBS) were taken from patients not later than 3 months after an HIV infection has been diagnosed through HIV-1&2 ELISA screening followed by confirmatory Western Blood and/or PCR testing. VBS were sent within 48 hours to the RKI laboratory facilities where blood was processed and stored frozen in aliquots at -70°C until use. Samples were tested using a commercially available HIV-1 specific IgG capture ELISA (BED-CEIA; Calypte Biomedical Corp., Lake Oswego, USA) (Dobbs et al., 2004; Parekh et al., 2002; McDougal et al., 2006). The evaluation and establishment of the test at the RKI laboratory were published elsewhere (Loschen et al., 2008).

The test showed acceptable sensitivity and specificity (80 and 86% respectively) which were similar to the values published earlier(Parekh et al., 2002). To increase the probability of BED-CEIA results to identify recent HIV infections we applied a lower cut-off for the normalized optical density (ODn) of ≤0.65. This measure increased specificity and positive predictive values to 97.6 and 93.6%, respectively (reduced sensitivity 45%).

Thus all samples identified as 'recent' could be considered with high probability to represent a recently acquired HIV infection, while accepting at the same time a reduced sensitivity (Loschen et al., 2008; Bätzing-Feigenbaum et al., 2009). In a next step the samples with BED-CEIA result "recent" were linked with the corresponding case-related KABP-data.

Quality control

For long term storage, the samples were frozen at -20°C or colder, with care taken to avoid freezing and thawing specimens no more than 4 times. In the European Centre for the Epidemiological Monitoring of AIDS (EuroHIV) collaboration project (EuroHIV Incidence Collaboration, Work Package 7 (Murphy et al., 2008) part of the samples were additionally tested by at least one other laboratory: at the (i) Health Protection Agency, Centre for Infections, 61 Colindale Avenue, London, NW9 5HT, UK; and at the (ii) Centre National de Référence du VIH, Centre Hopitalier Universitaire Bretonneau, 37044 Tours Cedex, France.

For the BED-CEIA control testing plasma from the samples collected in the pilot study was thawed and aliquots were sent at standard refrigeration temperature (2 - 8°C) to the collaborative laboratories in the UK and France. BED-CEIA was applied according to standard protocols.

Thirty one of thirty seven samples (84%) were sent to collaborative laboratories for additional quality control tests. The BED-CEIA results were confirmed for all thirty one samples as recently acquired HIV infections.

Data collection and description of the sub-sample for analysis

Cases were enrolled between November 1st, 2005 and February 28th, 2007 through convenience sampling in private practices and outpatient clinics in the study area of Berlin, Germany, when patients were seeking medical care to request HIV counselling and testing. There are close to 50 centres specialized in HIV/AIDS in the Federal Land of Berlin and all were asked to participate. 20 of the 50 centres recruited at least one patient. Of the 20 collaborating centres, four are outpatient clinics and 16 are private practitioners. The data collection process has been described in detail previously (Bätzing-Feigenbaum et al., 2009).

Inclusion criteria for patient recruitment were: (i) age 18 years or older; (ii) newly diagnosed HIV infection and time of venous blood sampling within 3 months from date of diagnosis; (iii) at time of blood sampling no clinically advanced AIDS disease (clinically stage C); and (iv) no antiretroviral treatment (ART) at time of blood sampling (Bätzing-Feigenbaum et al., 2009).

Eligible patients were informed by the study physicians orally and through a study information form. Participants were only recruited after giving written informed consent. Physicians contributed basic clinical and medical history data filling in a structured questionnaire ("physicians' questionnaire") (Bätzing-Feigenbaum et al., 2009).

Patients were asked to fill in a structured questionnaire ("patients' questionnaire") targeting on individual demographic data and KABP-data relating to HIV/AIDS. The patients' questionnaire included the following items:

- Individual behaviour regarding measures to prevent HIV transmission during six months before HIV diagnosis (11 questions);
- Assessment of personal risks for acquiring HIV during six months before HIV diagnosis (10 questions);
- General assessment of HIV transmission routes (11 questions);
- Additional demographic data (2 questions);
- General and specific knowledge about HIV/AIDS (6 questions);

Table 1. Comparison of basic demographic data (age group; country of origin) between the pilot study population (transmission risk category 'men having sex with men', MSM; with recently acquired HIV infection) [n = 37] and the data from newly diagnosed HIV infections in MSM reported in the national HIV surveillance system [n = 341] (Federal Land of Berlin; November 1, 2005 - February 28, 2007).

Comparative variables		HIV incidence pilot study [n = 37]		National HIV surveillance [n = 341]		
		n	valid %	n	%	valid %
Age group	20 - 29 years	12	32.4	95		27.9
	30 - 44 years	23	62.2	186		54.5
	> 44 years	2	5.4	60		17.6
Country of origin	Germany	35	94.6	268	78.8	89.3
	foreign origin	2	5.4	32	9.4	10.7
	total with valid data on origin	37	100.0	300	88.2	100.0
	unknown country of origin	0	0.0	41	11.8	
Total		37	100.0	341	100.0	

And - Sources of information about HIV/AIDS in the past 6 months (3 questions).

All data were collected anonymously and unlinked not allowing to identifying patients' identities retrospectively or prospectively. Participating physicians were paid an expense allowance per recruited case. Eligible patients were not offered any material compensation. However, physicians were allowed to pass on the allowance they received to the respective patient if they liked to do so.

The study population has been described previously (Bätzing-Feigenbaum et al. 2009). A total of 132 patients with newly diagnosed HIV infection were recruited. Of these 114 cases were eligible according to the predefined eligibility criteria. 102 of these specified MSM as HIV transmission risk category (89%), only 12 cases belonged to other transmission risk categories. BED-CEIA results of the 102 MSM blood samples revealed that at time of diagnosis 53 patients had recent and 49 patients had longstanding HIV infections. The BED-CEIA results were highly specific (ODn ≤ 0.65; high specificity defined with 97.6% that the HIV infection was acquired recently within the past 140 days before diagnosis) for 42 patients, whilst 11 had a BED-CEIA result in the "grey zone" with lower specificity (Bätzing-Feigenbaum et al., 2009). For 37 of the 42 MSM with highly specific BED-CEIA test result to be recently infected with HIV, patients' questionnaires with corresponding KABP-data were available. Thus data from 37 MSM with recently acquired HIV infection are eligible for this sub-analysis aiming to evaluate the use of KABP-data for HIV second generation surveillance in Germany.

Data analysis

Analyses were performed using SPSS 15.0 (SPSS Inc. Headquarters, Chicago, Illinois 60606, USA). Means of metric variables were analysed creating ANOVA tables. KABP-data from recently infected MSM were analysed descriptively.

RESULTS

The mean age of the study population was close to 34 years (range: 20, 53 years; s = 8.18). The age group 30 - 44 years prevailed with 62% (n = 23; Table 1). 35 participants stated Germany as country of origin where they spent most part of their life, whereas only two cases indicated foreign origin. The national German HIV surveillance at the RKI provided data from newly diagnosed HIV infections in MSM reported from the Federal Land of Berlin during the recruitment period (November, 2005 - February, 2007); however, information about the recency of the HIV infection is not available from this data source (RKI, 2008). Comparing these data with the study population (MSM with recently acquired HIV infection enrolled in private practices and outpatient clinics in Berlin) reveals that the study population is younger by mean of age (33.9 years and 35.3 years, respectively), the age group >44 years is less frequent (5% compared with 18%), and German origin is reported more often (Table 1).The education level of the study population of MSM from Berlin recently infected with HIV (n=37) was relatively high: 12 (32%) had a university examination degree as highest degree, 10 (27%) a university-entrance diploma, 8 (22%) a Q-level degree, and 6 (16%) an elementary school degree.

The knowledge on HIV/AIDS in Germany was present in a large proportion of the study population. 84% knew that HIV cases increased in Germany in the past years; nearly 60% estimated the number of newly diagnosed HIV cases per year in Germany well between 1,000 and 5,000 cases; and 40% estimated the total number of all HIV infections until end of the year 2005 correctly between 10,000 and 100,000 cases (data not shown). 70% did not agree with the statement that it is not that bad to be infected with HIV because there are new treatments available (however, 11% agreed with this statement) and 81% did not confirm that they protected themselves less properly due to new antiretroviral therapies (only 3% agreed with this statement). 95% did not approve that highly active antiretroviral treatment (HAART) can cure HIV/AIDS and 84% disagreed with HAART to prevent transmission of HIV. However, 87% confirmed that HAART can extent life time of people living with

Table 2. Assessment of various HIV transmission risks by MSM with recently acquired HIV infection (Federal Land of Berlin; November 1 2005 - February 28 2007) [n = 37].

Possible risk for HIV transmission [n = 37]	Estimated risk level											
	High		Medium		Low		No risk		Don't know		Not spec.	
	n	%	n	%	n	%	n	%	n	%	n	%
Toilette use	1	2.7	0	0.0	3	8.1	29	78.4	3	8.1	1	2.7
Everyday life contacts	0	0.0	1	2.7	4	10.8	31	83.8	0	0.0	1	2.7
Blood contact with intact skin	11	29.7	7	18.9	6	16.2	9	24.3	1	2.7	3	8.1
Pregnancy	21	56.8	10	27.0	0	0.0	0	0.0	4	10.8	2	5.4
Needle sharing	35	94.6	0	0.0	0	0.0	0	0.0	1	2.7	1	2.7
Oral sex with ejaculation	27	73.0	6	16.2	2	5.4	0	0.0	1	2.7	1	2.7
Oral sex without ejaculation	9	24.3	10	27.0	13	35.1	3	8.1	1	2.7	1	2.7
Oral sex with an HIV-infected receptive partner	8	21.6	5	13.5	15	40.5	4	10.8	3	8.1	2	5.4
Receptive sex (anal or vaginal) with ejaculation	36	97.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.7
Receptive sex (anal or vaginal) without ejaculation	19	51.4	16	43.2	1	2.7	0	0.0	0	0.0	1	2.7
Penetrating sex (anal or vaginal) with an HIV-infected partner	21	56.8	9	24.3	4	10.8	1	2.7	1	2.7	1	2.7

HIV/AIDS (PLWHA) considerably.

In the past six months before diagnosis of their HIV infection 14% of the study cases informed themselves regularly about HIV/AIDS, 57% occasionally and 24 % did not confirm having informed themselves about HIV/AIDS. Sources of information perceived in the past 6 months before diagnosis were posters (87%), advertisement in journals (81%), information through gay press (81%), information in television spots (60%), internet (49%), cinema spots (46%), and flyers from AIDS counselling organisations (43%). Radio spots and public events or presentations were states less frequently.

As most important sources of information about HIV/AIDS from a general point of view 78% of the study population stated conversation with friends and partners, Internet (76%), television (70%), daily newspapers (62%), “scene” journals (57%), and periodicals (51%), whereas other media like Public Health services, clinics, medical books, public speeches and events, radio and other sources were ranked as less important (data not shown).

Table 2 shows the answers concerning a number of sexual and non-sexual HIV transmission risks for HIV as assessed by the study participants. Concerning sexual transmission risks 97% estimated the risk for HIV transmission as high through passive anal intercourse with ejaculation and 51% without ejaculation. Oral sex with ejaculation was perceived as high risk for the passive partner by 73%, without ejaculation only by 24%. 57% thought active, penetrating sex with an HIV infected partner implied high transmission risk, 43% stated only a medium risk. Daily life contacts were estimated to have low or no risk by the majority of participants. 95% answered that needle sharing has a high HIV transmission risk Table 3 summarizes information about current living arrangements, partnership characteristics, and path, source of infection and country where the HIV infection happened. 51% live as singles and 35% in a homosexual partnership. 9 of 13 MSM with a steady partner stated that they have sex outside this partnership. 70% stated that they know where they acquired their HIV infection, and 46% said that they know the source personally. 46% indicated anonymous sexual contacts as transmission path (not including contacts with commercial sex workers). 16% acquired HIV infection through sex with their partner, 14% with a friend, and 8% in the context of a new relation. 95% acquired their HIV infection in Germany. 14% answered to know quite well and 79% supposedly the exact period when the HIV infection happened. 68% correlated the time when the HIV infection happened well within a period of 140 days before diagnosis (Table 3).

Table 4 displays the sexual risks taken in the past six months before diagnosis as indicated by the participants. Furthermore the number of personal sexual contacts and the relative frequencies of protection through condom use during different sexual practices in the past six months before the HIV infection was diagnosed are shown. 92% of the recently infected MSM answered that they had unprotected sexual contacts in the last six months before diagnosis, without taking into consideration the type of sexual intercourse (oral, anal and/or vaginal sex) and the HIV-serostatus of their sexual partners. 51% had active and 51% had passive unprotected anal intercourse, these proportions not completely overlapping making a total of 64% unprotected anal intercourse including active, passive or both types. Totally 82% had unprotected oral intercourse (70% penetrative and 16% receptive).19% stated unprotected anal intercourse with a person they knew to be infected with HIV (16% had penetrative and 11% receptive anal intercourse).

Another complex of questions asked, whether or not, and how consistent the participants used condoms during

Table 3. Partnership characteristics and information regarding path, source, and country of HIV acquisition in MSM with recently acquired HIV infection (Federal Land of Berlin; November 1 2005 - February 28 2007) [n = 37].

Question$ [n = 37]	n	%	n	%	n	%	n	%	n	%	n	%
(1) Currently living in a partnership?	Single		Homosexual Partnership		Heterosexual Partnership		Othe$r type		Not specified			
	19	51.4	13	35.1	1	2.7	1	2.7	3	8.1		
(2) Steady partnership?	No		Yes						Not specified			
	23	62.2	13	35.1					1	2.7		
(3) If applicable, duration of partnership?	2 - 6 Months		7 - 12 Months		> 12 months						Not applicable	
	4	10.8	1	2.7	9	24.3					23	62.2
(4) If applicable, sex outside of steady partnership?	No		Yes						Not specified		Not applicable	
	4	10.8	9	24.3					1	2.7	23	62.2
(5) Known source of infection?	Yes, known		Supposedly						Not specified			
	26	70.3	9	24.3					2	5.4		
(8) Source of infection known personally?	Yes, known		no						Not specified			
	17	45.9	15	40.5					5	13.5		
(6) Path of sexual HIV transmission?	Anonymous sexual contact*		Sexual contact with steady partner		Sexual contact with a friend		Sexual contact in a new relation		Not specified		Multiple sexual transmission paths	
	17	45.9	6	16.2	5	13.5	3	8.1	5	13.5	1	2.7
(7) Country where infection happened?	Germany		Abroad						Not specified			
	35	94.6	1	2.7					1	2.7		
(8) Period when infection happened?	Yes, known		Supposedly						Not known			
	3	13.5	29	78.4					5	13.5		
(9) Time of infection estimated within 140 days before diagnosis (recently)?	yes		no						Not specified			
	25	67.6	7	18.9					5	13.5		
(10) Source of infection known to be HIV infected?	Yes, known		No, not known						Not specified			
	3	8.1	12	32.4					22	59.5		

$ all questions referring to the past six months before HIV diagnosis.
* Not including prostitution.

sexual intercourse in different situations in the past months (not regarding the type of sexual intercourse). Almost 90% said that they always disposed of condoms in the past half year, and 62% said they always did use condoms during anonymous sexual contacts. 60% used condoms always during sex with a friend, 43% always at the beginning of a sexual relationship. 24% did not use condoms consistently when having sex with a person they knew to be HIV infected, 43% did use condoms in such situations, and 32% did not answer this question. We conclude that the majority of the latter did not have or did abstain from sexual contacts with partners they knew to be infected with HIV (data not shown).

The reasons why condoms were not used in the previous 6 months were related to the use of drugs and/or alcohol (5%), problems when using condoms (16%), partner's decision and own obedience (16%), and answers covering hope, beliefs and uncertain knowledge about HIV transmission risks (48%), the latter including 16% who said that they did not perceive their sexual partner to be at risk for being infected with HIV. The statements agreed to in this context of hope, beliefs and uncertain HIV-related knowledge were: (i) I believed that there was no transmission risk for me; (ii) I hoped that nothing would happen; (iii) I assumed that my partner was not infected with HIV; and (iv) I did not think that with what we were practicing a transmission risk existed (data not shown).

DISCUSSION

The BED-CEIA as one established method to identify recent HIV infections proved valid to identify incident

Table 4. Different types of unprotected sexual intercourse (no use of condoms) in the past six months before the diagnosis of HIV infection in MSM with recently acquired HIV infection (Federal Land of Berlin; Nov 1 2005 - Feb 28 2007) [n=37].

Types of unprotected sexual intercourse (without condom use) and number of sexual partners [n = 37]	unprotected (no condom use)		if unprotected: number of sexual partners …					not unprotected (condom use)		not specified	
			… 1	… 2-5	… 6-20	… >20	not spec.				
	n	%	n	n	n	n	n	n	%	n	%
Vaginal with partner(s) of unknown HIV serostatus	7	18.9	2	2	1	0	2	24	64.9	6	16.2
Vaginal with a partner known to be infected with HIV	1	2.7						33	89.2	3	8.1
Penetrative oral with partner(s) of unknown HIV serostatus	26	70.3	6	9	6	4	1	9	24.3	2	5.5
Penetrative oral with partner(s) known to be infected with HIV	6	16.2						26	70.3	5	13.5
Receptive oral with partner(s) of unknown HIV serostatus	6	16.2	2	2	0	1	1	26	70.3	5	13.5
Receptive oral with a partner known to be infected with HIV	6	16.2						26	70.3	5	13.5
Penetrative anal with partner(s) of unknown HIV serostatus	19	51.4	8	8	1	1	1	15	40.5	3	8.1
Penetrative anal with a partner known to be infected with HIV	6	16.2						27	73.0	4	10.8
Receptive anal with partner(s) of unknown HIV serostatus	19	51.4	8	6	3	0	2	15	40.5	3	8.1
Receptive anal with a partner known to be infected with HIV	4	10.8						28	75.7	5	13.5

infections, which is not possible in the majority of cases during routine HIV diagnosis. Judging descriptively the KABP data obtained from a small sample of MSM from Berlin, Germany recently infected with HIV, high risk behaviour could be observed with regards to protection efforts during sexual intercourse especially as to condom use. Though 90% of the study participants always disposed on condoms during the past half year (corresponding with the period when they acquired HIV infection), 62% used a condom always when having anonymous sex. 24% did not use always a condom when having sex with a partner they knew to be infected with HIV. 32% of the recently HIV-infected patients said that they hoped nothing would happen during sexual intercourse, or they believed or thought actually not to be exposed to an HIV transmission risk. 16% assumed that the sexual partner was not HIV infected. Interestingly the existing knowledge about the trends and dynamics of the HIV epidemic in Germany seems relatively good in this group of recently infected MSM from Berlin. However, a possible advantage through this knowledge with regards to preventive behaviour must be disputed. Though numerically and methodologically limited, the data sugest that almost half of recently HIV infected MSM in this pilot study were infected because hope, beliefs, and uncertain knowledge on risks for HIV transmission had guided their personal decisions on prevention efforts during sexual contacts in the past six months. The BED-CEIA could confirm with high probability that the HIV infection took place within this period. These findings have strong implications for amending prevention messages in Germany which explicitly intend to address MSM.

No negative controls (patients who seek medical care to test for HIV and revealing negative HIV test results) were enrolled at this stage which would have allowed for comparative analyses with the recently infected individuals. This limited design was chosen since in the pilot study the readiness of patients with newly diagnosed HIV infection to participate in the study was evaluated in the first instance. The willingness of persons who test negative for HIV to participate in HIV-related research is not foreseen as a limitation to the prospected future implementation of second generation HIV surveillance in Germany. To reduce selection bias of the HIV negative controls we choose a matched pairs case-control design for the nationwide incidence study.

The findings furthermore suggest that extension of HIV surveillance in Germany by adding continuous KABP data collection is feasible and will provide important additional data, because real-time data on sexual attitudes, behaviour and practices will become continuously available. Since these data have to be collected via treating physicians and after obtaining informed consent from the patients, selection bias is likely. Hence

KABP data collection should be complemented by an additional study arm with negligible selection bias.

These unbiased HIV recency test results and basic demographic data, basic laboratory results (CD4, VL), CDC stage, and data about transmission risk category, will be obtained from laboratories using surplus serum or plasma samples from routine HIV tests. Respective samples can be collected for additional anonymous HIV testing using the BED-CEIA according to the German national Protection against Infection Act (IfSG). These data without selection bias can be used to adjust the KABP data collected from the clinical study arm for age, sex and transmission risks.

To identify the causes of HIV transmission in recently infected individuals KABP data from negative controls must become part of the study design. This extended design will provide deeper insight into behavioural and attitudinal factors which protect from or increase risk for acquisition of HIV in different transmission risk categories in Germany. Special efforts will have to be made to improve contact and response rates of women, heterosexual men and persons originating from HPC who were underrepresented in the pilot study.

To our knowledge this second generation HIV surveillance approach is not yet made use of in other countries with concentrated HIV epidemic apart from Switzerland where, however, only 34% of patient questionnaires were returned and only 32% of these agreed to participate in an interview to explore more detailed sexual risk behaviours and attitudes towards prevention practices (Gebhardt et al., 2007). In Germany a country-wide study based upon the results of the pilot study was implemented in 2008 and will support HIV prevention with highly topical KABP data (Bätzing-Feigenbaum et al., 2008). The method will be amended in coherence with the pre-existing national surveillance.

Conclusion

Second generation HIV surveillance combined with HIV recency testing proved relevant and feasible to implement in countries like Germany with a concentrated HIV epidemic. Linking data of recently HIV infected persons with KABP data collected from the same patients will provide useful additional information to support efficient and highly topical prevention strategies. The results of the pilot study suggest currently existing high risk behaviour regarding condom use in recently HIV infected MSM in Berlin, Germany. The design of future HIV incidence surveillance has to consider special measures to avoid selection bias and to improve response rate of certain population groups at risk for HIV infection as for instance women, heterosexual men and persons with origin from HPC. In Germany second generation HIV surveillance based on epidemiological core data and collection of KABP data was first implemented in 2008.

Author's contributions

All authors participated in the critical discussion of the results, read and approved the final draft before submission.

JBF coordinated the study as well as doing the data cleaning and the majority of analysis and writing.

SL evaluated and established the laboratory methods at the RKI as well as doing the laboratory tests and the analysis of laboratory data.

SGM was responsible for data base management and cleaning of data as well.

RZ supported data analysis and gave important input to implementing the methodology in the national German HIV surveillance programme.

CK was responsible for the study design and implementation and performance of the laboratory methodology including quality control.

OH was responsible for epidemiological study design and its implementation and supported overall approach of the analyses and writing.

Competing interests

The authors declare they do not have competing interests.

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