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A review on viral hepatitis B surveillance in Singapore, 1999-2004

Introduction

Hepatitis B is a serious disease and can lead to complications such as persistent inflammation of the liver, liver cirrhosis and liver failure. In 2002, WHO estimated that more than 2,000 million people have been infected with the hepatitis B virus (HBV) in their lifetime. Of these, about 350 million remain infected chronically and become carriers of the virus. Three-quarters of the world's population live in areas where there are high levels of infection[1].

Hepatitis B has emerged as a public health problem in Singapore in the 1980s and active intervention activities were implemented through health education, immunization and active screening of pregnant women[2]. The impact of ongoing hepatitis B prevention and control activities are closely monitored by the Ministry of Health through triangulating of surveillance data obtained from routine notifications, hospital in-patients statistics, and the results of periodic seroprevalence studies.

A total of 98 cases of acute hepatitis B were reported in 2004, an increase of 53% compared to the 64 cases reported in 2003. All the cases presented with typical acute signs and symptoms and were serologically confirmed by the presence of hepatitis B surface antigen (HBsAg) and anti-HBc IgM antibody.

To assess the impact of various intervention programmes on the burden of hepatitis B in Singapore, a systematic review of the epidemiological data obtained during the period 1999-2004 was conducted.

Methods and materials

Surveillance data obtained from the mandatory notification system and the national seroprevalence survey conducted in 1999 were analysed. The most recent data on the incidence of acute hepatitis B were extracted from the national surveillance database which is maintained at the Ministry of Health. The results of routine antenatal hepatitis B screening carried out at the KK Women's and Children's Hospital (KKH) were collected and analysed to determine the changing trends of hepatitis B carrier rates among pregnant women.

Results

Incidence of acute hepatitis B

The annual incidence rate of acute HBV infection in Singapore was high in the 1980s, with a rate of 9.2 per 100,000 population in 1985. Since the national hepatitis B vaccination programme for infants born to hepatitis B carrier mothers was introduced in 1985 and subsequently extended to all newborns from 1987 onwards, there had been a sharp decline in the annual incidence rate in the 1990s (*Fig 1*). Immunisation coverage for infants below one year of age remained high from 1999 to 2004 (*Fig 2*).

During the study period, the overall annual incidence of acute hepatitis B continued to decline from 3.4 per 100,000 population in 1999 to a record low of 1.3 per 100,000 population in 2002. However, the incidence rate increased to 2.3 per 100,000 population in 2004 (*Fig 3*).

During the six-year period, there had not been any notification of acute hepatitis B in children aged below 15 years. The average annual incidence among those aged 15 years and above was 2.2 per 100,000 population, with the highest incidence found in the 25-34 year age group (*Fig 4*). In 2004, the incidence in the 25-34 year age group and 35-44 year age group was 4.2 per 100,000 and 3.0 per 100,000 population, respectively.

Population immunity & hepatitis B carrier rate

The 1999 national seroprevalence study revealed that about 60.0% of the population had no

Figure 1
Incidence of reported acute hepatitis B cases* in Singapore, 1985-2004

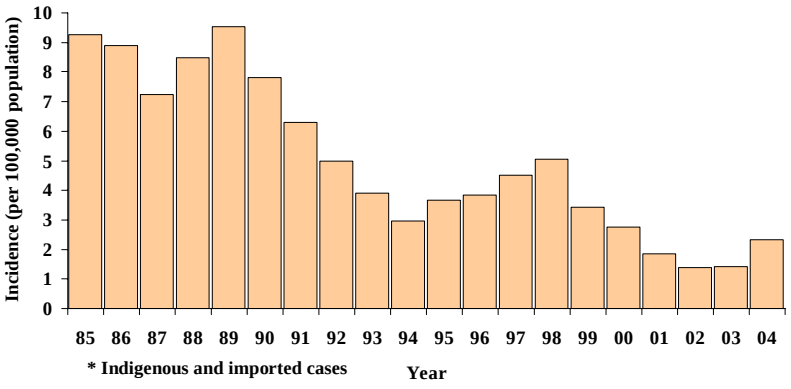


Figure 2
Acute hepatitis B incidence+ and immunisation coverage for infants*, 1985–2004

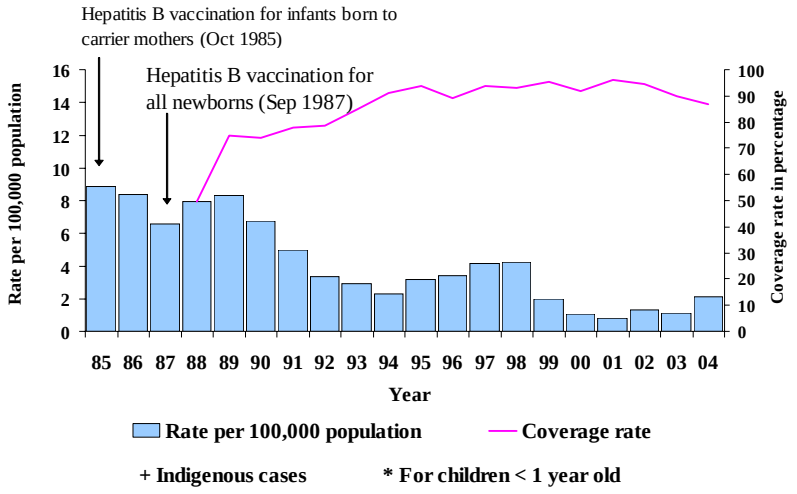


Figure 3
Reported acute hepatitis B in Singapore, 1999-2004

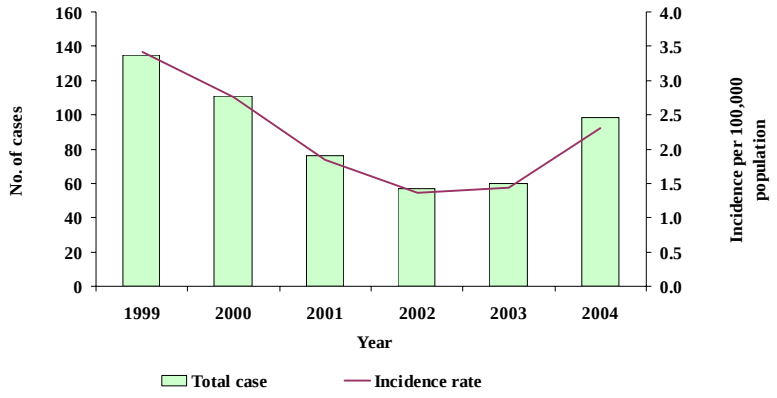
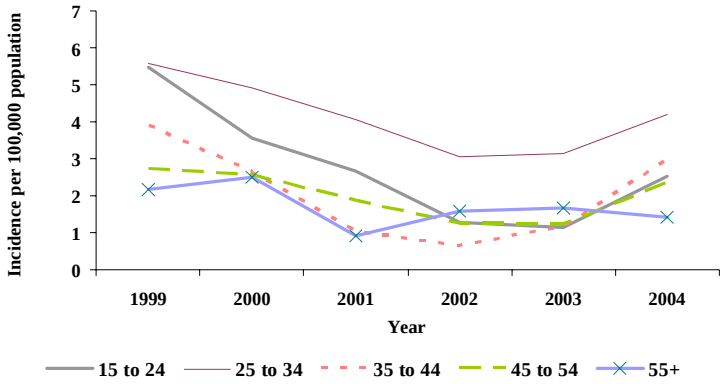


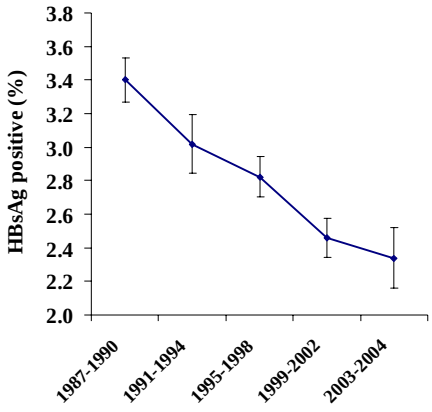
Figure 4
Trend of acute hepatitis B incidence by age group, 1999–2004



immunity to HBV, and the prevalence of antibody against hepatitis B surface antigen (anti-HBs) was lowest among those in the 18-29 year age group. Only about 28.0% of these young adults had immunity to HBV[3]. Over the period from 1999 to 2004, the highest HBV incidence rate was observed among those in the 25-34 year age group *(Fig* 4). This trend corresponded to the findings of the national seroprevalence study which showed that adults in this age-cohort were most susceptible to HBV infection.

The HBsAg carrier rate among antenatal women had declined significantly from 3.4% for the period of 1987-1990 to 2.3% for the period of 2003-2004 (p<0.001) (*Fig 5*).

Figure 5
Trend of HBsAg carrier rate with 95% confidence interval among antenatal women, 1987-2004



Conclusion

The national childhood immunisation programme has contributed to the effective control of acute hepatitis B in young Singaporeans below 15 years of age. The antenatal screening programme has also revealed that the proportion of hepatitis B carriers among pregnant women has declined over the years. The transmission dynamics of HBV infection among sexually-active hepatitis B carriers and the susceptible population would contribute to the future burden of HBV infection. Therefore, there is a need for a follow-up national seroprevalence survey to determine the proportion of susceptible population among Singaporeans since the implementation of the enhanced hepatitis B immunisation programme in 2001.

[Reported by Li HY, Ho YM, Ye T, Ang LW, Chow A, Communicable Diseases (Surveillance) Division, Ministry of Health]

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Travel-associated malaria in Singapore, 1995 - 2004

Introduction

Malaria accounted for up to three million annual deaths globally[1]. Each year, 10,000 to 30,000 travellers from industrialised countries were estimated to have contracted malaria[2]. WHO has declared Singapore to be malaria-free in 1982[3]. Since then, the Ministry of Health has continued to receive notifications of laboratory-confirmed malaria cases among Singapore residents. Majority of them had reportedly acquired the disease overseas and these were classified as imported cases. This article explores the burden of travel-associated malaria and its epidemiological trend among Singapore residents in the past 10 years from 1995 to 2004.

Materials and methods

The surveillance data obtained from mandatory notifications of malaria and the epidemiological information routinely collected during investigations of each notified case were collated and analysed. Singapore residents with travel-associated malaria were further analysed to determine their age, ethnic group, purpose of travel, countries visited and history of chemoprophylaxis.

Results

During the period 1995 - 2004, the average annual number of malaria cases reported was 276, which gave an average annual incidence rate of 8.6 per 100,000 population. None was classified as an indigenous case in accordance to WHO's epidemiological criteria. Singapore residents (i.e. citizens and permanent residents) represented approximately 20-32% of the total notifications, with the majority (95%) acquiring the infection overseas (*Fig 6*).

The purposes of travel included social visits, holidays, business and military service. Majority of the cases contracted malaria while on holidays or visiting relatives or friends living abroad (*Fig. 7*). The two countries where malaria were most commonly acquired were Indonesia and India.

The ethnic distribution of residents who contracted malaria overseas is presented in *Fig. 8*. Chinese accounted for 44.1%, Malays 33.6%, and Indians 16.4% of the cases.

In 2003, the incidence was highest among Malays (3.2 per 100,000 population), followed by

Figure 6
Annual notifications of malaria cases, 1995-2004

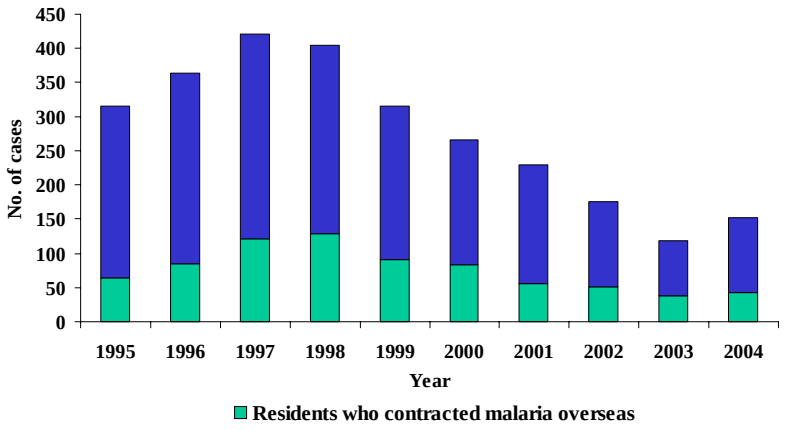


Figure 7
Purpose of travel among Singapore residents with imported malaria

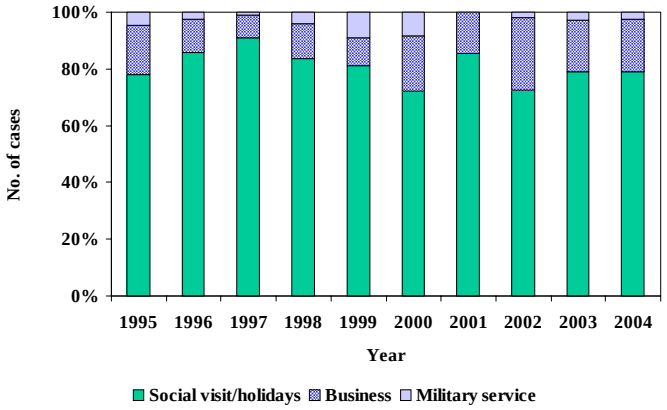
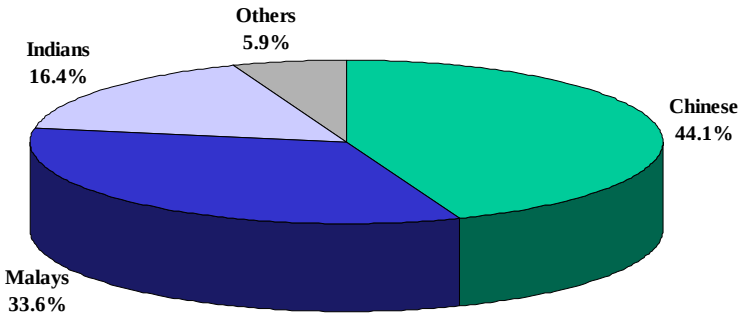


Figure 8
Ethnic distribution of malaria cases among Singapore residents, 1995-2004



Indians (2.5 per 100,000) and Chinese (0.8 per 100,000). The age-specific incidence was highest in the 25-34 year age group (3.0 per 100,000 population), followed by the 15-24 year age group (2.9 per 100,000 population).

During the study period, most malaria cases among Singapore residents had not taken any chemoprophylaxis prior to travel (91.0%), while 6.0% took irregular or incomplete prophylaxis. Only 3.0% reportedly completed the full course of chemoprophylaxis (*Fig. 9*).

Comments

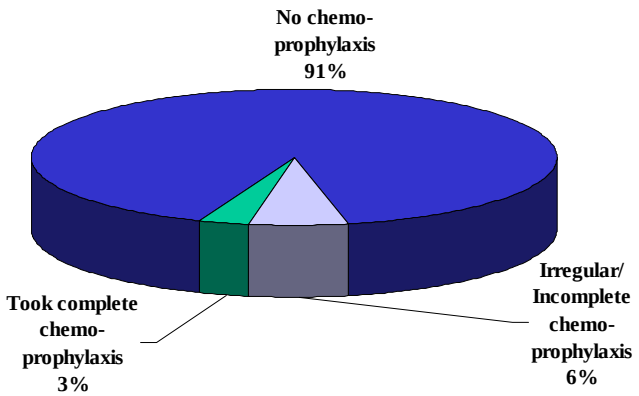
Malaria is highly endemic in many of the popular vacation and business destinations of Singapore residents. Although chemoprophylaxis is affordable and easily accessible to travellers, some Singapore residents have not taken the necessary precautions to prevent themselves from contracting the disease when travelling to these endemic areas.

The risk of acquiring malaria for travellers depends on their specific risk behaviours; namely, rural travel, night time exposure, unscreened accommodation, duration of stay and time of travel in the malaria-endemic area, especially during the high malaria transmission season, and the elevation of the destination.

To prevent Singapore residents from being infected, travellers should be reminded on all these risk factors and to take appropriate preventive actions, including protection against mosquito bites[4]. Malaria chemoprophylaxis provides a significant protection against malaria, and travellers should seek advice from their family doctors on malaria chemoprophylaxis at least four weeks prior to departure. In the event that they develop a fever, they should seek medical treatment promptly to prevent deterioration of the condition.

There is a need for further studies to understand why some Singaporean travellers do not take malaria prophylaxis when visiting malaria-endemic countries.

Figure 9
History of chemoprophylaxis among Singapore residents with imported malaris, 1995-2004



(Reported by Toh HY, Ye T and Chow A, Communicable Diseases (Surveillance) Division, Ministry of Health)

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Institutional outbreaks of norovirus gastroenteritis in Singapore

Norovirus gastroenteritis[1] usually presents as acute-onset vomiting, watery non-bloody diarrhoea with abdominal cramps, and nausea. Low-grade fever also occasionally occurs, and vomiting is more common in children. Dehydration is the most common complication, especially among the young and elderly. The causative agent[2] is a group of related, single-stranded RNA, non-enveloped viruses that cause acute gastroenteritis in humans. They are named after the original strain "Norwalk virus", which caused an outbreak of gastroenteritis in a school in Norwalk, Ohio, in 1968. Currently, there are at least four norovirus genogroups (GI, GII, GIII and GIV), which in turn are divided into at least 20 genetic clusters. The incubation period is 24-48 hours and symptoms commonly last 24-60 hours. Recovery is usually complete and there is no evidence of any serious long-term sequelae.

In the six-month period from Sep 04 to Feb 05, the Ministry of Health investigated into 3 institutional outbreaks of viral gastroenteritis involving a childcare centre, a nursing home and a destitutes' welfare home. The results of our investigations are reported herein.

Childcare centre

The first outbreak involving a childcare centre was notified on 28 Sep 04. The centre was located at a church premises and licensed by the Ministry of Community Development, Youth & Sports. It provided playgroup, nursery and kindergarten classes to children between 18 months and 6 years of age. The centre had a total enrolment of 87 children. There were 13 staff comprising the principal, 8 teachers, 2 cooks, an administrative officer and a cleaner. The premises was also used by children attending the Sunday school organized by the church.

A total of 16 cases experienced vomiting, diarrhoea and abdominal cramps between 17 and 29 Sep 04. The outbreak started at the Nursery 1 class where a child developed vomiting and abdominal cramps. The next day, several of her classmates became ill. The infection spread within the centre to involve other classes in three subsequent waves with the date of onset of illness of the last two cases on 29 Sep (*Fig.10*).

The attack rates of the affected classes were as follows :

Playgroup	: 4/16 x 100%	= 25 %
Nursery 1	: 7/17 x 100%	= 41.2 %
Nursery 2	: 4/19 x 100%	= 21.1 %
Kindergarten 1	: 1/19 x 100%	= 5.3 %

Two stool samples were taken and sent to the Dept of Pathology, Singapore General Hospital (SGH), for testing of norovirus and rotavirus. Both were positive for norovirus using reverse-transcriptase polymerase chain reaction (PCR).

Nursing home

The second outbreak which occurred in a nursing home was notified by the in-house doctor on 18 Jan 05 when 19 of the residents came down with diarrhoea and vomiting. The home had a total of 178 residents (excluding 71 daycare patients) and was supported by 85 nursing and 20 administrative staff. The residents were aged from 46-100 years.

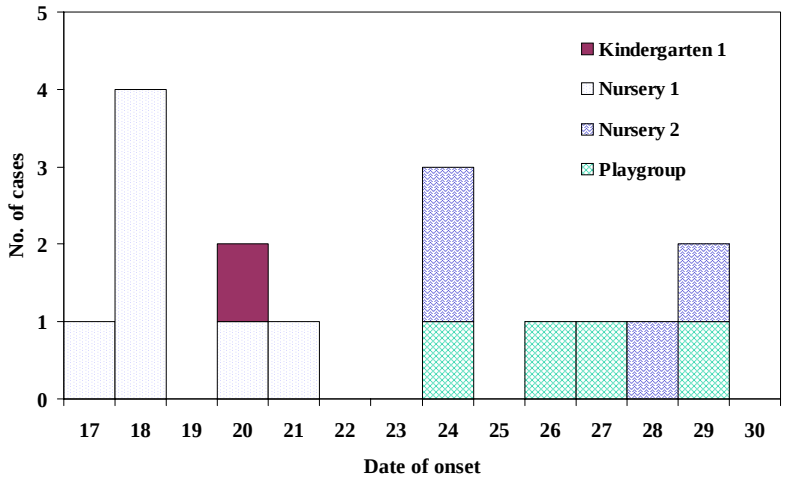
A total of 26 residents experienced diarrhoea and/or vomiting on 17-18 Jan 05. Their conditions were generally mild with the majority experiencing 1-2 episodes of gastrointestinal illness and recovering after 24 hours. The outbreak began with a crop of 4 cases on 17 Jan, followed by another crop of 22 cases on 18 Jan. No further transmission occurred after 18 Jan 05 (*Fig. 11*). The attack rate was 14.6 % (26/178 x 100).

All the 5 stool samples collected were tested positive for norovirus by PCR at the Dept of Pathology, SGH.

Destitutes' welfare home

The third outbreak involved a destitutes' welfare home and it was notified on 1 Feb 05. The home had 137 residents and was staffed by 13 full-time nurses, 1 part-time nurse, 8 administrative officers,

Figure 10
Time distribution of 16 cases of gastroenteritis at a childcare centre, 17–29 Sep 2004



22 healthcare attendants, 4 food handlers and 2 cooks. The age of the residents ranged from 24-104 years.

A total of 65 individuals comprising 61 residents and 4 staff developed diarrhoea and vomiting between 31 Jan and 4 Feb 05 (*Fig. 12*). The attack rate was 44.5% (61/137 x 100) for inmates and 8% (4/50 x 100) for staff. All of the cases were mild and recovered within 24 hours. Majority of the residents' illness were detected by the duty staff nurses during their ward rounds. Most of the inmates were dissociated and not cognizance of their surroundings.

Norovirus was detected by PCR in 2 stool samples collected from the inmates and tested at the Dept of Pathology, SGH.

Prevention and control

The three institutions were satisfactorily maintained, and no major irregularities in environmental and food hygiene were noted. For the nursing and welfare homes, daily meals were prepared at the in-house kitchen by food handlers and cooks trained in basic food and personal hygiene.

Figure 11
Time distribution of 26 cases of gastroenteritis at a nursing home, 17-18 Jan 2005

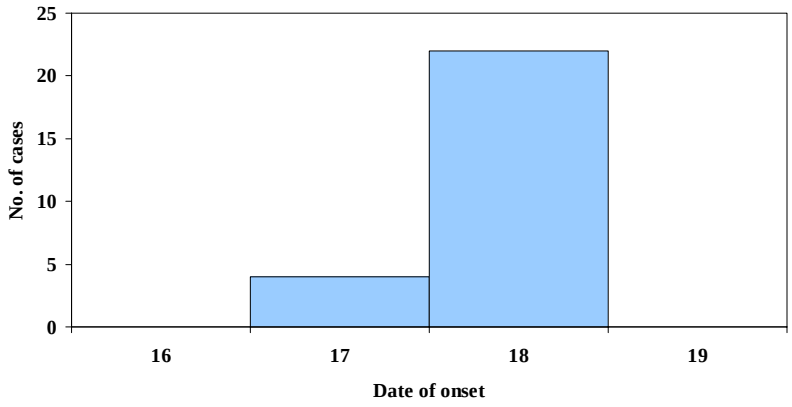
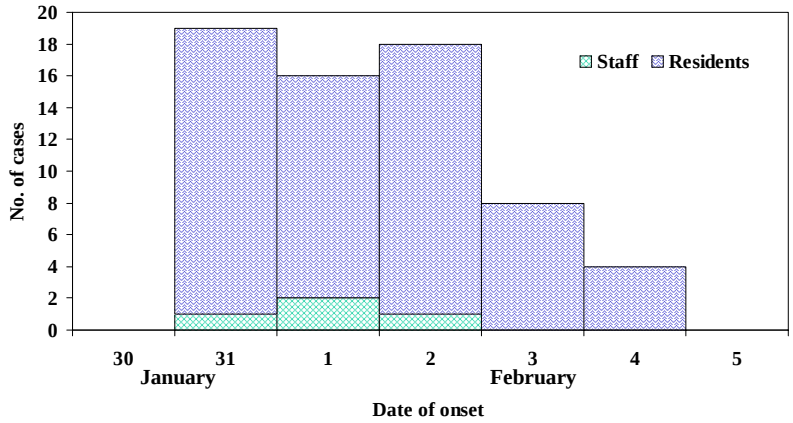


Figure 12
Time distribution of 65 cases of gastroenteritis at a destitutes' welfare home, 31 Jan–4 Feb 2005



The following measures were implemented to interrupt the chain of transmission:

- early detection and isolation of cases;
- removal and washing with hot water and soap for all clothing or linens that might have been contaminated with the virus after an episode of illness;
- careful flushing of vomitus and/or stools into the toilet;
- thorough cleaning and disinfection of contaminated surfaces immediately after an episode of illness by using a bleach-based household cleaner;
- maintenance of a high standard of personal hygiene by frequent hand washing, especially after toilet visits and change of diapers and before eating or preparing food;
- carefully washing of fruits, vegetables and other ready-to-eat foods;
- disposal of food that might have been contaminated by an ill person;
- removal of symptomatic food handlers from preparation of food until 3 days after they had recovered from illness; and
- maintenance of proper general environmental sanitation and hygiene

Comments

Noroviruses are transmitted primarily via the faecal-oral route, either by consumption of faecally contaminated food or water or by direct person-to-person spread. Transmission via fomites and aerosolization of vomitus has also been reported. During outbreaks of norovirus gastroenteritis, several modes of transmission have been documented[1]. The modes of transmission of the outbreaks at the nursing and welfare homes could not be determined as a number of inmates were elderly and senile and communicating with them was generally difficult. For the child care centre, person-to-person transmission was responsible for the propagation of the outbreak as evidenced by the epidemic curve. The outbreaks were promptly brought under control through early intervention with close cooperation and full support from the management of the affected institutions.

Although norovirus gastroenteritis is usually self-limiting and not life-threatening, the likelihood of more severe disease may be increased for immunocompromised persons and the elderly[3]. Risk factors in institutional settings include close contact among the resident population in recreation and living areas, and decreased personal hygiene among some aged residents due to incontinence, immobility, or reduced alertness.

(Reported by: Ng J, Low C, Chan PP, Suderman NR, Wong C, Yip R, Ng A, Lim S, Ooi PL, Disease Control Branch, Ministry of Health)

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Rapid tests for human immunodeficiency virus (HIV) infection

Introduction

The objectives for HIV testing are[1]:

- screening of blood and other body tissues (transfusion/ transplant safety);
- surveillance of HIV infection (unlinked and anonymous testing); and
- diagnosis of HIV infection/acquired immune deficiency syndrome.

Several HIV testing strategies have been developed. The commonest testing algorithm has been screening of serum specimens with EIA (enzyme immunoassay) and repeat testing of reactive specimens with the more specific Western blot assay[2]. This strategy is appropriate for screening in low-HIV prevalence populations due to concerns about false positive results.

However, this strategy has its inherent drawbacks[3]. EIA is a technically demanding technique which requires complicated machines and equipment. Batch testing is usually practised to fully utilize the 96-well microtitre set-up and thus laboratories may delay testing until a sufficient number of samples have been collected. Use of Western blot assay is limited by its high cost and the need for elaborate equipment. Other disadvantages of Western blot assay include the lack of consensus in the interpretation criteria and the occurrence of indeterminate results[4]. Many of the high-HIV prevalence countries are also resource poor and this strategy alone is not practical for their needs.

Rapid test kits

As early as 1990, alternative strategies for the detection of HIV antibodies were shown to be as sensitive and specific as the standard algorithm of EIA/ Western blot[5]. Improvement in diagnostic technologies has brought about development of rapid test kits. These tests deliver results within a very short period of time and open up the option of point-of-care testing.

There are three common immunological technologies used in these HIV rapid test kits[6]. They are:

Particle agglutination

The test kit uses minute HIV antigen-coated particles. In the presence of HIV antibodies, cross-linking occurs and results in agglutination. These assays require serum or plasma and typically require 10 to 60 minutes or more.

Membrane immunoconcentration (flow-through devices)

This technique uses solid-phase capture technology which involves the immobilization of HIV antigens on a porous membrane. The specimen flows through the membrane and is adsorbed into an absorbent pad; a dot or a line visibly forms on the membrane with a signal reagent. Several steps are required to complete the test and each test may take 15 minutes to complete. Serum and plasma are used though some devices come with a filter which allows whole-blood specimens to be used as well. A disadvantage

is that these devices require refrigeration for storage.

Immunochromatography (lateral-flow strips)

These strips incorporate both antigen and the signal reagent into a single nitrocellulose strip. The specimen is applied to an adsorbent pad from which it is wicked and then migrates across the strip. A line where HIV antigen has been applied will develop when a positive reaction occurs. A procedural control line that detects IgG is usually applied to the strip beyond the HIV-antigen line. Most of these strips can utilize whole blood, serum or plasma. They do not require refrigeration and test results are available in 15 minutes

There are two less commonly employed techniques[6]. The autologous red-cell agglutination test detects HIV antibodies with a hybrid antigen-antibody reagent which, when added to the red blood cells of the patient, agglutinates the patient's own red cells. The immunodot comb assay uses a solid plastic matrix with "teeth" attached to one another, to which HIV antigen is fixed to capture HIV antibodies. Patients' specimens are placed in wells spaced to accommodate each tooth of the comb and results for each specimen are visualized as a spot or dot on the corresponding tooth.

Besides blood specimens, rapid test kits which test saliva sample are also available. These include brands such as OraQuick and SalivaCard. Saliva samples are non invasive and may be more acceptable for surveillance purposes.

How good are these test kits?

Detailed data regarding EIA and rapid tests for HIV evaluated by the WHO are provided in the report series on *HIV Simple/Rapid Assays: Operational Characteristics*. The data shows that the sensitivity and specificity of some rapid assays are comparable to those of EIA. (See *Table 1* for a summary list of rapid tests and their operational characteristics). However, rapid tests may detect seroconversion samples a few days later that EIA. These differences may not be significant unless there are high rates of recent infections[7].

Also, for HIV screening, in areas where HIV prevalence is low (e.g. Singapore), the negative predictive value of a single rapid test is high. A negative rapid test does not require further testing and negative results with result-specific counselling can be provided to most persons at the initial visit. However, because the positive predictive value of a test will be low in areas of low prevalence, a positive test must be confirmed with a second test[8].

Advantages and disadvantages of using these test kits

Rapid tests have many advantages. Most of them are easy to use with a limited number of steps needed to perform the test. There is no need for sophisticated equipment and some rapid test kits can be stored without refrigeration, The more recent kits allow whole blood to be tested rather than serum or plasma. No formal training is required and the interpretation of the results is generally straightforward. Results are obtained typically around 15 minutes.

Rapid testing is not cost efficient for testing a large number of samples at a time. It may also cost more per individual test than EIA[9] (but there are cost savings with cheaper manpower and capital cost associated with buying sophisticated equipment) and

Table 1

Rapid test kits for HIV infection

Manufacturer	Product	Principle	Sensitivity %	Specificity %	Comments
Abbott Laboratories Abbott Park, Illinois USA	Determine HIV-1/2/0	Lateral flow	97.9-100	100	Complexity 1 Whole blood /serum Store at room temperature
	Retrocell HIV-1/2	Red cell agglutination	100	100	Complexity 2 Store at 2-8°C
	SUDS HIV-1	Flow through	97.9-99.9	77.4-99.6	Complexity 3 Store at 2-8°C
Agen Biomed Brisbane, Australia	SimpliRED HIV-1/2	Red cell agglutination	99.2	87.3	Complexity 2 Store at 2-8°C
	MicroRED HIV-1/2	Particle agglutination	98.5	99.5	Complexity 2 Store at 2-8°C
Bionor A/S Skien, Norway	Bionor HIV-1/2	Magnetic beads	100	98.8	Complexity 3 Store at 2-8°C
BioRad Laboratories Redmond, Washington USA	Genie II HIV-1/2	Flow through	97.8-100	99.7-100	Complexity 2 Store at 2-8°C
	Multispot HIV-1/2	Flow through	99.3-100	98.5-100	Complexity 3 Store at 2-8°C
Cal Test Diagnostics Los Angeles, USA	Red Dot HIV-1/2	Flow through	100	94.9	Complexity 3 Store at 2-8°C
Epitope, Inc. Beaverton, Oregon USA	OraQuick	Lateral flow	100	100	Complexity 1 Store at room temperature Whole blood, serum, saliva
Fujerebio Tokyo, Japan	Serodia HIV-1/2	Particle agglutination	100	98	Complexity 3 Store at 2-8°C
Genelabs Technologies Inc. Redwood City, California USA	HIV SPOT-1/2	Flow through	97-99	96-99	Complexity 2 Store at room temperature
Sayvon Diagnostics Ltd Ashdod, Israel	HIV SAV-1/2	Flow through	97.7	96.7	Complexity 2 Store at room temperature
Hepatika Laboratories Mataram, Indonesia	Entebe HIV Dipstick	Immunodot comb	100	96.4	Complexity 3 Store at 2-8°C
Immunochemical Laboratories Bangkok, Thailand	Dipstick HIV-1/2	Immunodot comb	100	98.2	Complexity 2 Store at 2-8°C
J Mitra & Co. New Dehli, India	HIV Tri-Dot	Flow through	99.6	99.7	Complexity 3 Store at 2-8°C
MedMira Laboratories Halifax, Nova Scotia, Canada	MedMira HIV-1/2	Flow through	99.0-100	100	Complexity 2 Store at room temperature. Whole blood, serum
Orogencis Ltd. Yavne, Israel	DoubleCheck HIV-1/2	Immunodot comb	100	99.7	Complexity 2 Store at room temperature
Ortho Diagnostics New Brunswick, New Jersey USA	HIVCHEK System 3	Flow through	98.2-100	98.8-100	Complexity 3 Store at room temperature

Manufacturer	Product	Principle	Sensitivity %	Specificity %	Comments
Saliva Diagnostic Systems New York, New York USA	Hema-Strip HIV-1/2	Lateral flow	98.8-99.6	99.9-100	Complexity 1 Store at room temperature Designed for finger stick
	Sero-Strip HIV-1/2	Lateral flow	98.4-99.9	99.6-100	Complexity 2 Store at room temperature
Span Diagnostics Surat, India	CombAIDS Visual	Immunodot comb	100	88	Complexity 2 Store at 2-8°C
Trinity Biotech Bray, Wicklow Ireland	Capillus HIV-1/2	Particle agglutination	98.6-99.9	98.2-99.6	Complexity 2 Store at 2-8°C
	SalivaCard HIV	Flow through	98.9	98.8	Complexity 2 Store at 2-8°C Saliva
	SeroCard HIV	Flow through	99.8-100	97.9-99.5	Complexity 2
	UniGold HIV-1/2	Lateral flow	98.6-99.8	99.6-100	Complexity 1 Store at 2-8°C Whole blood, serum
Universal Healthwatch Columbia, Maryland USA	Quix HIV-1/2/O	Flow through	100	99.8	Complexity 2 Store at 2-8°C Whole blood, serum
Wiener Laboratories	DIA HIV-1+2	Immunodot comb	99.6	99.4	Complexity 2 Store at 2-8°C

Notes to table:

Sensitivity and specificity entries with range represent published reports against multiple HIV-1/2 subtypes; entries with single figure represent data from a single independent evaluation, usually that of the WHO.

Complexity rating:

1. Sample manipulation limited to application followed by addition of buffer reagent or wash; easily read.
2. In addition to (1), centrifugation required; optional equipment optional.
3. In addition to (2), reagent or sample preparation required; multi-step assay.

(Source: Branson BM. Rapid test for HIV antibody. AIDS Review 2000 2:76-83)

interreader variability may provide inconsistent results with some assay formats (e.g. particle agglutination).

Currently, most HIV rapid test kits can detect both HIV-1 and HIV-2 but most of these tests do not differentiate between them[10]. This may not be important in HIV testing and counselling services. However, in areas where HIV-2 is endemic, this differentiation may be significant for initiating antiretroviral therapy.

Applications of rapid tests for HIV testing

Transfusion/ transplant safety

Screening assays for HIV for purpose of transplant and transfusion should be as sensitive as possible and should be able to detect infections as early as possible. It should also be specific to avoid unnecessary wastage of collected blood products. In many industrialized countries, the traditional EIA/Western blot strategy serves this purpose well.

In resource scarce settings, blood products are collected only when they are needed and blood banks typically do not store much blood products. Therefore, HIV testing is only performed on a few samples at any one time. Many of the wells deployed in the EIA will thus be unused and wasted. Besides, in these settings, the laboratories and staff are likely to be ill-equipped to do EIA and testing may not be even be carried out in the first place due to all these limitations. Thus, rapid test kits may play a role in screening for HIV in blood/ tissue products in these countries.

Surveillance

Rapid tests have advantages in testing of hard-to-reach populations such as intravenous drug users, commercial sex workers or geographically remote populations. The use of non- invasive methods for collection of specimens such as saliva may make surveillance of these populations more acceptable.

Diagnosis of HIV Infection

One main advantage of rapid test is that patients can often receive results within the same day. Many people who are tested for HIV never receive their results. A study in the US showed that only 63% of the subjects returned for their post-test counselling[11]. Rapid, on-site HIV testing is feasible, preferred by clients, and results in significant improvement in the number of persons learning their serostatus[12]. A study in Uganda showed that introduction of HIV rapid tests resulted in a 27% increase in the proportion of clients who learned of their serostatus and received counselling[13]. However, to further increase uptake in HIV testing, it is important to heighten awareness of these rapid tests which should also be made more broadly available[14].

For pregnant women who go into labour without prior HIV testing, point-of-care rapid testing provides HIV results faster. OraQuick rapid test was used as part of the MIRIAD (Mother Infant Rapid Intervention at Delivery) study in Chicago and the median turnaround time using rapid test kits was 45 minutes, compared to 3.5 hours for conventional laboratory testing. Rapid HIV testing of pregnant women not screened for HIV during prenatal care will help to decrease perinatal transmission rates by increasing the proportion of infected women and their infants receiving intrapartum and postpartum prophylaxis[15].

In occupationally acquired needle-stick injury in health care settings, rapid tests have a role in immediate evaluation of source patient, reduce patient anxiety and avoid unnecessary antiretroviral use in the healthcare worker. Use of the rapid test also results in substantial cost savings compared to EIA in these situations[16].

Comments

In Singapore, the manufacturers of HIV rapid test kits and their authorized representatives can apply for their use in approved healthcare institutions for HIV testing under the Voluntary Product Regulation Scheme administered by the Centre for Medical Device Registration (CMDR), Health Sciences Authority (HSA)[17]. All information and data related to the product, including the performance evaluation studies or clinical trial studies have to be provided in the application. The performance criteria include the analytical and diagnostic specificity and sensitivity, as well as the studies to be conducted using the targeted user group or patient group with the given instruction of use for the users to perform the test.

[Reported by Wong CS, Communicable Diseases (Policy) Division, Ministry of Health]

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