



# Prevalence of Hepatitis B Virus among Blood Donors in Khartoum State

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## Abstract

**Background:** Hepatitis B virus infections considered to be second cause of liver problem in Sudan. Aim of this study is to determine Hepatitis B prevalence among blood donors, to assess the sensitivity and specificity of ICT test compared to ELISA as gold standard method. As well determine the awareness of the disease among studied population.

**Methodology:** Questionnaires filled during direct speaking with participants. Specimens then collected and proceed.

**Result:** A 12.2% was the prevalence of HBV in Khartoum-Sudan with elevation (62.2%) in youth (20-30) age may associate with sexual practice and/or drug injection hence no evidence of contact to blood. ICT (Biorex) shown less sensitivity 81.8% compare to ELISA by giving 2sample false negative. Only 27 (30%) out of 90 donors have knowledge about hepatitis B and most of them lack knowledge about its vaccine. And 6 (6.7%) were vaccinated these numbers indicate that population are in need of general health awareness.

**Conclusion:** Screening method should be done by ELISA. Health awareness is needed as well introducing vaccination to the community also more researches required to confirm the result.

**Keywords:** Hepatitis B virus; ICT; ELISA; Prevalence; UMST; Khartoum-Sudan

## Introduction to Hepatitis

### Hepatitis

Hepatitis: means inflammation of the liver cells (hepatocyte), also it refers to group of viral infections that affect the liver [1].

**Aetiology of hepatitis:** Hepatitis is caused by variety of a common viral hepatitis (A, B, C, D, and E). Other viruses which causes hepatitis are Epstein-Barr virus (EBV), cytomegalovirus (CMV), Autoimmune condition, drugs and /or chemicals as alcohol overuse may also causes acute hepatitis that is similar to the viral one [2].

**Signs and symptoms of HBV infection:** The clinical features of acute hepatitis B are indistinguishable from that of other types of acute viral hepatitis. And most children under ages 5 years are asymptomatic, where as 30%-50% of persons  $\geq 5$  years have initial signs and symptoms which include Fever, fatigue, nausea,

vomiting, loss of appetite, dark urine and joint pain. Persons with chronic HBV infection might be asymptomatic, have no evidence of liver disease [3].

### Types of hepatitis

Viral hepatitis: some viruses may causes hepatitis although they are common known to causes other disease including (CMV, EBV). While others are the main causative agent of hepatitis such as:

- Hepatitis A: its cause by hepatitis A virus (infectious hepatitis)
- Hepatitis B: cause by hepatitis B virus (serum hepatitis)
- Hepatitis C: cause by hepatitis C virus (none A, non B hepatitis)
- Hepatitis D: cause by hepatitis D virus (Delta agent)

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- Hepatitis E: cause by hepatitis E virus

There is evidence of the existence of hepatitis G. Hepatitis G virus is a flavivirus, like HCV to which it is closely related. Non-viral hepatitis: this cause due to some autoimmune status, chemicals and drugs [4].

### Hepatitis B

Hepatitis B is an enveloped virus composed of double-stranded DNA, enclosed within a nucleocapsid core (HBcAg) surrounded by an outer lipoprotein envelope into which the surface antigen (HBsAg) is embedded. A third antigen, HBeAg, is soluble and usually released from liver cells with active HBV infection. When detected indicates a high degree of infectivity. However, in some people a mutation in the HBV genome results in failure to produce HBeAg, so HBV genome may be highly infectious but HBeAg negative. Measurement of HBV DNA levels is thus a more reliable [5].

**Pathogenesis:** Hepatitis B virus can cause acute or chronic, symptomatic or a symptomatic disease. When HBV enter the blood it spread to the liver, start to replicate in hepatocyte within (3 – 45) days or more depending on the infectious dose, route of entry (direct intravenous injection is more serious) and person immune status . The hepatitis B virus is not cytopathic, and liver injury in chronic hepatitis B is believed to be immunologically mediated [6].

**Acute infection:** Most acute Hepatitis B virus (HBV) infections in adult’s results in complete recovery, with minor symptoms appeared as Jaundice, fever and enzyme release. Detection of HBeAg component of the virion in blood indicates the existence of the active infection. HBsAg continue to be released in -to blood even after virion release has ended and till resolves of infection (about 6 months later). However it may promote hypersensitivity reaction due to HBsAg immune complexes and antibody [7-11].

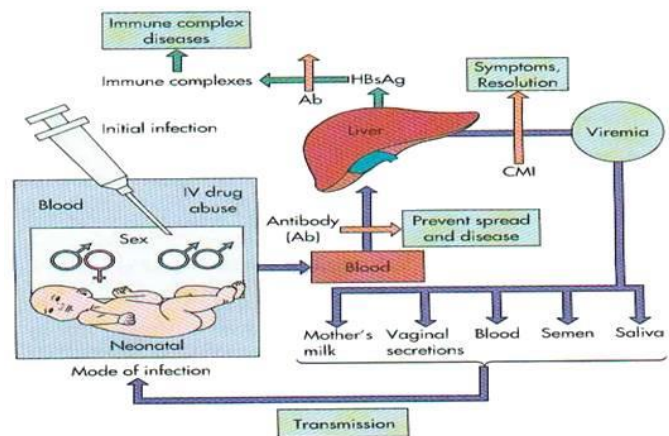
**Chronic infection:** (It is the major source of spread of disease). Insufficient T-cell can lead to chronic infection which occur in about 5-10% of adult people with HBV infection. That is why 90% of infected infants become chronic carriers (immature thymus). Also virus may make minimal cytopathic effect (CPE) when infection proceed for relatively long time without liver damage, during this viral genome integrated to hepatocyte chromatin and remain latent. Persons with chronic infection are often asymptomatic and may not be aware that they are infected, however can infect others that why they referred to them as carriers. Chronic hepatitis may develop to cirrhosis and hepatocellular carcinoma (HCC). Chronic infection is responsible for most HBV-related mortality.

**Transmission and epidemiology:** Despite availability of an effective vaccine, still HBV is a major health problem. It has average incubation period of 2-3 month. Word wide it’s estimated

to cause more than million deaths a year from its chronic effect. According to the CDC approximately, one in 20 people in the U.S.A is infected by HBV. About 5% of people infected by HBV get a chronic infection and there are more than one million Americans with chronic hepatitis. Hepatitis B virus considered to be the second cause of liver failure in Sudan. In developing countries, because of lack of awareness of the risk of disease, poor sterilization, economics and ignorance or lack of many public health educational programs are the main factors in it is prevalence. Hepatitis B virus transmitted by blood and blood products. Also it can transmit by saliva, serum, vaginal secretion and all other body fluid. The ratio of virus in blood related to other body fluid is about 1:1000 times. So high risk groups for HBV infection are [12-15]:

- People from endemic regions (china, part of Africa, Alaska...etc.).
- Babies of mother with chronic HBV infection.
- Intravenous drugs abusers.
- People with multiple sex partners (homosexual and heterosexual).
- Haemodialysis and other patients requiring blood and its products.
- health care personnel and staff members of mentally retarded institutions [5,8].

Figure 1 Shows Transmissions and body immune response to HBV. Injection into blood, replicate, viremia also transmission to various body secretion where other individual can infect. Symptoms are cases by CMI and immune complexes between HBsAg and antibody (Figure 1).



**Figure 1:** Transmissions and body immune response to HBV infection (8).

### Laboratory diagnosis

Hepatitis B Diagnosis usually done by serological detection of hepatitis B markers antigens, (Ag) and/or antibodies (Ab) in the blood by ELISA and ICT (screening) technique. Serological

markers vary depending on whether the infection is acute or chronic. Different serological markers testing are used whether for diagnosing or identifying the stage of disease as well immunity to HBV infection, these are [16]:

**HBsAg (hepatitis B surface antigen):** is first serological marker to appear and can be detected in an infected blood average of 4 weeks (range: 1-6 weeks) after exposure to the virus and its presence is indicative of an active infection regardless of whether the infection is acute or chronic. In order to differentiate them IgM anti-HBc is necessary to be test. HBsAg is an antigen used in hepatitis B vaccine [17].

**IgM Anti-HBc:** is often detectable at the time of clinical onset, and decline to not detectable levels within 6 months. It is diagnostic marker for acute hepatitis B infection, useful for differentiating recent infection from chronic carrier.

**Total anti-HBc:** (combination of IgM and IgG) is detectable in serum by the onset of clinical illness and persists for many years, in both how have cleared the hepatitis B virus and those become chronic carriers. In patient with chronic hepatitis B both HBsAg and total anti-HBsAg usually remain detectable for life [18].

**Anti-HBsAg:** Anti-HBsAg titres rise slowly after the disappearance of HBsAg in patient who does not progress to chronic infection. It generally indicates recovery and immunity from infection or previous active vaccination. There is a time interval of weeks to several months between the disappearance of detectable HBsAg and appearance of anti-HBsAg, only anti-HBc is detectable during this time which referred as (core window or second window). Anti-HBsAg also develops in a person who has been vaccinated against hepatitis B [19].

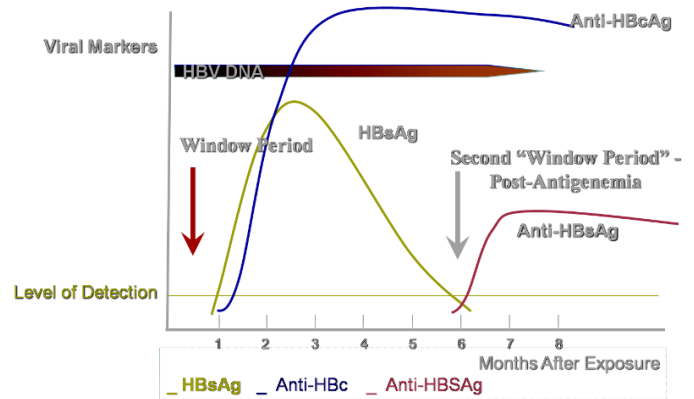
**HBeAg:** (hepatitis B e antigen) appears few days after HBsAg be detectable and disappear before it's gone, although it might persist for years in chronic carriers. Despite not necessary to be test, its presence indicates increase risk of infectivity.

**Anti-HBeAg:** appears at about the time that HBsAg disappears. It generally indicates a good prognosis, and the risk of infectivity and transmission is reduced. Anti-HBeAg present in 50%-75% of patients with chronic hepatitis B infection.

**HBsAg:** is the most commonly used test for diagnosing acute infection or detecting carriers. Chronic infection can be distinguished by Finding of HBsAg and lack of detectable antibody to this antigen and IgM –anti-HBc antibody [20].

### The window period of HBV infection

The “Window Period” is the period when a person is infected with HBV but prior to the appearance of detectable HBsAg. HBsAg appears an average of 4 weeks after exposure and may decline to undetectable levels within 4-6 months if the infection is resolved (second window). Figure 2 shows the window period of HBsAg detection in acute phase and in case of recovery. Blood Products Advisory Committee (Figure 2).



**Figure 2:** The window period of HBsAg detection in acute phase and in case of recovery [24].

HBV DNA is the first markers appear in plasma (0-40 days) during infection. Some infected blood may be transfused if it is donated during the window period so more advanced techniques such as PCR for detecting HB virus DNA are needed to resolve any doubt in the clinical profile of at risk donors even when ELISA test is negative. Also permits earlier detection of HBV infection in the donors resulting in earlier notification, follow-up, medical intervention and prevention of secondary transmission [21].

### Treatment and prevention

**Treatment:** HBV only treatment for acute infections is Supportive care with high carbohydrate /high protein diet to repair damaged liver cells. Chronic patients may be given anti-viral drugs as alpha-interferon. Drug called adefovir dipivoxil (nucleotide antilog) or Lamivudine, all can help in stop viral replication and prevent liver damage in many cases; none of the drugs considered curative. Liver transplantation is often a final option in treatment.

**Prevention:** Comprehensive strategy to eliminate hepatitis B virus was recommended in (1990-CDC) which include:

- Precautions and prenatal testing of pregnant women for HBsAg to identify new-borns who require prevention from prenatal infections. Infant of HBsAg positive mothers should be given hepatitis B immunoglobulin (HBIG) and hepatitis B vaccine as close as possible to birth. HBIG can only be given up to 10 days after delivery.
- Screening blood before transfusion.
- Effective Vaccine recommended and available which provide protection to about 95% for those receiving 3doses.
  1. Routine vaccination of infants.
  2. Vaccination of adolescents.

3. Vaccination of adults at high risk for infection.
  4. Further Vaccination of adults at increased risk for HBV infection (those in endemic areas) was published 2006 [22].
- Social awareness and health education, the abundant of circulating virus is high and the minimal dose is low that is such simple practices as sharing toothbrush or razors can transmit the infection.

### Literature Review

Study was conducted at Al-Rehman medical laboratory with ELISA (3rd generation) for HBsAg detection to 200 blood samples. Seven cases (3.5%) out of 200 were positive with ELISA. One of the seven was ICT negative, while all other six were also ICT positive, they concluded that low sensitivity of ICT in comparison to ELISA.

Retrospective study published by European journal of Epidemiology in Turkey Red Crescent Centres on population over sixteen years blood donors between 1989 and 2004 for HBV and HCV, HBsAg detection and HCV antibody detection, the overall prevalence was 4.19% for HBsAg and 0.38% for HCV antibody during the study period -1989 [15]. The sero-positivity of Hepatitis B virus was done by Perpetua E N. for a total of 3446 (295 were found to be positive) donors who were attended the blood bank of OLA Catholic Hospital, Oluyoro Ibadan, Nigeria; and screened for Hepatitis B virus between January 2007 to December 2011 using Hepatitis B surface antigen (HBsAg) ELISA to determine the prevalence of HBsAg. The seropositivity of Hepatitis B virus infection was found to be 8.56%. It is concluded that the Seroprevalence of Hepatitis B in this region is high according to the global patterns of transmission although it's reduced base on previous studies. Another Study done in Kamothe, Navi Mumbai- India, to Check the Specificity & Sensitivity of ICT with ELISA, this study show that show that 2-5% of adult population are HBV positive amongst 135 randomly selected patients, 50 positive and 85 negative by rapid diagnostic test (ICT). It was observed that in comparison with ELISA, rapid ICT test had 94.2% sensitivity (3 false negative) and 97.61% specificity (2 false positive). Sero-prevalence of HBsAg also carried by Ado A, et al. On Shika, Zaria, Kaduna-Nigeria blood donors in June 2008 using HBsAg latex. Thus study show that high prevalence was observed between 30-39 years (26.7%) no prevalence was observed between 15-19 years and 45-54 with highest in male (86.7%) compared to female (13.3%). Ali aduo M A, Saeed Ali Y A. conducted a study during the period from May to July 2007, in the city of Nyala using ICT and confirmed with 3rd generation ELISA.

(2 false negative) ICT results for HBsAg detection were observed. The seroprevalence of hepatitis B virus (HBV) and the possible

risk factors among blood donors in Nyala, South Dar Fur State of western Sudan for a total of 400 male blood donors, (6.25%) were found reactive for HBsAg. The highest seroprevalence (30.8%) was found between 19-24 and 37-42 years of age. Unprotected sexual activities (20%) was the Most apparent predisposing risk factor, followed by razor sharing (13.3%), parenteral drug injections (10%), history of migration to Egypt and alcoholism (6.6%), tattooing and surgical procedures (3.3%), where (36.6%) were not aware for their condition. Serum alanine aminotransferase (ALT) was elevated in (30.7%) of HBV seroreactors. In comparing ICT with ELISA shown that (2 false negative) i.e. low ICT sensitivity which rely on that short incubation tests do not detect low affinity or low concentration of antibodies. Another study (cross-sectional) conducted by Mudawi H, et al. Dec 2000 was aimed to determine the prevalence and risk factors for transmission of hepatitis B virus (HBV) infection on the population of Um Zukra village in Gezira state of Central Sudan. The participants were interviewed for risk factors of viral hepatitis. Blood samples were then collected and tested for HBsAg. A total of 404 subjects were screened (ICT) with a mean age of 35 years; 54.9% were females, HBsAg were reactive in 6.9% of the studied population. Exposure to HBV increased with increasing age. The only significant risk factor for transmission of infection was a history of parenteral antischistosomal therapy. In another study done Nigeria among blood donors (175) of age 20-40 years and HIV Infected patients 490 (age 17-60years) Twenty-five (14.3%) and 127 (25.9%) of blood donors and HIV patients respectively were found to be reactive to HBsAg, with the male (14.6%) slightly higher than female (12.9%), and highest rate between 51-60 years (44%) followed by 31-40 of ages (28.2%). Result show high endemicity of HBV infection in Jos-Nigeria (Figures 3 and 4).

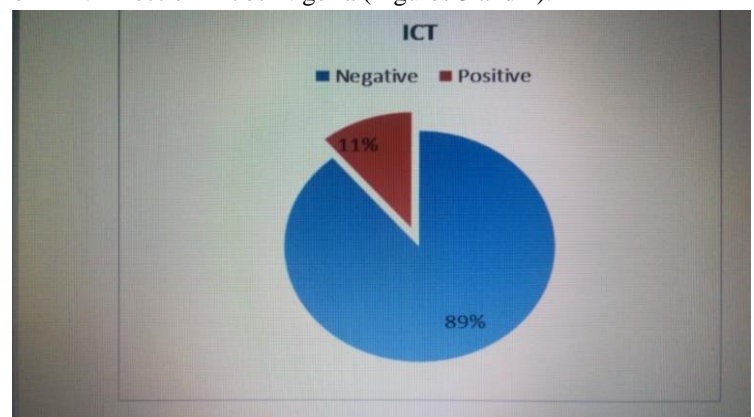


Figure 3: Show ICT test results.

### Objectives

**General objectives:** To determine the prevalence of HBV among blood donors in Khartoum state.

**Specific objectives:** To detect HBsAg in serum of donors in Khartoum state. To compare the ICT test sensitivity and specificity with ELISA. To estimate the level of awareness and the significance of the society education with health programs and vaccine. To detect seropositivity of HBsAg among different Age groups.

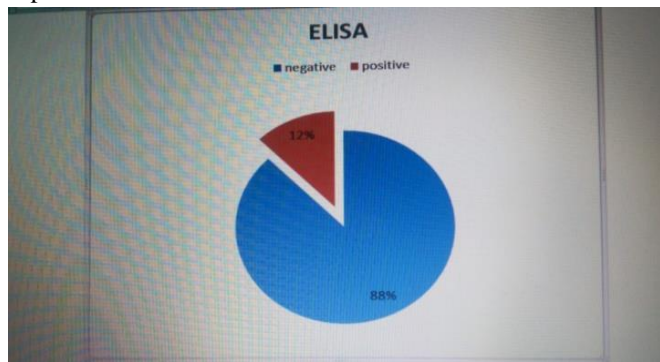


Figure 4: ELISA results.

**Justification:** Hepatitis B is one of the blood born disease and despite availability of it's an effective vaccine still considered a major health problem. Worldwide 2 billion have been infected and 350million will develop chronic effect. In developing countries, expose to contaminated therapeutic equipment are common in many setting also because of lack of awareness of infection control practices, poor sterilization, economics, and ignorance of many health programs as (vaccination). Most asymptomatic carriers may not be aware that they are infected, however they can infect others, hence this study is aimed to determine the prevalence of HBV in blood donors and estimate social awareness also ensure ICT sensitivity and specificity comparing to ELISA as the gold standard technique.

### Study design and Study area

A descriptive analytic hospital based study conducted in Khartoum teaching hospital Blood Bank in Khartoum State, Sudan. Ethical clearance was obtained from SUMASRI ethical review board.

### Study population

Included all voluntary male blood donors who were eligible for blood donation according to Khartoum blood bank policy, after receiving agreement to participate in the study.

### Study sample

A total of 90 randomly selected blood samples were collected from the study subject then received at microbiology lab (virology) for testing of HBsAg.

### Selection criteria

**Inclusion Criteria:** Eligibility for blood donation. Valid consent from the donor for participation in the study.

**Exclusion Criteria:** Initial refusal of the donor to participate in the research. Excuse of the donor to not fill some required data or his own decision to terminate participation.

### Specimen's collection

Blood were collected by venepuncture and immediately 2.5 ml from each sample were delivered in to a sterile, clean dry blood container without anti-coagulant (plain). The containers were left for 30minutes on the bench at room temperature for the blood to clot. Then centrifuged the clotted blood at 3000rpm for ten minutes to separate sera. The harvested sera for each specimen labelled within two hours of collection and stored at 4C. Serum samples initially tested for HBsAg by ELISA (AMS-U.K). Data were analyzed by Microsoft statistical package for social sciences (SPSS). Samples then restored at -20C and tested with ICT (Biorex) two weeks later in (Alrybat hospital blood bank).

### Enzyme link immune-sorbent assay

**Principle:** The method used was an Enzyme link immune-sorbent assay, for qualitative HBsAg detection in human serum or plasma. Based on the principle of antibody sandwich using polystyrene micro- well strips pr-coated with monoclonal antibodies specific to HBsAg, during incubation with sample the specific immune complex formed if HBsAg presence in the sample (serum), which captured on the solid phase. After washing to removed excess serum protein, second antibody conjugated with the enzyme peroxidase (HRP-enzyme) and directed against HBsAg is added in to the wells. During second incubation steps these conjugated antibodies will be bound to any complexes formed previously (first step), and unbound conjugated antibody then removed by washing , chromogen solutions containing tetramethyle-benzidine(TMP) and urea peroxide add in the presence of antibody-antigen antibody(HRP) `` sandwich`` the colourless chromogen is hydrolysed to blue colour product which turn yellow after stopping the reaction with sulfuric acid. The amount of colour intensity can be measured and it's proportional to the amount of antigen captured in the well and sample respectively. Wells containing samples negative for HBsAg remain colourless.

### ELISA Testing Procedure

#### Interpretation of result

**Negative result:** Tests given an optical density less than the cut-of value (0.151) were considered negative (no reactive) (Table 1).

**Positive result:** Samples given optical density greater than or equal to the cut-of value (0.151) considered reactive (indicated that HBsAg detected with this ELISA test) (11-AMS). All steps

and work were done following the instructions of the manufacture kit was considered. The results were read and recorded also company (see appendix) with its quality control steps. Storage of revised with virology lab supervisor.

**Table 1:** Summary of ELISA assay procedure.

Added sample diluents	20MI
Added sample	100MI
Incubate (first )	60 minutes
Added HRP-conjugate	50MI
Second incubation	30minutes
Washed	5 times
Coloring solution added	50ML(A)+ 50MI(B)
Incubated	30minutes
Reaction stopped (sulfuric acid)	50 ML stop solution
Absorbance readied at	450/630nm
The tests absorbance was readied in spectrophotometer and calculated the cut –of value, then final results interpreted.	Cut-of value= $*Nc*2.1$ *Nc= the mean absorbance value for three negative control.

**Table 2:** Absorbance reading –El-10170H (A to H).

	A	B	C	D	E	F	G	H
2-1	0.045	0.042	1.834	1.748	0.026	0.027	0.026	0.028
2-2	0.029	0.025	0.026	0.024	0.026	0.027	0.024	0.065
2-3	0.028	2.66	0.022	2.014	0.022	0.028	0.021	0.233
2-4	0.027	0.028	0.022	0.022	0.020	0.024	0.018	0.024
2-5	0.027	0.020	0.020	0.020	0.024	1.317	0.023	0.029
2-6	0.030	0.028	0.022	0.023	0.027	0.022	0.055	0.025
2-7	0.023	0.021	0.030	0.022	0.021	0.020	0.170	0.031
2-8	0.029	0.027	0.025	1.947	2.078	0.023	0.022	0.029
2-9	0.026	0.022	0.020	0.163	0.028	0.021	0.022	0.025
2-10	0.024	0.027	1.050	0.021	0.021	0.020	0.021	0.024
2-11	0.022	0.023	0.019	0.020	0.029	0.023	0.024	0.029
2-12	0.026	0.022	0.025	0.025	1.632	1.630	0.020	0.022
	(blank)	(N.C)	(N.C)	(N.C)	(P.C)	(P.C)		

A (2-12)=blank.

B (2-12), C (2-12), D (2-12) =negative control.

E (2-12), F (2-12) =positive control.

Underlined reading = positive samples

-Cut-of value = $0.022+0.025+0.025 *2.1$

= $0.072* 2.1= 0.151$

### Immune chromatography test (ICT)

**Principle:** HBsAg rapid test device (serum /plasma) is qualitative test for HBsAg detection. the membrane coated with anti HBsAg –antibody on the test and line region of the device, during testing specimens react with anti-HBsAg conjugated-antibody particles

the mixture migrate (by capillary action) upward on the membrane chromatography to react with anti-HBsAg antibodies on the membrane and generate a coloured line. The presence of this coloured line indicated appositve result (two line test and control).

**ICT - procedure:** 50 ML serum sample was pipette by sterile pipette and dispensed in to the specimen well(s) of test device(s). Results were interpreted within 15 minutes. (No interpreted test last for more than 30 minutes). In case of no colour appear in

control line the test was considered invalid then repeated. Procedural and its quality control included as manufacturer's instructions.

**Table 3:** Showing results of both ELISA and ICT (n=90).

		ELISA		Total
		Positive	Negative	
ICT	positive	9 (TP)	1 (FP)	10
	Negative	2 (FN)	78 (TN)	80
Total		11	79	90

**Table 4:** Showing validity of ICT test compared to ELISA.

Sensitivity	81.8%
Specificity	98.7%
positive predictive value (PPV)	90%
Negative predictive value (PNV)	97.5%

**Table 5:** Shows Hepatitis B and vaccination awareness.

	Have Knowledge about HBV	Have no Knowledge about HBV	Have Knowledge about HBV vaccine	Have no Knowledge about HBV vaccine	Vaccinated
Frequency	27	63	18	72	6
Percent	30%	70%	20%	80%	6.7%

### Result interpretation

**Positive result:** Two distinct coloured lines appear.

**Negative result:** Only one colour appears (control line only).

### Ethical consideration

Formal Ethical Clearance from Sudan Medical and Scientific Research Institute (SUMASRI) and participant's consents were obtained, also acceptance of the hospital authority (see appendices). The remaining of the blood and waste products were treated appropriately and safely disposed (Table 2).

### Results

#### Results of ELISA compared to ICT

Eleven serum samples (12.2%) out of 90 were positive by ELISA and 79 negative, ten were ICT positive (80 negative). Same nine sample that given positive by ELISA were also ICT positive; plus other one that already ELISA (-ve), while two were negative by ICT which ELISA positive (Table 3).

- Sensitivity % = true positive / (true positive + false negative)\*100
- Specificity% = true negative / (true negative +false positive)\*100
- Positive predictive value (PPV) %=( true positive /total positive)\*100
- Negative predictive value (PNV) %=( true negative /total negative) \*100
- Although ICT was specific in detecting HBsAg (98.7%), but has low sensitivity (81.8%) (Table 4).

High prevalence was on age group of 20-30 (62.2%) and 31-40 (30%) years. where was less in the age below the 20 years (2.2%) (Figure 5).

Only 27 out of 90 individuals were had knowledge with hepatitis B and 63(70%) were lack information about it. Most of the studied population don't knows if there is vaccine to hepatitis B or no these about 72 of them (80%) and 6 (6.7%) only vaccinated against hepatitis B (Table 5).

### Discussions

12.2% is the prevalence of hepatitis B among blood donors in Khartoum-Sudan that submitted by this research, this indicate high hepatitis B prevalence in this area (high endemicity). The prevalence of hepatitis B infection is high if compared with previous studies conducted in Gezira state-central Sudan (6.9%), Nyala-south Darfur (6.25%) (Both were intermediate) also higher than Nigeria 8.9%, Turkey 4.19%, India 5% and Pakistan 3.5%. May due to unprotected sexual practices, drug injections and illegal immigrants from endemic countries, hence only donor were health related and all were negative as well all individual receiving previous donation were also negative this exclude expose to contaminated equipment and poor sterilization from the expected prevalence factors.

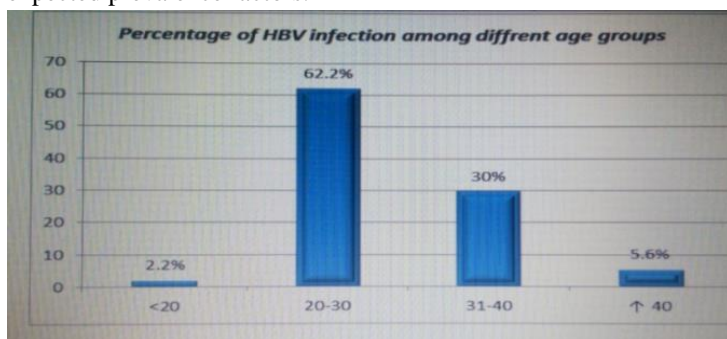


Figure 5: Showing distribution of positive HBsAg among different age groups.

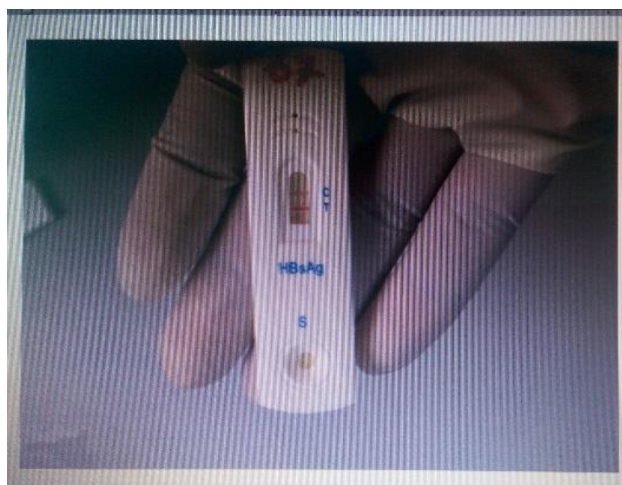


Figure 6: ICT device show positive result – Copy.

High hepatitis B prevalence was seen among mean of age groups (20-30 years) which is near to those in Nyala (19-24 years) although with different parentages 62%, 30% respectively. Whenever elevations in youth (20-30years) with no clear reasons of contact to blood; seropositivity could be associated with sexual practice and drug injection among Sudanese in their third decade of life. ICT (Biorex) results has shown less sensitivity 81.8% (2 false negative) as in previous studies (false 1 negative) for Acon-USA, 3 false negative 94% sensitivity and (2 false negative). This

indicate low ICT sensitivity comparable to ELISA for detection very low amount of HBsAg. Only (30%) out of 90 donors have knowledge about hepatitis B and most of them lack knowledge about hepatitis B vaccine. Only (6.7%) were vaccinated and these numbers indicate that population are in need of general health education [20-23].

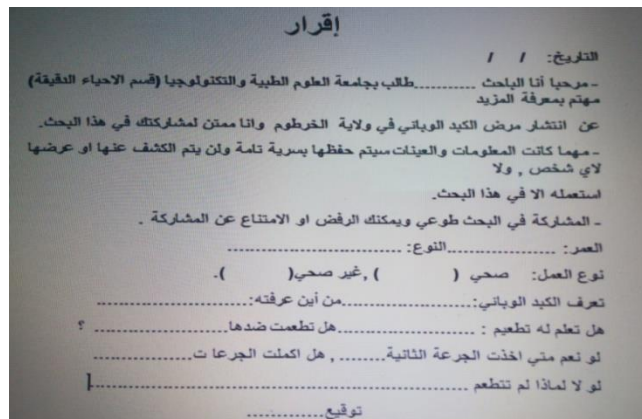


Figure 7: Donor Consent form.

## Conclusion

HBV infection became endemic in Khartoum city, with even higher percent than other parts of Sudan like Gezira, Nyala. It is common among 20-30 years age group. May be associated with sexual practices and injection drug users. Culturally female do not donate blood in Sudan. ICT should not be considered as final screening test in donation blood, even in emergency case there is about 2% infected blood may be transfused. No community health education programs and hence low population awareness concerning hepatitis [24].

## Recommendations

Screening blood for transfusion should be done by ELISA method. Social health educational programs should be promote by different health sectors to reduce new infection and transmission rate. Hepatitis B vaccine schedule in Sudan should extend to adult rather than children alone and rural must covered. More researches should be carrying out by authorized governmental health bodies with large sample size to confirm this result including the predisposing risk factors. And may exclude and/or list the standard ICT companies, especially for transfusion purposes (Figures 6 and 7).

## Other Materials and Reagents Used

- Micropipettes (automated).
- Incubator
- Washer
- Spectrophotometer (reader)

- Commercially available test kit containing solid phase support system, -reagent, control.
- Distilled water
- Gloves
- 70% alcohol and cotton
- Commercially HBsAg devices, reagents.
- Safety pox
- Blood container
- HBsAg ICT devices.
- Flask
- Papers
- Calculator

## Abbreviations

ICT: Immunochromatography Test; ELISA: Enzyme-linked immunosorbent assay; EBV: Epstein-Barr virus; CMV: Cytomegalovirus; HCV: Hepatitis C virus; DNA: De-oxy ribonucleic acid; HBcAg: Hepatitis B core Antigen; HBsAg: Hepatitis B surface Antigen; HBeAg: Hepatitis B e Antigen; HBV: Hepatitis B virus; CPE: Cytopathic effect; HCC: Hepatocellular carcinoma; CDC: Centre for Disease Control and Prevention, USA; CMI: Cell mediated immunity; PCR: polymerase chain reaction; HBIG: Hepatitis B immunoglobulin

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