LABORATORY-BASED HEPATITIS C SURVEILLANCE FOR SOUTH AFRICA, 2017

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Executive summary

There is no active national surveillance for hepatitis C virus (HCV) in South Africa. Analysing laboratory data can assist with estimating the prevalence of HCV amongst patients who seek medical attention in healthcare facilities. National Health Laboratory Service (NHLS) HCV data were analysed to understand the testing pattern and demographic distribution of the disease for the year 2017. HCV data were extracted from the NHLS central data warehouse. Patients were considered exposed to HCV if they were positive for anti-HCV antibody. Patients positive with HCV viral load test were regarded as viraemia with active infection. Demographic analysis was based on age, gender, province, district or sub-district. HCV genotyping data were analysed to describe genotype circulation in South Africa. Of 10 138 patients tested for HCV exposure, 28% (2 917/10 138) were shown to be anti-HCV positive. Overall prevalence for South Africa was 5/100 000 population for those seeking care in the public sector in 2017. Gauteng Province had the highest prevalence at 11/100 000 population, with other provinces ranging from 2 to 4/100 000 population, likely reflecting referral patterns to tertiary healthcare facilities in Gauteng Province. Peak age distribution in males was 25-29 years and in females 30-34 years. Genotypes 1 (34%) and 5 (29%) were commonly detected in South Africa in 2017. It is concluded that HCV testing data from public health sector facilities can be used to monitor the prevalence of HCV in South Africa. Monitoring HCV data can be used to improve screening and treatment guidelines in support of the target of viral hepatitis elimination by 2030.

Introduction

Hepatitis C virus (HCV) causes acute and chronic hepatitis, ranging in severity from a mild illness lasting a few weeks to a serious, lifelong illness. Acute HCV infection is usually asymptomatic and is only rarely associated with life-threatening disease. About 15-45% of infected persons spontaneously clear the virus within 6 months of infection without any treatment. However, 60-80% of infected people will develop chronic HCV infection, of which 15-30% have the risk of developing liver cirrhosis within 20 years.[1] The use of unsafe healthcare procedures and drug injection with non-sterile needles were the leading causes of new HCV infections, accounting for approximately 1.75 million new infections in 2015. Globally, 71 million people have chronic hepatitis C, of which 2.3 million persons are co-infected with HIV.[2]

The prevalence of HCV is unknown in South Africa, with estimates of 0.1% in the general population and 0.03% in blood donors.[3,4] HCV prevalence information in high-risk groups is also limited in South Africa. High-risk groups for HCV infection include intravenous drug users, men having sex with men (MSM), HIV-infected persons, patients on haemodialysis, patients with a history of blood transfusions or organ transplantation, health care workers after needlestick injuries, and children born to HCV-infected mothers. HCV prevalence in HIV co-infected persons is low in South Africa.[5] From a study in Cape Town, HCV prevalence in MSM showed a high prevalence of 27% of whom 37% were co-infected with HIV.[6] This is pertinent because high HCV prevalence in high-risk groups may have an impact on transmission of the disease and planning for other prevention and treatment strategies.

The 67th World Health Assembly of the World Health Organization (WHO) recognized viral hepatitis as a public health threat and targeted elimination by 2030.[7] One of the action plans for the WHO African Region (2016-2020) focuses on setting up strong and reliable information systems to estimate the prevalence of HCV.[8] The WHO guideline 2017[9] provides an algorithm for screening using serological tests, in which a positive HCV-antibody result indicates a current or past infection. In order to confirm a current infection, a nucleic acid test (NAT) for the detection of HCV ribonucleic acid (RNA) should be performed directly following a positive HCV serological test to establish active infection (viraemia).

The aim of this project was to extract data from the National Health Laboratory Service (NHLS) Central Data Warehouse (CDW) for 2017 to determine the number of patients with hepatitis C antibody (seroprevalence), the number of patients with viraemia in public health facilities and the demographic distribution of HCV exposure and infection. These data represent HCV laboratory testing performed in all NHLS laboratories countrywide.

Methods

HCV data extracted from the NHLS CDW was de-duplicated to ensure that each patient was counted only once. De-duplication utilised a matching system that included name, surname, gender and date of birth followed by the assignation of a unique identifier. Those that did not match were further validated by checking the hospital identifier. Data for patients managed clinically in more than one health facility may have been missed due to lack of a unique patient identifier.

Patients were considered exposed to HCV if they were positive for anti-HCV antibody. Patients positive for HCV viral load and/or genotype were regarded as having active infection. Data analysis was performed on anti-HCV tests and HCV viral load test using Stata 14 and Microsoft Excel. Demographic analysis was based on age, gender, province, district or sub-district. HCV genotyping data were analysed to describe genotype circulation in South Africa.

Results

HCV antibody testing

A total of 10 401 patients was tested for HCV antibody or viral load, of which 10 138 were tested by HCV serology and 744 had an HCV nucleic test (Figure 1). The hepatitis C seropositivity rate amongst samples tested was 28% (2 917/10 401). Eighty-four percent (2 462/2 917) of the patients who tested positive by HCV serology were not followed up with a HCV viral load or any other nucleic acid test for confirmation.

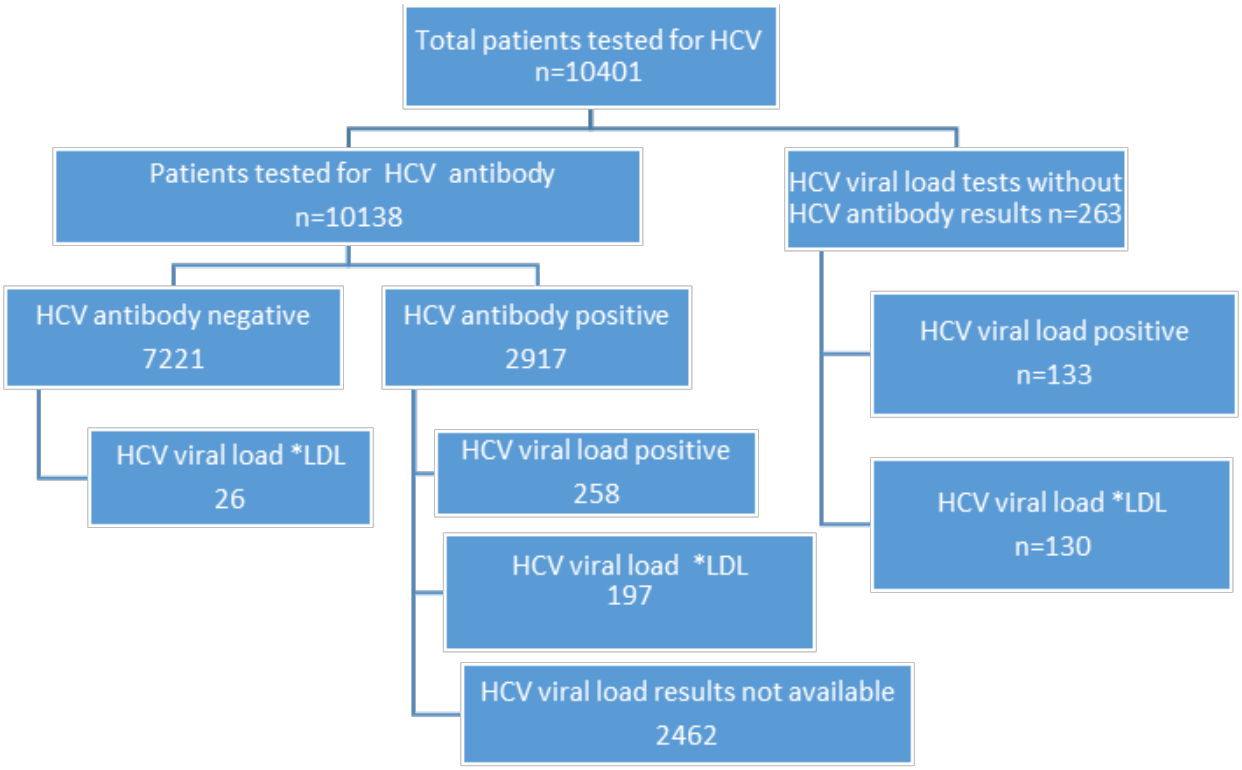

Figure 1: Patients tested for hepatitis C virus by test method from the public health sector in South Africa, 2017. *LDL = lower than detectable limit.

Gauteng Province showed the highest number of patients that tested positive by HCV serology and HCV viral load, accounting for 51% and 58% prevalence respectively (Table 1). HCV antibody prevalence in South Africa for 2017 was 5/100 000 population. Gauteng Province had the highest HCV seroprevalence with 11/100 000 population compared to other provinces that ranged from 2-4 per 100 000 population (Table 2). Information on gender was available on 99% (2 896/2 917) of HCV seropositive patients of whom 65% (1 880/2 896) were males. For HCV antibody-positive males, the most predominant age groups were 20-44 years, and for females, 30-34 years.

Table 1: Provincial distribution of hepatitis C seropositive and viraemic patients in South Africa, 2017.

Province	Hepatitis C Antibody		Hepatitis C Viral Load	
	HCV antibody positive (Number)	HCV antibody positive (Percentage)	HCV viral load test positive (Number)	HCV viral load test positive (Percentage)
Eastern Cape	265	9	33	8
Free State	80	3	5	1
Gauteng	1497	51	230	58
KwaZulu-Natal	346	12	25	6
Limpopo	232	8	6	2
Mpumalanga	149	5	2	1
North West	125	4	10	3
Northern Cape	34	1	1	0
Western Cape	189	6	82	21
Total	**2 917**	**100**	**394**	**100**

Table 2: Hepatitis C virus (HCV) seroprevalence by province, South Africa, 2017.

Province	Population	Anti-HCV positive cases	Anti-HCV prevalence Per 100 000 population
Eastern Cape	6,773,279	265	4
Free State	2,765,817	80	3
Gauteng	13,820,216	1,497	11
KwaZulu-Natal	10,924,776	346	3
Limpopo	5,789,937	232	4
Mpumalanga	4,344,146	149	3
North West	3,809,369	125	3
Northern Cape	1,202,802	34	3
Western Cape	6,478,870	189	3
South Africa	**55,909,212**	**2,917**	**5**

Hepatitis viral load testing

Sixteen percent (455/2 917) of the patients who tested positive by HCV serology had a viral load test. Of the 747 patients tested for viral load, 53% (394) were positive. Males accounted for 63% (251/394) of viraemic patients, showing two age group peaks at 20-39 and 65-69 years. For viraemic females, the peak age group was 55-74 years (Figure 2).

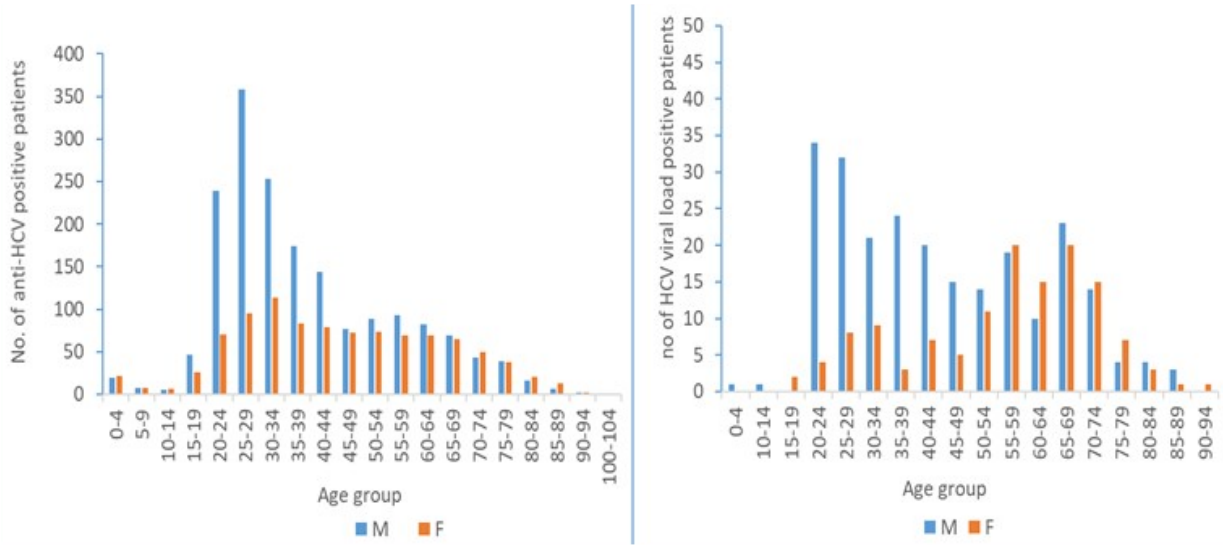

Figure 2: Age and gender of hepatitis C virus (HCV) antibody-positive (N=2738) and HCV viral load (N=394) patients in South Africa, 2017. The left block shows anti-HCV-positive patients and the right block shows HCV viraemic patients.

HCV genotypes

Of the 747 viraemic patients, 160 had an HCV genotype test. Circulating HCV genotypes were identified from six of South Africa's nine provinces. There were no genotype data information from Limpopo, Mpumalanga and Northern Cape provinces. HCV genotypes 1-5 were found to be circulating. Genotypes 1 (34%) and 5a (29%) were common (Figure 3). Genotype 2 was detected in the North West and Western Cape provinces. The common subtypes were genotype 1a (34%), 1b (13%) and 3a (10%) (Table 3).

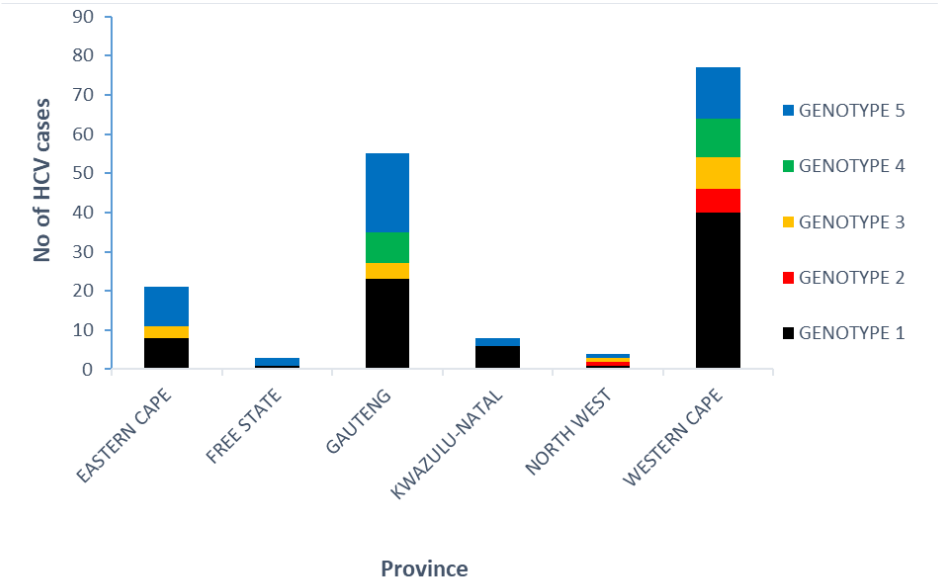

Figure 3: Hepatitis C virus (HCV) genotypes from diagnostic tests by province, South Africa, 2017. n=168 HCV cases.

Table 3: Hepatitis C virus (HCV) sub-genotypes detected by province, South Africa, 2017. n=168.

HCV genotype	HCV sub genotyping	Eastern Cape province	Free State province	Gauteng province	Kwazulu-Natal province	North West province	Western Cape province	Sub genotype Total	Sub genotype percentage	HCV genotype Total
1	genotype 1a	3	1	18	2	0	33	**57**	34%	**79**
	genotype 1b	5	0	5	4	1	7	**22**	13%	
2	genotype 2 (no sub genotype ascribed)	0	0	0	0	1	2	**3**	2%	**23**
	genotype 2a/c	0	0	0	0	0	2	**2**	1%	
	genotype 2b	0	0	0	0	0	2	**2**	1%	
3	genotype 3a	3	0	4	0	1	8	**16**	10%	**16**
4	genotype 4 (no sub genotype ascribed)	0	0	8	0	0	5	**13**	8%	**18**
	genotype 4a	0	0	0	0	0	1	**1**	1%	
	genotype 4b	0	0	0	0	0	1	**1**	1%	
	genotype 4c/d	0	0	0	0	0	3	**3**	2%	
5	genotype 5a	10	2	20	2	1	13	**48**	29%	**48**

Discussion

The NHLS laboratories, which serve approximately 80% of the South African population, were a useful source for national hepatitis C data. The study showed an overall HCV seroprevalence rate for 2017 of 5/100 000 persons.

Hepatitis C antibody tests do not discriminate between IgM or IgG presence. It is therefore difficult to conclude from an antibody result alone whether an individual is actively infected with the virus. A confirmatory nucleic acid test is necessary to indicate current infection. NHLS laboratory data shows that only 8% (258/2917) of anti-HCV positive test results have an active infection confirmed by a HCV viral load test. This suggests that the testing algorithm to confirm an HCV antibody-positive case was seldom followed by a confirmatory nucleic acid test. There are several factors that may affect this testing pattern. The study interrogated data from 01 January 2017 to 31 December 2017 - it is possible that antibody tests were done in previous years and viral load performed in 2017. The testing algorithm for hepatitis C is not widely understood, the viral load test is expensive and there is no public treatment programme for HCV in South Africa.

The number of patients having a viral load test was high in Western Cape (45%) and Gauteng (21%) provinces, where there are established liver clinics to manage the disease.[9] The heterogeneous circulation of HCV genotypes 1-5 in South Africa during 2017 corroborates data from earlier studies.[10] In this study, sub-genotypes 1a and 5a were predominant. A recent study on key populations found that genotypes 1a and 3a were prevalent among people who inject/use drugs. Data concerning circulating genotypes can assist in the planning of HCV therapeutic programmes.

It is concluded that the NHLS Central Data Warehouse can be used for surveillance purposes to understand the prevalence and epidemiology of hepatitis C in South Africa. This information can assist in the development of guidelines for prevention, screening and treatment.

Acknowledgments

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