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Hepatitis C virus seroprevalence, testing, and treatment capacity in public health facilities in Ghana, 2016 – 2021; A multi-centre cross-sectional study.

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Abstract:	<p>The current burden of Hepatitis C virus infection and the availability of HCV-related services in Ghana are not well described. Previous estimates on HCV seroprevalence in the country are outdated. This study investigated the HCV seroprevalence and testing and treatment capacity in Ghana. A multi-centre cross-sectional study was conducted in which laboratory and blood bank registers from 17 public healthcare institutions in Ghana were reviewed. A survey on cost and availability of HCV-related testing and treatment was also performed. Crude and pooled estimates of HCV seroprevalence, frequency and median cost of available diagnostic tests and medicines were described. The crude HCV seroprevalence was 2.62% (95% CI 2.53 – 2.72) and the pooled estimate was 4.58% (95% CI 4.06 – 5.11) among 103,609 persons tested in laboratories. Age (OR 1.02 95% CI 1.01 – 1.02) and male sex (OR 1.26 95% CI 1.08 – 1.48) were predictors of a positive anti-HCV RDT test. Northern administrative regions in Ghana had the highest HCV seroprevalence ranging from 8.3 – 14.4%. Among 55, 458 potential blood donors, crude HCV seroprevalence was 3.57% (95% CI 3.42 – 3.72). Testing was through Rapid Diagnostic Test (RDT) kits in most facilities, and only 2 of 17 centres were performing HCV RNA testing. The median cost of an anti-HCV RDT test was \$0.97 (0-1.61) and \$3.23 (1.61 – 7.58) for persons with and without government health insurance respectively. The median cost of a 12-week course of the pan-genotypic direct-acting antiviral therapy sofosbuvir-daclatasvir was \$887.70. In conclusion, there are significant regional differences in HCV burden across Ghana. Limited access to and cost of HCV RNA and DAA therapy hinders testing and treatment capability, and consequently HCV elimination efforts. A national HCV program supported with a sustainable financing plan is required to accelerate HCV elimination in Ghana.</p>
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- Vertebrate embryos or tissues

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Additional data availability information:

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2 Ghana, 2016 – 2021; A multi-centre cross-sectional study.

3

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35

36 **Abstract**

37 The current burden of Hepatitis C virus infection and the availability of HCV-related services
38 in Ghana are not well described. Previous estimates on HCV seroprevalence in the country are
39 outdated. This study investigated the HCV seroprevalence and testing and treatment capacity
40 in Ghana. A multi-centre cross-sectional study was conducted in which laboratory and blood
41 bank registers from 17 public healthcare institutions in Ghana were reviewed. A survey on cost
42 and availability of HCV-related testing and treatment was also performed. Crude and pooled
43 estimates of HCV seroprevalence, frequency and median cost of available diagnostic tests and
44 medicines were described. The crude HCV seroprevalence was 2.62% (95% CI 2.53 – 2.72)
45 and the pooled estimate was 4.58% (95% CI 4.06 – 5.11) among 103,609 persons tested in
46 laboratories. Age (OR 1.02 95% CI 1.01 – 1.02) and male sex (OR 1.26 95% CI 1.08 – 1.48)
47 were predictors of a positive anti-HCV RDT test. Northern administrative regions in Ghana
48 had the highest HCV seroprevalence ranging from 8.3 – 14.4%. Among 55, 458 potential blood
49 donors, crude HCV seroprevalence was 3.57% (95% CI 3.42 – 3.72). Testing was through
50 Rapid Diagnostic Test (RDT) kits in most facilities, and only 2 of 17 centres were performing
51 HCV RNA testing. The median cost of an anti-HCV RDT test was \$0.97 (0-1.61) and \$3.23
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53 median cost of a 12-week course of the pan-genotypic direct-acting antiviral therapy
54 sofosbuvir-daclatasvir was \$887.70. In conclusion, there are significant regional differences in
55 HCV burden across Ghana. Limited access to and cost of HCV RNA and DAA therapy hinders
56 testing and treatment capability, and consequently HCV elimination efforts. A national HCV
57 program supported with a sustainable financing plan is required to accelerate HCV elimination
58 in Ghana.

59

60 **Keywords:**

61 Hepatitis C virus, anti-HCV, viral hepatitis, children, adolescents, Ghana, sub-Saharan Africa

62

63 **Introduction**

64 Each year, approximately 1.5 million new Hepatitis C virus (HCV) infections occur globally,
65 and it is estimated that, as of early 2020, 56.8 million people in the world were living with
66 chronic HCV infection (1, 2). HCV infection remains a significant risk factor for the
67 development of chronic and end-stage liver disease (3). The World Health Organisation
68 (WHO) estimates that in 2019, there were close to 300,000 HCV-related deaths, largely due to
69 cirrhosis and primary hepatocellular carcinoma (HCC) worldwide (1). Globally, the population
70 attributable fraction (PAF) of HCV infection to HCC is approximately 20%, however, this
71 differs depending on geographic location, with a PAF of 11% and 79% for eastern Asia and
72 northern Africa respectively (4).

73 In sub-Saharan Africa (SSA), the estimated HCV viraemic prevalence is 0.8%, and about 9.2
74 million people in the region are living with HCV (5). The burden of HCV varies by SSA region.
75 Modelled estimates of viraemic HCV infection in southern Africa suggest a prevalence of 0.35
76 – 0.75%, whilst in western and several northern African countries, the viraemic prevalence is
77 between 0.7-1.3% (2). Notably within West Africa, modelled estimates suggest a higher burden
78 of viremia in Ghana and Burkina Faso, and the prevalence is reported to be between 1.3-2.3%
79 (2). There are few **county**-specific population-based studies on HCV within SSA and estimates
80 of disease burden are limited by the accuracy of serological testing, and the limited availability
81 of molecular tests to determine viraemia (6, 7).

82 Since the development of the global health sector strategy (GHSS) on viral hepatitis 2016 -
83 2021 (8), there has been a global effort to put in measures that will help countries reach
84 elimination targets by the year 2030 (9). Key strategies for achieving these goals include the
85 development of national hepatitis control programs and the scaling up of HCV testing and

86 treatment (10). The GHSS 2022-2030 update includes targets for 90% of people living with
87 HCV are diagnosed and that 80% are cured. Furthermore, an incidence target of 5 cases per
88 100,000 per year has been set (11), and although there has been a decline in global burden of
89 HCV infection in recent years (2), it is unlikely that countries will achieve elimination targets
90 by 2030 if more is not done to improve HCV testing and treatment at the country level (12).
91 The challenges to HCV response in SSA include a lack of population-based screening
92 programs, high cost and poor access to HCV RNA or core antigen testing, limited access to
93 affordable treatment and lack of political will in some countries to address HCV care (7, 13).
94 In Ghana, the estimated national HCV seroprevalence in a systematic review of studies
95 conducted between 1995 and 2015 was 3.0% (14), however more recent estimates of HCV
96 burden are lacking. Furthermore, the existing national policy on viral hepatitis published in
97 2014 (15), is based on local data obtained before the year 2014. To determine progress towards
98 HCV elimination and inform revised policies on HCV testing and treatment in Ghana, up-to-
99 date epidemiological data are required. Furthermore, an assessment of testing and treatment
100 capacity, availability, and affordability are necessary to develop strategies that will address
101 country-specific challenges which hinder the progress towards HCV elimination. This study
102 therefore aimed to determine the HCV seroprevalence in Ghana, and the testing and treatment
103 capacity related to HCV infection across public healthcare institutions in the country.

104

105 **Materials and Methods**

106 **Study Design**

107 A cross-sectional study was conducted to determine the HCV seroprevalence using laboratory
108 and blood bank registers of public health institutions in Ghana. Secondly, a survey was
109 conducted in which heads of laboratory and pharmacy services for each institution were asked

110 to provide information on the types of HCV-related tests and medicines available, as well as
111 the cost of tests and medicines in their facility for the year 2021.

112 **Sampling approach**

113 Ghana Health Service hospitals, teaching hospitals, public health reference labs and faith-based
114 institutions, providing HCV-related testing in each of Ghana's 16 administrative regions were
115 eligible for data collection. After the country was zoned into northern, middle, and southern
116 zones, a purposive sampling approach was used to select at least 2 two regional hospitals, 2
117 district hospitals, 1 faith-based hospital and 1 public health **refence** laboratory, as well as all
118 teaching hospitals located within each zone.

119 **Data collection**

120 Data collection took place between February 2021 and December 2021. During the data
121 collection period, all laboratory and blood bank records for HCV-related testing performed
122 between 1st January 2016 to 31st December 2021 in the various study sites were reviewed. In
123 total, 103,609 laboratory register entries and 55,458 blood bank register entries were retrieved
124 for this study. Registers from which data were obtained were paper based, with data either
125 hand-written or typed electronically in Microsoft Word or Excel. Data were recorded in these
126 registers as monthly or yearly aggregates, or alternatively, on a case-by-case basis for
127 individual cases tested. Data abstracted for this study included total number of people tested
128 for HCV, and the number of cases that were either positive or negative. Data for age, gender,
129 and year of testing were also abstracted where available. Three field workers per study site had
130 access to patient data, which contained patient name and hospital ID number, however no
131 information that could identify individual participants was abstracted during or after data
132 collection. Additionally at each institution, we conducted a survey on laboratory testing and
133 treatment capacity, and cost of testing and treatment for HCV using a study questionnaire. The
134 survey was conducted among the heads of the laboratory and pharmacy units of each

135 institution. Data collected included price of HCV-related tests and medicines, types of testing
136 available, average number of tests performed per month and limitations to testing.

137 **Statistical analysis**

138 Descriptive statistics are reported including frequencies and percentages (categorical variables)
139 and mean with standard deviation (continuous variables) **are** reported. Crude and pooled
140 estimates **are** reported for HCV seroprevalence. Crude estimates were determined using total
141 persons positive for anti-HCV (numerator) divided by total persons tested (denominator)
142 multiplied by 100. Pooled estimates were determined by treating each administrative region as
143 a sub-group with inverse-variance weighting and recalculation of the overall prevalence (16).
144 Logistic regression was used to determine predictors of HCV seropositivity. For cost of testing
145 and treatment, the median cost and interquartile range were determined. The frequency and
146 proportion of tests and medicines available at each institution were also determined. To handle
147 missing data, available case analysis was used. Data analysis was performed using Stata,
148 version 17; StataCorp software.

149

150 **Results**

151 *Records reviewed and availability of data*

152 Out of 23 sites selected for data collection, data was available for 17 (73.9%) sites. Data was
153 collected from 5 teaching hospitals, 6 regional hospitals, 3 district hospitals and 3 faith-based
154 institutions, spanning 12 out of 16 administrative regions in Ghana. A total of 103,609
155 laboratory register entries from January 2016 to December 2021 were recorded. Of these,
156 22,876 entries were individual patient-level data whilst 80,733 were data reported from
157 monthly or yearly aggregates. Additionally, 55,458 blood bank entries were reviewed from 13
158 blood banks. Data reported from each site varied by year because not all facilities could retrieve
159 paper-based records for every year requested.

160

161 *HCV seroprevalence from hospital laboratory registers*

162 Seroprevalence estimates were obtained from results from testing with rapid diagnostic test
163 kits (RDT) recorded in laboratory registers. Out of 23,175 records in which gender information
164 was available, males comprised 12,871 (55.5%) and females 10,304 (44.5%) of persons tested.
165 Out of 19,752 records where age information was available, the median age of persons tested
166 was 31 years (IQR 23-45). In total 2,721 out of 103,609 individuals were anti-HCV positive,
167 representing a crude HCV seroprevalence of 2.62% (95% CI 2.53 – 2.72) across the country.
168 The pooled HCV seroprevalence based on sample size per administrative region was 4.58%
169 (95% CI 4.06 – 5.11). The HCV seroprevalence was lowest in the 0-11 years age group (2.13%)
170 and highest in the 60+ years age group (7.59%) (Figure 1). Age was a predictor of a positive
171 anti-HCV RDT test (OR 1.02 95% CI 1.01 – 1.02). Males were more likely to test positive than
172 females (OR 1.26 95% CI 1.08 – 1.48) (Table 1).

173

174 **Figure 1.** Hepatitis C antibody (Anti-HCV) seroprevalence based on laboratory-based rapid
175 diagnostic tests (RDTs) by age group, 2016 – 2021. 0-11 years (n=1126), 12-17 years (n=906),
176 18-29 years (n=7075), 30-39 years (n=4132), 40-49 years (n=2668) 50-59 years (n=1736) 60+
177 years (n=2109).

178 When the burden across the country was evaluated, the highest HCV seroprevalence was found
179 in the Upper East (14.44%) and Upper West (13.54%) regions of Ghana (Figure 2). This trend
180 was similar when the burden across regions was examined in children aged less than 18 years.
181 Where data on age were available, it was found that seroprevalence was highest in the Upper
182 East (7.8%) and Savannah (6.0%) regions, and lowest in the Greater Accra region (0.5%)
183 (Figure 3).

184

185 **Figure 2.** HCV seroprevalence based on laboratory-based RDT tests by region, 2016 – 2021
 186 (all ages). Map Source: <https://www.mapchart.net/africa-detailed.html>

187
 188 **Figure 3.** HCV seroprevalence in children and adolescents (<18 years) based on laboratory-
 189 based RDT tests by region, 2016 – 2021.

190 Table 1. Factors associated with HCV seropositivity among hospital attendants between 2016
 191 - 2020.

	Adjusted Odds Ratio*	95% CI	P value
Sex			
Male	1.262	1.075 – 1.480	0.004
Age (years)	1.018	1.014 - 1.022	<0.001
Year			
2016	Ref		
2017	0.39	0.19 – 0.80	0.01
2018	0.35	0.12 – 0.51	<0.001
2019	0.44	0.22 – 0.88	0.02
2020	0.52	0.26 – 1.05	0.07
Region			
Volta	Ref		
Central	1.32	0.77 – 2.28	0.31
Eastern	1.02	0.58 – 1.79	0.95
Greater Accra	2.09	1.11 – 3.93	0.02
Bono	4.26	2.29 – 7.92	<0.001
Upper East	11.45	6.76 – 19.40	<0.001
Western	0.86	0.25 – 3.02	0.82
Savannah	5.48	2.87 – 10.46	<0.001
*Multivariable model adjusted for age (continuous) gender (male, female), year (categorical) and region (categorical)			

192

193 *HCV seroprevalence from blood bank registers*

194 A total of 1,980 out of 55,458 people screened at blood banks were anti-HCV positive,
195 representing a crude seroprevalence of 3.57% (95% CI 3.42 – 3.72). The pooled HCV
196 seroprevalence was 2.65% (95% CI 2.30 – 3.01). The regions with the highest seroprevalence
197 were the Upper West region (11.28%) followed by the Upper East region (6.87%) (Figure 4).

198

199 **Figure 4.** HCV seroprevalence among potential blood donors by region based on RDT
200 testing 2016 – 2020.

201

202 *Laboratory capacity assessment*

203 Out of 17 study sites, only two teaching hospitals were performing HCV RNA testing for
204 establishing the presence of viremia (Table 2). Of these, one centre had capacity to perform the
205 test on-site, and the other outsourced the testing to a private diagnostic company. In the
206 remainder of the sites, patients were advised to use private diagnostic companies for HCV RNA
207 testing. Only one facility conducted HCV genotyping. Rapid diagnostic testing was widely
208 available across all sites; however, ELISA-based testing was limited to **teaching** (4/5) and a
209 few regional hospitals (3/17). RDT kits available varied by brand, with some laboratory staff
210 uncertain whether the test kits in use were approved by the Ghana Food and Drugs Authority.
211 Examples of RDT brands used included DiaSpot, Wondfo, Abbott SD Bioline™, InTec,
212 HighTop, and Global RDT. At the time of the study, the Ghana FDA list of accredited HCV
213 RDT kits included only the Wondfo HCV kit. The Abbot SD Bioline and InTec RDT were
214 listed in the WHO prequalified in vitro diagnostic products. No centre was performing HCV
215 core antigen (cAg) testing. Direct-acting antiviral (DAA) therapy was not stocked in any
216 hospital pharmacy visited; however, it was reported that these medicines could be obtained
217 from private pharmacies if the patient could afford to pay out of pocket. Each hospital

218 pharmacist asked referenced the same pharmacy/supplier located in Accra, the capital of
 219 Ghana, for purchase of sofosbuvir-daclatasvir.

220

221 Table 2 Summary of HCV-related tests available by type of health facility (2021).

	Teaching	Regional	District	CHAG	Total n/N (%)
<i>Diagnostics</i>					
Anti-HCV (RDT)	5/5	6/6	3/3	3/3	17/17 (100)
Anti-HCV (serology)	4/5	3/6	0/3	0/3	7/17 (41.2)
HCV cAg	0/5	0/6	0/3	0/3	0/17 (0)
HCV RNA*	2/5	0/6	0/3	0/3	2/17 (11.8)
HCV Genotyping	1/5	0/6	0/3	0/3	1/17 (5.9)
<i>Therapeutics</i>					
Pan-genotypic therapy**	0/5	0/6	0/3	0/3	0/17(0)

HCV= Hepatitis C virus, RDT=Rapid Diagnostic Test, cAg= Core antigen, RNA= Ribonucleic acid. *One site performed test on-site, and the other outsourced to a private laboratory. **Medication was not available in the hospital pharmacy but was available on request from private pharmacies.

222

223

224 Table 3. Summary of HCV testing and treatment costs

	Subsidized price with government health insurance USD Equivalent* Median (Range)	Non-subsidized price without government health insurance USD Equivalent* Median (Range)
<i>Diagnostics</i>		
Anti-HCV (RDT)	0.97 (0 ⁺ – 1.61)	3.23 (1.61 – 7.58)
Anti-HCV (ELISA)	3.15 (1.96 – 8.07))	7.26 (5.65 – 50.03)

HCV RNA	Not subsidized	88.77 (88.77 – 129.12)
<i>Therapeutic</i>		
12-week course of pan-genotypic therapy	Not subsidized	887.70
*1 GHS = USD 0.1614 at the time of data collection		
†Only one facility offered this test for free		

225

226 *Cost of diagnosis and treatment*

227 The price for anti-HCV testing was based on health insurance status. Cost of testing for both
228 RDT and ELISA was subsidized if an individual had government health insurance; \$0.97 vs
229 \$3.23 for RDT and \$3.15 vs \$7.26 for ELISA for insured vs non-insured patients respectively.
230 However, for HCV RNA, there was no subsidy on cost of testing, and patients had to pay out-
231 of-pocket regardless of insurance status. It was reported by laboratory heads that the cost of
232 testing was dependent on the price of the test from the supplier. DAA therapy was not
233 subsidized by government health insurance. A 12-week course of pan-genotypic DAA
234 sofosbuvir-daclatasvir was \$887.70. Table 3 summarizes diagnostic and treatment costs.

235

236 **Discussion**

237 In this study we report a pooled HCV seroprevalence of 4.6% in patients tested at public health
238 care facilities, which is slightly lower than reported in neighbouring countries. Seroprevalence
239 estimates from a systematic review in Cameroon, in which 87% of studies included were
240 facility-based, reported a pooled anti-HCV prevalence of 6.5% (17) whilst in north-east
241 Nigeria, the reported seroprevalence among 560,857 out-patient clinic patients and 60,285 in-
242 patient admissions attending a tertiary referral centre was 6.9%. In Ghana, the national HCV
243 seroprevalence based on a systematic review by Agyeman et al in 2016 was 3.0% (14), however
244 more recent nationwide estimates are not available. The difference in seroprevalence between
245 this and Agyeman’s study may be influenced by the type and quality of diagnostic tests used

246 in studies included in the systematic review, including the sensitivity and specificity of test
247 kits, or may reflect the different populations in the two studies. In the present study, data
248 reviewed included that from hospital lab results of patients who may likely have been tested
249 because of clinician suspicion of HCV infection or its related conditions such as chronic liver
250 disease, or alternatively in the work-up for conditions in which HCV is highly co-morbid such
251 as chronic renal failure or sickle cell disease. Notwithstanding these possibilities, it is important
252 to note that the population tested in hospital laboratories also includes persons directed by
253 clinicians to undergo testing for non-HCV-related conditions such as pregnant women, patients
254 attending outpatient clinics with long term chronic conditions such as hypertension, and healthy
255 individuals undergoing routine medical screening. On the other hand, the study by Agyeman
256 and colleagues reviewed studies comprising significantly low-risk populations, with their
257 estimate heavily influenced by large studies conducted among blood donors. This is likely to
258 have led to a lower estimate of national seroprevalence in their study.

259 Upon comparison of the disaggregated HCV seroprevalence among blood donors in the
260 Agyeman study of 2.6% to the anti-HCV prevalence among blood donors in this study, we
261 found a similar estimate of 2.7%. Seroprevalence was likely lower among potential blood
262 donors compared with the rest of the study population because prior to testing, individuals **are**
263 routinely assessed for eligibility to donate using a standard screening form to eliminate persons
264 who are likely to test positive for HIV, HBV, or HCV as per Ghana's national blood donation
265 guidelines (18), thus making this population low-risk. Reported anti-HCV prevalence in studies
266 from other countries in the SSA region among blood donors range from 0.8% in Ethiopia (19)
267 to 2.32% in Mali (20), and 6.9% in neighbouring Burkina Faso (21).

268 This is the first study to explore the HCV seroprevalence in the majority of administrative
269 regions in Ghana, since previous studies on HCV have largely been conducted in the Greater
270 Accra and Ashanti regions (14, 22, 23, 24, 25, 26). Significantly, there was unequal burden of

271 disease across the different administrative regions, with the northern regions demonstrating the
272 highest seroprevalence (8.6-14.4%) and the Greater Accra Region in southern Ghana
273 demonstrating lowest seroprevalence (1.0%). A similar pattern has been reported with the
274 burden of Hepatitis B Virus (HBV) in Ghana (27). Northern Ghana, compared with the rest of
275 the country, has lower access to healthcare, weaker healthcare infrastructure, lower rates of
276 hospital deliveries and lower doctor-to-patient and nurse-to-patient ratios (28, 29, 30), which
277 may explain the higher burden of HCV in this part of the country. Furthermore, cultural
278 practices such as scarification of the face and other parts of the body which may occur as early
279 as the first week of life, for purposes of tribal and family identification, spiritual protection and
280 traditional medicine use are more prevalent in the northern regions than in the south (31), and
281 likely contribute to higher rates of HCV transmission in the region. In addition to this,
282 chieftaincy and ethnic conflicts which occur at a higher rate in Northern Ghana, may lead to
283 increased HCV burden directly through blood exposure or indirectly through weakened
284 socioeconomic and health infrastructure (32, 33). Southern Ghana was found to have the lowest
285 anti-HCV prevalence in this study. In the Greater Accra region, a 2020 study conducted in a
286 public hospital among 728 patients reported an HCV seroprevalence of 1.6% (26), close to our
287 reported estimate in the same region of 1.0%.

288 Several factors may contribute to the HCV burden in Ghana. This includes a poor level of HCV
289 knowledge and awareness in the population, which may mean individuals are less likely to be
290 aware of their HCV status and therefore would be less likely to undertake practices to limit
291 spread (6). For example, studies in the Ashanti region demonstrated that the majority of study
292 participants had never heard of HCV and were unaware of its modes of transmission (24, 34).
293 It is possible that healthcare provider knowledge on HCV is also inadequate, since some studies
294 suggest knowledge gaps in HBV-related care among providers in Ghana (35, 36, 37), however
295 specific studies on knowledge of HCV among healthcare workers in Ghana are lacking. If the

296 same is true, and HCV knowledge among healthcare workers in Ghana is insufficient, this may
297 mean that healthcare workers may be less likely to screen, treat, or link HCV patients to
298 appropriate care. Other factors such as blood to blood exposure including through scarification
299 as previously described, unsafe male circumcision practices and intravenous drug use (IVDU)
300 are potential contributory factors to HCV infection in Ghana and remain a probable mode of
301 transmission (38). The degree to which IVDU is prevalent in Ghana is not well established,
302 however a study among inmates reported that roughly one third of inmates had a history of
303 intravenous drug use (39). In a study of 323 person who inject drugs (PWID) and persons who
304 use drugs (PWUD) conducted in four regions in Ghana, HCV seroprevalence was reported to
305 be 5.6% (40). There is evidence to suggest that a significant proportion of PWID in Ghana
306 reuse and share needles due to the high cost and difficult access (39, 41). Currently there are
307 limited harm reduction programmes for PWID in Ghana, with no formal syringe exchange
308 programmes for this key population (38).

309 A further mode of HCV spread may be through vertical transmission from pregnant women to
310 their babies. Studies among pregnant women have demonstrated seroprevalence data ranging
311 from 2.7% in the Central region (42) to 7.7% in a study in the Ashanti region (23). Although
312 anti-HCV testing is recommended as part of routine antenatal care screening in Ghana, this test
313 is not free in many public health facilities, and a proportion of pregnant women may not be
314 able to pay out-of-pocket. For example, in this study, only one centre offered the anti-HCV test
315 at no charge for insured patients. Furthermore, unlike Human Immunodeficiency Virus (HIV),
316 HBV, and syphilis, neither the maternal health record book nor the labour ward registers in
317 Ghana require recording of HCV status, therefore midwives or antenatal clinic nurses may
318 overlook HCV testing during pregnancy and delivery.

319 This study found a seroprevalence of 2.13% among children aged 0-11 years and 3.31% among
320 those aged 12-17 years attending healthcare facility laboratories. A recent global systematic

321 review reported an anti-HCV seroprevalence in African children (<20 years old) of 3.02%,
322 with seropositivity of 2.45% in those aged <10 years and 4.74% in those between ages 10 – 20
323 years (43). In Ghana, a study at the Princess Marie Louis Children’s Hospital in the Greater
324 Accra Region reported a seroprevalence of 0.5% from a hospital population of 200 children,
325 comparable to this study’s finding of 0.5% in the same region (25). The anti-HCV prevalence
326 found in this study, particularly in the Bono, Savannah and Upper East regions demonstrate the
327 need to include eligible children (above 3 years of age) and adolescents in a screening and
328 treatment program for HCV in Ghana, in line with current guidance (44, 45).

329 Although RDT kits were widely available in all sites visited, it was concerning to note that
330 laboratory personnel were uncertain whether these kits were either approved for use by the
331 Ghana Food and Drugs Authority or WHO pre-qualified. A previous study found that out of
332 17 different HCV RDT kits used in 374 public and private diagnostic laboratories in Ghana,
333 only 2 (11.8%) were WHO pre-qualified (46). At study sites visited, procurement of test kits
334 was handled at the facility level by procurement officers or laboratory personnel, with no direct
335 input from the Ghana National Viral Hepatitis Control Program nor Ministry of Health. It is
336 known that the performance of RDT kits is variable, and sensitivity may range from 75% to
337 100% (47, 48). Consequently, the use of non-approved RDT kits may increase the chances of
338 false negative or false positive anti-HCV results, which may therefore under- or overestimate
339 HCV seropositivity if this method is used as the sole screening tool (49). The variability in
340 price of anti-HCV kits was also of concern, and this is likely due to the different brands of kits
341 used, since laboratory personnel reported that pricing was dependent on the price from the
342 supplier. A specific policy on test kit procurement involving purchase and subsequent
343 distribution by the Ghana National Viral Hepatitis Control Program will not only ensure that
344 FDA approved or WHO-prequalified kits are used but may also bring some stability to pricing

345 in public health facilities. Furthermore, the poor availability of ELISA testing in sites visited
346 emphasizes the need to ensure the use of pre-qualified HCV RDTs.

347 PCR testing for HCV RNA was only available in two centres visited, with one of these
348 outsourcing to a private laboratory. Qualitative or quantitative HCV RNA testing is crucial for
349 determining which patients require direct-acting antiviral (DAA) therapy. In the absence of
350 PCR capacity in public hospitals, patients must often patronise private laboratories. In addition
351 to limited availability, the high cost of \$88.7 found in this study poses a significant barrier to
352 HCV treatment in Ghana (6, 14, 46). If Ghana is to achieve scale-up of testing and treatment,
353 there is a pressing need to increase PCR testing capacity. One way may be to leverage the
354 improved PCR testing capacity in some public health facilities in response to the COVID-19
355 pandemic. Furthermore, there is a need to decentralise testing to, **at** a minimum, regional
356 hospital level. To increase testing access, it may also be necessary to consider alternate methods
357 for testing, including the use of dried blood spot sampling (DBS), which is cheaper and less
358 vulnerable to strict cold-chain storage and transfer requirements (50), in place of venous blood
359 sampling. Furthermore, development of testing algorithms based on HCV core antigen testing
360 (51), which is currently not available in Ghana, may be an alternate way to scale-up testing and
361 treatment in the country.

362 In this study, no hospital visited had stock of DAA medication in their pharmacies, but it was
363 noted that these drugs could be obtained from privately run pharmacies if the patient could
364 afford the treatment. There are currently no government subsidies on the cost of medications
365 and current pricing in the country for a 12-week course of pan-genotypic therapy appears
366 higher than in other African countries such as Nigeria and Cameroon (\$750) (52). A 2022 cost-
367 utility analysis in four African countries estimated the generic price for a 12-week course of
368 sofosbuvir/daclatasvir to be \$195 and for sofosbuvir/velpatasvir to be \$450 (53). For many
369 patients requiring HCV treatment in Ghana, personal income may be insufficient to cover the

370 current costs of diagnosis and treatment. Relying on complete government financing may also
371 not be practical or sustainable (52). To improve treatment access, strategies to overcome these
372 costs are necessary, and may include shared financing between governments and individuals,
373 improved global access programs, reduced pricing by large diagnostic and pharmaceutical
374 companies and increased advocacy by civil society groups and patients to expand access to
375 care.

376 The strengths of this study include the broad coverage of administrative regions in Ghana, and
377 the inclusion of data different types and levels of public health facilities, which provided
378 previously unreported data on HCV seroprevalence in certain regions in the country.
379 Furthermore, we were able to provide age-related estimates of HCV seropositivity, highlighting
380 the need to include children in any HCV screening and treatment program in Ghana. Another
381 major strength of this study is that we were able to collect information on capacity and pricing
382 of HCV testing and treatment in Ghana, which can directly inform policy in the country.

383 Limitations of this study included the use of secondary data, which meant that not all
384 institutions were able to provide data for all the years of interest. In addition to this, the majority
385 of the data was aggregated, which limited the ability to assess for risk factors in the study
386 population. Furthermore, the study population comprised hospital attendants, whose
387 seroprevalence estimates may be higher than that of the general population. There is also a
388 need to assess the prevalence of viraemic HCV infection, rather than seroprevalence at the
389 national level since such population-based data are lacking in Ghana. Finally, the use of varied
390 brands of RDT test kits with different sensitivity and specificity may have affected the accuracy
391 of prevalence estimates.

392 **Conclusion and recommendations**

393 The uncertainty of the true national HCV prevalence in the general Ghanaian population
394 emphasizes the need for additional population-based studies to improve disease burden

395 estimation, including the HCV incidence, viraemia prevalence, and mortality associated with
396 HCV in the country. Possible solutions will be to undertake strategies such as testing of stored
397 population-based samples or undertaking a national testing campaign for HCV. In this study,
398 we have identified that there are significant regional differences in HCV burden across Ghana,
399 with the northern regions demonstrating the highest HCV seroprevalence. Targeting
400 prevention, testing and treatment policies for northern Ghana may therefore be warranted.
401 Limited access to and cost of HCV RNA testing and DAA therapy hinders testing and treatment
402 capability, and consequently HCV elimination efforts. There may be a need to improve HCV
403 awareness in Ghana, through multiple avenues including a national campaign by the Ministry
404 of Health. An improved policy on RDT kits is required, with measures put in place to ensure
405 that only Ghana's FDA or WHO prequalified test kits are used in the public and private sectors.
406 Finally, a national program for HCV elimination including a financing plan for sustainability
407 is important if Ghana is to achieve the 2030 viral hepatitis elimination targets.

408

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418

419

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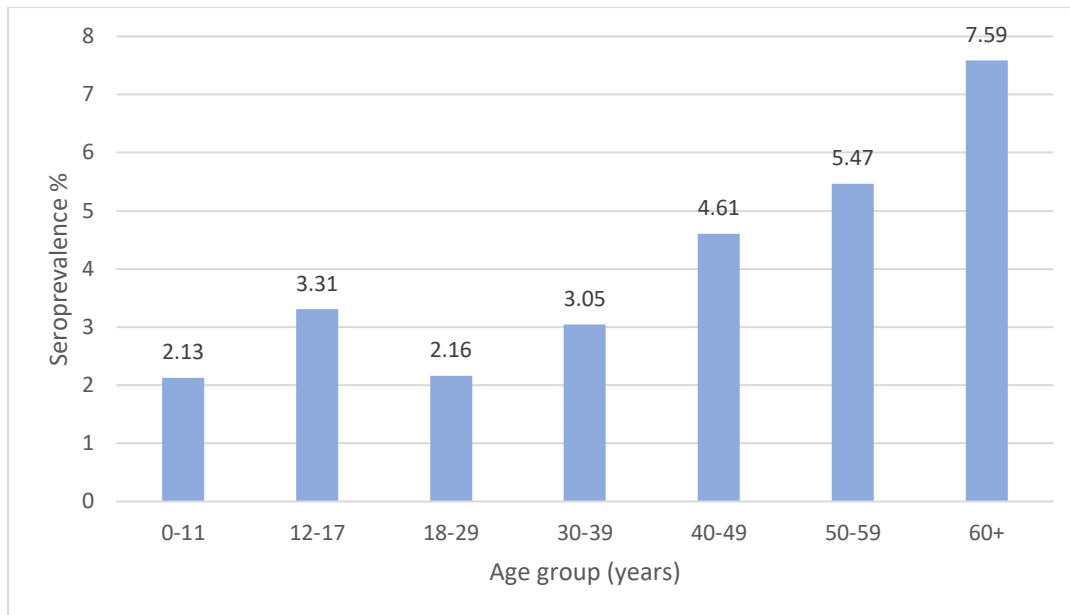


Figure 1. Hepatitis C antibody (Anti-HCV) seroprevalence based on laboratory-based rapid diagnostic tests (RDTs) by age group, 2016 – 2021. 0-11 years (n=1126), 12-17 years (n=906), 18-29 years (n=7075), 30-39 years (n=4132), 40-49 years (n=2668) 50-59 years (n=1736) 60+ years (n=2109).

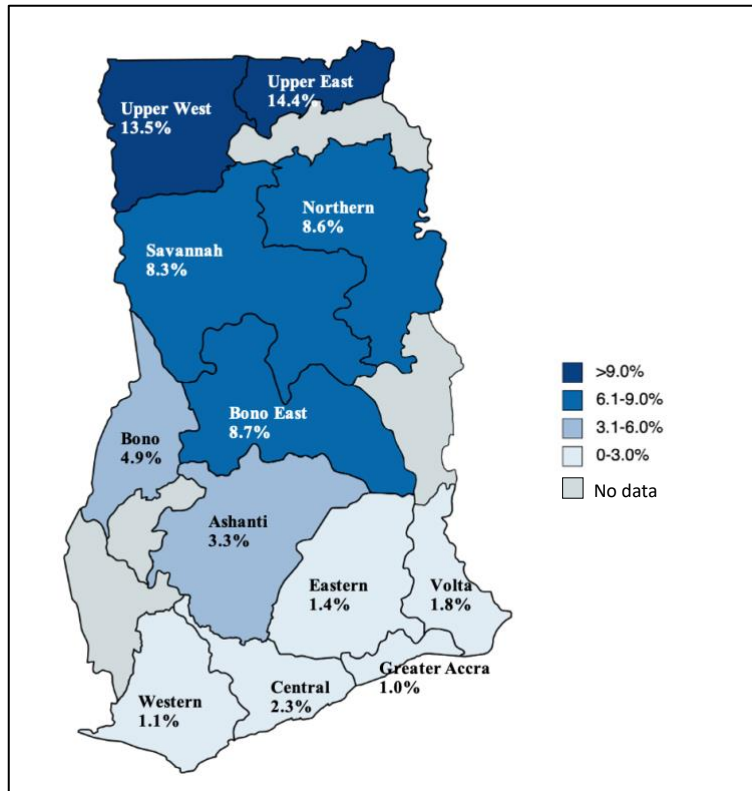


Figure 2. HCV seroprevalence based on laboratory-based RDT tests by region, 2016 – 2021

(all ages). Map Source: <https://www.mapchart.net/africa-detailed.html>

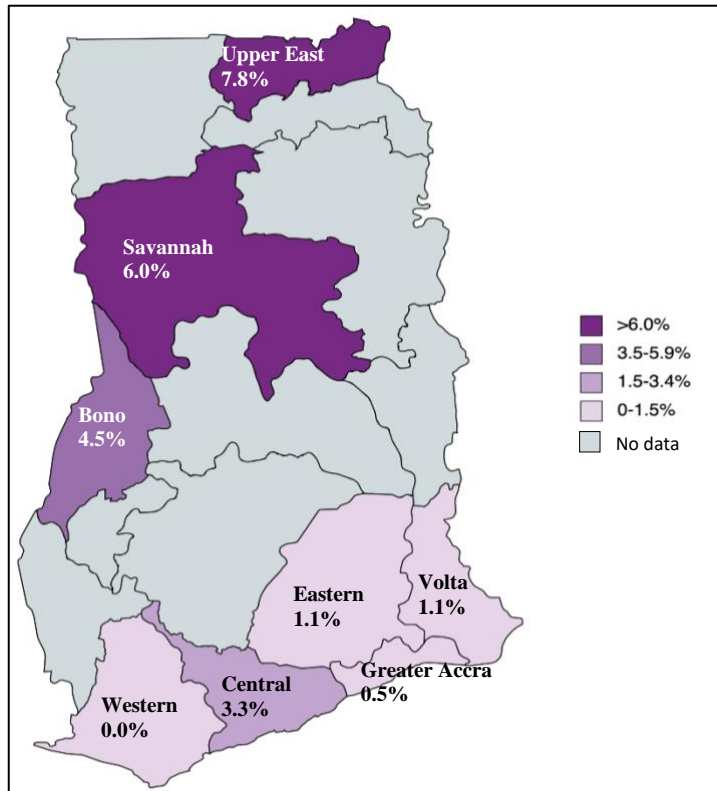


Figure 3. HCV seroprevalence in children and adolescents (<18 years) based on laboratory-based RDT tests by region, 2016 – 2021

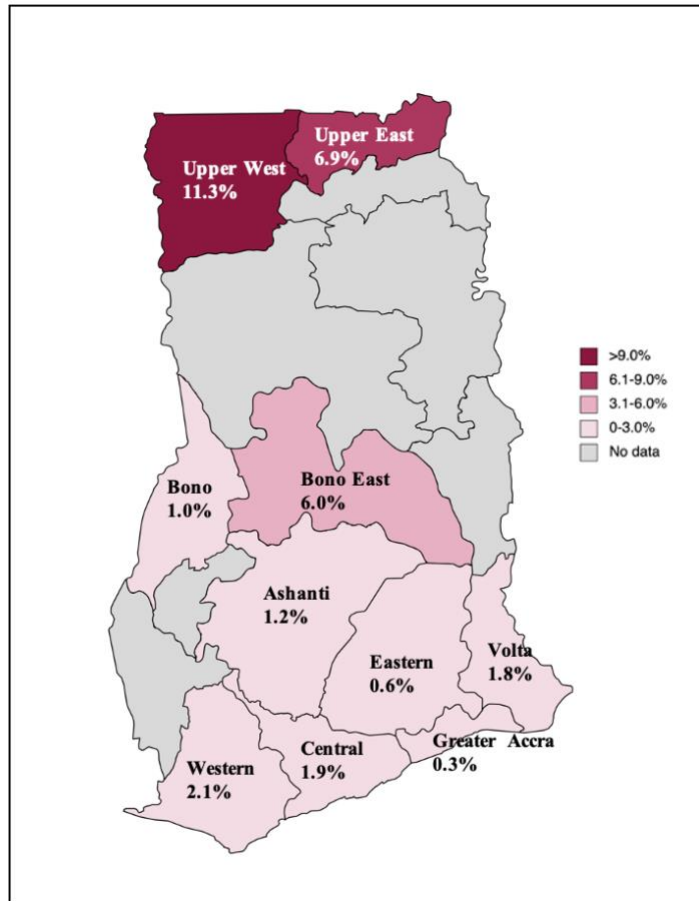


Figure 4. HCV seroprevalence among potential blood donors by region based on RDT testing 2016 – 2020