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MINI THESIS

Title: Barriers to accessibility to Antiviral treatment for Patients with Chronic Viral Hepatitis C in Egypt

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Abstract

Background: Egypt has the highest burden of Hepatitis C Viral infection (HCV) in the world with 10% between 15- 60 years old having HCV antibodies and 7% having chronic HCV infection. HCV is more concentrated among rural, aged, less educated, and poor population groups in addition to patients who require frequent blood transfusion or on renal dialysis, and injection drug users. Despite advancement in antiviral treatments with higher than 90% sustained virologic response (efficacy), access remains limited. The government strategy tied expanding the access to antiviral treatment to a price reduction through subsidies, but an expansion of HCV treatment coverage was not observed. This suggests a broader range of barriers in addition to the financial affordability.

Methodology: This descriptive, qualitative study thus aimed to explore the various barriers that patients with chronic HCV experience in accessing antiviral treatment in Egypt. Twenty-seven semi-structured interviews with a wide range of stakeholders were conducted. Interviewees included national politicians, government officials, and health workers, mid-level managers in pharmaceutical industry, civil society activists and patients with HCV.

Results: Interviewees indicated that the poor access to HCV antiviral treatment is due to numerous factors. In the area of health polices: passive privatization processes, domination of charity vs rights-based approach, lack of evidence-driven policies, poor health governance system, and limited health budgets were frequently reported. In the area of health system (structure and functionality): the interviewees pointed out the weakness of health information and viral hepatitis surveillance systems, the urban-biased concentration of HCV diagnostic and treatment services, and the limited coverage of health insurance especially amongst rural inhabitants. In relation to demographic socio-economic characteristics, there was a general consensus that financial ability, place of residence, employment status and gender continue to predict patients' access to antiviral treatment.

Conclusion: The financial affordability predicts access to antiviral medicines which is arbitrated by steady deterioration in social and economic protection mechanisms in the Egyptian society. However, the poor access is also determined by the country's political context, the organisation of national healthcare system in addition to patients' demographic and socio-economic characteristics.

Declaration

‘I declare that the mini-thesis “Barriers to accessibility to Antiviral treatment for Patients with Chronic Viral Hepatitis C in Egypt” is my own work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references’.

Candidate

Dr. Hani Serag

January 08, 2017

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Hani Serag

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Abbreviations

AASLD	American Association for the Study of Liver Diseases
CMV	Cucumber Mosaic Virus
CNS	Central Nervous System
DAA	Direct Antiviral Agents
EDHS	Egypt Demographic and Health Survey
EHIS	Egypt Health Issues Survey
FVC1	Forced Expiratory Volume
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IDSA	Infectious Disease Society of America
IMF	International Monetary Fund
MCGN	Minimal-change glomerulonephritis
MDRD-4	Modification of Diet in Renal Disease 4 variable formula
MOF	Ministry of Finance
MOHP	Ministry of Health and Population
NANBH	Non-A, Non-B Hepatitis
NCCVH	National Committee for the Control of Viral Hepatitis
NYHA	New York Heart Association Functional Classification
SVR	Sustained Virologic Response
SVR12	Sustained Virologic Response measured after 12 weeks of treatment
SVR24	Sustained Virologic Response measured after 24 weeks of treatment
WB	World Bank

Definitions of key terms

- **Compensated liver cirrhosis** describes a stage in which the liver can still perform important functions. Liver support medicine and strict diet are useful.

- **Decompensated liver cirrhosis** is a life-threatening condition associated with jaundice, ascites, variceal haemorrhage and hepatic encephalopathy. Liver transplantation should be considered.

- **Direct-acting Antiviral Agents** are a new generation of antivirals with the ability to target nonstructural proteins of the virus and result in disruption of viral replication and infection.

- **HCV genotypes** refer to genetically distinct forms of the virus based on variation in the virus Ribonucleic Acid (RNA). The virus was isolated in at least 6 major genotypes and about 50 sub-genotypes. Identifying the genotype informs the treatment regime (Hepatitis Central, 2016).

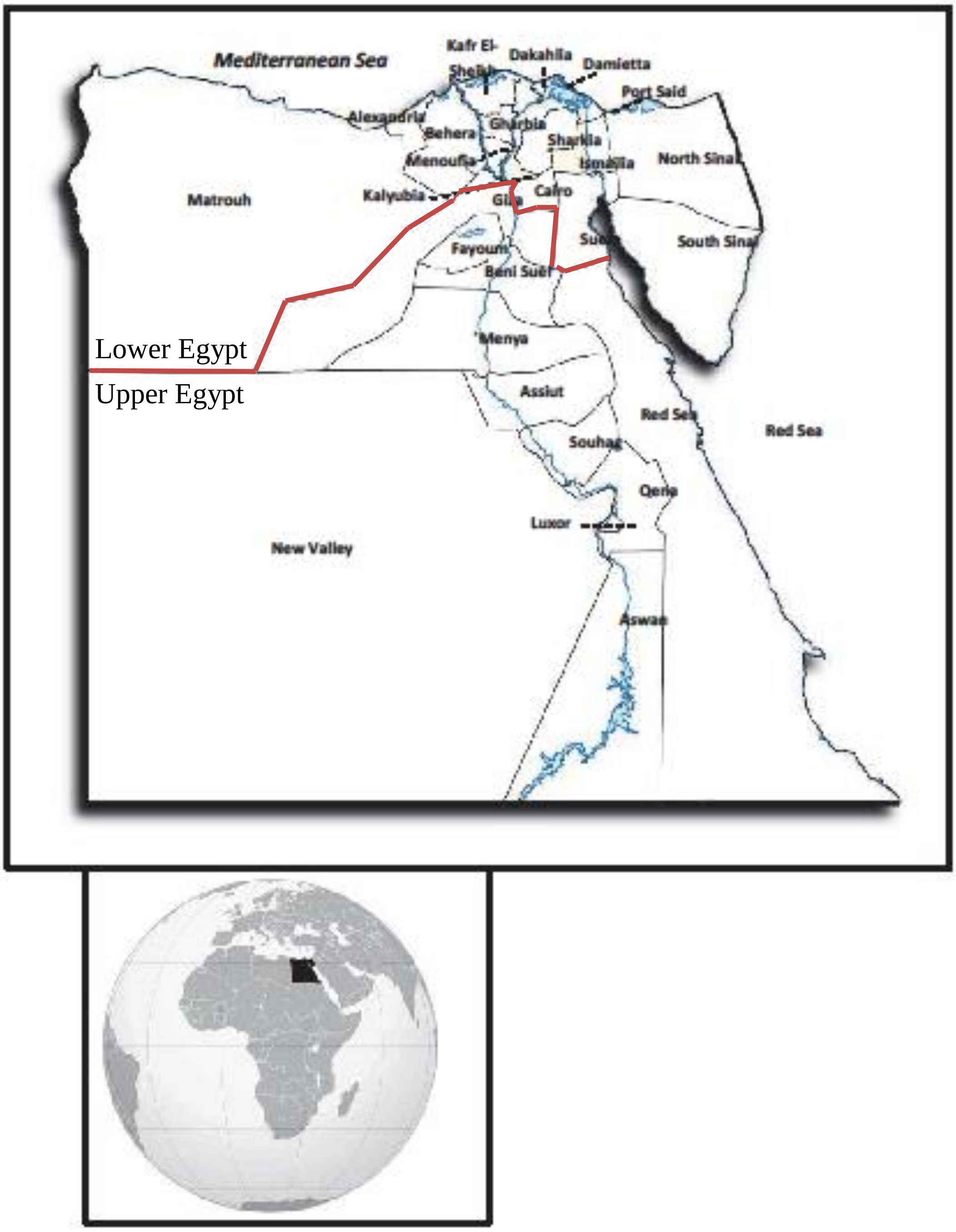
- **HCV viral load** measures the virus genetic materials (usually defined in international units) in a certain volume of blood (usually one cubic milliliter). The significance of HCV viral load is related to the detective threshold of different diagnostic techniques and the duration of treatment while it has no significant correlation with the prognosis (Hepatitis Central, 2016).

- **Hepatocellular Carcinoma** is a type of primary liver cancers (starts in liver) and it can expand through giving metastases to other organs/tissues, most commonly to the lungs, lymph nodes and bones. In most cases, it cannot be cured but cancer palliative measures and liver supportive treatment increase the life expectancy (WebMD, 2016; Katyal, Oliver, Peterson, *et al.*, 2000).

- **Liver Cirrhosis** describes an irreversible and slowly progressing condition in which healthy liver tissue is scarring (being replaced with scar tissue). This will eventually prevent the liver from performing its functions properly. The spread of the scar tissue slows and eventually blocks the flow of blood through the liver and hence the processing of nutrients, hormones, enzymes. It also slows the production of essential substances, e.g. amino acids (protein) and it produces toxins (WebMD, 2016; MedicineNet, 2016).

- **Lower Egypt** is a commonly used term to describe the Northern part of Egypt while **Upper Egypt** describes the South. These terms refer to the geographical fact that the Egyptian land is downgrading towards the Mediterranean Sea.
- **Nosocomial** is a hospital-acquired infection.
- **Sero-prevalence of HCV** refers to the frequency of individuals with HCV antibodies in blood. Sero-prevalence is used rather than simply prevalence to differentiate between the prevalence of antibodies and the prevalence of HCV RNA (called HCV RNA prevalence).
- **Sustained virologic response** means permanent clearance of the virus indicated by the absence of the HCV RNA at certain points during the treatment course (Ghany, Strader, Thomas *et al*., 2009).

Egypt Map



Source: Egypt Health Issues Survey (MOHP, El-Zanaty and Associates, and ICF International, 2015).

Chapter (1). Introduction and Background

Introduction to the problem

Egypt has the highest burden of Hepatitis C Viral infection (HCV) in the world (WHO, 2012). Egypt Demographic and Health survey (EDHS) 2008 concluded that 14.7% (9.3 million) Egyptians between 15- 59 years had HCV antibodies and 9.8% (6.2 million) had chronic HCV infection (El-Zanaty and Way, 2009). EDHS 2015 (published in 2016) suggested a significant decline in prevalence where 10% of population between 15 -59 had HCV antibodies while 7% had chronic HCV (MOHP - Egypt, El-Zanaty and Associates, and ICF International, 2015)[1].

Breban, Doss, Esmat, *et al.* (2014) suggested that slightly less than 150,000 Egyptians acquire HVC every year. They argued that the assumptions used for the modelling of earlier estimated incidences of 500,000 (Miller and Abu-Raddad, 2010) and 100,000 (the official record of ministry of health) were invalid. If the current trends continue, within two decades, nearly a quarter of a million deaths are predicted from HCV-related chronic liver diseases and cancer (Lehman and Wilson, 2009). The high ongoing transmission of HCV is largely linked to inadequate infection control during medical and dental procedures in healthcare facilities (Paez-Jimenez; Sharaf-Eldin, Rimlinger *et al.*, 2010).

Socio-economic status predicts the likelihood of exposure to HCV. HCV prevalence is higher among rural, aged, poor, illiterate, and male populations. In rural settings, HCV prevalence is 11.7% compared to 7.1% among urban population. It is strongly associated with age: it rises from 1% (among 15-19 years old) to 33.9% (among 55-59 years old). It is 12.7% among population in the lowest wealth percentile versus 6.5% among those in the highest. It is 16.2% among those who received no formal education versus 8.4% among those who completed high school or higher. It is 12.4% and 8.1% in males and females, respectively (MOHP - Egypt, El-Zanaty and Associates, and ICF International, 2015). The higher prevalence among the rural and aged population is possibly linking the exponentially

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[1] The EDHS 2015 was made available for public in in July 2016, two years after the completion of data collection for this study. Accordingly, the main reference that study participants referred to while sharing their perspectives on the size of HCV in Egypt was the EDHS 2008.

increased HCV incidence to the population's exposure to unsafe injections during the schistosomiasis treatment campaign in the 1960s through to the 1980s (Cuadros, Branscum, Miller, *et al.*, 2014). See figure (2) in appendix (1).

At present, there is no vaccine available for HCV but there is efficacious curative antiviral treatment. In December 2014, the American Association for the Study of Liver Diseases (AASLD) recommended a 12-week antiviral triple therapy of Simeprevir, Peginterferon Alfa-2a and Ribavirin for HCV genotype-4[2] (AASLD, 2014; Dhawan, 2014), the genotype accounting for 90% of the HCV infections in Egypt (CDC, 2012). This treatment regime showed sustained virologic response at 12 weeks (SVR12) ranging from 79-96% (Jacobson, 2013; Moreno, Hezode, Marcellin, *et al.*, 2013). In comparison, the previous standard regime of Peginterferon Alfa-2a and Ribavirin was recommended for 24 weeks and had SVR24 of 51%.

Problem statement

Despite the recent and ongoing advancements in curative treatments for HCV, access to the antiviral treatment remains limited in Egypt. In 2008, the National Committee for the Control of Viral Hepatitis (NCCVH) published a 5-year strategy (2008-2012). It estimated that in 2008 the number of HCV patients who would be eligible for antiviral treatment was 600,000 (Dalglish, 2008). However, from 2008-2011, only 190,000 patients received the treatment. The number of patients receiving treatment was 22,000 in 2008, increasing to 65,000 in 2009 and then declined gradually to 58,000 and 45,000 in 2010 and 2011, respectively (CDC, 2012). In a more recent survey, 38% of HCV patients between 15-59 years, in a nationally representative sample, self-reported receiving HCV antiviral treatment. The percentage was 29.7% in women and 41.7 % in men. However, the majority of them self-reported receiving the old treatment regime (interferon) with a 51% cure rate while only 4.8% reported receiving new antiviral medicines (Sofosbuvir or Olysio) with 79-96% cure rate (MOHP - Egypt, El-Zanaty and Associates, and ICF International, 2015) .

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[2] At present, six genotypes of HCV with multiple subtypes were identified. These virus derivatives have not shown significant differences in pathogenicity. However, clinical trials showed significant variations in their responsiveness to treatments discovered till now. This heterogeneity also represents one of the main obstacles to the vaccine development (CDC, 2014).

The strategy, which the Egyptian health authorities continue to follow, tied expanding the access of HCV antiviral treatment to the distribution of a relatively low-priced course of the antiviral treatment through governmental medical facilities based on strict guidelines. During the last decade, the Egyptian government has repeatedly adopted the approach of negotiating with pharmaceutical companies a reduced price-HCV antiviral treatment for the use within public sector. For example, in 2008, the government reached an agreement with two transnational pharmaceutical companies (Merk and Roche) to produce locally-packed Pegylated Interferon at US$ 2,000 (to be paid by the patients) instead of US$ 12,000 (the international price) for a 48-week[3] treatment course (Kaplan and Swan, 2012). The reduced price represented 47% of the average annual Egyptian family income and 56% of the annual income of rural households in the fiscal year 2010-2011[4].

In 2014, the Egyptian Government repeated a similar deal with Gilead (a US-based pharmaceutical company) to purchase a preparation of Simeprevir (as a part of the currently recommended triple therapy) at US$ 900(to be paid by the patients) instead of US$84,000 (the original price in the US market) (Fick and Hirschler, 2014). This significant reduction in the cost was not reflected in a corresponding expansion of the HCV treatment coverage. This suggests that cost is still beyond the affordability of patients and/or there are a broader range of barriers (Dalglish, 2008; CDC, 2012; Ford, Singh, Cooke, *et al*., 2012). Such uncertainties reflect a knowledge gap in identifying the barriers to HCV antiviral treatment and/or the ability of the limited existing knowledge to guide an informed decision making process.

It is evident from the existing literature that patients in Egypt face a range of barriers when trying to access antiviral treatment for chronic HCV. These include, but are not limited to, financial affordability. As the Centres for Disease Control (2012) has suggested other barriers may also include factors related to the health policies and the national health governance, the structure of healthcare system, socio-economic dimensions, and care-seeking behaviour of patients (CDC, 2012).

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[3] While the standard previous regime was 24-week course, it had to be repeated twice in most of cases due to the limited efficacy.

[4] These percentages are estimated based on the records of the Egyptian Central Agency for Public Mobilization and Statistics (2010-2012) published in early 2012.

Rationale and contribution to the field

Inaccessibility to HCV treatment can result in costly-to-manage complications (e.g. massive cirrhosis, hepatocellular carcinoma) which can be fatal. Recent evidence showed that the full coverage of HCV antiviral treatment of patients receiving injections or invasive medical procedures on a regular basis (the main source of HCV spread) will significantly reduce the self-sustained transmission rate (Francesco, 2014).

Studying the barriers to treatment among Egyptian patients is key to develop effective strategies to combat the HCV problem in Egypt. Such a strategy is needed more than ever to stop the ongoing transmission of HCV and the severity of its consequences (physical, psychological and the social impacts on patients and their families). The current study thus aims to make a contribution to informing the development of more effective strategies for expanding the coverage of HCV treatment.

The study setting

This study has a national scope and thus was not confined to a particular geographical setting; however the majority of interviewees were from Cairo (the capital of Egypt and an urban governorate) and Al-Dakahlia (one of the major governorates in Lower Egypt and mainly rural) – see the map of Egypt in page 4). Interviews were conducted with twenty-seven individuals who represent a wide range of stakeholders. These included three politicians from different political parties (based in Cairo), three senior government officials (based in Cairo), three academics (based in Cairo), four health workers (two primary care physicians and two hepatologists working in public primary care and specialized facilities – two were based in Cairo and two were based in Dakahlia), two mid-level managers working in the pharmaceutical industry (public and private – based in Cairo), four civil society activists (half of them from Cairo and half of them from Dakahlia), and eight patients with HCV (four of them had either received antiviral treatment and four were denied antiviral treatment – half of them were from urban settings in Cairo and half of them were from rural settings Dakahlia). Informants (especially with regards to the patients) were recruited in a way which was sought to represent the diversity of the Egyptian population, based on place of residence (urban and rural), gender (women and men), social class and religion (Muslims and Christians). Similarly, the importance of capturing a range of experiences and perspectives on the key issue guided the way the researcher recruited key informants from policy makers and politicians at a national level to healthcare workers and community activists working at a local level.

The research design and methodology of the study

Adopting a descriptive qualitative design, the researcher used the semi-structured interview as a technique for data collection. The qualitative approach was chosen as it better suits the exploratory and descriptive nature of this study. In addition, the qualitative design provided opportunities for better description of pathways through which identified barriers affect the access to antiviral medicines through probing with the interviewees (Sullivan and Sargeant, 2011). The researcher conducted a total of twenty-seven interviews with: three parliamentarians, three senior governmental officials, three academics based at a local university, four healthcare workers (two primary care physicians and two hepatologists), two representatives working in public and private local pharmaceutical companies, four representatives from civil society organizations and social movements active in Egypt and, importantly, eight patients diagnosed with HCV.

An outline of the report

The report includes seven chapters. Chapter-1, the introduction, provides a summary to the background of HCV and its magnitude, describes the problem statement, justifies the research, and defines its contribution to the field, describes the study settings and summarizes the design and methods. Chapter-2, the literature review, summarizes the available knowledge and describes the knowledge gap in barriers to HCV antiviral treatment. Chapter-3, the methodology, states the overall objective and specific aims. It also describes in details and motivates the use of a qualitative approach and discusses the rigor, the data collection tools and describes the study population and the sampling technique. In addition, it discusses the ethical considerations including the procedures of recruitment of study participants, obtaining their informed consent and protecting their confidentiality. Chapter-4, the findings, presents the reported barriers to HCV antiviral treatment categorized as per their relation to health polices, organization of the healthcare system, socio-economic conditions, and patient behaviour of seeking health services. Chapter-5, the discussion, provides an interpretation of the results under the same categories of the findings. Chapter-6, the conclusion and recommendations, summarizes the findings and provides and promotes set of suggestions using the same categories as the findings.

Chapter (2). Literature Review

Epidemiology and Burden of Disease of HCV

HCV is a world-wide prevalent public health problem with an increasing global burden of disease. A systematic review using a model-based meta-analysis concluded that the prevalence and number of people with HCV antibodies has increased between 1990 and 2005 from 2.3% [with 95% uncertainty interval (UI): 2.1-2.5%) to 2.8% [with 95% UI: 2.6-3.1%] and from 122 million to greater than 185 million during this time period (Mohd-Hanafiah, Groeger, Flaxman, *et al.*, 2013). More than 75% of those HCV infected develop chronicity. Chronic HCV is a leading cause of serious liver complications including liver cirrhosis, hepatocellular carcinoma, and end-stage liver failure (Chen and Morgan, 2006; Highleyman, 2013). A systematic analysis of the global burden of disease estimated deaths from HCV related causes by 500,000 every year (Lozano, Naghavi, Foreman, *et al.*, 2010).

Egypt has the highest burden of HCV in the world (WHO, 2012). Egypt Demographic and Health survey remains the most reliable source of HCV-related morbidity estimates. Studying a nationally represented sample of 11,126 Egyptians (15 to 59 years old), it concluded that in 2008, 14.7% (9.3 million) Egyptians had HCV antibodies (sero-prevalence) and 9.8% (6.2 million) had chronic HCV infection (El-Zanaty and Way, 2009). Egypt Health Issues Survey (EHIS) 2015 (made publicly available in 2016 after finalizing the data collection of the current work) suggested a significant decline in prevalence where 10% of population between 15 -59 had HCV antibodies while 7% had chronic HCV (MOHP, El-Zanaty and Associates, and ICF International, 2015). The significant decline in the HCV prevalence is controversial not only because of the absence of proper explanation in the EHIS, but also because of the contradiction with previous studies. In a systematic review, researchers concluded no evidence for a decline of statistical significance in the HCV prevalence in both the general population and at-high-risk population groups (Mohamoud, Mumtaz, Riome, *et al.*, 2013).

The estimation of incidence of HCV in Egypt significantly varies among different studies. A statistical model estimated that nearly 7/1,000 (or the equivalent of 500 000) Egyptians acquire HCV every year (Miller and Abu-Raddad, 2010). Based on such estimation, nearly quarter million deaths are predicted from HCV-related chronic liver diseases and cancer within 20 years if the current incidence continues (Lehman and Wilson, 2009). A more recent review suggested that slightly less than 150,000 Egyptians acquire HCV every year (Breban, *et al.*, 2014). It argued that the assumptions used for the modelling of earlier estimated incidence of 500,000 (Miller and Abu-Raddad, 2010) and 100,000 (the official record of ministry of health) were invalid.

As a blood born virus, the transmission of HCV is largely linked to inadequate infection control during medical and dental procedures in healthcare facilities (Paez-Jimenez, *et al.*, 2010). This was supported by a systematic review which in addition identified specific population groups at high or direct risk of acquiring HCV infection: patients with other types of viral hepatitis, multi-transfused patients, thalassemia patients, schistosomiasis patients, patients on haemodialysis and injection drug users. The latter five categories are subject to blood work related procedures within healthcare settings (Mohamoud, *et al*., 2013).

Socio-economic status predicts the likelihood of exposure to HCV. The prevalence is higher among rural, aged, poor, illiterate, and male populations. In rural settings, HCV prevalence is 11.7% compared to 7.1% among the urban population. It is strongly associated with age: it rises from 1% (among 15-19 years old) to 33.9% (among 55-59 years old). It is 12.7% among the population in the lowest wealth percentile versus 6.5% among those in the highest. It is 16.2% among those who received no formal education versus 8.4% among those who completed high school or higher. It is 12.4% and 8.1% in males and females, respectively (MOHP - Egypt, El-Zanaty and Associates, and ICF International, 2015). The higher prevalence among rural and aged population is possibly linking the exponentially increased HCV incidence to the population's exposure to unsafe injections during the schistosomiasis treatment campaign in the 1960s through to the 1980s (Cuadros, *et al.*, 2014).

A systematic review described high discrepancies in measuring prevalence and incidence of HCV in Egypt (Mohamoud, *et al.* 2013). These discrepancies exist as different researchers studied different population sub-groups at different risk of HCV, using different methodologies.

This clearly indicates the need to establish a standardized systematic surveillance system that collects routine data on HCV from all health facilities and is thus also able to provide the public health community with an understanding of those most at risk of acquiring the disease.

Healthcare system and the national response to HCV epidemic

Egypt has a highly complex system in terms of healthcare provision and financing. The healthcare provision incorporates a large network of public, non-profit, and private facilities (WHO, 2013). While contributes to a high level of coverage and accessibility, it causes a serious degree of fragmentation especially with a clear lack of integration among different types of services and lack of coordination among different healthcare providing entities (Oxford Business Group, 2017). Public health expenditure, in general, is low and has diverse financing mechanisms including tax-based financing, premium-based insurance coverage and out-of-pocket for direct payments at the time of service (WHO, 2013). Out-of-pocket expenditure continued to increase to reach 55.7% in 2014 (WHO, 2016).

The national response to the issue of HCV in Egypt was drawn up by the NCCVH in terms of 5-year strategy documents published by the Ministry of Health and Population (MOHP) namely; (1) Egyptian National Control Strategy for Viral Hepatitis 2008-2012, and (2) Plan of Action for the Prevention, Care and Treatment of Viral Hepatitis, Egypt 2014-2018. These two 5-year strategic plans adopted four areas to focus on, namely: surveillance and monitoring, prevention and safety of medical procedures, patient management and research (Dalglish, 2008; Ministry of Health and Population, 2014).

In the areas of surveillance and monitoring, the Plan of Action 2014-2018 provided a brief assessment of the weaknesses of the current system emphasizing underfunding and fragmentation as major concerns. Yet, consisted with the previous strategic planning of 2008, it continues to promote the surveillance of viral hepatitis as a vertical project rather than as an integral part of the national health information system even in the long-term. In addition, it did not provide any solutions to address the underfunding. Despite acknowledging the capacity of human resources as a key factor in maintaining the surveillance system, both documents could not provide concrete activities to build the capacity of relevant personnel at national and local levels.

In the area of prevention, the two strategic planning documents prioritized infection control within medical facilities and health education especially among at-risk groups. They failed to refer to or propose the development of the necessary guidelines and follow-up mechanisms to reduce the rates of the transmission of viral hepatitis during medical and dental procedures in both public and private healthcare facilities.

In the area of patient management, they prioritized case detection and treatment. However, they limited the proposals for enhancing case detection to improving the laboratory capacity rather than a national viral hepatitis screening program that detect the cases at an early stage for improved chances for prognosis. They also shied away from specifying clear targets such as a certain reduction of the rate of transmission within a certain period of time.

In the area of research, the two strategic planning documents focused on building research capacity for clinical research which is greatly needed. However, they undermined the need for public health research that continues to identify determinants of and barriers to combating the viral hepatitis problem.

In general, the two strategic planning documents ignored, to a great extent, addressing the underlying causes and specifically the social determinants related to the incidence of infection and access to treatment. For example, it failed to propose actions to improve the geographical distribution of HCV-related preventive and curative services to be proportionate to the distribution of the disease burden. It also failed to integrate the national response to viral hepatitis within the health system. It touched upon the need for multi-sectoral action without suggesting concrete steps to achieve it.

Treatment of HCV

Houghton and colleagues isolated HCV, previously known as Non-A, Non-B Hepatitis (NANBH) for the first time in 1989 (Houghton, 2009). Since then, researchers have tested several potential vaccines in animal trials. Only one vaccine was tested on a small scale in humans showing potential success in preventing chronic HCV infection; however, it has not yet been tested in clinical trials (Steckelberg, 2015). The slow progress in the development of a vaccine for HCV is related to several reasons, among them are the diverse genetic characteristics of the virus (HCV has at least six main genotypes and about 50 sub-genotypes); the limitation related to the presence and the use of animal models in research related to vaccine testing especially due to the role of animal rights activists and the high associated cost; the difficulties related to recruiting at-high-risk groups in vaccine clinical trials: hard-to-reach groups in developed countries (mostly drug users) and weak health system and shortage of trained staff in developing countries (Steckelberg, 2015).

There is, though, efficacious curative antiviral treatment. In December 2014, AASLD and IDSA recommended a 12-week antiviral triple therapy of Simeprevir – a Direct Acting Antiviral (DAA), Peginterferon alfa-2a and ribavirin for HCV genotype-4, the one responsible for 90% of the HCV infections in Egypt (AASLD and IDSA, 2014; Dhawan, 2014). This treatment regime showed sustained virologic response at 12 week (SVR12) of 79-96% (Jacobson, 2013; Moreno, *et al.*, 2013). This treatment regime represents a significant advancement in the ability of curing HCV in comparison with the previous standard regime of Peginterferon Alfa-2a and Ribavirin for 24-48 weeks (WHO, 2012) and had sustained virologic response of 54-56% for HCV genotype-4 (Butt, Khan, Shaikh *et. al*., 2009; CDC, 2012). The duration of treatment using this old regime and its success represented by the virologic response depended on the HCV genotype, the viral load, the race, age, weight, and the level of pathogenicity (Swan and Raymond, 2004). In Egypt, the treatment success rate using the old treatment regime was estimated at 51% (CDC, 2012).

HCV antiviral treatment is a life saving measure. Rated as class I (indicating general agreement) level A (indicating that data are obtained from multiple clinical trials) evidence[5], the antiviral treatment of HCV (using the current recommended regime) reduces all-cause mortality and liver related adverse consequences including hepatocellular carcinoma and massive cirrhosis. Accordingly, AASLD and IDSA recommended the antiviral treatment for all patients with chronic HCV infection except for those with short life expectancies due to properly diagnosed end-stage condition. The indications of the antiviral treatment included patients with HCV combined with HIV/AIDS, patients with compensated and decompensated cirrhosis and patient with hepatocellular carcinoma (AASLD and IDSA, 2014).

In Egypt, the government reached an agreement with a transnational company (Gilead Sciences, Inc.) producing a DAA preparation (commercially known as Sovaldi) to purchase the 12-week treatment course at $900 instead of $84,000 (the latter being the selling price in USA). The agreement included that the DAA preparation, produced outside Egypt will have a

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[5] AASLD and IDSA adapted their evidence classification and level from the American College of Cardiology and the American Heart Association Practice (2011) (AASLD and IDSA, 2014).

different packaging and an indication that it can be only sold by the Egyptian Government. The agreement was reached in 2013 for one year subject to renewal (Esmat, 2015).

The NCCVH commissioned a subcommittee of seven members to suggest eligibility criteria and treatment protocol for the new antiviral regime of DAA. The subcommittee developed a scoring system for prioritizing patients with HCV based on urgency of need and expected benefits from treatment. The scoring system suggested adding points or deducting points according to clinical stage of disease, co-morbidities, age, and previous trials of antiviral treatment as described in the table below. In addition, it suggested a threshold score for receiving the state-provided treatment. The authors of the scoring defended the need for prioritizing criteria to ensure the optimal use of the limited resources and rationalized the threshold score based on the estimated number of patients who can be served within the available budget. In addition to the scoring system, the sub-committee suggested guidelines and treatment protocols for each category of cases (mostly based on comorbidities). These protocols were adapted from the guidelines published by AASLD and ISDA after considering the availability of treatment types in Egypt (El-Fishawy, *et al*., 2015).

Scoring of patients with Chronic HCV for DAA treatment priority

Positive points	
Post-renal transplant	5 points
Regular Dialysis	5 points
Cryoglobulinemic vasculitis	5 points
Non-hodgkin B-cell lymphoma	5 points
Biopsy confirmed minimal-change glomerulonephritis (MCGN) with hypocomplementemia	4 points
Biopsy-confirmed MCGN without hypocomplementemia	3 points
Nephrotic syndrome regardless of histological type	2 points
Previous treatment failure	2 points
co-infection HBV, human immunodeficiency virus (HIV) or cucumber mosaic virus (CMV)	2 points
Stage of kidney disease measured by modification of diet in renal disease 4 variable formula (MDRD-4)	1 point/stage
Stage of liver disease assessed by fibroscan	1 point/stage
Negative points	
Age >70	−1 point/5 years
Decompensated cirrhosis	−3 points
Concurrent drug–drug interaction with selected Protocol	−3 points
Concomitant heart disease	−1 point/NYHA (New York Heart Association Functional Classification) score

Concomitant pulmonary disease	−1 point/−10% Forced Expiratory Volume (FVC1)
Concomitant central nervous system (CNS) disease	−1 point/10% disability

Source: El-Fishawy, *et al.*, 2015.

El-Fishawy, *et al.*, 2015 stated that they underwent a five-step process that incorporates a literature review, selecting evidence-based protocols, peer-review debate, online professional survey and preparing a final document to be published and to be used by the government. There are however, a number of weak points in the study. Firstly, the authors failed to motivate the scoring system for prioritizing patient groups. While insisting on describing class and level of evidence for the selection of treatment protocols, they enumerated the prioritization criteria and the relative weight of each with no explanation on how these relative weights respond to ‘urgency of need and expected benefits from the treatment’ as they noted.

Secondly, the threshold of eligibility to the state-provided treatment is estimated based on the state budget allocated to support one scenario which is purchasing low-cost preparation of Simeprevir (commercially named Sovaldi) from the producing pharmaceutical transnational company (Gilead Sciences, Inc.). This decision affects lives, quality of lives and livelihood of millions of Egyptian families and it should have been taken based on political and societal dialogue rather than a limited professional consultation. The adopted scenario ignored other possibilities like the use of a compulsory licence to locally produce the DAA medicine.

Thirdly, the authors selected the treatment protocol based on the availability of the medicines in Egypt. While availability is a justifiable criterion, the availability in this particular case depends on a single agreement between the Egyptian government and the transnational pharmaceutical company. It ignored other options for making the newly-released DAA medicines available for Egyptian patients. The impression is that this study was made to mediate and support a political decision.

Determinants of access to HCV antiviral treatment

The majority of HCV patients worldwide do not have access to the new DAA treatment regime. The treatment rates remain less than 25% in USA, less than 5% in Europe and less than 3.5% in developing countries (Razavi, *et al*, 2013). The high cost of treatment is an overriding determinant of poor access to treatment of chronic HCV patients worldwide and especially in low and middle-income countries in which 85% of HCV patients reside (Phelan and Cook, 2014). As in 2014, the cost of the recommended 12-week course of Sofosbuvir (one of the preparations of DAA) is \$84,000 (or \$65,000 – a discounted price), \$53,000 in UK, \$5,000-\$10,000 in middle income countries and \$900 in low-income countries (Hill, *et al.*, 2014). The minimum cost of production of a 12-week course was estimated at \$68-136 when calculations were made for the use on a large-scale treatment program in developing countries. (Hill, *et al.*, 2014). The high selling price of DAA decided by the manufacturing companies represents a direct barrier to individual access to treatment if either self-paid or supported through mass treatment programmes sponsored by the state in developing countries. However, this barrier is further determined by the modalities of global governance for health. The Trade-Related Intellectual Property Rights (TRIPs) protects any new pharmaceutical or medical products for 20 years (Razavi, *et al*, 2013). While flexibilities contained in the TRIPs agreement allow governments to take exceptional measures, including the use of compulsory licence, to address public health issues, the use of these flexibilities would make a developing country subject to major forms of pressure from powerful states (specifically USA and the European Union Countries). These modalities of global health governance gave the chance to the Sofosbuvir-producing company (Gilead) to make a net profit of \$11 billion during the first 15 months of sales after accounting for research and development, marketing, and legal associated costs (Hill, *et al.*, 2014).

In Egypt, the cost of the recommended 12-week course of the new DAA was estimated as \$900 during the years 2014 and 2015 (Esmat, 2015). This figure does not cover the cost of the entire treatment regime. It also excludes other related medical expenses (e.g. diagnostic procedures) and non-medical expenses (e.g. transportation). There are other determinants, apart from cost, which influence the access patients have to HCV antiviral treatment in Egypt.

Other determinants are the organization and plans and schemes of healthcare services. In Egypt, the state-provided ‘low-priced DAA medicine’ is only available based on the previously discussed prioritizing criteria. This itself represents a barrier to treatment for large groups of HCV patients. This ‘low-priced medicine’ is only provided through 26 specialized centres across the country which represents a distance barrier. In other countries, access to

HCV treatment is affected by insurance coverage. In USA, research on a large study population of 10,582 persons investigated the relationship between the health insurance status and the treatment candidacy of hepatitis C patients (Stepanova, Kanwal, El-Serag *et al.*, 2011). It revealed that only 36.3% of patients eligible for treatment had any type of health insurance. It concluded, utilizing a multivariate analysis, that HCV infection is an independent predictor of no health insurance, even after adjusting for the demographic disparity (odds ratio, 0.43; 95% confidence interval, 0.24-0.7). In China, the social insurance covers only 40% of the cost of the HCV antiviral treatment, hence, a relatively small number of patients can benefit from this coverage as they have to pay the full cost *first* and then claim it back later from the insurance (Coalition of Asia-Pacific Regional Networks on HIV/AIDS '7-Sisters', APN+, ANPUD *et al.*, 2010).

Social exclusion and marginalization were reported as determinants for the access to HCV treatment. While in USA, a cross-sectional study investigating the determinants of access to HCV treatment in 208 patients concluded that independent predictors for not receiving a treatment were the following parameters: being unmarried (Odd ratio 0.36, P=.02), being female (odds ratio 0.36, P=.02) and being alcoholic (odds ratio 0.08, P=.0008) (Morrill, Shrestha and Grant, 2005). No studies were available on the socio-economic factors that influence access to HCV treatment in Egypt.

In summary, the available literature highlights the cost of HCV antiviral treatment as a major barrier to access. A number of studies have also discussed the influence of selected socio-economic factors on access to HCV antiviral treatment. In Egypt, apart from the cost, other barriers related to the socioeconomic status, the health policies and the organization of healthcare service have not yet been explored.

Chapter (3). Methodology

Aim and Objectives

The assumption of this research is that barriers to access antiviral treatment for chronic HCV include, but are not limited to, financial affordability of patients. Other barriers include factors related to the health policies and the national health governance, the structure of the healthcare system, socio-economic factors, and the care-seeking behaviour of patients.

The study was conducted to achieve the following aim and objectives:

Aim

To explore and describe the various barriers that patients with chronic viral hepatitis C experience in accessing antiviral treatment in Egypt.

Objectives

- To describe the influence that the current policy choices within the Egyptian healthcare system have on facilitating or hindering the access patients with chronic viral hepatitis C have to antiviral treatment;
- To describe the impact that the current national health budget allocation for HCV has on the access patients with chronic viral hepatitis C have to antiviral treatment; and
- To describe the various socio-economic factors that potentially influence the access patients with chronic viral hepatitis C have to antiviral treatment.

Approach and theoretical framework

The study adopted a social determinants approach to identify and describe a wide range of factors that influence the access of HCV patients to antiviral medicines. The theoretical framework illustrated in figure (1) categorizes the determinants to antiviral medicines to three interlinked groups of predictors: demographic and socio-economic characteristics, clinical factors, factors related to the organization of healthcare system and factors related to health and health-related polices. These groups impact the access of HCV patients to antiviral medicines directly or through affecting the eligibility to the treatment or availability of treatment or health services.

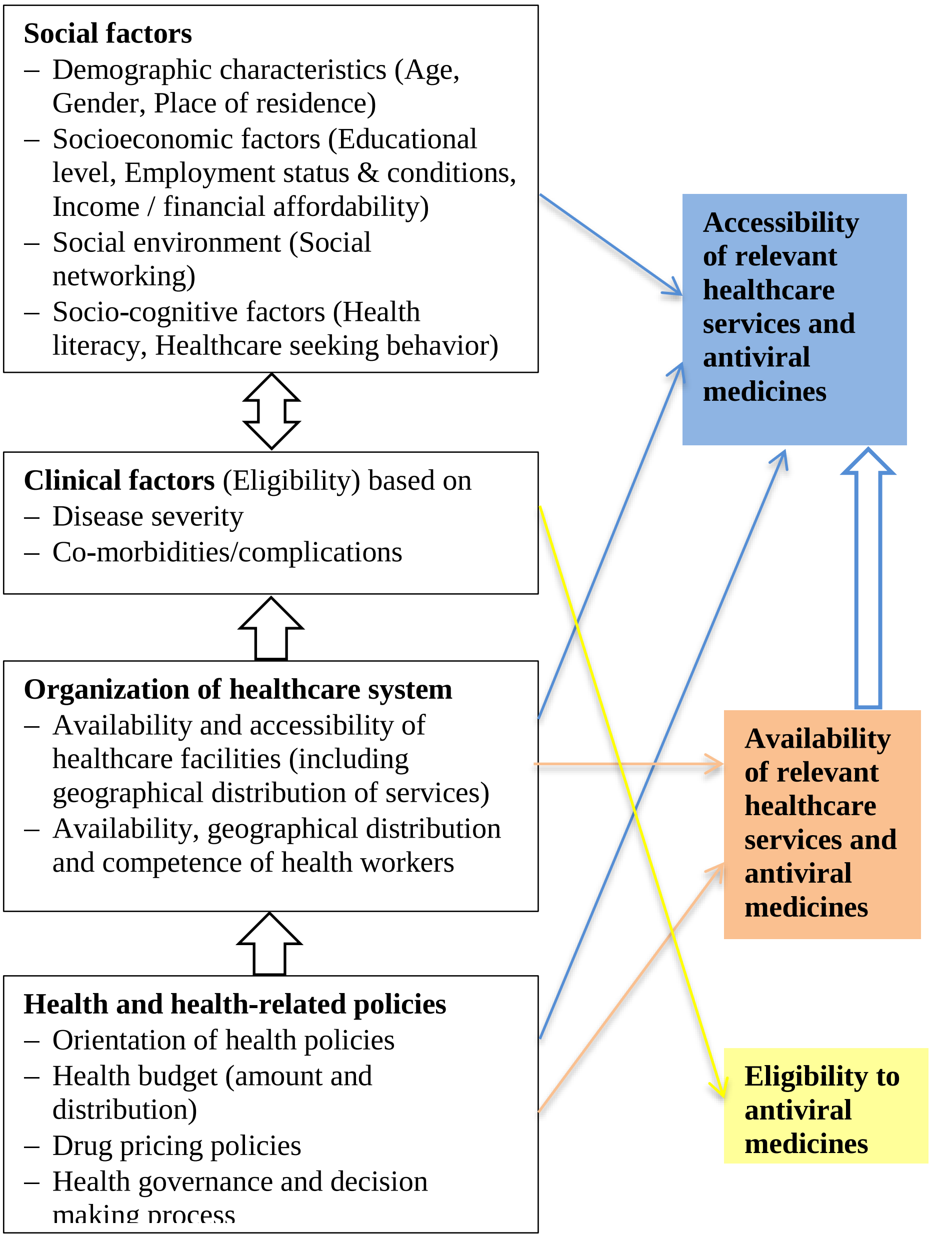

Figure (1). Suggested theoretical framework of factors affecting access to HCV antiviral treatment

Study design

This descriptive study used a qualitative research methods design and utilized the semi-structured interview as a technique for data collection. The qualitative approach was chosen as it better suits the exploratory and descriptive nature of this study. As described in the literature review (Chapter 2), limited knowledge exists about the barriers patients with HCV face in accessing antiviral treatment in Egypt. The qualitative approach was used not only to identify and describe in some depth possible factors that limit HCV patients' access to antiviral treatment, but more importantly to contribute to a better understanding of the origin of these factors and the pathway through which each factor affects the access, i.e. what, why and how (Sullivan and Sargeant, 2011). The use of the qualitative approach would also assist in generating hypotheses to be tested through further analytical studies to establish numerical values and relations between the selected identified barriers (independent variables) and the access to antiviral treatment (as a dependent variable). This is supported by the theory that the qualitative approach provides a holistic manner for understanding the situation and helps researchers to identify set of variables among them statistical relations can be established by quantitative methods, i.e. generate rather than test hypotheses (Hancock, 2002; Maudsley, 2011).

The use of semi-structured interviews in this research provided the interviewees with a reflective space to express their knowledge, experiences and even impressions about barriers related to accessing HCV antiviral treatment with preliminary, yet not rigid, list of pre-set questions and assumptions. It provided me with flexibility to probe or ask the interviewees to further elaborate on their initial responses to the key questions and thus obtain a richer description or interpretation and analysis where appropriate. Yet, having pre-developed set of questions and probes kept the interviews focused.

With continuous guidance from my supervisor, I took the full responsibility for developing the study design and data collection protocol; identifying and recruiting the study participants; conducting the interviews; designing and performing the analysis; and writing the report including eh literature review.

Study population, sample, and sampling procedures

The sampling aimed primarily to ensure balanced representation of key stakeholder groups whose point of views would be influential and leading to the adoption of the study findings especially with the political sensitivity of the topic of the study. Accordingly, I used a purposive (non-probability, judgemental and selective) sampling technique. I first identified six categories of stakeholders to cover the broad and diverse spectrum of stakeholders' experience related to HCV in Egypt. These included: policy makers and politicians, academics and researchers, healthcare workers, patients diagnosed as HCV positive, representatives of pharmaceutical industry, and civil society activists belonging to non-governmental organizations of social movements.

While selecting the interviewees, I used the technique of maximum variation sampling to ensure that informants from each of the six categories represent different perspectives and have experiences to contribute to a richness of data. For example, while selecting the patients, I considered the diverse participants (men and women, urban and rural residents, poor and rich, etc.). I also avoided recruiting extreme or outlying 'cases' i.e. informants known with extremely unusual opinions or atypical experiences were excluded to provide a better chance for the study findings to be acknowledged and used (Given, 2008). For example, while developing the list of potential interviewees, I excluded academics who are known to have strong political stands. This was partly to avoid extreme opinions of highly politicized academics, especially since there is a category for politicians who represent political parties.

I started with a preliminary list of potential interviewees then I used the 'snowball' sampling technique by asking each person I interviewed to nominate others especially from same category. However, nominations were carefully studied to ensure the diversity in the sample.

The final study sample comprised twenty-seven participants spread across the six categories in the following manner:

<u>Policy makers/politicians:</u> Three parliamentarians representing different political parties and three officials who are serving in the Ministry of Health (two of whom were members of the National Committee for the Control of Viral Hepatitis).

Academics/researchers: Three academics who are working for local universities or research institutes and who are primarily focused on conducting research related to HCV.

Service providers (healthcare worker): Four healthcare providers were interviewed from those who work directly with patients with chronic HCV. The four practitioners were selected to cover different levels of healthcare provision: two primary healthcare practitioners who represent the first line of dealing with the patients with chronic HCV, and two hepatologists who are engaged with the diagnosis and treatment of HCV. The selection of participants in this category covered both urban and rural settings.

Patients diagnosed as HCV positive: Eight patients were recruited as study participants: four of them (one woman and three men) had already received antiviral treatment and four (two women and two men) had not received any antiviral treatment. In selecting patients' consideration was given to gender (three women and five men); covering different geographical settings (three were from urban settings and five from rural settings), different social classes (based on location of their residency), different schemes of healthcare coverage (two were insured and six were not insured patients), different levels of education (three were illiterate, two had completed high school, two were university graduates and one had completed post-graduate studies). All patients were between 40 and 60 years.

Pharmaceutical industry: Two mid to high-level managers working in pharmaceutical companies were interviewed (one from the public sector and one from the private sector). These two participants were selected from companies that produce components from the interferon (old) HCV antiviral treatment regime.

Civil society organizations and social movements: I interviewed four health activists who belong to a national health movement (one), national non-governmental organizations/networks (two), and an Egyptian trade union (one). Their representation of the diversity of civil society was considered when sampling within this category.

I reached the final study sample through the following process:

Firstly, through consultation with two persons who have a long experience in research and work in the field of HCV (acknowledged in this report), I started with a list of eighteen potential study participants (four politicians from different political parties, four academics, three healthcare providers, two mid-level managers from pharmaceutical companies, five health activists from civil society organizations).

I then contacted all these potential interviewees through phone calls, e-mails, or in-person (at their work places) to inform them about the study, its overall purpose, and objectives and to request that they consider participating in the study. Sixteen of the initial eighteen potential participants agreed to be interviewed with one of the politicians and one health activists declining the invitation.

Secondly, at the end of the interview with each of the initial sixteen interviewees, I asked each to suggest other potential study participants after explaining the criteria of selection.

Through this process, I then approached the remaining 11 interviewees. While requesting nominations from already recruited study participants, I strictly applied the criteria of diversity to avoid, as possible, the selection bias. These criteria varied from a group to another. For example, for patients my criteria included representation of men and women, urban and rural settings, different social classes (based on whether they live in poor or well-off neighbourhood). For politicians, the criteria included the representation of different political parties with distinguished political stands. In addition, I reviewed the profiles of the politician on my potential list to ensure diversity in their educational and social backgrounds I was also keen to represent female and make politicians.

Patients (diagnosed as HCV positive) were the last group I interviewed as I expected intense emotions during the interviews with HCV patients who have no access to medicine and I tried to avoid carrying these emotions while interviewing informants from other categories. Ten patients were nominated by the two hepatologists (one in Cairo and one in El Mansoura[6]) and I obtained their details from the hospital/clinic records. I asked the administration of the hospital and the secretary of the clinic to make an initial contact and request permission for me to contact them by phone or a visit. The ten patients accepted that I call/visit them, however during the initial phone call/visit, only six agreed to participate in the study. The main reason of the refusal was linked to the political sensitivity of the topic. Of

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[6] The capital of one of the Egyptian governorates located in the heart of large number of rural settings.

these six patients, only five ended up being interviewed as one patient felt uncomfortable to sign the consent form and the interview was thus terminated.

As with the other categories of study participants, I asked each interviewed patient to nominate others till the criteria for patient diversity was met.

Through this process seven more patients were identified but only three of them completed the interview. Four interviews in the second round were terminated at an early stage when patients felt uncomfortable to sign the consent form or were too emotional to continue with the interview – at which point I suggested that the interview be drawn to a close.

In a few cases in both rounds, the decision of not completing the interview was influenced by a family member. In one example, the son of the interviewee insisted that he attends the interview and in the middle of the session, he indicated that I (the researcher) should not be using poor people to carry out research and through that receive an advanced degree when his father was not benefiting anything from these questions. I clarified that in my research, I have patients from different social classes and re-emphasized that they can end the interview at any time if it causes any inconvenience which was the option he chose.

In all the cases of patients with HCV that I interviewed and who had no access to treatment, I suggested certain paths such that they join the paid-by-state treatment scheme and I helped them fill in the application form through a follow up visit where that was needed.

Data collection

Individual, semi-structured interviews were conducted with twenty-seven interviewees belonging to the six categories described above. Individual interviews, rather than focus group discussions, were held so as to provide interviewees with an environment in which they felt comfortable to share their experiences about possible barriers to treatment, especially those related to the political context and policy choices. Egypt faces severe political challenges: the rising armed attacks by religion extremists provoked the current regime to deny the rights to free expression, free assembly, and free association (Human Rights Watch, 2015).

I utilized an interview guide for all categories of interviewees (see Appendix 3). Each guide included a set of open-ended questions. The questions contained in the guide covered some or all of the study objectives. In addition, in most of the interviews, I made use of additional probing questions when I felt that I wanted the interviewees to further elaborate on their initial response to certain questions. As Rice and Ezzy (1999) and Hancock (2002) note a researcher should use probing to have their questions adequately answer without acquiring certain answers by leading questions. A probe (or a follow up question) serves to clarify a provided answer or request more details and supportive examples (Liamputtong and Ezzy (2005).

All the twenty-seven interviews were conducted during the period from February 1st to May 31st2014. All interviews were conducted in the Arabic language (the official language in Egypt). Interviews lasted, on average, 50 minutes (with 40 minutes being the shortest interview and one hour and 15 minutes the longest). The interviews with patients were significantly longer in comparison with the interviews of other interviewee categories as they, understandably, gave more details about their experience of living with the illness. All interviews were conducted in the privacy of patient's homes and at the workplace in the case of the other five interviewee categories.

In terms of considering and reflecting on my role as a researcher in this study, it ought to be noted that I am a medical doctor by training and an Egyptian citizen. Over the past 20 years I have worked as both a clinician within the Egyptian health system and as part of a public health research team, affiliated to a civil society organization, conducting several large-scale public health research projects. I have also played an active role in the Peoples Health Movement, a global network of health activists, civil society organizations and academic institutions which advocates that the social, environmental, and economic determinants of health are comprehensively addressed.

Data management and analysis

At the start of each interview I introduced myself, the purpose of the study and the anticipated process of the interview. Thereafter I obtained informed consent from the interviewee before proceeding with the interview. The process of obtaining informed consent is discussed later in this chapter.

The recording, management, and analysis of data in this research study included the following. As a part of the consent process, I requested permission for digital recording. Twenty interviewees agreed to have their interview digitally recorded. I took detailed hand-written notes in the remaining seven interviews. Note-taking was a preferred option over digital recording by one parliamentarian, two government officials, two representatives of pharmaceutical companies and two patients.

I developed a transcript [7] of each of the twenty-seven interviews in Arabic (the same language of the interviews). I asked all the interviewees, at the end of the interviews, whether they wished to read a summary of the interview. Nine interviewees asked for the summary, namely, three officials, three academics, one physician and two from the pharmaceutical industry. I shared the summaries with these nine interviewees by e-mail a week after each of their interviews. Five of them responded to the e-mail acknowledging the receipt of the interview summary and four acknowledged receipt through a follow-up phone call. No changes were suggested from any of the nine interviewees. One shared resource materials to support his earlier responses (although all of these resources were not for public use and thus not used in any way in this thesis).

The responses collected through all of the interviews were first organized under five headings in alignment with the study objectives: (1) Reported descriptions of access to antiviral treatment of HCV**;** (2) Reported barriers to antiviral treatment of HCV that are related to national health policy; (3) Barriers related to the organization and functionality of the healthcare system (system and clinical factors); (4) Barriers related to demographic and socio-economic factors; and (5) Barriers related to patient health services seeking behaviour. I then identified similarities and differences in the responses from each category of study participants to the study objectives and began to identify themes that emerged across the objectives and categories of participants.

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[7] Many interviewees, especially with the patients, had a tendency to provide details outside the scope of the questions put to them - despite my efforts to keep the interview focused on the guide questions. During the transcript process, I typed a summary of relevant responses supported by word-by-word quotes from the interviewee when appropriate.

Credibility and Trustworthiness

In qualitative research rigor aims to achieve the needed "trustworthiness" in terms of credibility, transferability, dependability, and confirmability (Lincoln and Guba, 1985). This was considered in the study in the following manner:

Confirmability was attempted through proper documentation for continuous checking of the data. This included identifying and thoroughly describing negative cases that are different or contraindicated with findings of previous studies; and conducting a data audit to check possible types of bias in the techniques of data collection or data analysis (Shenton, 2004). As outlined previously, I categorized the responses of all interviewees based on the interview guides and study objectives. While applying the open coding, I accounted for all responses including those that were unique. While reporting the findings, I documented the responses linked to the study objectives and categories (and subcategories) of the study participants using quotes from the responses.

After my initial analysis of the data I shared the transcripts and detailed list of the themes and sub-themes/headings that I had identified with two researchers to verify the accuracy of the subheadings (the codes). After their revision, I organized a discussion among the three of us and reached an agreement on a final list for the list of codes/items under each heading.

Dependability was ensured through examining the barriers to HCV treatment in different contexts and in taking into consideration the different influential factors by, for example, interviewing male and female patients from different places of residence, different social classes, etc. These strategies helped me to contextualize the results, increasing the dependability, i.e. explaining and accounting for the factors that influence the study findings, if repeated.

Transferability (external validity) refers to the extent of the possibility to generalize the study findings. In general, the findings of any qualitative study are linked to and influenced by the context and setting of the study. Checking the transferability was not the research’s primary goal. Instead it is the responsibility of those who wish to check the generalization of the study findings to other settings. The responsibility of the researcher was limited to a detailed description to the study context and settings. However, in the current study, I attempted to examine the study question in different settings through recruiting different categories of study participants and varied informants within each category. In addition, the analysis has accounted for the variations of settings that might influence the study findings (Morse, Barrett, Mayan, *et al*., 2002).

Ethical Considerations

Ethical clearance was first obtained from the University of Western Cape before the study commenced on December 9th, 2013 (see Appendix 4). All potential interviews were provided with detailed information about the study - in person - and also provided with an information sheet (see Appendix 5A). The information sheet was translated and given to the interviewees in Arabic (see Appendix54B). Those who showed a willingness to participate were asked to sign a consent form (see Appendices 5A and 5B). The consent form was presented to study participants in English or Arabic based on their preference. During the data collection, I strictly considered/followed the following principles and procedures:

Informed consent: I provided all potential study participants with information about the study; assured them that the information obtained from them will only be used for the purpose of the study; and informed them about the time needed for the interview. All participants were given the option to refuse the interview or end it at any time with no need to declare reasons. They were also informed that they have the right not to answer any of the questions during the interview. Permission to digitally record the interview was requested before participants were asked to sign the consent. As indicated previously (Section 3.3) the interviews with four of the patients were terminated at the very beginning of their interviews as they either did not feel comfortable signing the consent form or, at an early stage of the interview, got too emotional for it to be appropriate for us to continue the interview process.

In terms of process, after giving all prospective interviewees a verbal explanation and a written information sheet - and responding to any questions they might have had, I asked the prospective interviewees whether they would like to participate in the study before asking them to consider signing the consent form. Those who could not read and write were asked if they felt comfortable informing a literate member of their household or a friend about the study and having them sign the consent form on their behalf. Three patients who were illiterate asked a member from their household (a son in one case and daughters in the other two cases), to read the consent form and sign on their behalf.

Anonymity: As the researcher, I assured each interviewee that any personal data, characteristics, or quotes that could potentially identify them would not be used in the report so as to insure anonymity. Each interviewee has been given a number (and a corresponding description) in this report – both of which were reviewed by a colleague to ensure that there were no identifiers.

Confidentiality: All interviews were conducted with privacy in mind with only the interviewer and the interviewee being were present in the interviews in 24 of the 27 interviews. Only three patients from rural settings preferred to have a family member attend the interview (educated daughters or sons). All electronic files of digital recording of the interviews, the corresponding transcripts, the list of interviewees with real names and the list of interviews with numbers (unique identifiers) have been kept in a secure location in my home and will be ultimately carefully erased and disposed of in five years once I and my supervisor feel that the study has been finalized and reported on sufficiently.

Chapter (4). Results

Size of HCV Problem in Egypt

There was a significant discrepancy among the interviewees regarding their perceptions and descriptions of the size of the HCV problem in Egypt.

While commenting on the **prevalence**, 17 out of the 27 interviewees (1 politician, 3 officials, 3 academics/researchers, 3 health workers, 3 patients, 2 industry-related and 2 civil society activists) expressed their confidence in the nationally adopted figure of the Egypt, EDHS 2009 (El-Zanaty and Way, 2009). Eight of the 17 (1 politician, 2 officials and 3 academics, 1 health worker, and 1 civil society activist) specifically emphasized the robustness of the representativeness of the EDHS sample and the accuracy of the sampling procedures.

Ten interviewees (2 politicians, 1 health worker, 5 patients and 2 civil society activists) questioned the accuracy of the nationally adopted figure for the prevalence of HCV in Egypt indicating that this figure is an underestimation of the size of the problem. These interviewees shared two reasons why they did not support the 2009 EDHS figures, which included:

- The disagreement of these figures with their personal observations (reported by 8 interviewees: 1 politician, the health worker, the 5 patients, 1 civil society activist). For example, as one of these interviewees shared:

  "In our village, each household has one or more person with this virus" (Interviewee 21, male patient from a rural setting); and
- Lack of trust of the results of national studies undertaken in the era of the Mubarak[8] regime (reported by 5 interviewees: the 2 politicians, the health worker, and the 2 civil society activists). As one interviewee shared:

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[8] Mubarak is the fourth president of Egypt. He came to power in 1981 till he stepped down as result of 18 days of mass demonstration of the Egyptian revolution 2011. He and his two sons were later convicted of corruption and given 3-year prison sentences each.

> *"This survey was conducted in the era of Mubarak's regime when results of national studies used to be filtered or modified to give a false image of the problems we faced"* (Interviewee 2, politician).

Regardless of the interviewee's agreement or disagreement with the nationally adopted figure for the prevalence of HCV, the majority of interviewees (20 of the 27 interviewees across all of the categories) indicated that this figure is outdated as the EDHS was conducted in 2008. They suggested that given that this was approximately 7 years ago (2008), they anticipated that the prevalence would be higher. Reported reasons for this view included:

- The high rate of uncontrolled, ongoing HCV transmission combined with the gradual reduction of the case-fatality rate due to the non-curative liver function supportive treatment (reported by 6 interviewees: 2 officials, 2 academics, and 2 civil society activist); and
- The high rate of uncontrolled, ongoing HCV transmission combined with absence of a comprehensive national response to combat the spread of the infection - including poor access to antiviral treatment (reported by 13 interviewees: 3 politicians, 1 academic, the 7 patients and 2 civil society activist). As described by one interviewee:

  > *"Every day we hear that another neighbour learned that he/she has HCV and no money to spend on the expensive treatment - the government does not care"* (Interviewee 19, female patient from an urban setting).

Three interviewees suggested that the prevalence of HCV is decreasing. The reasons they give to back up this perception were:

- An increase in access to curative medicine[9] (reported by 2 officials). And as one noted:

  > "*During the last decade, MOHP worked hard to ensure the safety of the blood banks which resulted in combating the transmission – MOHP has also subsidized the interferon which increased the access of the poor to a curative treatment*" (Interviewee 5, a health official); and

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[9] The interviewees were referring here to the previous standard antiviral treatment regime (a 24-week course of Pegalated Interferon and Ribavirin).

- An increase in HCV-specific mortality (reported by 1 patient), who suggested this was the case because:

  > *"Of course, the number of people with HCV is decreasing: patients are poor - we do not have money for the treatment and we do not have health insurance"* (Interviewee 21, male patient from a rural setting).

All of those interviewed could not provide an actual estimate for the HCV **incidence** nor described a trend. The academics agreed that estimating the incidence through a national study with a representative sample is extremely difficult and indicated the importance of establishing an accurate surveillance system. One of the academics referred to a recent systematic review of the epidemiology of HCV in Egypt (Mohamoud, *et al*, 2013) that provided a range for the HCV incidence from 0.8 to 6.8 per 1,000 person-years. The politicians and health workers agreed that the incidence is higher than 7/1,000 person-year based on their own observations and experience.

Interviewees also discussed **two other parameters** related to the size of the HCV problem in Egypt. These were:

- The population affected - here there was general consensus amongst all interviewees that HCV is more prevalent in rural areas of Lower Egypt in comparison with other geographical divisions and that this was most common among the poor. The majority of those interviewed remarked that this distribution was as a result of the mass historical exposure to unsafe injections during the schistosomiasis treatment campaign in the 1960s through to the 1980s.
- The "real size" of the affected population - 20 interviewees (the 3 politicians, 1 official, 2 academics, the 8 patients, the 2 industry-related and the 4 civil society activists) discussed how HCV does not only affect the person infected but affects the whole family which means that the real size of the problem is at least four times higher than the number of the affected population – or an estimate based on the prevalence. As two of the interviewees stated:

  > *"If we agreed that the HCV prevalence is only 14.7% and the family of each patient consists of only 4 persons, we can say that nearly 60% of the Egyptian population is affected"* (Interviewee 25, civil society activist).

> *"It is not only me who is ill. I have 5 children - the eldest is 12 years - I cannot care for them. My husband is a carpenter who earns our income day-by-day – he leaves his work to come with me to the hospital every week and they do not treat me. We become poorer with each new day"* (Interviewee 20, female patient from a rural setting).

Interviewees used different terms to describe the HCV issue in Egypt: the majority of whom referred to it as a *'public health crisis'*, others suggested it was a *'national security-related problem'* or a 'disaster'.

Access to antiviral treatment for HCV

The majority of the study participants described access to antiviral treatment for HCV as either 'very poor' (20 participants) or 'poor' (6 participants). Collectively there were two main reasons put forward by interviewees to support this position:

Firstly, there was no observable and/or documented change in the size of the HCV problem in Egypt and one of the main reasons is the inaccessibility to the antiviral curative treatment – this was reported by politicians, officials, academics, physicians, patients, and civil society activists.

Secondly, the sales of HCV antiviral treatments are disproportionate to the high disease prevalence which means that the available antiviral treatment is underutilized – this was noted by the manager of a pharmaceutical company:

> *"It is not only our company … the market of HCV antiviral drugs is very slow despite the fact that we have the highest prevalence of HCV in the world"* (Interviewee 23, pharmaceutical industry-related).

One official (Interviewee 6) described the access as 'reasonable' and claimed that *"any objective description should be linked to what is possible within our constrained resources"*. This interviewee also claimed that they had observed a gradual increase in the number of patients who received state-subsidized HCV antiviral treatment.

The interviewees noted that their opinions about the extent of access patients had to antiviral treatment for HCV were informed by the following:

- Personal observation was reported by 21 participants.

> "*We see patients who cannot access medicines every day and we cannot do anything for them"* (Interviewee 13, Hepatologist).

- Complaints received from patients and their families were reported by 7 participants (3 politicians, 2 officials and 2 civil society activists). One official indicated that statistics of beneficiaries of state-subsidized treatment are the most reliable source while other officials were hesitant about the accuracy of such records.

> *"We do not have an advanced surveillance system that gathers detailed records of local health facilities into a unified national database - nobody, I think, can provide an accurate number of HCV patients who benefited from the subsidized medicines especially when the subsidy comes from different mechanisms and schemes"* (Interviewee 4, Official).

- General official statistics were reported by 5 participants (2 academics and 3 civil society activists). The two academics emphasized that official records are not usually available and up-to-date.

> "*Unfortunately, we have better access to official records when we work as consultants with international donors rather than regular Egyptian academics"* (Interviewee 8, Academic).

The civil society activists acknowledge the importance of official statistics even when they are not timely and lack accuracy.

- Research was mentioned as a source by 6 participants (3 academics and 3 civil society activists). The participants indicated that research on access to treatment for HCV patient is limited.

> "*Most of the available research work is from small-scale studies for master or PhD degrees in community medicine"* (Interviewee 7, academic).

- Representatives of the pharmaceutical industry reported states' records as their main source of knowledge about the consumption of HCV antiviral treatment.

> *"I cannot claim that this is an exceptionally accurate source because small number of patients would have access to imported medicines through atypical channels, yet it is a reliable source"* (Interviewee 23, Pharmaceutical Industry).

Table (1) in Appendix (2) shows the descriptions of access to HCV antiviral treatment reported by different categories of study participants in addition to their reported source of information and supportive argument.

Factors affecting access to HCV antiviral treatment

Factors related to national health policies

Using open coding, I located the health policy-related factors reported by interviewees under five themes: orientation of national health policies, health planning, implementation of national health plans, governance for health-related decision making including budgets, and health budgets. (See table 2 in Appendix 2).

Orientation of national health policies

Public versus private healthcare provision: As shown in table (4) in appendix (2), more than half of the interviewees (14 of 27) described a trend of increasing the role of the private sector in healthcare provision and commoditization of healthcare services and medicine simultaneously, with a significant decline in the quality of care provided by public health facilities. There was a consensus on the negative impact of this trend on access to quality healthcare and medicine including antiviral treatment. However, there were different perspectives, supported by arguments, on how this trend was originated and its impact on the long-term.

Three interviewees have spoken in favour of this trend. Two participants (an official and an academic) argued that increasing the role of private sector in healthcare provision is a global growing trend with which Egypt had to align itself even if it causes negative drawbacks on the short-term.

> *“We cannot afford not to be a part of the changing world and we all need to pay the bill of the change to collect the fruits later”* (Interviewee 6, official).

The academic explained that:

> “*The Egyptian market in healthcare just started to move to the right direction through accommodating large-scale healthcare business - the growing market of healthcare will reach maturity in a decade and will regulate itself”* (Interviewee 8, Academic).

The same academic interviewee acknowledged that:

> “*Healthcare and medicine are commodities, one should pay for but there are mechanisms to alleviate the burden of direct payment at the time of service”* (Interviewee 8, Academic).

A primary care physician argued that:

> “*We need to give a complete chance to the private sector to lead the healthcare provision after suffering from inefficient and corrupted public sector for decades*” (Interview 11, physician).

Eleven participants (2 politicians, 5 patients, 1 industry-related and 3 civil society activists) accused this trend for current deterioration of access to healthcare and medicine and raised concerns about expected further deterioration in the future. A politician and two civil society activists argued that Egyptian public health system has a large number of well-distributed facilities across the country which used to work. They added that the health public sector was intentionally left to deteriorate to provide a wider space for the private sector to fill-in the gap.

> “*This is a passive privatization process that intends to create demand for private sector and cultivate anger from the public sector”* (Interviewee 3, politician).

Five patients (2 with treatment and 3 without treatment) emphasized that private clinics and hospitals became the first choice for patients, if they can afford the associated costs.

> “*I have been sick for a year and kept visiting healthcare unit of our village mostly every month and the doctor gave me ‘analgesic’- my liver disease was only diagnosed*

> *when I went to a private doctor who requested lab investigations"* (Interviewee 16, female patient from a rural setting).

They all agreed that visiting a private clinic of a doctor can be a back door to access free service/treatment from the public hospital he/she also works for.

A politician, an industry-related and a civil society activist argued that this 'passive privatization' of health sector is a feature of the health sector reform imposed by the foreign donations and it is a part of a general withdrawal of the state from service provision including the basic services like health and education.

> "*This is what the international aid agencies asked our government to do – the governments started to sell out the public companies and factories since mid-nineties – now it is the turn of health and educational sectors" (*Interviewee 25, civil society activist).

Charity versus rights-based model: Nineteen participants described a domination of a 'charity model' in dealing with the access to HCV antiviral treatment; however, they see it differently. Five interviewees (one politician, one official, one health personnel, one patient and one from the industry) appreciated this trend. They used three main arguments: (1) the rights-based approach in health is inspirational but not a practical goal; (2) the tendency for a charity based-approach is a legitimate response to the limitation of state's health budget; and (3) the current policy succeeded to secure several ways through which patient can access free or cheap HCV antiviral treatment including the paid-by-state treatment program supported by the MOHP; (4) this trend encourages contributions from the rich to support HCV treatment for the poor through the mosques or churches-owned facilities.

> *"We need to think practically – the rights-based approach is good to talk about as an inspirational goal, but cannot be implemented in a low or middle-income country"* (Interviewee 6, official).

> *"What matters is making the treatment available rather than which approach we follow – I think that the current trend secured HCV treatment to a larger number of patients in comparison with the past. If we insisted on the absolute responsibility of*

> *the state – it made opportunity for other players to share responsibility"* (Interviewee 2, politician).

> *"We could not have the medicine unless the mosque paid for it – we need all mosques and churches to collect more money from the rich"* (Interviewee 16, female rural patient with treatment).

Fourteen interviewees (one politician, one official, 2 academics, 1 physician, 5 patients and 4 civil society activists) opposed the dominant charity approach using three arguments as follows: (1) Escalation of this trend is a part of the agenda imposed by the international monetary institutes, the International Monetary Fund (IMF) and World Bank (WB), of state withdrawal from the service provision including health services; (2) Distributing the resources available for treatment through charity models with poor governance structures increases inequity in access.

> *"Instead of increasing the government support to the health insurance which has clear guidelines and governance structure, the government allocated EGP 1.9 billion to the paid-by-state treatment program in which the decision is purely administrative and is not regulated at all – it opens large doors for corruption and hinders equity in access to treatment"* (Interviewee 3, politician).

> *"We cannot keep begging to receive our treatment – aren't we citizens in this country?"* (Interviewee 21, rural male patient without treatment).

(3) The right to health is protected by the international treaties and the Egyptian constitution, but not enforced.

> "*The current policies represent a violation to the constitution and international human rights treaties signed by Egypt"* (Interviewee 11, primary care physician).

Formulation of national health policies and plans

Sixteen interviewees reported lack or absence of health evidence-driven policies and plans as a barrier to rational distribution of resources which hinders the access of the poor to health services and medicines including the treatment HCV antiviral treatment.

While acknowledging, the lack of connection between HCV treatment policies and evidence concluded by academic research, an official from MOHP argued that

> *“Evidence from research is important but is not and should not be the solo drive for policies …. Factors like national budgetary priorities and requirements of donors are equally important”* (Interviewee 5, official).

Seven interviewees (3 politicians, 3 academics and 1 industry representative) indicated that this disconnection between research and policies decreased the demand for policy research.

> “*I spent 10 years working on health policy and systems research focusing on priority health problem in Egypt and recommended tons of evidence-driven policies – I cannot find a reason to continue – I am just adding to the crowd of library selves*” (Interviewee 9, Academic).

Eleven interviewees (2 politicians, 2 academics, 2 health personnel, 2 patients and 3 civil society activists) argued that there is a severe lack of policy and system research in general and HCV-related.

> “*We do not have enough of policy and system research to drive policies and if we have, the governments would not use it”* (Interviewee 26, civil society activist).

Three interviewees (a politician, an academic and a patient) argued that the lack of health policy and system research is part of a general trend of non-appreciation of the value of research or fear of it.

> *“The government allocates less than 2% of the national budget for research in general which reflects its belief in its value”* (Interviewee 9, academic).

> *“The research is scary for dictatorships because it will educate people on the denied facts”*. (Interview 1, politician).

> “*Health policies and systems research in the area of HCV treatment may provide policy recommendations the government like to avoid, like the use of compulsory licences to locally produce HCV antiviral “treatment “for example”* (Interviewee 15, male urban patient on treatment).

Implementation of national health plans

All categories of study participants who were represented in almost three-quarters of the interviewees (20/27) indicated that access to HCV antiviral treatment, commonly described as a national health priority, is not translated into a nation-wide action with clear periodic targets. The interviewees suggested reasons for the gap between planning and implementation:

Five interviewees (1 politician, 2 academics and 2 civil society activist) explained that the NCCVH 5-year Strategy (2008-2012) did not include targets for the antiviral treatment coverage resulting in the lack of evaluation criteria for the implementation. Eighteen interviewees (2 politicians, 2 officials, 2 academics, 2 health workers, 2 industry-related, 6 patients and 2 civil society activists) linked the gap to a general lack and inequitable distribution of human and financial resources.

> *"The government is not serious about treating patients with hepatitis C – the financial resources allocated for the entire national program to combat viral hepatitis is limited especially for the rural areas that are in most need"* (Interviewee 1, politician).

Seven interviewees (1 politician, 1 official, 1 academic, 1 industry-related and 3 civil society activists) blamed the quality of health system management at the local level and inequitable distribution of specialist health workers.

Governance for health

<u>The weakness of MOHP in processes of health-related decision making:</u> Ten interviewees (representing all categories of study participants except for patients) considered that the MOHP is a weak party in the health-related decision-making processes. They mentioned the following examples or supportive arguments. Six interviewees (1 politician, 1 official, 1 academic, 1 industry-related and 2 civil society activists) stated that passing a new health insurance law with universal coverage could have enhanced the access to the HCV antiviral treatment as part of the benefit package. They explained MOHP has drafted several versions of the law and the Ministry of Finance (MOF) blocked all of them from passing to the parliament while being discussed in the cabinet.

> "*The MOHP drafted 13 drafts during the last 10 years – One by one was disagreed by the cabinet which listens to the powerful MOF. The MOF argued that such a law exerts a burden on the state budget"* (Interviewee 6, official).

A civil society activist added that the MOF refused the draft of the law even after a significant compromise was made, giving the authority of changing the benefit package to the minister of health and the authority of changing the premium to the chief minister.

> "*This compromise practically meant that the government, without returning back to the parliament, can increase the premium and reduce the benefit package. Even though, the MOF refused the law"* (Interviewee 24, female civil society activist).

Three interviewees (1 politician and 2 civil society activists mentioned that MOHP has been systematically excluded from being a party in any health-related trade negotiations. They gave an example of discussions related to intellectual property right in the trade negotiations which affects the possibilities of accessing new medicines including those for HCV with cheaper price of local manufacturing.

> *"In all trade-related negotiation, Egypt was represented by either the powerful MOF or Ministry of Foreign Affairs (MOFA) – the later was only used when diplomacy is needed. The MOHP has never been even consulted while the negotiations are related to or affecting the access to medicine and medical products"*. Interviewee 1, politician).

One civil society activist mentioned that MOHP, represented Egypt and adopted the Abuja Millennium Declaration (2001) which set 15% of annual national budget of African Union countries to improve health sector.

> *"Since 2001, more than 10 health ministers could not even bring this issue "the 15%" on the agenda of the cabinet"* (Interviewee 27, Male civil society activist)

<u>The weakness of the state in the international aid negotiations:</u> Ten interviewees (1 politician, 2 officials, 2 academics, 1 primary care physician, 1 industry-related and 3 civil society activists) pointed out the negative impact of international assistance (foreign donations) using supportive arguments. Nine interviewees (1 academic, 2 official, 2 academics, 1 industry-

related and 3 civil society activists) explained that the international partners fund what fits their mandate regardless our national priorities.

> *"The donors preferred to fund governmental and civil society projects that address HIV/AIDS with prevalence less than 1% rather than HCV with prevalence of 15% - I know that we must prevent the HIV/AIDS from further spread, but meanwhile, we need to allocate available funds in accordance with our priorities even if these funds are obtained from international agencies"* (Interviewee 8, female academic).

Five interviews (1 official, 1 academic, 1 industry-related and 2 civil society activists) argued that the international aid to healthcare in Egypt represented a small percentage of health expenditure; however, the donors used this to shape the direction of health sector reform focusing on state withdrawal from healthcare provision and promoting vertical curative programs. They explained that the national program to combat viral hepatitis was hence designed as a vertical program.

> *"We used to have a primary healthcare system that worked with a good geographical distribution of facilities. We could have used the budgets (from both domestic and external sources) to enhance the capacity of our system to combat viral hepatitis including proper investment to secure the antiviral treatment instead of building a parallel structure"* (Interviewee 4, Official).

Three interviewees (1 politician and 2 civil society activists) stated that receiving foreign donations by health sector limited the choices of increasing access to HCV antiviral.

> *"How can we receive donation, if a negligible portion of our healthcare spending, from the international donors like USAID and WB. Then we use the compulsory licence to locally produce cheap antiviral medicines? These donors protect the intellectual property rights before the right to health and promote healthcare as a commodity"* (Interviewee 26, female civil society activist).

National Health Budget and budget allocated for combating viral hepatitis

All interviewees elaborated on budgets-related barriers and highlighted two main issues: (1) budgets available for combating HCV generally and enhancing access to antiviral treatment; and (2) the use of available budgets. Three interviewees (1 politician, 1 official and 1 hepatologist) acknowledged the lack of budgets available for combating viral hepatitis in Egypt, especially HCV. However, they clarified that this is due to the lack of budget available for healthcare generally, which the government cannot increase without a significant increase in gross domestic product (GDP).

> "*It is not only the budget for HCV antiviral medicines or HCV prevention and treatment that is limited. It is not even the dramatically low national health budget. The whole budgets for social security and basic services including health are very low, but the government cannot increase them unless we have more national resources and a significant increase in GDP*" (Interviewee 2, male politician).

They described the use of the limited available resources as reasonable. The official argued that:

> *"The priority, while allocating the limited financial resources, should be given to support for enforcing the regulations, which is the core function of MOHP, rather than providing services and subsidizing medicines, which is the function of the society in large"* (Interviewee 6, female official).

The politician indicated that channelling the majority of funds allocated for HCV treatment through the paid-by-state treatment program was a positive decision.

> *"It kept most of the available limited funds for the treatment of the poor. If it was channelled through the health insurance for example, it could have been spent on other items as a part of a large pool"* (Interviewee 2, male politician).

The remaining twenty-four interviewees used supportive arguments while criticizing the limitation of budget availability and its distribution and use. While considering the limited national financial resources, these interviewees viewed that the total governmental health budget is very low in comparison to allocations for other items; and the allocations for combating HCV and accessibility to its antiviral treatment is disproportionate to the public health crisis in Egypt.

> *"We know that we have limited national resources, but we cannot prioritize spending on infra-structure for new coastal resorts for the rich over the health and lives of the poor"* (Interviewee 15, urban male patient).

Sixteen interviewees (2 politician, 1 official, 2 academics, 2 physicians, 5 patients, 1 industry-related and 3 civil society activists) argued that channelling a large portion of the money available through the paid-by-state treatment program that lacks clear publicly-announced criteria, made the access to the HCV antiviral treatment subject to an administrative decision.

> *"It is only those who have connections who could get the treatment from the paid-by-state treatment program – because I did not have connections, I was left out to die slowly – Who cares? We are a lot of people in the country"* (Interviewee 20, rural female patient).

Six interviewees (1 politician, 1 official, 1 primary care physician, 1 patient and 2 civil society activists) criticized the use of a portion of the limited resources to establish and equip specialized centres for viral hepatitis. They argued that these funds should have been used to strengthen the entire system (especially the primary healthcare facilities) to combat the disease and to further subsidize the antiviral medicine.

> *"Yes, we have limited resources, but we intentionally lost a good portion of them in making new buildings for the specialized centres. We weaken our primary care system when disqualifying it from the national response to the HCV question"* (Interviewee 4, male official).

<u>Factors related to organization and functionality of healthcare system (system and clinical factors)</u>

Using open coding, I categorized the reported system and clinical factors under five themes: Disease surveillance and information system, availability and accessibility, affordability, and preventive and promotive services. See Table (3) in Appendix (2).

Disease surveillance and information system

Fifteen interviewees (representing all categories of study participants except for patients) reported the weakness of the routine health information system in general and the HCV surveillance system in particular. The interviewees perceived the surveillance and information system as a barrier to HCV antiviral treatment because it is supposed to provide continuously updated data on HCV diagnosed patients, including the need for treatment and eligibility, thus informing better planning and budget allocation.

While acknowledging the weakness, 2 interviewees (1 official and 1 academic) defended the current surveillance system emphasizing the design that allows case reporting from all public healthcare facilities across the country, including the rural primary healthcare units, into a central national database. They highlighted the need for time to see the outcomes in terms of accurate registry and case reporting in addition to intensive and ongoing training for the included personnel.

> *"It is too early to judge a system that practically started few years ago. We need to train our personnel especially in rural areas. The training manuals are ready. We just need time to implement them to have the system function properly"* (Interviewee 6, official).

Thirteen interviewees were less optimistic. Five interviewees (1 politician, 2 academics, 1 industry-related and 2 civil society activists) believed that the successive governments avoided proper implementation of a surveillance system in fear of exposing the gap between plans and needs.

> *"The ministry of health has the capacity to implement a surveillance system that works but none of the successive governments were keen to push it forward. It will simply expose the huge gap between what the reality is and what they say and between the need and plans. In other words, it will create a demand for a proper action for which there is no political will"* (Interviewee 25, civil society activist).

Eight interviewees (2 officials, 4 health personnel, 1 industry-related and 2 civil society activists) argued that the health system in Egypt does not have the culture for evidence-driven decision making. They indicated that the system is good but not enforced because of the lack of demand.

> *"The system is excellent, but physicians are reluctant to use it as they know that it will be a waste of time. The data will not be used to inform decisions"* (Interviewee 4, male official).

Availability and accessibility of viral hepatitis-related services

Twenty-two interviewees (representing all categories of study participants especially patients) indicated that the distribution of viral hepatitis specialized centres is one of the main barriers to timely diagnostic and curative services including the access to the subsidized HCV antiviral treatment. Four interviewees (1 politician, 1 official, 1 academic and 1 hepatologist) defended the centralization of public governmental diagnostic and curative services of viral hepatitis in 26 centres using three arguments. Firstly, the number of specialized centres and the geographical distribution of these has improved and the government/MOHP cannot afford a larger number of such specialized services. Secondly, the diagnosis and proper treatments of viral hepatitis is sophisticated and needs equipped specialized medical centres and well-trained specialists/hepatologists, hence such centralization is needed. Thirdly, these specialized centres work as secondary care and accept referrals from all primary healthcare level facilities.

Nineteen interviewees criticized this centralization model for public viral hepatitis diagnostic and treatment services. Eighteen interviewees (2 politicians, 1 official, 1 academic, 2 primary healthcare physicians, 1 hepatologist, 7 patients and 4 civil society activists) indicated that there are millions of Egyptians suffering from viral hepatitis; accordingly, the diagnostic and curative services should be available in each urban and rural primary healthcare facility.

> *"We are talking about one/fifth of the Egyptian adult population living with hepatitis B and/or C, there is no way to have them diagnosed and treated"* (Interviewee 10, female primary care physician).

Nine interviewees (1 politician, 1 academic, 1 primary care physician, 1 hepatologist, 1 patient, 1 industry-related and 3 civil society activists) stated that the waiting time is long which results in delay in the diagnosis and treatment.

> *"The delayed diagnosis in many occasions hinders patient opportunities for the cure as it gives time for the progression of cirrhosis"* (Interviewee 12, hepatologist).

> *"Such centralization of public service and the long waiting time produce inequities in access. The rich will simply go to private facilities and buy non-subsidized antiviral while the poor will wait until they reach their turn in treatment or death"* (Interviewee 15, urban patient with treatment).

Affordability

Twenty-five interviewees (representing all categories of study participants) considered the limited coverage of health insurance (or any form of solidarity schemes) an important barrier to the HCV antiviral treatment. They all agreed that the limitation of insurance coverage increases the out-of-pocket payment which makes the financial affordability a decisive factor in accessing the antiviral treatment.

While sharing the same criticism about the healthcare financing, three interviewees (1 politician, 1 official and 1 academic) emphasized the serious attempts of MOHP to move towards universal coverage of the health insurance which was not possible till now due to the expected financial burden on the state budget.

> *"The new law has been ready for over than five years, but the national budget cannot afford subsidising it and the government did not also want to increase the premium over a certain limit"* (Interviewee 6, female official).

They also emphasized that the successive governments presented partial solutions like the paid-by-state treatment program which enabled a large number of HCV patients to access antiviral treatment.

Nine interviewees (2 politicians, 1 official, 1 academic, 1 patient, 1 industry-related and 3 civil society activists) considered the delay in applying universal health insurance coverage consistent with the withdrawal of the state from service provision.

> *"The state can apply a new health insurance law tomorrow, but it will be designed to cover a limited package by a reasonable premium, without any subsidy from the state. In this case, the expensive HCV antiviral medicines will not be covered which might*

> *lead to unrest providing that 15% of our population are living with HCV. Accordingly, the government prefers the delay and the 'palliative' solutions like the paid-by-state treatment program"* (Interviewee 15, urban male patient).

Preventive and promotive services

Sixteen interviewees (representing all categories of study participants) considered that lack of proper health education, as a key preventive and promotive measure, is a major barrier to access HCV antiviral treatment. Most of the participants used broad definitions for health education to incorporate patient, community, and societal levels (including integrating health education on HCV in school educational curricula).

Five interviewees (1 politician, 1 official, 2 health personnel and 1 patient) stated that lack of health education delays the diagnosis, and hence eligibility for treatment.

> *"We may have the treatment available but the patient cannot access it because his/her case is not eligible due to massive cirrhosis, for example"* (Interviewee 13, female hepatologist).

Ten interviewees (1 politician, 2 academics, 3 patients, 4 civil society activists) indicated that most of patients do not know what are their rights and where they can get the treatment.

> *"They told me that I have hepatitis C and there is a treatment but very expensive and as a farmer, I have no health insurance. Nobody told me that I can get it from the paid-by-state treatment program. Now I know and I applied 6 months ago and am waiting for my turn" (*Interviewee 20, rural female patient).

Demographic and socio-economic factors

Using open coding, I categorized the reported factors in respect of demographic and socioeconomic factors under five themes: financial ability, place of residence, employment status and gender. See Table (4) in Appendix (2).

Financial ability

All the interviewees emphasized that the financial ability remains one of the major factors shaping access to HCV antiviral treatment. Twenty interviewees (2 politicians, 3 officials, 3 academics, 4 health personnel, 3 patients, 2 industry-related, 3 civil society activists) indicated that the financial ability depends on the household income and the number of dependents, while seven interviewees (1 politician, 5 patients and 1 civil society activist) described the financial ability using the terms ‘the poor’ and ‘the rich’.

While acknowledging the financial inability as a major barrier to HCV antiviral treatment, two interviewees (1 politician and 1 official) argued that this is a common predictor for access to healthcare services and medicines in general. They added that the subsidized antiviral treatment, the paid-by-state treatment program, and charity funds mobilized by the faith-based organizations affiliated to mosques and churches succeeded to make financial status less of a predicting factor for the access to HCV antiviral treatment.

> *“This is not a unique phenomenon in Egypt. Poverty is a global predictor to access healthcare services including medicines”* (Interviewee 6, female official).

The remaining twenty-five interviewees considered that financial ability predicts access to antiviral treatment (and healthcare in general) is unacceptable. Six interviewees (1 official, 1 academic, 1 physician, 2 civil society activists) argued that HCV is more prevalent among the poor which means that the majority of the patients will not access the treatment if financial ability continue to predict it. Nine interviewees (1 academic, 4 patients, 1 industry-related and 3 civil society activists) argued that proper budget for health and better use of available budgets would delink the access to medicine from the financial requirements. They blamed the paid-by-state treatment program for widening the equity gap in access emphasising the nature of its governance which favours patients who have connections (who are usually from the middle class), rather than those who do not have such influence and are most in need.

Place of residence

Twenty-five interviewees considered that living in rural settings compromise the access to the HCV antiviral treatment. While acknowledging poorer access of rural residents, four interviewees (2 officials, 1 academic and 1 industry-related) emphasised a trend of giving priority to rural residents as part of the wider policy focusing on rural development. Nineteen interviewees (2 politicians, 1 official, 3 physicians, 8 patients and 4 industry-related) emphasised that the gap in access between urban and rural settings is merely a creation of the way the health system is organized and health services are distributed. They argued that while

HCV is more concentrated in rural areas, related diagnostic and treatment services besides human and financial resources remain concentrated in specialized urban centres.

Employment status

Nineteen interviewees suggested that employment status predicts the access to HCV antiviral treatment. There was an agreement among these participants that agriculture workers who have no or limited land ownership in rural settings and informal employees in urban settings have less access to the HCV antiviral treatment. Two interviewees (1 official and 1 academic) argued that this is changing due to the scaling up of the paid-by-state treatment program.

> *"These categories of population do not have access to any health insurance plan and cannot afford the cost of the antiviral medicines. Now, they are given priority in the paid-by-state treatment program"* (Interviewee 6, female official).

Fifteen interviewees (1 official, 1 academic, 3 health physicians, 6 patients, 1 industry-related and 3 civil society activists) emphasized that these population groups do not have access to any health insurance or subsidized/free treatment.

> *"Those people are marginalized. They neither are enrolled in any insurance or solidarity schemes nor have access to the paid-by-state treatment program because they have no connections"* (Interviewee 26, female civil society activist).

Seven interviewees (3 politician, 2 primary care physicians and 2 civil society activists) added that the limitation in access is not only to the antiviral treatment but rather to HCV-related preventive, curative and rehabilitative services. One physician argued that this makes them more susceptible to acquire HCV in the first place.

Gender

Fifteen interviewees (including all the 12 female study participants) suggested that women have less access to HCV antiviral treatment. Twelve interviewees (2 politicians, 1 official, 3 academics, 3 patients and 3 civil society activists referred to this as a general gender-based discriminatory culture in the society including discrimination in access to all healthcare services. Four interviewees (three females and 1 male - 2 physicians and 2 civil society activists) stated that most of Egyptian families especially in rural areas give priority to men to access healthcare services and treatment.

Patient health services seeking behaviour

Interviewees reported three factors that influence individual or family health service seeking behaviour: age, health literacy and gender. See table (5) in appendix (2).

Age

Twenty-five participants suggested that age influences individual and family behaviour in seeking health services including HCV antiviral treatment. Thirteen interviewees (1 politician, 2 officials, 2 academics, 3 physicians, 3 patients and 2 civil society activists) argued that, within families – especially the poor, the elderly’s complains are frequently ignored and dealt with as just age-related symptoms.

> *“Such behaviour delays the diagnosis or widens the intervals of follow up and sometimes the case is complicated to the extent that antiviral medicines might not be useful”* (Interviewee 13, female hepatologist).

Twenty interviewees (1 politician, 1 official, 2 academics, 4 physicians, 7 patients, 2 industry-related and 3 civil society activists) argued that elderly patients either complain less or give themselves less priority in seeking healthcare.

Health Literacy

Seventeen interviewees (2 politicians, 1 official, 2 academics, 4 health workers, 4 patients, 1 industry representative and 3 civil society activists) blamed lack of health literacy in delaying the diagnosis of treatment of HCV especially among rural inhabitants.

Gender

Twelve interviewees suggested that gender predicts family and individual health services or treatment seeking behaviours. Ten interviewees including 7 women (1 politician, 1 official, 1 academic, 2 physicians, 3 patients, 1 industry-related and 1 civil society activist) reported that women seek health services less than men and voluntarily give priority to other family members especially children.

Five interviewees (1 politician, 1 academic, 1 physician, and 2 civil society activists) reported that families, especially in rural areas in Upper Egypt discriminate against women in accessing healthcare services, including treatment.

In the following chapters (Discussion and recommendations), I will summarize the key findings; discuss their agreement or disagreement with findings of previous studies or statistics; and discuss their implications and the possibility of using them to inform actions to combat the HCV problem in Egypt in general and enhance the accessibility to antiviral treatment in particular.

Chapter (5). Discussion

This study set out to examine whether the barriers to access antiviral treatment for chronic HCV in Egypt are not only limited to financial affordability, but are rather associated with a broader range of social determinants of health. The analysis of the interviews with the twenty-seven study participants, who represented a range of stakeholder groups, supports this assumption. Besides their agreement that financial affordability - often determined by household income and the number of dependents - remains a major barrier to HCV antiviral treatment in Egypt, the interviewees mentioned a wide range of additional barriers that contribute to the inaccessibility of HCV treatment. These additional barriers include gaps related to: the country's health information system; health and healthcare policies; health governance system and structure (at both national and local levels); the structure and organization of the healthcare system in Egypt; and socio-economic and cultural characteristics of patients including their healthcare-seeking behaviour.

Size of HCV Problem in Egypt

The analysis of the data collected from the interviews shows significant discrepancy amongst the interviewees in their understanding and description of the prevalence, incidence, and trend of HCV in Egypt. This mirrors the findings of a relatively recent systematic literature review which described high variations in HCV incidence which ranged from 0.8-6.8/1,000 person-year. The review also described a wide range of HCV prevalence estimates in the general population (0 – 40%) and in certain population groups (Mohamoud, *et al.*, 2013).

There was general consensus across all categories of the interviewees that there is an uneven distribution of the burden of disease with respect to HCV: with higher prevalence amongst the rural inhabitants, the poor and the aged (60 years old and above) groups of the population. Mirroring the participant's understanding, it ought to be noted that the 2008 EDHS showed high variations in HCV prevalence based on demographic and socio-economic characteristics. Indeed, the survey reported the HCV prevalence at 18.0% and10.3% amongst rural and urban inhabitants, respectively; 18.6% and 10.2% amongst the population in the lowest and highest wealth quintile, respectively; 24.0% and 10.5% amongst those who were illiterate and those who completed high school or higher, respectively (El-Zanaty and Way, 2009). More recently, the 2015 EHIS concluded that whilst there had been a significant decline in the prevalence of HCV between 2008 and 2015 in the *general* population, disparities based on socio-economic and demographic determinants persist with an HCV prevalence of 15.2% and 8.0% among rural and urban inhabitants respectively; an HCV prevalence of 15.8% and 6.6 % among the population of lowest and highest wealth quintile respectively; and an HCV prevalence of 21.7% and 6.7% among those who were illiterate and those who completed high school or higher, respectively (MOHP - Egypt, El-Zanaty and Associates, and ICF International, 2015)[10]. In addition, in their systematic review on HCV incidence and prevalence in Egypt concluded that there is higher HCV prevalence – although again with significant variations of estimates - in patients with certain comorbidities such as amongst patients who have experienced multiple blood transfusion and amongst those on renal dialysis. (Mohamoud, Mumtaz, Riome, *et al.*, 2013)

The results of this study also indicate a variation amongst representatives of different stakeholder groups in trusting the official statistics on the country's HCV incidence and prevalence. Among the interviewees, the politicians, patients, and civil society activists tended to be more critical of the official records than academics, health workers and industry-related personnel.

Findings from previous studies on HCV have highlighted a similar lack of trust in the official health records. For example, in their systematic review, Breban, *et al*. (2014) concluded that official estimates of HCV incidence that the MOHP uses had been calculated based on an invalid assumption. The authors of this review in fact estimated the HCV incidence was slightly less than 150,000 news cases per year in 2014 in comparison with the 100,000 cases per annum that was adopted as the official figure by the MOHP at this time.

The 2015 EHIS (as an official publication of the MOHP) indicated that there had been a significant decline in HCV prevalence between 2008 and 2015 in the general population (MOHP - Egypt, El-Zanaty and Associates, and ICF International, 2015). In comparison, the systematic review by Mohamoud, *et al.* (2013) concluded that there was no evidence of a

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[10] It ought to be noted that during the course of this study the previous EDHS i.e. the 2008 EDHS was used as a reference point by both the researcher and interviewees. The 2008 one was used given that the most current one (EHIS 2015) had not yet been published at the time of data collection.

decline of statistical significance in the HCV prevalence in both the general population and at-high-risk population groups over this period.

Access to HCV antiviral treatment

Most of the interviewees described the access to HV antiviral medicines as ‘very poor’ or ‘poor’. The interviewees reported that their assessment of the access to treatment is based on personal observations, research (although limited), sales statistics of HCV antiviral treatments and patients’ complaints.

In the 2015 EHIS 38% of HCV patients between 15-59 years self-reported receiving some HCV antiviral treatment (29.7% in women and 41.7 % in men). However, the majority of them reported receiving the old treatment regime (interferon) with a 51% cure rate whilst only 4.8% reported receiving the new DAA medicines (Sofosbuvir or Simeprevir) with a 79-96% cure rate (MOHP, El-Zanaty and Associates, and ICF International, 2015; Jacobson, 2013; Moreno, *et al.*, 2013).

The limited access to antiviral treatment, especially among the high-risk groups, contributes to the ongoing transmission of HCV. Evidence highlighted by a recently published article in the Lancet on HCV in Egypt showed that the full coverage of HCV antiviral treatment - especially to patients receiving injections or invasive medical procedures on a regular basis (the main source of HCV spread due to the lack of measures to prevent the nosocomial transmission), will significantly reduce the self-sustained transmission rate (Francesco, 2014).

Barriers to antiviral treatment

Barriers to HCV antiviral treatment, reported by the interviewees, can be categorized in relation to health policies (including the health budget), the organization and functionality of the healthcare system, and socio-economic and demographic factors - including health seeking behaviour on the part of the patient.

Barriers related to health policies

Orientation of national health policies: The study findings emphasized two features related to the orientation of national health policy in Egypt, namely: ‘passive privatization’ and the gradual withdrawal of the State from its role of duty bearer of healthcare provision. Along with this comes a decline in a rights-based approach to healthcare. A technical discussion paper published by WHO in 2006 indicated that one of the causes of ‘passive privatization’, is the reduction of government spending on health as a percentage of the total social health expenditure. This often results in a lack of medicines and motivated health workers within the public health facilities and thus increases the demand for and the utilization of the private sector – the services of which only some citizens can afford to access. This represents one of the healthcare consequences of the move to market economy accompanied by gradual decline in the role of the state in service provision as a part of the social and economic development (WHO/EMRO, 2006). This process was reflected in massive increase in the out-of-pocket expenditure on health from 47.9% of the total expenditure on health in 1995 to 55.7% in 2014 (WHO, 2016). Importantly, Rashad (2011) concluded that 7.4% of households in Egypt fall under the poverty line[11] because of having to make out-of-pocket health payments.

Formulation, implementation, and enforcement of national health policies: The findings from this study illustrate that there is often a lack of evidence-based health policy and planning in response to the HCV burden of disease in Egypt. Interviewees reported that the decision to negotiate a reduced price for DAA with the producing multinational company rather than the use of compulsory licensing for DDA local production, as one of the flexibilities contained in TRIPs agreement, has been made to comply with extra-territorial pressure rather than being as evidence-driven decision.

The interviews with representatives of key stakeholder groups, particularly politicians and civil society activists also highlighted the weak enforcement of HCV-related policies especially in respect to the equitable geographical distribution of financial and human resources which have resulted in lack of effective action to prevent and treat HCV amongst those most in need, e.g. the rural population including their access to antiviral medicines.

These views appear similar to the sentiments expressed by the country WHO representative in Egypt. In an interview with an independent Middle Eastern electronic newspaper ‘al-monitor’ he said *“What you see in Egypt is typical of a health system that has been neglected by the government and this is not since yesterday or since the revolution. This has been*

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[11] The cited reference adopted the poverty line of USD 1.25/day as defined by the World Bank 2011.

happening for the last 20 or 30 years." (Rios, 2014). In addition, the WHO official document that describes the 'Country Cooperation Strategy' between WHO and Egypt (2010-2014) explicitly stated that health policies and strategies are not usually supported by evidence or regulations (WHO/EMRO, 2010).

This disconnect between the national policies and robust base of evidence drawn from research/data is attributable to several factors among them are: (1) the lack of (or lack of trust in) local data due to significant weakness of the routine health information system which prevents serious attempts of informed needs assessment at local/community level which would facilitate more decentralized priority settings; (2) the absence of protocols for data sharing, usage and dissemination in both public and private healthcare sectors leads to the fragmentation and reparation of research work (El-Mahdawy, 2015); and (3) the reduction of governmental spending on healthcare contributed to widening the gap between policies and their implementation. It led to lower incentives for healthcare workers and managers who let top the private sector or stayed unmotivated (WHO, 2016). The lack of coherent, evidence-driven policies and the gap between policies and practice, result in uninformed plans for HCV treatment needs and impacted on the availability, accessibility and utilization of HCV diagnostic and treatment services including the antiviral medicine (Rios, 2014; El-Mahdawy, 2015 and WHO, 2016).

Governance for health: The interviews highlighted two governance related issues that appear to be impacting on the access the HCV patients have to antiviral drugs, namely; weakness of MOHP in health-related decision making and the negative impact of international assistance (foreign donations). A common perception amongst interviewees was that MOHP does not have the power to negotiate higher budgets for health, which has a negative effect on the required budget allocation for free or affordable HCV antiviral treatment for patients in Egypt. In addition, the MOHP does not take part in the negotiation of multi- or bi-lateral trade-related agreements, even when the negotiations have direct impact on access to healthcare and medicines.

External financial resources (mainly international assistance funds) have never exceeded 2.72% of the total health expenditure during the period from 1995 to 2014 (WHO, 2016). This small contribution provides donors with enough power to impose their own interests on the health system reform. Referring to the European Commission[12], civil society activists claim that this power has not been used to pressurize the government to coordinate a genuine consultative process around the highly controversial new draft health insurance law which may create a solidarity pool in terms of finance but will facilitate further spread of privatization of healthcare facilities (Oxfam, 2011). This new law could have the potential to enhance access to HCV antiviral treatment if it provides proper economic protection for the access to healthcare and medicine, and adopts progressive financing mechanisms for healthcare.

Budget: The interviews revealed general agreement amongst interviewees on the limitations of the health budget generally and the allocations for combating HCV including the enhancement of access to antiviral medicine. The majority of interviewees also criticized channelling a big portion of the fund through paid-by-state treatment program rather than a better regulated channel with clear governance structure and decision procedures.

From 1995 till 2014, the general government health expenditure did not exceed 8.07% of the total government expenditure. It was 5.59% in 2014 (WHO, 2016). The government currently allocates 20% of the total governmental spending on health to HCV (Aly, 2015). This 20% represents a considerably high percentage of the annual governmental health budget especially in a country with a dual high burden of infectious and non-communicable diseases like Egypt. However, the amount of funds allocated for HCV ($80,000,000) is too small to treat more than 3,500.000 persons from 0-59 years reported with active chronic HCV (MOHP - Egypt, El-Zanaty and Associates, and ICF International, 2015). The figure of 3.5 million does not include people with active chronic HCV and over 59 years who might increase this figure profoundly especially with a clear association between HCV and older age.

Barrier related to the organization and functionality of health healthcare system

Disease surveillance and information system: The results of this study highlight a general weakness in the national health information system and the HCV disease surveillance system

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[12] The European Commission is the EU's executive arm. It takes decisions on the Union's political and strategic direction. This includes financial aid to countries, institutions and individuals.

in particular. As emphasized by the interviewees, a robust surveillance system is essential to enhance the responsiveness of the health system to HCV and the evaluation of the adopted strategies and interventions. Some interviewees suggested that the weakness of the country's surveillance system is a political choice – in other words, the weakness of the system is being used as a means of preventing the public from understanding the true extent of the HCV problem and that the main source of HCV transmission is the country's inadequate medical and health facilities. Other interviewees however defended the current surveillance system emphasizing that it is well-designed and requires time to provide the needed information.

The Egyptian National Control Strategy for Viral Hepatitis (2008-2012) planned a surveillance system that would collect data from 256 district surveillance units throughout the country. Interestingly, some limitations in the system's anticipated accuracy were already noted in the strategy, namely, a lack of sufficient time for health workers to do their reporting; a lack of capacity for HCV diagnosis at the local facilities which would result in under-reporting, and the limits on the coverage of the surveillance system given data is only collected from governmental facilities (Dalglish, 2008). The national HCV strategy adopts the use of *multiple* rather than a *unified* HCV surveillance system and thus draws on a national HCV prevalence survey, the surveillance of sentinel groups (pregnant women, blood donors, and military recruits), and a system for monitoring the viral hepatitis related mortality (Dalglish, 2008). The rationale behind such a strategy, i.e. the use of multiple rather than a unified surveillance system is not motivated for in the strategy – and the estimated savings or cost of such a system is also not accounted for.

In 2012, MOHP presented the *Plan of Action for the Prevention, Care and Treatment of Viral Hepatitis, Egypt* (2014-2018). The current plan in fact highlighted the fragmentation and limited coverage of the surveillance system, and the inconsistency of reporting viral hepatitis cases within the country. The plan suggested that the lack of funds was one of the main reasons for such programmatic weakness and indicated that the enhanced capacity of diagnosis and reporting of HCV should be priority areas. This was consistent with the earlier 2008 strategy (MOHP, 2012).

Availability and accessibility of diagnostic and treatment centers: Interviewees reported a significant centralization of HCV diagnostic and curative services. HCV antiviral treatment is provided through twenty-six centres - all urban-based. The enrollment of patients in the governmental treatment plan starts with a web-page registration system (Doss, 2015). The geographical distribution of the treatment centres and the electronic procedures of enrollment add additional barriers to accessing antiviral treatment given that a higher prevalence of HCV is amongst rural, aged and illiterate groups of the population.

Affordability: Some interviewees (mainly the health officials) reported efforts to reduce the financial barriers to HCV-related medical care, e.g. the paid-by-state treatment program. However, there was some consensus amongst the interviewees that the patients' financial affordability of the services continues to predict the access to HCV antiviral treatment. The association between financial affordability and access to essential treatment reflects a gap in the country's national health system and the national social security system as a whole. The significantly low governmental spending as a percentage of total healthcare spending (i.e. 2.06%) increased the out-of-pocket spending to 47.9% of the total health expenditure (WHO, 2016). Such high out-of-pocket spending increases the financial barriers to healthcare in general and particularly to relatively expensive medicines like the HCV antiviral medicines – and most notably among the uninsured population since the majority of them living in rural settings, where HCV is more prevalent.

Preventive measures: Some of the interviewees suggested that lack of proper health education about HCV contributes to delay the diagnosis of HCV which in turns, hinders the treatment success by advancing complications such as liver cirrhosis. In agreement with these reflections, the 2015 EHIS described the considerable variation in HCV knowledge linked to place of residence, and socio-economic circumstances. Essentially, rural and poor population groups, where HCV is more prevalent, have less knowledge about the disease and its transmission (MOHP - Egypt, El-Zanaty and Associates, and ICF International, 2015).

Barriers related to socio-economic and demographic factors

Financial ability: There was consensus amongst the interviewees that the financial ability of patients continues to predict access to HCV antiviral treatment.

A recent study estimated the price of the treatment course of Sofosbuvir (one of the most common DAA in Egypt) as equivalent to 0.21% (more than 1/5) of the average annual wage. This estimation excludes the price of other components of the HCV treatment and the associated indirect costs (Iyengar, Tay-Teo, Vogler, *et al*., 2016). However, it ought to be noted that this study's estimation of the average annual wage did *not* take into account the variation in wages between urban and rural settings, the number of dependents living on the wage and the current high inflation rate in Egypt. For example, it was estimated that the average household income in rural areas was 77% of the average household income in urban settings (CAPMAS, 2014) while the household size in rural settings is 12% of that in urban settings (UNICEF, 2015). This implies differential financial affordability based the place of residence where it is a stronger determinant of access to HCV antiviral medicines in rural settings. In addition, these estimations are made for the subsidized treatment offered by the MOHP centers and not based on the market price for those who are not considered as priority cases, based on the scoring system described in the literature review of this thesis.

Place of residence, employment status and gender: The study results indicated that living in a rural setting, being unemployed and/or a being a woman compromises one's access to HCV antiviral medicine. Interviewees referred to the compromised access among rural inhabitants partially to the imbalanced geographical distribution of the public centers for HCV. The effect of place of residence may also be mediated by the higher levels of poverty, lower levels of HCV knowledge, and relative lack of transportation in rural settings, based on the findings of EHIS 2015 (MOHP, El-Zanaty and Associates, and ICF International, 2015). This needs further analytical studies to establish statistically significant associations.

Possible mediators conveying the impact of unemployment and gender on the access to HCV antiviral medicine include: (1) both the unemployed and women are two of the highest uninsured groups; and (2) general gender-based discrimination in access to healthcare. This needs further analytical studies to establish the extent and nature of such potential mediating effects.

Chapter (6). Conclusions and Recommendations

Conclusion

The financial affordability of HCV patients continues to predict their access to antiviral medicines which is resulted from the steady deterioration in social and economic protection mechanisms in the Egyptian society. The current poor access is also determined by a wide range of factors related to the Egyptian health policies and health budget, the organization of healthcare system health system factors, the socio-economic status of patients and their healthcare-seeking behaviour.

I plan to share a copy of this thesis, after being accepted, with members of the NCCVH and request appointments to discuss the use of the study findings. In addition, I have started to pursuit sources of funding to convert some of the recommendations of this study into project with smart objectives. Any future projects will engage multi-stakeholders especially the MOHP, academic partners, civil society organizations, and patient groups.

Recommendations

From the study findings, I suggest the following.

In the area of research

Causal mapping: The wide range of social determinants that shape the access to HCV antiviral medicines suggests the need to undertake further research to draw a causal mapping for determinants of access to treatment in HCV as an example for a multi-faceted public health problem. This approach will help in illustrating the complexity of interactive determinants shaping access to HCV antiviral treatment in networks of causal pathways which will point out the major barriers to tackle to achieve the best outcomes (Joffe and Mindell, 2006). The suggested research would benefit from multi-disciplinary team and the utilization of mixed (qualitative and quantitative) methods. Such a research project would be able to provide more concrete evidence to support policy alternatives that increase the access to healthcare services amongst patients with HCV in general and to HCV new DAA medicines, in particular.

Evidence-driven priority setting: Access to HCV-related healthcare services vary based on the place of residence. This motivates for the need for evidence-driven priority setting at local (district) level. Such a process would be best informed by health system/service research plans conducted by health authorities at district level, with a technical support by the departments of community medicine and public health at the well-geographically distributed schools of medicines. There would also create a demand for research to investigate the feasibility of decentralizing the HCV diagnostic and treatment services including detailed assessment for the needed human and laboratory capacities and the cost involved.

Investigating the financial impact of HCV: The high cost including, but not limited to, the antiviral medicines continues to represent a major barrier to adequate management of HCV. This suggests a need for research that adopts a model of economic analysis to estimate the percentage of HCV patients who fall below the poverty line because of cost of treatment (including but not limited to antiviral medicines). Such research would provide evidence to further rationalize the need for progressive health financing mechanisms.

Investigating the causes of delayed HCV diagnosis: One of the reasons contributing to unsuccessful HCV treatment outcomes is the delay in diagnosis. Some interviewees suggested that this delay was related to patients' knowledge whilst others emphasized that the responsibility lay with the health system. This suggests a need for more focused studies that examine the relationship between access to knowledge about HCV, the process of HCV diagnosis and the causes of a delayed diagnosis – and feasible strategies to reduce such untimely delays.

In the area of health system

Surveillance system: The study clearly showed the importance of a comprehensive surveillance system as an integral component of the national health information system. The surveillance system should be able to collect real-time data on screening, diagnosis, lab work, treatment and follow up at all healthcare facility levels (public and private). This entails proper design of the surveillance system that utilizes the universally available internet technology and intensive and on-going training and supervision of the relevant members of the health workforce – especially at the peripheral levels.

A well-designed surveillance system that reports all new HCV cases (nation-wide) and includes follow- up procedures for cases diagnosed with HCV and the monitoring of HCV-related mortality would significantly increase the confidence the public health community has in the official health records. It is also essential for assessing treatment coverage and determining gaps in general population as well as among certain at-high-risk population groups. In addition, such a surveillance system will provide timely data to inform central and local planning and prioritization.

Comprehensiveness, decentralization and coordinated response: The findings shows a negative impact on access to HCV related healthcare service and medicines due to the adoption of a vertical planning approach: with HCV services being provided through specialized HCV centers - separated from the general healthcare public facilities. There is an urgent need to integrate the preventive, diagnostic, curative, rehabilitative and promotive services related to HCV within the healthcare system taking an advantage of the very well-geographically distributed primary healthcare units across the country. This entails ongoing training of primary healthcare physicians and other relevant members of the health workforce.

Several studies support the need to decentralized, yet well-coordinated and harmonized responses to the HCV question in Egypt (El-Zanaty and Way, 2009; MOHP - Egypt, El-Zanaty and Associates, and ICF International, 2015; Mohamoud, *et al.*, 2013). Importantly, decentralized interventions should be informed by local needs assessments and priority setting processes. For example, should it recognizes the higher HCV prevalence in rural areas, an effective national strategy then needs to redistribute the diagnostic and treatment services and increase the concentration of services in the rural areas.

The high prevalence among patients with comorbidities (especially renal dialysis patients) – as highlighted by (Mohamoud, *et al.*, 2013), indicates that there is ongoing transmission of HCV within the tertiary healthcare facilities which needs an effective strategy for nosocomial prevention.

<u>In the area of health policies, orientation and approaches</u>

Universality and rights-approach: A universal access to newest, with highest efficacy and curative rate, HCV antiviral medicines should be granted by the government for all patients diagnosed with HCV regardless of their gender, age, place of residence, financial ability, or employment status. The government needs to significantly increase the budget allocation to attain this goal without affecting the services to other patients. This should also include the use of all policy alternatives to reduce the treatment cost which would include producing generic medicines and use of compulsory license as needed and as appropriate.

The lack of coherent, evidence-driven policies and the gap between polices and practice result in uninformed plans for HCV treatment in Egypt. This in turn impacts on the availability, accessibility and utilization of HCV diagnostic and treatment services including the antiviral medicines. This highlights the need for policy research to provide in-depth analyses on the relation between evidence and HCV related polices and to suggest policy alternatives to close the gap between policy and practice.

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Appendix (1). Geographic Distribution of incidence and prevalence of HCV and possible linkage to the ‘anti-schistosomiasis treatment campaign

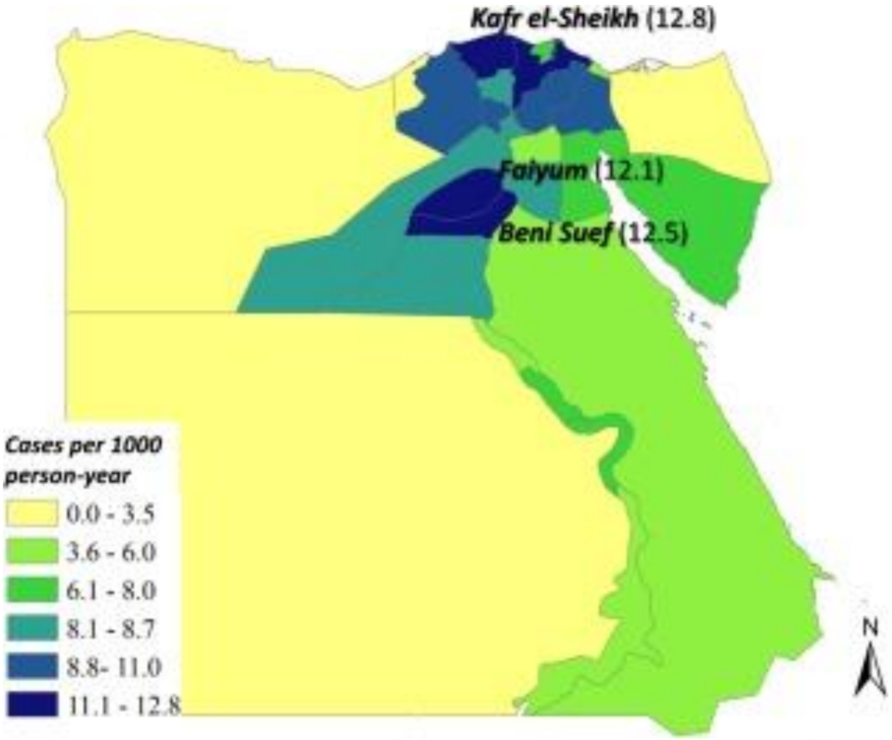


Figure (1). Geographical distribution of the estimated average annual hepatitis C virus (HCV) incidence rate that has been experienced by the living adult Egyptian cohort. Source: (Cuadros, *et al*., 2014).

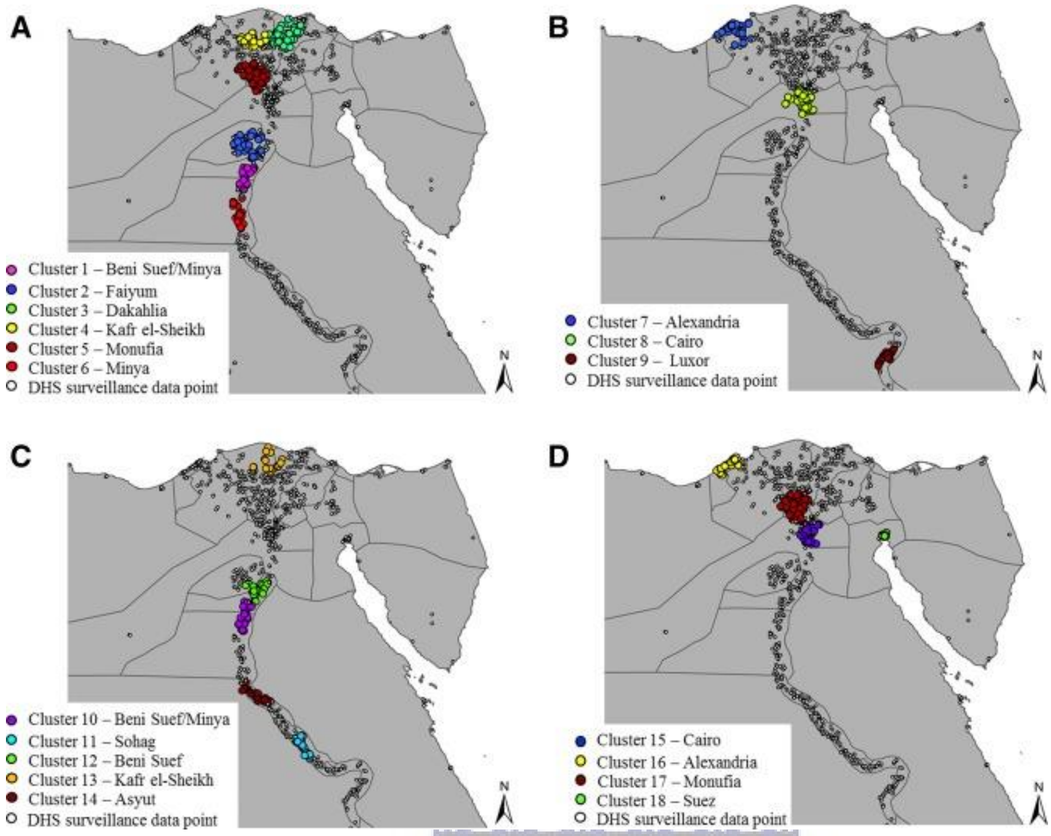


Figure (2). Geographical distribution of the clusters of high (A) and low (B) hepatitis C virus (HCV) prevalence, and of high (C) and low (D) exposure to parenteral antischistosomal therapy. The grey dots indicate locations where the surveys were conducted. Source: (Cuadros, *et al*., 2014).

Appendix (2). Summary tables for the open codes and key findings

Table (1): Reported descriptions of access to antiviral treatment of HCV

Category of participants	No.	Reported descriptions			Reported source	supportive arguments
		VP	P	R		
Politicians	3	2	1		☐Personal observations. ☐Complaints they receive.	☐The size of the problem is increasing which would not be the case if patients receive treatment.
Officials	3	1	1	1	☐Personal observations, and Complaints received. ☐Statistics of beneficiaries of state-subsidized treatment.	☐The trend of HCV – the size of the problem is stationary. ☐Growing number of patients who receive subsidized treatment. ☐ Accessing the progress in a context of constrained resources.
Academics	3	3			☐Research (however limited - mainly thesis for academic degrees in community medicine). ☐Official statistics (when accessible & updated).	☐The trend of HCV – the size of the problem is stationary.
Primary care physicians	2	1	1		☐Personal observation from working closely with HCV patients	☐The majority of HCV patients do not receive treatment
Hepatologists	2	2				
Physicians (total)	4	3	1			
Patients (treatment)	4	3	1		☐Personal observation	☐The majority of HCV patients do not receive treatment
Patients (no treatment)	4	4				
Patients (total)	8	7	1			
Industry	2	1	1		☐Personal observations. ☐Sales statistics	☐The sales of antiviral drugs are disproportionate with the HCV prevalence
Civil society	4	3	1		☐Personal observations. ☐Patient complaints. ☐Research and statistics (however limited)	☐The majority of HCV patients do not receive treatment. ☐The size of the problem is increasing which would not be the case if patients were able to receive treatment.
Total	**27**	**20**	**6**	**1**		

Table (2): Reported barriers to antiviral treatment of HCV that are related to national health policy

Barriers	**Politicians (3)**	**Officials (3)**	**Academics (3)**	**Primary care physicians (2)**	**Hepatologists (2)**	**All health personnel (4)**	**Patients (treatment) (4)**	**Patients (no treatment) (4)**	**All patients (8)**	**Industry (2)**	**Civil society (4)**	**Total (27)**
(Orientation) Trend of increasing the role of private sector in healthcare provision & commoditizing healthcare services & medicine	2	1	1	1	0	1	2	3	5	1	3	**14**
	Key supportive arguments and remarks: Public sector is not efficient – the private sector should lead healthcare provision – the government role is the regulation □The governments (intentionally) left the public health sector to deteriorate to give the private sector wider space (*passive privatization*)- private doctors/clinics became the first choice if patients afford it - the government withdraws from the service provision (including the basic services like health and education)											
(Orientation) The domination of charity model vs right-based model in healthcare	(1+1)2	(1+1)2	2	1	1	(1+1)2	4	2	(1+5)6	1	4	**19**
	Key supportive arguments and remarks: There are several ways poor patients can access HVC antiviral treatment, e.g. paid-by-state treatment program and charity organizations affiliated to churches and mosques □ The government generously finances paid-by-state treatment program (a charity model) instead of injecting the money to the general budget of healthcare system (a right-based model)											
(Planning) Lack/absence of evidence-driven policies and plans	3	1	3	0	2	2	1	1	2	2	3	**16**
	Key supportive arguments and remarks: Evidence from academic research is not and should not be the only policy driver □ There is a lack of health policy and system research as a part of depreciation to the research value and inappropriate budgetary allocation for research in general □ Research may highlight unwanted policy alternatives											
(Implementation/Enforcement) Lack of actions pertinent to perception of HCV as a public health crisis	2	1	3	1	1	2	4	2	6	2	4	**20**
	Key supportive arguments and remarks: Absence of periodical targets in the plans □ Lack and inequitable distribution of financial and human resources □Poor quality of health system management at local level.											
(Governance) The	2	1	1	1	0	1	0	0	0	1	4	**10**

Barriers	**Politicians (3)**	**Officials (3)**	**Academics (3)**	**Primary care physicians (2)**	**Hepatologists (2)**	**All health personnel (4)**	**Patients (treatment) (4)**	**Patients (no treatment) (4)**	**All patients (8)**	**Industry (2)**	**Civil society (4)**	**Total (27)**
weakness of MOH in health related decision making	Key supportive arguments and remarks: MOH did not have the power to pass a new health insurance law, which would have increased the access to HCV treatment, to the parliament MOH was excluded from the participation in health-related trade negotiations, even when their main focus was related to medicines and medical products MOH did not have the power to discuss the implementation of an agreement it adopted (Abuja Declaration) which would have increased health budget and further support of HCV free/cheap medications.											
(Governance) The negative impact of international aid (foreign donations)	1	2	2	1	0	1	0	0	0	1	3	**10**
	Key supportive arguments and remarks: The foreign donations supports priorities of international partners rather than domestic priorities: access to HCV antiviral treatment is not on these donor's agendas The foreign donation represent a small fraction of the total social expenditure on health, but used by the international development partners to certain policy direction, e.g. vertical programs Receiving foreign donations prevented the Egyptian government from using options like compulsory licence to enhance the accessibility to HCV antiviral medicines through cheap local production.											
(Budget) The lack and/or the use of funds designated to combat HCV	(1+2)3	(1+2)3	3	2	(1+1)2	3	4	4	8	2	4	**27**
	Key supportive arguments and remarks: The budget allocated for combating HCV generally and enhancing the access to antiviral medicines in particular is limited, yet, it is proportionate with the state budget and GDP The use of the limited available budget is reasonable and channelling a portion through the paid-by-state treatment program is a right decision to secure the majority of the available limited funds for the treatment of the poor The allocated budget for health is disproportionate with other less important item on the state budget and the allocation for HCV is disproportionate with a public health crisis Channelling large portion of funds through the paid-by-state treatment program negatively impacted the equitable access The limited available funds should have been used in strengthening the primary healthcare level to combat HCV question and treatment rather than establishing new specialized centres.											

Table (3): Barriers related to the organization and functionality of healthcare system (system and clinical factors)

Barriers	**Politicians (3)**	**Officials (3)**	**Academics (3)**	Primary care physicians (2)	Hepatologists (2)	**All health personnel (4)**	Patients (treatment) (4)	Patients (no treatment) (4)	**All patients (8)**	**Industry (2)**	**Civil society (4)**	**Total (27)**
(Disease surveillance and information system) The weakness of the health information system & viral hepatitis surveillance system	1	(1+2)3	(1+2)3	2	2	4	0	0	0	2	2	**15**
	Key supportive arguments and remarks: The surveillance system is essential for proper planning, follow up and evaluation of a national response to viral hepatitis including plans to enhance access to HCV antiviral medicines □The current surveillance system of viral hepatitis is well-designed, it just need time and training of personnel to show results □Successive governments avoided the implementation of proper surveillance system in fear of further exposure of the magnitude of the problem □ There is no culture for evidence-driven policy/intervention, hence there is no demand for enforcing proper implementation of a surveillance system											
(Availability and accessibility) The limited geographical spread of diagnostic and curative services	2	3	2	1	2	3	3	4	7	1	4	**22**
	Key supportive arguments and remarks: The distribution of viral hepatitis specialized centres is a barrier to timely diagnostic and curative services including the access to subsidized HCV antiviral medicines. The number of specialized centres is increased and their geographical distribution is improved - the government cannot afford a larger number of such specialized services. The diagnosis and proper treatments of viral hepatitis is sophisticated - need equipped medical centres and well-trained specialists. There is a referral system from the primary care. Viral hepatitis is a prevalent problem that needs better geographical distribution of services. Such centralization cause significant delay in diagnosis which hinders the cure opportunities and produce inequity.											
(Affordability) The limited coverage of insurance/solidarity system and increase of out-of-pocket payment	(1+2)3	(1+2)3	(1+1)2	2	2	4	4	4	8	1	4	**25**
	Key supportive arguments and remarks: There was a consensus on that the limitation of insurance coverage increases the out-of-pocket payment which makes the financial affordability a decisive factor in accessing the antiviral medicines There are serious attempts of MOH to move towards universal coverage of the health insurance but it did not work due to the expected financial burden on the state budget □ The delay in applying universal health insurance coverage consistent with the withdrawal of the state from the service provision											
(Prevention) Lack/absence health education	1	1	2	1	1	2	2	2	4	2	4	**16**
	Key supportive arguments and remarks: Lack of health education delay the diagnosis, hence eligibility to treatment □ Most of patients do not know what are their rights and where they can get the treatment											

Table (4): Barriers related to demographic and socio-economic factors

Barriers	**Politicians (3)**	**Officials (3)**	**Academics (3)**	**Primary care physicians (2)**	**Hepatologists (2)**	**All health personnel (4)**	**Patients (treatment) (4)**	**Patients (no treatment) (4)**	**All patients (8)**	**Industry (2)**	**Civil society (4)**	**Total (27)**
(Financial ability) Low household income and high number of dependents	(1+2)3	(1+2)3	3	2	2	4	4	4	8	2	4	**27**
	Key supportive arguments and remarks: Subsidized medicines, the paid-by-state treatment program and charity funds mobilized by the faith-based organizations succeeded to make the financial inability less predicting factor to the access to HCV antiviral medicines □ HCV is more prevalent among the poor, the majority of the patients will not access the treatment if financial ability continues to predict it □ Proper budget for health and better use of available budgets would delink the access to medicine from the financial ability □ Paid-by-state treatment program widened the equity gap in access due to its governance system which favour patients who have connections and usually from the middle class rather than the poor.											
(Place of residence) Living in rural setting	3	(2+1)3	(1+2)3	2	2	4	3	4	7	1	4	**25**
	Key supportive arguments and remarks: Living in rural settings compromise access to HCV antiviral medicines □ There is a trend of giving priority for rural residence as a part of the wider policy focusing on rural development □ The gap in access between urban and rural settings is a creation of the healthcare system they used the examples of centralization of services and geographical imbalance in funds distribution.											
(Employment status) Being an agriculture worker with no or limited land ownership and informal or temporary employment	2	(1+1)2	(1+1)2	2	1	4	2	4	6	1	3	**19**
	Key supportive arguments and remarks: This is changing due to the scaling up of the paid-by-state treatment program □ These population groups do not have access to any health insurance or subsidized/free treatment □ Limitation in access is not only to the antiviral medicines but rather to HCV-related preventive, curative and rehabilitative services											
(Gender) Being a woman have less access	2	2	3	1	1	2	2	1	3	1	2	**15**
	Key supportive arguments and remarks: This to a general gender-based discriminatory culture in the society including discrimination in access to all healthcare services □ Most of Egyptian families especially in rural areas give priority to men to access healthcare services and treatment											

Table (5): Barriers related to Patient health services seeking behaviour

Barriers	**Politicians (3)**	**Officials (3)**	**Academics (3)**	**Primary care physicians (2)**	**Hepatologists (2)**	**All health personnel (4)**	**Patients (treatment) (4)**	**Patients (no treatment) (4)**	**All patients (8)**	**Industry (2)**	**Civil society (4)**	**Total (27)**
(Age) Elderly patients have less access	2	2	3	2	2	4	4	4	8	2	4	**25**
	Key supportive arguments and remarks: In poor families, elderly's complains are frequently ignored and dealt with as just age-related symptoms Elderly patients either complain less or give themselves less priority in seeking healthcare											
(Health literacy) Rural residents seek medical help late	2	1	2	2	2	4	2	2	4	1	3	**17**
	Key supportive arguments and remarks: Health literacy in delaying the diagnosis of treatment of HCV especially among rural inhabitants											
(Gender) Women seeks/accesses medical seeking health services less than men	1	1	2	1	1	2	1	1	4	1	1	**12**
	Key supportive arguments and remarks: Women seek health services less than me and voluntarily give priority to other family members especially children Families, especially in rural areas in Upper Egypt discriminate against women in accessing healthcare services including treatment											

Appendix (3): Interview guide - sample of questions used for the semi-structured interviews[13]

A. English version

Self-Introduction, thanking the informant, introducing the research and describing the interview procedure:

My name is Hani Serag, I am a medical doctor and currently a MPH student of the School of Public Health of the University of Western Cape, South Africa. As a part of my masters' study, I am doing a research on the barriers to the access to the anti-viral treatment for the viral hepatitis-C. For the sake of this study, I will interview relatively large number of informants who are belonging to policy making, service providers, academia, patients with Hepatitis C, pharmaceutical industry and civil society activists. I assume that the results of this research would inform evidence-based strategies to enhance the access of the patients with chronic viral hepatitis-C to the antiviral treatment.

I wish to thank you for accepting to meet you for this interview. I appreciate if I can take around 45 minutes from your time. I have few questions to ask, but please feel free to elaborate issues outside the scope of the questions whenever you feel important. Of course, you have the right to end the interview at any point.

I wish you agree on recording this interview digitally. If you wish, I commit myself to provide you with a summary of the transcription of the interview before I use it in my research.

Questions and probes

- From your knowledge and observation, how can you describe the size of hepatitis-C in Egypt?
    - Based on what do you build your description? (Studies, observations from your practice, observations from your daily life, etc.)

---

[13] The questions were asked in Arabic language.

  - Based on your description/analysis, do you consider HCV in Egypt as health problem, major health problem, public health crisis, or any other preferred terminology?

- From your knowledge and observation, how can you describe the accesses to the antiviral treatment for HCV in Egypt?

  - Based on what you have built your description? (Studies, observations from your practice, observations from your daily life, etc.)

- From your point of view/knowledge/observations, what are the main factors that affect the access to the antiviral treatment for patients with chronic hepatitis-C?

  - *Based on answer of the interviewee, probing questions will be used to stimulate detailed description, analysis and sources of information that support his/her answers.*

- You mentioned (you did not mention) the role of the national health policy. Do you think that HCV and the access to antiviral treatment have the right place on the priority agenda of the government/ministry of health and population?

  - Why did you say that? Can you elaborate, share evidence?

  - *Based on the answer, probing questions will be asked to include or exclude: the policy orientation (ideology that governs the health policy), the governance and decision making, the use of international agreements and treaties (e.g. the use of flexibilities contained in the TRIPs agreement such as the compulsory license), etc.*

- Based on your knowledge and point of view, what are the policy alternatives for enhancing the access to antiviral treatment for HCV?

  - What are the most feasible alternatives from your point of view?

  - Why do you think that [the alternatives] are the most feasible?

- The lack of funds is one of the arguments that being used by the ministry of health to defend its inability for significant increase of the coverage of the antiviral treatment. How do you interpret this argument?
    - Is the problem linked to the total health budget in general? Or to the allocation for drugs? Or the allocations for the HCV antiviral treatment specifically?
    - From your point of view, what are the alternative solutions?
- You mentioned (you did not mention) the structure and organization of the healthcare provision system. Can you elaborate more on how does this structure affect patients' access to HCV antiviral treatment?
    - *Probes to include or exclude the geographical distribution and capacity of health facilities, the training and distribution of healthcare personnel, the mal practice, etc.*
- You mentioned (you did not mention) the socio-economic and cultural factors related to patients. From your point of view, knowledge and/or observations, what are the main socio-economic and cultural factors?
    - *Probes to include or exclude the place of residence, gender, social class, religion, service-seeking bahaviour, etc.*
- What would be your concrete suggestions/recommendations for enhancing the access to antiviral treatment among patients with chronic HCV?
    - *According to the answer, probing questions will, be used to question the feasibility of each recommendation, the appropriate order for these recommendations.*
- My final question for you is do you think that these recommendations (you suggested) could realistically be implemented in the near future?
    - *Why?*

Additional questions for patients

- When did you know that you have HCV?
- How did you know? (accidently, regular check-up, upon certain complain)
- Where do you follow up? (Public health facility? Private health facility? What type)
- Do you have health insurance? (Public of private?)
- Have you received any treatment for the HCV? (Medicines for enhancing the liver functions, antiviral treatment, others?)
    - *If received antiviral, who pays for it? (You, your health insurance, the government, support from family or others, etc.)*
    - *If did not receive antiviral treatment, why?*
- Can you tell me about your journey since you knew you have HCV?
    - *Probing questions to better learn about the factors helped to access treatment of barrier to treatment.*

B. Arabic Version

تقديم عن الباحث، وشكر للمبحوث، وتقديم عن البحث

أنا إسمي هاني سراج – طبيب، وحالياً طالب ماجستير في الصحة العامة بجامعة ويسترن كيب بجنوب إفريقيا. لجزء من دراستي للماستير، أقوم حالياً بإجراء دراسة على العوائق التي تحول دون الوصول للأدوية المضادة للفيروسات لمرضى التهاب الكبد الوبائي ج. يستلزم إجراء هذه الدراسة عقد مقابلات مع عدد كبير نسبياً مِن مَن لديهم معلومات عن المرض وينتمون للفئات التالية: صانعي القرار، و مقدمى الخدمات الصحية، وأكاديميين، ومرضى مصابين بالتهاب الكبد الوبائي ج، وعاملين في مجال صناعة الدواء، ونشطاء في مجال العمل الأهلي المتعلق بالصحة. وأتوقع أن تساعد نتائج هذه الدراسة على توجيه استراتيجية تستند لبراهين لتحسين وصول مرضى التهاب الكبد الوبائي ج للأدوية المضادة للفيروسات الخاصة بالمرض.

أود أن أشكركم على الموافقة على استضافتي لإجراء هذه المقابلة، والتي أرجو أن يتسع وقتكم لها، وأتوقع أن تستغرق خمس وأربعين دقيقة. سأطلب منكم خلال المقابلة الإجابة على بعض الأسئلة، لكن أرجو منكم التطرق في إجاباتكم لموضوعات ذات صلة ترونها مهمة إن لم تتضمنها اسئلتي. وبالطبع لكم الحق تماماً في إنهاء المقابلة وقتما شئتم.

أتمنى الحصول على موافقتكم على التسجيل الصوتي للمقابلة. يمكنني – إن رغبتم – عرض ملخص مكتوب للمقابلة عليكم قبل استخدام أي من إجاباتكم في الدراسة.

الأسئلة والاستفسارات

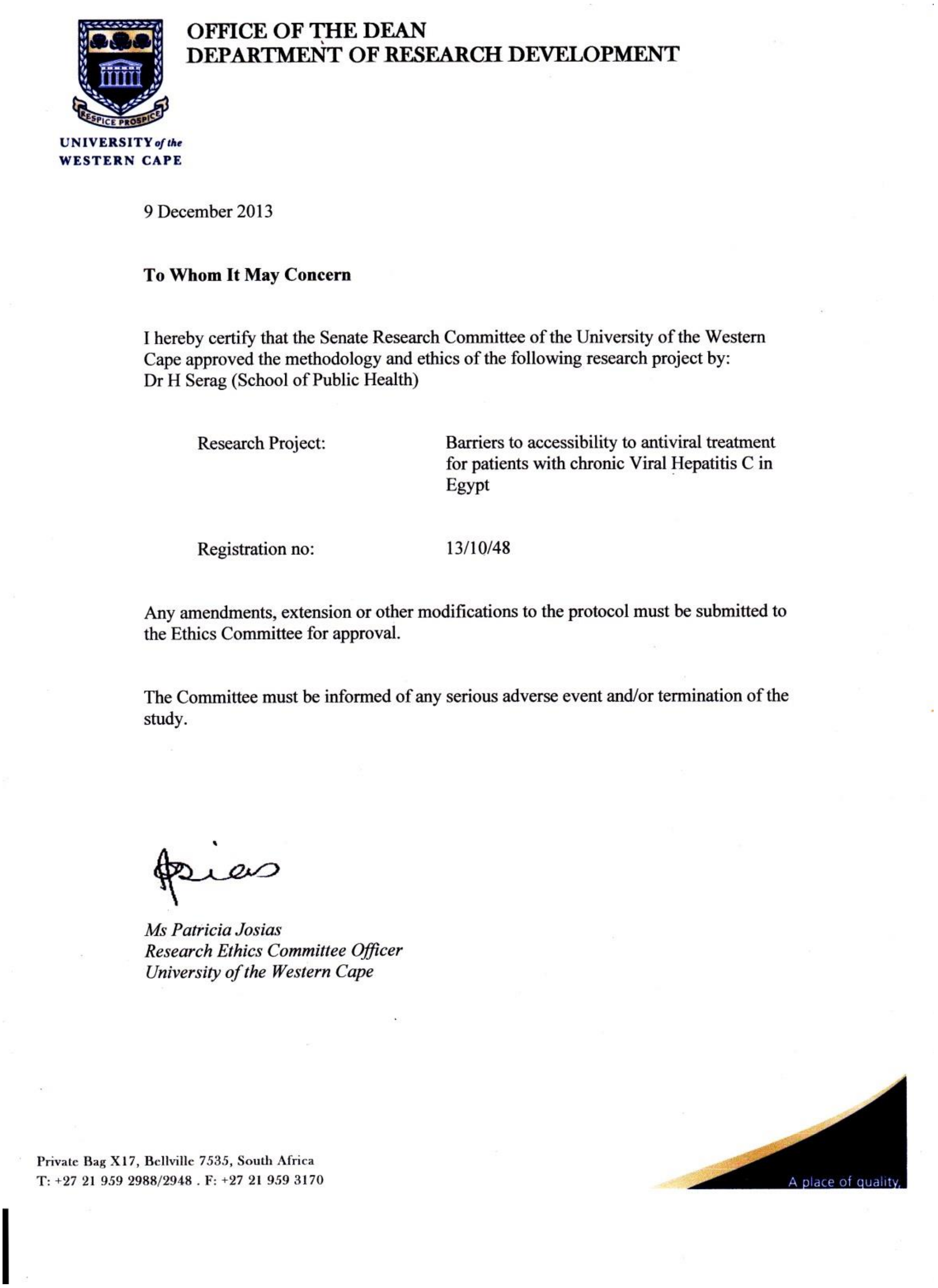
- من خلال معلوماتكم وملاحظتكم، كيف تصفون حجم التهاب الكبد الوبائي ج في مصر؟
  - علام بنيتم وصفكم (على دراسات، أم ملاحظات خلال عملكم، أم ملاحظات خلال نشاطكم اليومي المعتاد، أم غير ذلك)؟
  - بناءً على وصفكم وتحليلكم، هل تعتبرون التهاب الكبدالوبائي ج في مصر: مشكلة صحية، أم مشكلة صحية كبرى، أم كارثة صحية، أم تفضون استخدام تعبير آخر.
- من خلال معلوماتكم وملاحظتكم، كيف تصفون الوصول للأوية المضادة للفيروس الخاصة بالتهاب الكبد الوبائي ج؟
  - علام بنيتم وصفكم (على دراسات، أم ملاحظات خلال عملكم، أم ملاحظات خلال نشاطكم اليومي المعتاد، أم غير ذلك)؟
- بناءً على آرائكم، أو معلوماتكم أوملاحظتكم، ما هي العوامل الرئيسية التي تؤثر في وصول المرضى للأوية المضادة للفيروس الخاصة بالتهاب الكبد الوبائي ج في مصر؟
  - بناء على إجابة المبحوث، قم بتوجيه أسئلة استيضاحية للحصول على وصف تفصيلي، وتحليل، والمصادر التي ساهمت في تشليل هذه الإجابات.

- قد ذكرتم (أو لم تتطرقوا لـ) دور السياسة الصحية الوطنية. هل تعتقدون أن الالتهاب الكبدي الوبائي ج، والوصول لمضادات الفيروس الشافية للمرض تحتل المرتبة الصحيحة على قائمة أولويات الحكومة أو وزارة الصحة والسكان؟
  - لماذا تتعتقدون ذلك. هل يمكنكم التوضيح ببعض الإسهاب وتدعيم ما ذكرتموه البراهين، إن وجدت؟
  - بناء على إجابة المبحوث، قم بتوجيه أسئلة استيضاحية لتضمين أو استبعاد: توجهات السياسة الصحية (الأيديولوجيا التي تحكم السياسة الصحية)، والحوكمة واتخاذ القرار، تفعيل استخدام الاتفاقيات الدولية (على سبيل المثال استخدام المرونات المنصوص عليها باتفاقية التربس مثل الترخيص الإجباري).
- بناءً على معلوماتكم وآرائكم، ما هي السياسات البديلة التي لتحسين وصول المرضى لمضادات الفيروس الشافية لالتهاب الكبد الوبائي ج؟
  - ما هي البدائل الإكثر قابلية للتطبيق من وجهة نظركم؟
  - لماذا تعتقدون أن هذه البدائل هي الأكثر قابلية التطبيق؟
- قلة الموارد المالية هي إحدى العوامل التي تستخدمها وزارة الصحة والسكان لتبرير عدم قدرتها على توفير مضادات الفيروس الشافية لالتهاب الكبد الوبائي ج بشكل أفضل. كيف ترون ذلك؟
  - هل تتعلق المشكلة بإجمالي الميزانية المخصصة للصحة؟ أم بالميزانية التي يتم تخصيصها للدواء بصورة عامة؟ أم بالميزانية التي يتم تخصيصها لمضادات الفيروس الشافية لالتهاب الكبد الوبائي ج؟
  - من وجهة نظركم، من هو البديل الأمثل للتغلب على مشكلة نقص الموار المالية؟
- قد ذكرتم (أو لم تتطرقوا لـ) دور هيكل وتنظيم خدمات الرعاية الصحية. هل يمكنكم توضيح كيفية تأثير هيكل وتنظيم خدمات الرعاية الصحية على وصول المرضى لمضادات الفيروس الشافية لالتهاب الكبد الوبائي ج؟
  - بناء على إجابة المبحوث، قم بتوجيه أسئلة استيضاحية لتضمين أو استبعاد: التوزيع الجغرافي والطاقة الاستيعابية لوحدات الرعاية الصحية، وتدريب وتوزيع العاملين الصحيين، وتدهور الأداء من قبل العاملين الصحيين، وغير ذلك؟
- قد ذكرتم (أو لم تتطرقوا لـ) دور العوامل الاجتماعية والاقتصادية والثقافية المرتبطة بالمرضى. من وجهة نظركم أو معلوماتكم أ ملاحظاتكم، ماهي أهم هذه العوامل؟
  - بناء على إجابة المبحوث، قم بتوجيه أسئلة استيضاحية لتضمين أو استبعاد العوامل التالية: مكان الإقامة، والنوع الاجتماعي، والطبقة الاجتماعية، والدين، والسلوك المرتبط بالبحث عن الرعاية الصحية، وغير ذلك.
- ما هي اقتراحاتكم وتوصياتكم لتحسين وصول المرضى لمضادات الفيروس الشافية لالتهاب الكبد الوبائي ج؟
  - بناء على إجابة المبحوث، قم بتوجيه أسئلة استيضاحية تتعلق ببحث امكانية تطبيق هذه القتراحات والتوصيات، وكذلك ترتيب هذه التوصيات وفقاً للأولوية.
- سؤالي الأخير هو: هل تعتقدون أن هذه التوصيات والاقتراحات قابلة للتطبيق في المدى القريب؟
  - لماذا؟

أسئلة إضافية للمرضى

- متى عرفتم أنكم مصابون بالتهاب الكبد الوبائي ج؟
- كيف عرفتم (مصادفة، أم خلال متابع طبية دورية، أم عند الشكوى من أعراض محددة)؟
- أين تتلقون المتابعة الطبية (وحدة رعاية صحية حكومية، أم وحدة رعاية طبية خاصة، أين نوع من الوحدات)؟
- هل لديكم تأمين صحي؟ حكومي ام خاص؟
- هل تلقيتم أي علاج لالتهاب الكبد الوبائي ج؟ ما هو (أدوية محفزة لوظائف الكبد، أم مضادات للفيروس، أم أدوية أخرى)؟
    - إذا كان المبحوث قد تلقى أدوية مضادات للفيروس، استفسر عن: من تحمل التكلفة (المريض، أم التأمين الصحي، أم الحكومة، أم دعم من الأسرة، أم غير ذلك)؟
    - إذا لم يكن المبحوث قد تلقى أدوية مضادات للفيروس، استفسر عن السبب: لماذا؟
- حدثني عن رحتلكم مع التهاب الكبد الوبائي منذ علمتم أنكم مصابون به.
    - استخدم أسئلة استيضاحية تركز على العوامل المؤثرة في الوصول للعلاج.

Appendix (4). The approval of the Senate Research Committee of the University of the Western Cape on the methodology and ethics of the research project



UNIVERSITY of the
WESTERN CAPE

OFFICE OF THE DEAN
DEPARTMENT OF RESEARCH DEVELOPMENT

9 December 2013

To Whom It May Concern

I hereby certify that the Senate Research Committee of the University of the Western Cape approved the methodology and ethics of the following research project by:
Dr H Serag (School of Public Health)

Research Project:	Barriers to accessibility to antiviral treatment for patients with chronic Viral Hepatitis C in Egypt
Registration no:	13/10/48

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

Private Bag X17, Bellville 7535, South Africa
T: +27 21 959 2988/2948 . F: +27 21 959 3170

A place of quality.

Appendix (5). The consent form

A. English version[14]

Consent Form

Title of Research Project: **Barriers to accessibility to Antiviral treatment for Patients with Chronic Viral Hepatitis C in Egypt**

The study has been described to me in language that I understand and I freely and voluntarily agree to participate.

My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant's name . . . .

Participant's signature . . . .

Witness . . . .

Date . . . .

---

[14] Most of the study participants were able to read the consent form and information sheet in English. Only some of the patient may not be able and for them, Arabic copy has been made available.

B. Arabic Version

نموذج الموافقه

عنوان المشروع البحثي: **العوائق التي تحول دون الوصول للأدوية المضادة للفيروسات لمرضى التهاب الكبد الوبائي ج المزمن في مصر**

قد تم وصف الدراسة لي بلغة أفهمها، وقد وافقت طوعاً على المشاركة.

قد تمت الإجابة على جميع أسئلتي. وأتفهم أنه لن يتم الشف عن شخصيتي، وأنه يمكنني الخروج من الدراسة في أي وقت بدون إبداء أسباب، وأن هذا لن يؤثر على سلبياً بأي طريقة.

إسم المشارك: . . . .

توقيع المشارك: . . . .

شاهد: . . . .

التاريخ: . . . .

Appendix (6). The information sheet

A. English Version

INFORMATION SHEET

Project Title: Barriers to accessibility to Antiviral treatment for Patients with Chronic Viral Hepatitis C in Egypt

What is this study about?

This is a research project being conducted by Hani Serag at the University of the Western Cape.

We are inviting you to participate in this research project because you one of people who can inform about better strategy to enhance the access to the antiviral treatment for patients with chronic hepatitis C as being belonging to one of six categories identified as stakeholders in this study (patients, policy makers, healthcare personnel, pharmaceutical industry, academics and civil society organizations).

The purpose of this research project is to explore and describe the various barriers that patients with chronic viral hepatitis C experience in accessing antiviral treatment in Egypt. This would assist a better informed national strategy to enhance the access to the antiviral treatment among patients with chronic hepatitis C.

What will I be asked to do if I agree to participate?

You will be asked to kindly respond to series of questions that will try to identify the different barriers to the access to the antiviral treatment among patients with chronic hepatitis C. The questions will deal with your knowledge, point of view and observations regarding:

- the size of hepatitis-C in Egypt;
- the accesses to antiviral treatment for HCV in Egypt;
- the main factors that affect the access to the antiviral treatment for patients with chronic hepatitis-C; and
- suggestions/recommendations for enhancing the access to antiviral treatment among patients with chronic HCV.

As a patient with chronic viral hepatitis C, I will also ask you to elaborate on:

- when and how did you know that you have the disease?

- Where do you follow up?
- Whether or not you received antiviral treatment?
- Whether or not you have health insurance?
- Where or not you received antiviral treatment (interferon), if not why?
- I will also like to learn about any problems you faced during your journey with the disease.

You can end the interview at any time with no need to give me reasons. You can refuse to answer any of the questions and you can ask me about the reason of any of the questions.

I will take from your time a maximum of an hour. I also wish to have your permission to record the interview (only of you feel comfortable about that) as it will help me to retrieve your answer better.

Would my participation in this study be kept confidential?

I will do my best to keep your personal information confidential. To help protect your confidentiality, all files of digital recording and transcripts will be kept away from any misuse (by keeping them in a locked cabinet and on the computer with a password). They will be ultimately carefully erased and disposed of once I feel that the study has been finalized and reported on sufficiently.

Any information you give will not be shared with any other interviewee linked to your name. Your name will not be mentioned at all in any of the reports or articles that might be developed for the findings of this research. Your identity will be protected to the maximum extent possible.

What are the risks of this research?

There may be some risks from participating in this research study.

{For patients} During the interview, you will be asked to elaborate about your journey with the viral hepatitis C infection and may be its complications on you and your family. This might touch upon sensitive issues or remind you with difficult situations. Please feel free to ask me to stop questioning or probing at any time. You may also wish to pause the interview session for a while and we will start again at your convenience. You can also wish not to respond to one or more of the questions.

{For all study participants} During the interview, I may ask about your opinion on issues related to health policies and your opinion might not be in favour of the current policies. I assure you that whatever you will say will be confidential. The records of all interviews will be kept safely away of any misuse and I will take all the measures to prevent tracking the narrative in the study report back to you.

What are the benefits of this research?

This research is not designed to help you personally, but the results may help the investigator learn more about the barriers to access to the antiviral treatment of chronic hepatitis C.

Describe the anticipated benefits to science or society expected from the research, if any.

The studies related to the socio-economic barriers to the access to the antiviral treatment of chronic viral hepatitis C is very limited in Egypt. I wish that the finding of this research will contribute to better understanding of these barriers. The research findings might also be utilized by the authorities to assist the development of better and more effective strategies to enhance the access to the antiviral treatment among patients with chronic viral hepatitis C.

Do I have to be in this research and may I stop participating at any time?

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

Is any assistance available if I am negatively affected by participating in this study?

There will not be any harm resulted from your participation in the research.

What if I have questions?

This research is being conducted by Hani Serag at the University of the Western Cape. If you have any questions about the research study itself, please contact Hani Serag at telephone number: 0100 392 6549 or e-mail address: hserag@phmovement.org.

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Director:

Prof Helene Schneider
School of Public Health
University of the Western Cape
Private Bag X17
Bellville 7535
hschneider@uwc.ac.za

Dean of the Faculty of Community and Health Sciences:

Prof Jose Frantz
University of the Western Cape
Private Bag X17
Bellville 7535
jfrantz@uwc.ac.za

This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.

B. Arabic Version

عنوان المشروع البحثي: العوائق التي تحول دون الوصول للأدوية المضادة للفيروسات لمرضى التهاب الكبد الوبائي ج المزمن في مصر

علام تركز هذه الدراسة؟

يقوم بهذا المشروع البحثي هاني سراج، طالب الماجستير جامعة ويسترن كيب بجنوب إفريقيا.

نحن ندعوك لمشاركة في هذا المشروع البحثي لأنك من هؤلاء الذين يمكنهم مدنا بمعلومات تساعد في تطوير استراتيجية أفضل لتحسين وصول مرضى التهاب الكبد الوبائي ج للأدوية المضادة للفيروسات الخاصة بالمرض، وأنك تنتمي لواحدة من الفئات ذات الصلة التي تركز عليها الدراسة وهي: صانعي القرار، و مقدمى الخدمات الصحية، وأكاديميين، ومرضى مصابين بالتهاب الكبد الوبائي ج، وعاملين في مجال صناعة الدواء، ونشطاء في مجال العمل الأهلي المتعلق بالصحة.

الغرض من هذا البحث هو استقصاء ووصف العوائق المختلفة التي تحول دون الوصول للأدوية المضادة للفيروسات لمرضى التهاب الكبد الوبائي ج المزمن في مصر. وقد يساهم ذلك في تطوير استراتيجية أفضل لتحسين وصول مرضى التهاب الكبد الوبائي ج للأدوية المضادة للفيروسات الخاصة بالمرض.

ما الأسئلة التي سأتلقاها إن وافقت على المشاركة؟

سيطلب منك التفضل بالإجابة عن مجموعة من الأسئلة، والتي تحاول تحديد العوائق المختلفة التي تحول دون الوصول للأدوية المضادة للفيروسات لمرضى التهاب الكبد الوبائي ج المزمن في مصر. وتتعلق هذه الأسئلة بمعلوماتكم، وآرائكم، وملاحظاتكم حول ما يلي:

- حجم التهاب الكبد الوبائي ج في مصر
- الوصول للأدوية المضادة للفيروسات الخاصة بالتهاب الكبد الوبائي ج
- العوامل الأساسية التي تؤثر في وصول المرضى للأدوية المضادة للفيروسات الخاصة بالتهاب الكبد الوبائي ج
- اقتراحات أو توصيات لتحسين وصول المرضى للأدوية المضادة للفيروسات الخاصة بالتهاب الكبد الوبائي ج

وكأحد مرضى التهاب الكبد الوبائي ج، سأقوم أيضاً بسؤالكم عن ما يلي:

- متى وكيف عرفتم أنكم مصابون بالمرض؟
- أين تتلقون المتابعة الطبية؟
- إذا كنتم قد تلقيتم أي علاج لالتهاب الكبد الوبائي ج؟
- إذا ما كان لديكم تأمين صحي؟
- وسأطلب منكم الحديث عن رحلتكم مع التهاب الكبد الوبائي منذ علمتم أنكم مصابون به.

يمكنكم إنهاء المقابلة في أي قت دون إبداء أسباب. كما يمكنكم رفض الإجابة عن أي من الأسئلة. ولك الحق في الاستفسار عن السبب وراء أي من أسئلتي.

لن آخذ من وقتكم أكثر من ساعة واحدة. وأود أيضاص الحصول على موافقتكم على تسجيل المقابلة تسجيلاً صوتياً (فقط إذا كنتم تشعرون بارتياح تجاه ذلك). سياساعدني ذلك على استرجاع إجاباتكم بصورة أفضل.

هل سيتم الحفاظ على سرية مشاركتي في هذه الدراسة؟

سأبذل قصار جهدي للمحافظة على سرية بياناتكم الشخصية. من أجل الحفاظ على سرية البيانات، سيتم حفظ كافة الملفات الورقيه وكذلك الخاصة بالتسجيل الصوتي بعيداً عن أية امكانية للعبث بها حيث سيتم تخزينها في درج يتم غلقه بإحكام أو على الكمبيوتر بكلمة سر. سيتم مسح كافة الملفات تماماً وبحرص فور تيقني أن الدراسة قد استكملت وأنني انتهيت من كتابة التقرير بصورة مرضية.

ل يتم إطلاع إي من المشاركين الآخرين على أي من المعلومات التي ستعطيها لي بصورة قد تشف هويتكم. ولن يكشف عن اسمكم نهائياً في أي من التقارير أو المقالات التي يمكن كتابتها باستخدام نتائج هذه الدراسة. وسيتم الحفاظ على سرية هويتكم باقصى درجة.

ما هي المخاطر المحتملة من جراء المشاركة في هذه الدراسة؟

قد يكون هناك بعض المخاطر من جراء مشاركتكم في هذه الدراسة.

(للمرضى) أثناء إجراء المقابلة الشخصية، ستسأل للتحدث عن رحلتك مع التهاب الكبدالوبائي ج وتأثير ه على أسرتكم. وقد يذكركم ذلك بموضوعات ذات حساسية أو موافق صعبة مررتم بها. أرجو منكم أن تطلبوا من التوقف عن الأسئلة في أي وقت. كما يمكنكم وقف المقابلة لفترة على ان نستكملها حينما تشعرون بارتياح. ولكم كل الحق في رفض الإجابة عن أي من الأسئلة.

(لكافة المشاركين) أثناء المقابلة الشخصية، قد أقوم بسؤالكم عن أرائكم بشأن موضوعات تتعلق بالسياسات الصحية، وقد لا تتفق آرائكم مع السياسات القائمة. أطمئنكم على أن ما ستقولونه – اي كان - سيبقى محاطاً بسرية كاملة. سيتم حفظ كافة الملفات الخاصة بالمقابلات الشخصية بعيداً عن أي امانية للعبث، وأنني سأتخذ كافة الإجراءات اللازمة لمنع إمكانية التعرف على علاقتكم بأي رأي يرد في تقرير الدراسة.

ماذا سأستفيد من المشاركة في هذه الدراسة؟

لم يتم تصميم هذه الدراسة لمساعدتك بصورة شخصية، لكن نتائجها قد تساعد الباحث على فهم أعمق للعوائق المختلفة التي تحول دون الوصول للأدوية المضادة للفيروسات لمرضى التهاب الكبد الوبائي ج المزمن في مصر.

الدراسات المتعلة بالعوائق الاجتماعية والاقتصادية التي تحول دون الوصول للأدوية المضادة للفيروسات لمرضى التهاب الكبد الوبائي ج المزمن في مصر قليلة جداً. أتمنى أن تسهم نتائج هذه الدراسة في فهم أعمق لهذه العوائق، وان يتم استخدام النتائج من قبل دوار صنع القرار للمساهمة في تطوير استراتيجية أفضل لتحسين وصول مرضى التهاب الكبد الوبائي ج للأدوية المضادة للفيروسات الخاصة بالمرض.

هل أنا مرغم على المشاركة في هذا البحث؟ وهل لي أن أتوقف عن المشاركة في أي وقت؟

مشاركتكم في هذه الدراسة طوعية تماماً. لكم أن تختاروا عدم المشاركة نهائياً. وفي حال إذا ما قررتم المشاركة، يمكنكم التوقف في أي وقت. قراركم بعدم المشاركة من البداية او التوقف عن المشاركة في أي وقت لن يتسبب في أي عقاب أو خسران أية فائدة.

هل ستكون هناك مساعدة إذا ما أثرت على المشاركة في الدراسة سلبياً؟

لن تسبب مشاركتكم في الدراسة في اي ضرر.

ماذا لو كانت عندي أسئلة؟

يتم إجراء هذا البحث بواسطة هاني سراج طالب الماجستير بجامعة ويسترن كيب. إن كان لديكم أية أسئلة تتعلق بالبحث ذاته، برجاء الاتصال بهاني سراج تليفونيا على رقم: 01003926549 أو البريد الإلكتروني .hserag@phmovement.org

إذا كان لديكم أية أسئلة تتعلق بهذه الدراسة أو بحقوقكم كمشارك في الدراسة، أو إذا وددتم الإبلاغ عن أية مشكلات واجهتموها أثناء مشاركتكم، يمكنكم الاتصال بالآتي ذكرهم:

المديرة

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عميد كلية المجتمع والعلوم الصحية

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قد تمت الموافقة على هذا البحث بواسطة لجنة البحوث بجامعة ويسترن كيب.