Can people who inject drugs in Nepal achieve the universal access to the harm reduction program and hepatitis C treatment?

Closing the gap: From Policy to practice for reduction health inequities on HCV control

A Policy Discussion Paper

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"Can people who inject drugs in Nepal achieve the universal access for the harm reduction program and hepatitis C treatment?"

A thesis submitted in partial fulfillment of the requirement for the degree of Master of Public Health by

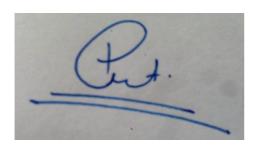
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Nepal

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The thesis "Can people who inject drugs in Nepal achieve the universal access for the harm reduction program and hepatitis C treatment?" is my own work.

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Dedication

This work is dedicated to my lovely extremely supportive wife who has shown a tremendous amount of patience and understanding for last 7 years, my two lovely cute devil beautiful daughters, my mom and dad, family and friends who have always enlighten me to show the respect and serve the poorest, most needy and the vulnerable people across the continent. They motivated me to pursue further in achieving the academic excellence to serve the humanity at its best around the globe with knowledge and experience from the field of public health.

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Abbreviations

amFAR: The Foundation of AIDS Research

AIDS: Acquired Immune Deficiency Syndrome

CDC: Centers for Disease Control and Prevention

DAA: Directly Acting Antivirals

DALYs: Disability Adjusted Life Years

DoHS: Department Of Health Services

FCHV: Female Community Health Volunteer

FIDU: Female Injecting Drug Users

GDP: Gross Domestic Product

GFATM: Global Fund for AIDS TB and Malaria

GIZ: Deutsche Gesellschaft für Internationale Zusammenarbeit

HC: Health Centre

HCV: Hepatitis C Virus

HIV: Human Immunodeficiency Virus

HP: Health Post

IBBS: Integrated Biological and Behavioral Surveillance

IHME: Institute of Health Matrix and Evaluation

INGO: International Non Governmental Organization

LMIC: Lower and Middle Income Country

MMT: Methadone Maintenance Therapy

MoHA: Ministry of Home Affairs

MoHP: Ministry of Health and Population

MSM: Men having Sex with Men

NCASC: National Centre for AIDS and STD Control

NCB: Narcotic Control Bureau.

NGO: Non-Governmental Organization

NSEP: Needle and Syringe Exchange Program

OST: Opioid Substitution Therapy

PHC: Primary Health Care

PHCC: Primary Health Care Centre

Peg-INF/RBV: Peg Interferon alpha /Ribavirin

PLHIV: People Living With HIV

PWID: People Who Inject Drugs

QALY: Quality Adjusted Life Year

RNA: RiboNucleic Acid

SHP: Sub Health Post

SVR: Sustain Virologic Response

TUTH: Tribhuvan University Teaching Hospital

VDC: Village Development Committee

WHO: World Health Organization

UN: United Nations

UNAIDS: United Nations Programme on HIV/AIDS

UNODC: United Nations Office on Drug And Crime

Name: Hemant Bogati, Nationality: Nepalese

Abstract

Background: Nepal is experiencing challenges with increasing number of hard drug users. Hepatitis C Virus (HCV) prevalence are evolving amongst People Who Inject Drugs (PWID). Harm reduction program coverage for PWID appears low. There was no HCV treatment available for HCV mono infected PWID from the government. The aim of the review was to investigate the need for a more central and comprehensive policy, and improved programme on prevention and treatment of HCV amongst PWID.

Methods: A comprehensive search was undertaken of Nepalese policy documents. PubMed, VU e-Library, Google Scholar, Science Direct and Scopus was used to find the primary articles/reports abstracts examining harm reduction program and HCV treatment outcomes in PWID from 1990 to 2017.

Results: Four peer reviewed articles for Nepal, 20 peer reviewed articles from other countries, and 55 additional reports met the inclusion criteria. There is currently no HCV policy in Nepal. The prevalence rate of HCV in PWID was found to be 41.9% (95% CI: 37–47%). OST (Opioid Substitution Therapy) coverage was documented between 5-40% for the PWID. The needle and syringe exchange program coverage range from 0.6% for FWID (Female Who Inject Drugs) up to 53% in PWID. The number of needles/syringes distributed per PWID in 2016 was estimated to be 29 (substantially lower than the recommended 200+). HCV+ treatment coverage was below 5%.

Conclusion: Without a comprehensive policy for HCV, Nepal is unlikely to achieve the WHO/UNODC/UNAIDS target for universal access to HCV prevention, treatment and care for PWID. Further studies are needed to assess the long-term effectiveness of harm reduction and HCV treatment in PWID.

Key words: Hepatitis C Virus (HCV), People who Inject Drugs (PWID), Policy, Harm Reduction (OST & NSEP), Nepal.

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Introduction

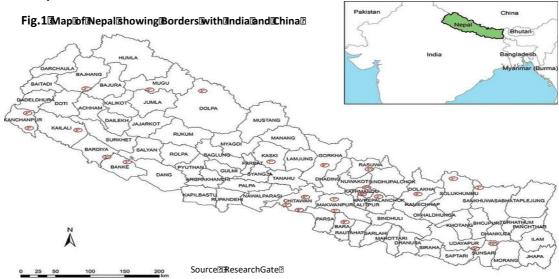
By profession, I am a medical doctor who has been working in the humanitarian field around the globe for the last ten years as a medical team leader. In 2014, I was working with Doctor Without Borders at a project in Uzbekistan where we were running HIV program including hepatitis C screening and treatment in a government hospital with coordination and collaboration with Ministry of Health. After drug registration and getting approval from the governmental authority to import the generic cheaper hepatitis C drugs into the country to implement the hepatitis C treatment program in HIV centre and its success in treating hepatitis C patients, it steered me to investigate the hepatitis C scenario in my own country Nepal. This thesis is about the issue of increasing absolute numbers of people who inject drugs in Nepal every year that is linked with risk of growing transmission of hepatitis C infection. It will reflect further on the lack of HCV policy in place with concerns of limited availability on recently revolutionary Directly Acting Antivirals (DAA) for hepatitis C treatment. It questions on explaining existing model of harm reduction care [(Opioid Substitution Therapy)/Needle and syringe exchange programs (NSEP)] delivered to people who are into substance abuse. I was unable to find any literature for Nepal that dissects the dimensions of drug addiction [Mainly in People Who Inject Drug (PWID)], OST/NSEP and availability of transformed life-saving hepatitis C treatment. With this thesis, I hope to accomplish the understanding of how these different elements are unified that can play a role of catalyst to make the existing system of harm reduction care more accessible, available, robust and efficient by having a central HCV policy. It can help to minimise the HCV prevalence with the available treatment and reduce its associated morbidity and mortality in the country.

HCV infection has become a major public health issue around the globe with highest prevalence rates reported from the poor developing countries from Africa and Asia (Mohamed, 2015). Many PWID do not know their hepatitis C infection status; those who know lack hepatitis C treatment and modest harm reduction program (OST/NSEPs) and as a result they have become an important source of HCV infection in their societies (Mitchell, 2010). It draws attention to the problem countries are facing worldwide that needs a comprehensive policy which is effective with good coverage, integrated, accessible and with holistic approached programs to tackle the drug use and HCV confinement including Nepal in its context. Securing human rights for PWID will reduce DALYs and prevent the risk of further HCV transmission. WHO strategy of Global Health Sector Strategy (GHSS) on viral hepatitis 2016-2021 aims to eliminate viral hepatitis by 2030 as a public health threat (WHO, 2017b). Under the sustainable development goals, United Nations has placed the strengthening of prevention and treatment program for substance abuse in goal number three and aims to control the epidemic of Hepatitis infection by 2030 while ensuring healthy lives and promoting the well-being for all at all ages (UN, 2015b).

Chapter I: Country Background

1.1Geography

Nepal is a landlocked country, which is situated between India and China. In the east, west, and south, Nepal has borders with India while on the North high mountainous range; country lies near China. The country has been divided geographically into three east-west ecological belts: the Northern range – Mountain, the Mid range – Hill, and the southern range – Terai as a flat land (CBS, 2015b). It has an area of 147,181 Sq. Km. with an average length of 885km(East to West) and an average width of 193 km (North to South) (CBS, 2015a).



Having weak law enforcement in border control (mainly southern range) with India in three different directions, the use of illicit drug trafficking and mobility has built up significantly over decades (CBS, 2013). Its consequences reflect on increasing use in the number of pharmaceutical drugs such as buprenorphine, benzodiazepines, chlorpromazine and dextropropoxyphene with which drug users make a drug cocktail and inject it to create a more cost effective way of taking drugs in Nepal (Ojha et al., 2014).

In September 2015, Nepal's constituent assembly in the light of embracing federalism in Nepal (Federal Democratic state of Nepal) divided the current administration by ecological region (Mountain, Hill and Terai) into seven federal states where each state is divided into urban and rural areas (NDHS, 2016).

1.2 Demography

The population of Nepal is 28.03 million with an annual growth rate of 1.35% (CBS, 2015b). After the implementation of the federalism in Nepal, regarding urban and rural location classification there has been structural change as of March 2017 which makes the total population living in the urban area 59% and the rest of 41% population living in the rural area (NDHS, 2016).

The highest population is in capital Kathmandu (1,744,240) followed by Morang (96,5370), Rupandhei (88,0196), Jhapa (81,2650) and kailali (77,5709) [CBS, 2015a].

Kathmandu has the highest estimated number of hard drug users (36,998) trailed by Sunsari (7407), Kaski (6917), Morang (6451), Jhapa (6008), Rupandhei (5997), Chitwan (4515), Banke (4050) and Parsa (2130) while the other regions comprise 11,097 drug users (CBS, 2013). Figure 4a & 4b show the male and female hard drug users distribution in Nepal.

1.3 Socio – Culture

Nepal has a wide range of culture, caste and ethnicity, extending from east to west and north to south. A significant portion of the population follows Hinduism while Buddhism, Christianity and Islam are minorities (CBS, 2015a).

In the context of Nepal, people who are into substance abuse (specially PWID) are subject to discrimination and stigma by all levels of society. The society and the culture immediately put the drug user and the people who are dependent on it into a box where the community believes that these people have a moral blemish, or a person has a weak character rather than a chronic disease that requires treatment (Birdsall and GIZ, 2016).

An Australia hepatitis C study revealed that 62% of the PWID discrimination came from family or society for just only using the drugs (Day, 2003). It shows the problem the drug users face around the world in their socio-cultural aspect.

PWID are often criminalised and detained with the assumption that they are a threat to society (UNAIDS, 2014). It hinders people who use drugs in seeking medical care and even pushing them further in commencing risky practices such as sharing needles and increasing the spread and transmission of HCV.

1.4 Economy

The economy of Nepal is sustained by services and other activity (52.4%), agriculture (32.5%), and industry (15.1%) (UN, 2016). Nepal per capita GDP was 743 US dollar in 2015 (World Bank, 2017). The majority of people are employed in the agriculture (66.5%) while employment in services and other activity accounts for 22.4%. The industry employment is about 11.2% whereas the unemployment (% of the labour force) was documented 3.1 % in 2014 (UN, 2016). 29% of the drug users in Nepal don't have any job or occupation (CBS, 2013).

1.5 Education

Overall Nepal literacy rate is 65.9% with the literacy rate for the male being 75.1%, and female is 57.4%. However, the disproportion of the distribution of literacy rate can be seen between urban (82.2%) and rural (62.5%) areas in Nepal (CBS, 2015b). The education level of drug users varies from secondary level education (41.9%) to school leaving certificate until college certificate level (34.2%) (CBS, 2013).

1.6 Political and Administrative Division

The country, for administrative purpose, has been divided into 75 districts with northern mountainous region consisting of 16 districts, middle hilly region having 39 districts and southern terai region constituting 20 districts (CBS, 2015a). Before entering the federalism, Nepal had 217 municipalities (including 1-metropolis and 12-sub metropolis) and 3157 village development committees (VDC) where municipalities were considered as an urban area and VDC as a rural area of the country (CBS, 2015b).

1.7 Health System of Nepal

1.7.1 Historical Background

In 1956, Nepal introduced its first General Health plan, which included Malaria, Leprosy and Tuberculosis control program, the Smallpox Eradication programs and Family Planning and Maternal Child Health activities (Rai et al., 2001). By 1990s Nepal headed with the second long term health plan and policies (1997-2017), which helped considerably to improve in the development of the health system with the component of gender equality, equitable access, the principle of community participation and decentralisation of the health system (Regmi et al., 2010).

1.7.2 Health System: Health Care Delivery

Ministry of Health and Population (MoHP) overall sees the health system with its stewardship and plays a major role in policymaking and planning and coordinates with different governmental and non-governmental sector (DoHS, 2015). It has six Divisions:

(1) Administration Division, (2) Curative Services Division, (3) Policy, Planning and International Cooperation Division, (4) Public Health Administration and Monitoring and Evaluation Division, (5) Population Division, and (6) Human Resources and Financial Management Division.

There are three departments under MoHP: Department of Health Services, Department of Drug Administration, Department of Ayurveda.

The responsibility of carrying preventive, promotive, diagnostic and curative health care provision throughout the Nepal is assigned to Department of Health Services (DoHS). PHCC (Primary Health Care Centre) HC (Health Centre), HP (Health Post), SHP (Sub- Health Post) are the means to provide the primary health care to the population. The health care services are designed into HP to PHCC to the district, zonal, sub – regional, regional and finally to central level hospitals. Each level above the HP is a referral point in the network. Table 1 shows the number of different health care facility in Nepal.DoHS with other responsibility it is also in charge of working in the epidemiology and disease control division with the accountability of controlling epidemics, pandemic and endemic diseases.

Table 1. Health Care facility under Department of Health Services

Health Care facility type	Number
Central Hospital	6
Regional Hospital	3
Sub-regional Hospital	3
Zonal Hospital	10
District Hospital	75
Primary Health Care Centre	202
Health Post	3805
Sub-Health Post	12,908

Source: DoHS, 2015

The responsibility for assuring and maintaining the quality of drugs is undertaken by the department of drug administration together with the regulation of import, export, sale, production and distribution of drugs. Ayurvedic care and its related health care provision with a part of health promotional activities are carried out by Department of Ayurveda.

1.7.3 Health Care Financing

Nepal total expenditure on health per capita (Intl \$) was 137 while total expenditure on health as % of GDP was 5.8% in 2014 (WHO,2014a). The general government health expenditure as a percentage of government expenditure was 11.17% in 2014 (WHO,2014b). Nepal health budget depends on the international aid and donors that make up around 50 % of its total health budget that creates challenges for its sustainability and moreover funding of the donors in financing health expenditure has remained eccentric (Uprety et al.,2016).

1.8 Health Profile

The observed life expectancy in Nepal for a male is 68.1 years while 71.2 years is for the female with the top three most common cause of death in the population being due to non-communicable diseases, which are ischemic heart disease, chronic obstructive pulmonary disease and cerebrovascular disease (IHME, 2015). In 2015, the percentage of consultation for the communicable disease was 31.4% and for the non-communicable disease was 69% in the outpatient department whereas in the inpatient department the burden of communicable disease was 15.3% out of which 20% mortality was documented. The burden of non-communicable disease was 84.7% of which 80% mortality was observed (DoHS, 2015).

The disease pattern continues to change due to epidemiology creating new challenges for the health system in Nepal out of which hepatitis C is an emerging one. Hepatitis C in Nepal is less common in general population and mainly found in PWID (Karki et al., 2009). Limited treatment for hepatitis C is available from the government sector. (MoHP,2015). However, some of the private providers can arrange treatment from the other countries provided that the patient can pay the money out of pocket.

Chapter II: Epidemiology of HCV in Nepal, Global Overview of existing strategy for HCV control, Problem Statement, Justification, Objective, Research Question and Study Method

2.1 Epidemiology of HCV in Nepal

2.1.1 Introduction

Hepatitis C is a disease, during which the hepatitis C virus (HCV) ultimately affects the liver. It can cause both acute and chronic hepatitis infection. The severity of the disease can be mild during few weeks to severe leading to lifelong illness. Hepatitis C virus is a blood borne virus that can be transmitted through sharing needle and injection amongst drug users, unsafe injecting practices, unsafe health care and during the blood transfusion if not screened properly. HCV is highly infectious (a much smaller quantity of blood necessary to transmit infection) in comparison to HIV (WHO, 2009). A person could get reinfected with HCV even if he/she was cured before. It is estimated that globally more than 71 million people are chronically infected with hepatitis C infection and a significant number of those chronically infected will develop liver cirrhosis or liver cancer out of which nearly 399,000 people die every year (WHO, 2017a). A vaccine for hepatitis C is not available at the moment. There are research programs ongoing, but because of the high mutation rate of the virus, it will be a long time before it is available (HCV Advocate, 2015).

2.1.2 Drug users and HCV prevalence

HCV has the highest prevalence (67%) amongst the People Who Inject Drugs (PWID) in the world and are increasingly being reported from the Lower Middle-

Income Countries [LMIC] (Nelson et al., 2011; Hajarizadeh et al., 2013). The primary route of these transmissions being reuse of syringe and needles with rising trend on unsterilized syringes or shared injecting equipment (WHO, 2016).

According to Central Bureau of Statistic, there were around 92000 hard drug users¹in Nepal in 2013 out of which 52,174 were PWID² (CBS, 2013). Fig. 2 shows the route, number and percentage of hard drug users.

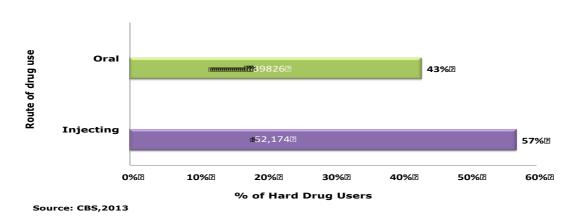


Fig. 2 Distribution of Hard Drug Users in Nepal

The total PWID that were 57% of total hard drug users, 13% of them shared the needle with somebody else (CBS, 2013). The IBBS (Integrated Biological and Behavioral Surveillance) for PWID (People Who Inject Drugs) conducted in three different regions of Nepal in 2015, which for the first time included the HCV in the report showed that the HCV prevalence rate was between 2.6% in FWID to 47.5% in PWID [Fig. 3] [Table 2] (IBBS, 2015abc). HCV in Nepal is mainly affecting the PWID. According to the IBBS survey done between years 2015-2017 showed that HCV prevalence was three to five fold higher in comparison to HIV amongst the PWID (IBBS, 2015abc; 2016ab; 2017abc). Fig.3 shows the prevalence of HIV and HCV between PWID in different year and regions of Nepal.

The different HCV prevalence estimates for the PWID in Nepal differ widely. In the in 2016 Harm Reduction International report presented the HCV prevalence amongst the PWID at 87.3% referenced from Nelson et al., systematic review that extrapolates the data from the year 1997-2002 (HRI, 2016). A report from WHO in 2010 indicated the data for PWID HCV prevalence rate at 85.5% in the Kathmandu valley referenced from 2003, Shrestha IL paper (WHO, 2010). HCV prevalence was even higher a decade ago in comparison with the estimated prevalence rate of 41.9% from randomly selected sample study of Kinkel et al. in 2015. According to government figures, overall HCV prevalence rate amongst PWID in Nepal ranges from 50-96% and has been known as a leading cause of morbidity and mortality amongst this key population (NCASC, 2015). However, the government figure does not indicate the methodology on how the data was obtained. For this paper when required to be associated the prevalence data of HCV in PWID has been considered from the recent study of Kinkel et al. i.e.

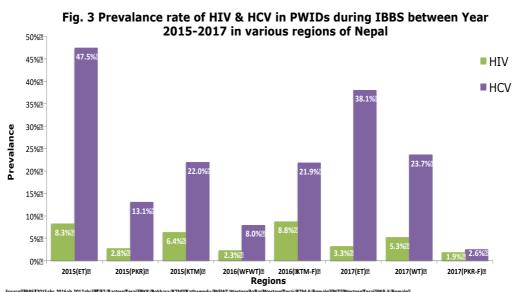
 $^{^{1}}$ Hard drugs include all form of synthetic opiates and chemical substances (e.g. Diazepam, Heroin, Buprenorphine, Propoxyphene, etc.). Those who consume only marijuana and alcohol are not included in the category for meaning of hard drug users for this study purpose.

 $^{^2}$ PWID are the drug users from the hard drug user population who use the mode of drug administration as injecting opiates and chemical drugs like Diazepam, Heroin, Buprenorphine, etc.

41.9% overall prevalence rate of HCV in PWID in Nepal (This may be a conservative estimate).

2.1.3 Geographical distribution

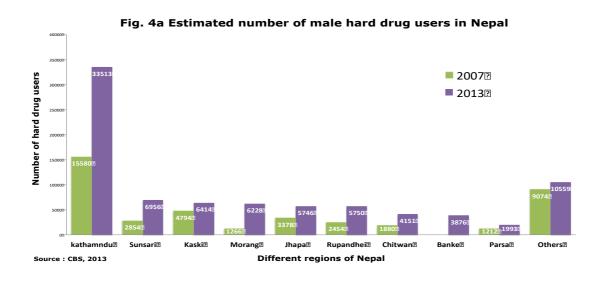
Kathmandu suffers the biggest burden and increase of drug users (from 17,458 in 2007 to 36,998 in 2013) in comparison to other regions (Fig. 4a &4b). But IBBS data for PWID in 2015 and 2017 showed that Eastern Terai (ET) bears the highest HCV prevalence rate amongst the surveillance regions (Fig. 3).

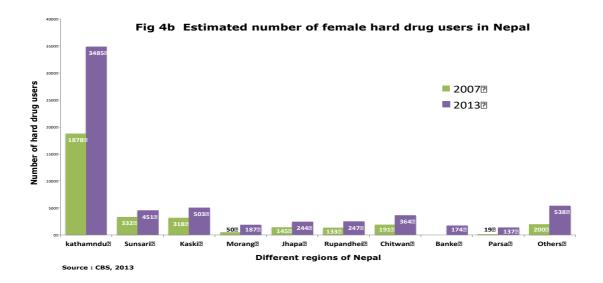


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2.1.4 Sex and age distribution of hard drug users

The estimated number of male and female HCV infected is not known in Nepal. However, CBS report in 2013 reflected that the figures of male hard drug users have significantly increased in almost all region of Nepal in comparison to 2007 and comparison with the female (CBS, 2013). 93.1% of drug users were male whereas female accounted for 6.9%. 76% drug users were below 30 years with 20-24 years old being the highest proportion followed by 25-29 years old group (CBS, 2013). According to CBS data, it can be expected that the HCV prevalence in Nepal can be higher in male PWID than in female PWID. Fig. 4a and 4b show the estimated number of male and female hard drug users in 2007 and 2013.

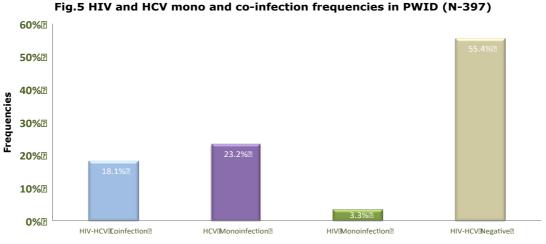




2.1.5 HCV Mono and HIV-HCV Co-infection

The HIV-HCV coinfection data had never been reported in Nepal until 2015. IBBS survey in the year 2015 and 2016 for PWID showed that the HIV-HCV coinfection data ranges from 0.6%-12.5% in various regions of Nepal [Table 2] (IBBS 2015b, 2016ab).

A research article presented for hepatitis C testing and treatment in Amsterdam, Holland amongst drug users (N- 449), 267 users were found out to be having HCV antibodies. 183 out of 267 were HCV viremic (presence of HCV-RNA in the blood). Out of 183, 49 were HIV-HCV co-infected while 134 were HCV monoinfected (Lindenburg et al., 2011). The study (N-397) conducted on HIV and hepatitis C among PWID in three regions of Nepal showed the similar pattern of HCV monoinfected cases. 18.1% of the participant with known HIV status were found out to be HIV/HCV co-infected while HCV monoinfected of 23.2% (χ 2-p<0.001) was discovered for the participants [Fig. 5] (Kinkel et al., 2015).



Source : Kinkel et al., 2015

Because of their common mode of transmission, co-infection is typical in both HIV and HCV. In a study done amongst patients attending at Nepal public health laboratory for Anti-HIV testing in Kathmandu showed that out of 678 samples, 105 tested HIV positive. Out of those 105, 16 infected patients were people who inject drugs, and 13 of them were HCV co-infected (Ojha et al., 2013). However,

HCV monoinfected data were not available for the HIV negative sample mainly due to study design.

Another study amongst PLHIV (N-319) displayed that 130 PWID were discovered to be HCV positive (Poudel et al., 2014). The research article has shown that PLHIV who are injecting drug users can be more vulnerable; especially MSM (men having sex with men) to get infected with HCV via sexual mode of transmission due to rough sexual technique and per mucosal transmission factors (Danta et al., 2007; Urbanus et al., 2009). However, the sexual mode of transmission of HCV infection being reported is much less common around the world (WHO, 2017a). There are no data and reports available for Nepal regarding sexual transmission of HCV amongst PWID.

2.1.6 Morbidity and Mortality

There is a lack of data for the PWID, HCV infection and HIV-HCV coinfection related morbidity and mortality in Nepal.Though HIV related mortality with their unknown HCV and injecting drug use status was estimated 4722 in 2011, which was the highest number among any country in the world (WHO, 2011; NCASC, 2012).

2.2 Global Overview of existing strategies for HCV control

A case study on drug policy change for heroin-assisted treatment in Switzerland showed that using four-pillar drug policy (including harm reduction, prevention, treatment and law enforcement) brought a positive impact on policy change and positive outcomes of heroin-assisted treatment during the time of AIDS epidemic in the country. It used the innovative approach of treating chronic and treatment resistant heroin addicts by medical prescription of heroin (Uchtenhagen, 2010). The observational study from the Switzerland showed the extensive scientific and political preparation for wide public debates were the key factors to help to establish the new policy. The four pillars drug policy helped significantly to reduce the morbidity and mortality related directly (drug overdose) and indirectly (death from hepatitis and HIV) in the Switzerland (Savary et al.,2009). It shows that the policy change remains crucial to achieving the good outcome regarding harm reduction programs and treatment.

According to a systematic review of needle/syringe programs and opiate substitution programs in LMIC; with the full implementation of the structural level harm reduction program, the coverage showed that prevalence of HCV decreased (range -4.2% to -10.2%) while HCV incidence remain stable in one of the studies (Des Jarlais, 2013). The review concluded that harm reduction programs appear to be effective in reducing HCV in LMIC as in high-income countries only if the programs are implemented on a large full-size scale.

Reports have underlined that NSEP and OST service provision is effective in averting HCV infection when planned strategically. A report by Australian government showed that 96,667 cases of hepatitis C were prevented between 2000 and 2007 with the harm reduction program (DOHA, 2009). The cost-benefit analysis of needle and syringe exchange program by comparing the monetary value of all benefits of a program with all costs of that program for the Australian government turned out to be one Australian dollar invested in the NSEP, the return in the cost saving was twenty-seven Australian dollar considering patient cost and productivity gains and losses. The net financial saving was 1.03 billion Australian dollars. This evidence shows that harm reduction program is not merely benevolent approach to drug users, but it shows a substantial amount of efficiency maximisation in an economic evaluation to the country by minimising the cost of hepatitis C treatment.

Treatment of hepatitis C with the introduction of interferon free DAA shows the paradigm shift where HCV can be treated and cured within a shorter duration (12-24weeks), well tolerated and with minimal side effect than non-contemporary peg-IFN/RBV treatment (Florian et al., 2015). Studies have shown that countries such as the United States, where guidelines recommended including the active PWID for the HCV treatment, in veracity; many service providers were unwilling to treat PWID with the arguments on non-adherence, increased susceptibility to side effects, and the risk of reinfection through continuing to inject (Aspinall et al., 2013). Nepal's strategic planning on the treatment of hepatitis C appears static and lacks development and vitality. It does not include the majority of HCV infected PWID population (only HIV-HCV coinfected) who carries the biggest burden of disease. And like in the United States the service providers in Nepal aided by the government are unable to provide new DAA treatment to all HCV positive active people who inject drugs. The systematic review and meta-analysis of the Aspinall et al. showed that PWID who are eligible (having no decompensated liver cirrhosis, cardiac failure, or auto-immune disease) and motivated enough to commence on the treatment demonstrated high adherence, low discontinuation of therapy and a low rate of reinfection among the PWID.

Research has shown that mainstream health care poses barriers for PWID to access services while PWID-targeted PHC centres increased the accessibility and acceptability by providing non-judgmental, cost free and anonymous services at the location where PWID often come together at suitable opening hours (Islam et al.,2012). These peripheral services increased the engagement and satisfaction of the PWID. The study further established that by offering primary health care in combination with the harm reduction program even where it is contemplated to oppose the existing drug policy, it showed this tailored approach has the perspective to facilitate the outlet to function as a medical facility for PWID.

2.3 Problem Statement

Nepal has no specific policy on hepatitis-C and low access to treatment. For the 150,000 PWID, the extra problem is low coverage of harm reduction programs, increasing the risk of HCV infection.

The estimated number of drug users in Nepal has doubled over the last six years; 46,309 in 2007 reaching to 92,000 in 2013 with an annual growth rate of 11.36% [Fig. 4a &4b] (CBS, 2013). The numbers of PWID are higher than oral drug users (Fig. 2). A 2016 report by the Nepalese Narcotics Control Bureau estimated that the number of drug users has sprung up from 92,000 to 150 thousand (NCB, 2016).

There is not yet a central HCV policy in Nepal. Harm reduction programs (OST & NSEPs) exist, but coverage and effectiveness for preventing HCV infection are low.

In a study among randomly selected PWID HCV prevalence rate was up to 41.9% [95% CI: 37–47%] (Kinkel et al., 2015).HCV treatment in Nepal which used to cost a lot in the past remains difficult despite the recent revolution in efficacy and affordability of the treatment that has become easier for countries like Nepal to get access to generic less expensive drugs (MoHP, 2016; WHO, 2016).

Nepal re-introduced an Opioid Substitution Therapy (OST) program in 2007 after a temporary closure in 2002. From 2009 Nepal received the technical assistance for OST program from German Federal Ministry for Economic Cooperation and Development(BMZ), the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ). However the number of people who received OST services together with needle and syringe exchange program remains asymmetrical throughout the concentrated PWID region of Nepal such as Kathmandu valley, Eastern Terai,

Western Terai and Pokhara, largely ranging from low to medium level coverage according to WHO/UNODC/UNAIDS technical guide indicator [Table 2] (WHO, 2009; MoHP, 2016).

So, does it indicate the most important issue is the absence of central HCV policy, which should include large scale harm reduction and HCV treatment, and results in displaying the minimal impact of the service provided to both the existing PWID and the newly evolving PWID? Or is it more important to address a disproportionate coverage level of the program, which could have played a role in the new incidence of HCV in the country either by drug relapse and going back to injecting behaviour or through needle sharing? [13% of the total PWID (52174) reported to be sharing needles (CBS, 2013)] Although there are no data available and it is challenging to obtain the incidence of HCV in Nepal.

The Research question of this paper is:

Is there a need for an explicit HCV comprehensive policy for PWID in Nepal?

2.4 Justification

After the inclusion of HCV infection and HIV-HCV co-infection data in the IBBS survey from 2015 by National Centre for AIDS and STD Control (NCASC), the extent of the HCV prevalence has started to become visible from different parts of Nepal showing the magnitude of the problem in various places of the country especially in PWID (Fig. 3 & Table 2). HCV is still not a notifiable disease in Nepal. Apart from the IBBS data, there are limited other publications on HCV prevalence.

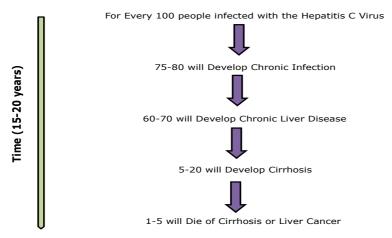
The reason to conduct this study is, as there are evidence-based interventions proven to be working for HCV control and Nepal lacks an HCV based central policy; there are knowledge gaps, missing strategies and lot of new development in the field of HCV treatment. There are policies for HIV, but HCV is just merged under HIV strategic planning without a full-scale approach (MoHP, 2016). The problem of HCV has a solution, which Nepal can solve with available resources but it seems like Nepal hasn't been doing that yet in its maximum capacity with no aligned policy. This study has been carried out to understand how it can be improved. It will try to identify gaps in the current policy and propose evidence-based and context-appropriate solutions to the problem.

A systematic review and meta analysis conducted in upper-middle and high-income countries for hepatitis C disease progression in PWID showed that without the HCV treatment, PWID would develop liver sequelae (compensated cirrhosis, decompensated cirrhosis and hepatocellular carcinoma) in mid- to late-adulthood. It concluded that delay in the HCV treatment for PWID until they reach the advanced liver fibrosis would extend the infectiousness to thirty years. Therefore to eliminate HCV as a source of infection in PWID early engagement in care and treatment with scaled up effective HCV prevention is essential (Smith et al., 2015).

Three-quarters of the drug users in Nepal are relatively young between the age group of 15-29 years (Birdsall and GIZ, 2016), which is the productive population of the country. It raises the questions and concerns about the prospect of the country regarding its productivity and future for those young generations. With the increasing number of young hard drug users in Nepal every year it is now impossible not to see the matter and needs urgent attention from the government to tackle it before it becomes the epidemic in the country fostering towards a public health threat.

According to the American CDC, the risk of progression to cirrhosis of liver among those with chronic HCV infection is 5-20% over 15-20 years with the mortality rate of 1-5% (Fig. 6)

Fig. 6 Risk of progression to different disease states among those infected with HCV Risk of progression to different disease states among those infected with HCV



 $Source: \ http://www.cdc.gov/hepatitis/HCV/PDFs/HepCGeneralFactSheet.pdf$

It means that people who are infected with HCV (particularly young people in Nepal) have not yet entered into the chronic phase. The progression to cirrhosis and liver cancer can be stopped by Hep-C treatment. Subsequent reinfection in the HCV-cured can be prevented by harm reduction programs. OST /NSEP scaling up remains crucial for new and existing PWID for the prevention and to reduce the further transmission of HCV Virus.

There is scarce literature published on the prevalence of hepatitis C in Nepal. There is no research looking into benefits of having full scaled up OST/NSEP intervention and HCV treatment for PWID. This paper looks into the necessity for a clear, thorough policy on hepatitis C and evidence based solutions to strengthen the existing OST/NSEPs and HCV treatment program in the health care system of Nepal.

2.5 Objective

To study the need for an explicit HCV comprehensive policy on reducing HCV related morbidity and mortality among PWID in Nepal.

2.5.1 Specific Objectives

- 1. To review existing policy, plan and coverage on harm reduction programs for PWID and their role in prevention or mitigation of HCV transmission.
- 2. To discuss the new developing hepatitis-C treatment availability and affordability for the PWID.
- 3. To inform policy makers about the need for a comprehensive HCV policy.

Table 2. Different Key Indicators from Integrated Biological and Behavioral Surveillance (IBBS) among People Who Inject Drugs (PWIDs) in Nepal.

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	N 345	N 340	N 360	N 345	N 340	N 300	N 160	N 360	N 300	N 155
	2011		2015		2016		2017			
Key Indicators	Pokhara	Kathmandu	Eastern Terai of Nepal	Pokhara	Kathmandu	Western to Far Western Terai Highway Districts	Female Who Inject Drugs (FWIDs) in Kathmandu Valley	Eastern Terai Of Nepal	Western Terai of Nepal	Female Who Inject Drugs(FWIDs) in Pokhara Valley
HIV Prevalance	4.6%	6.3%	8.3%	2.8%	6.4%	2.3%	8.8%	3.3%	5.3%	1.9%
Hepatitis C Prevalance	NA *	NA*	47.5%	13.1%	22.0%	8.0%	21.9%	38.1%	23.7%	2.6%
Co- infection of HIV and Hepatits C	NA*	NA*	NA	0.6%	NA	12.5%	5.6%	NA**	NA**	NA**
Shared Needle in the past week	2.5%	5.2%	71.4%	1.1%	3.8%	12.0%	15.6%	NA**	NA**	16.0%
Used Non Sterile Syringe/Needle in the Past Month	6.1%	4.3%	12.6%	3.0%	4.0%	5.9%	6.3%	NA**	NA**	7.1%
Used Non Sterile Injecting Equipments (A bottle, spoon, cooker, vial/container, cotton/filter and rinse water) in the Past Month	80%	33%	11.1%	2.7%	4.3%	8.9%	9.7%	NA**	NA**	10.5%
Received OST Services Ever	5.9%	4.5%	22.5%	14.0%	7.1%	9.6%	25.0%	40.0%	14.9%	5.8%
Needle Obtained from needle exchange progra	47%	26%	53.3%	21.3%	49.9%	42.0%	4.4%	NA**	NA**	0.6%

Source: IBBS (2011ab, 2015abc, 2016ab, 2017abc)

^{*} IBBS Survey only Started including Hepatitis C Virus prevalence and Co – infection data from 2015. It was never been documented and notified before.

^{**}These data are not published yet in the recent IBBS 2017 fact sheet. Final full report of IBBS 2017 is due to come out.

2.6 STUDY METHODS

A thorough literature and report review with descriptive analysis and a desk study for policy discussion paper has been carried out to obtain an insight into the various aspects of the problem with different perspectives. The research question will be answered exclusively through a review of existing literature, policy documents and reports. A conceptual framework was adapted to analyse and discuss the problem.

2.6.1 Key Words:

Hepatitis C Virus (HCV), PWID (People Who Inject Drugs), Injecting Drug Users (IDUs), Policy, HIV, HIV-HCV Co-infection, Harm Reduction, OST (Opioid Substitution Therapy), Needle exchange centres, Needle and Syringe Exchange Program (NSEP), HCV Treatment, Substance Abuse, Nepal, LMIC.

2.6.2 Search Strategy:

This study is focused on literature review and reports. The literature was obtained from both published and unpublished literature on HCV, PWID, HIV-HCV and OST/NSEP on the Internet. A literature search was done using different databases and search engines like PubMed, VU e-Library, Google Scholar, Science Direct and Scopus with the help of key words to find the scientific publications. Google search engine was used to collect gray literature such as reports, e-books, and fact sheets. MoHP website was searched, and snowball technique was used for the strategy and policy documents on HCV, PWID, HIV-HCV, OST/NSEP for Nepal and the WHO, UNAIDS, UNODC, IHME, WorldBank and UN sites were explored to obtain other associated documents.

Literature available in English from 2000 to 2017 was searched. However, some of the literature before 2000 are also used because of their relevance in key information. PubMed search was performed using MeSH (Medical Subject Heading) terms and their combinations. Similarly, in other search engines, key words and combinations were used.

Combination of search terms entered were "Hepatitis C Virus AND People Who Inject Drugs ", "People who inject drugs OR injecting drug users", "Harm Reduction for PWID AND Nepal ","Harm reduction AND global strategy", "Harm reduction Policy AND Nepal", "HCV Policy AND Nepal", "Opioid Substitution Therapy AND Nepal", "Substance abuse AND health care for Injecting Drug Users", "needle and syringe exchange program for injecting drug users AND LMIC", "HIV-HCV OR coinfection", "HCV treatment AND people who inject drugs". Hand searching of reference lists was also undertaken.

Inclusion criteria included article /reports that described the HCV component, OST, NSEP, PWID, Harm reduction program and HIV-HCV coinfection for Nepal. Exclusion criteria were defined as article /reports not containing HCV and Harm reduction component.

A total of 200 articles and reports were found during the search. Only 4 peer-reviewed literature were found for Nepal with the given inclusion criteria. 20 Global peer-reviewed articles were identified through electronic database searching directly or indirectly that described HCV, harm reduction program.

2.7 Limitation of the Methodology:

This paper is doing a policy analysis on a policy and strategy that does not exist explicitly. There are inadequate articles and data available for the specific information. There was limited access to NGO data that helps government on policy making. The HCV prevalence rate is not the representative data for all

PWID and might not be the correct estimate of the HCV prevalence rate in Nepal. All of the data and information that are accessed in this study are taken from reports and previous studies that may have different objectives than this study. This paper is trying to interpret different studies to a direction that previous studies did not go.

2.8 Conceptual Framework:

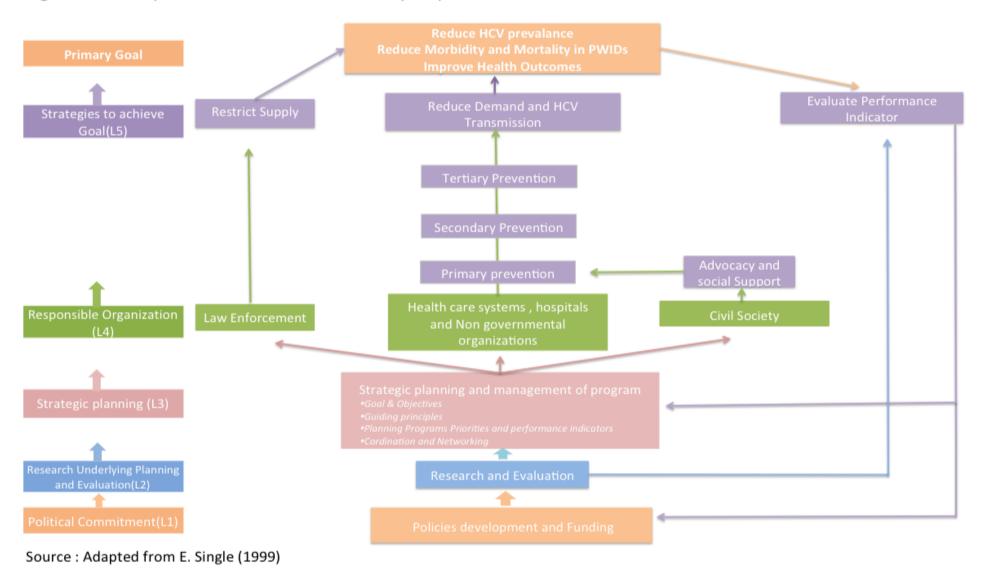
The conceptual framework (Fig. 7), which is essential to dichotomize for analysing the problem and finding the explanation, has been drawn from the Erik Single's 1999 paper "A Harm Reduction Framework for Drug Policy in British Columbia". This framework is centred on policy on how to reduce the harm related to drug use within the limited available resources. The reason to use this framework is that of its alignment with the injecting drug use and its associated harm together with the blood borne infection such as hepatitis C and HIV among PWID (Single, 1999). However, the setting might be different for Nepal but risk taken by the drug users such as unsafe drug use or needle sharing, pharmacological effect of psychoactive substances that arouses the drug craving and the environment (unhygienic and unsterile) in which consumption occurs almost remains analogous around the globe (UNODC, 2016).

Originally Single has discussed three strategies (demand reduction, supply interdiction and interventions directed at drug users) for his framework. The adapted framework has added a fourth strategy as an HCV treatment component together with harm reduction strategy (OST/NSEP) for PWID. Single framework describes the harm reduction based drug policy while adapted framework will discuss harm reduction policy together with the association between the PWID and HCV.

Considering the five different level of conceptual framework, the different components of the framework; Level 1(L1): political commitment for policy and funding, Level 2(L2): research and evaluation, Level 3(L3): strategic planning, Level 4(L4): responsible organization, Level 5(L5): strategy to achieve goal for harm reduction and HCV prevention will be analyzed with the help of available data, literature, policy and reports to understand what is already on the ground and what are the gaps. During analysis level 4 and 5 will be combined with the elements of respective levels.

The reason to combine the level 4 and 5 is since sharing needles and syringes amongst the PWID increases risk of HCV transmission, it is essential to have a synergy between responsible authority such as law enforcement, service providers and civil society in the alignment with the goal achievement strategy in order to restrict the drug supply, reduce demand and HCV transmission. The framework aims to explain those two levels with a congregating approach to see the association structured with four pillars; harm reduction, prevention, treatment and law enforcement.

Fig. 7 A Conceptual Framework on HCV Policy response



Chapter III: Study Results/Findings

In this Section the findings of the study will be presented at different levels of conceptual framework: political commitment, research and evaluation, strategic planning and management of programs, responsible organization to achieve strategic goals to lower the drug use and control HCV infection where the available policy, reports, data and literature will be interpreted and analyzed. Discussion of the findings will be carried out in the next chapter.

3.1 Political Commitment

Political willingness to support the PWID and its related program such as harm reduction especially NSEPs was low but has been showing improvement in Nepal slowly over decades. However, it remained controversial and was considered as encouraging people to use drugs, which was not an acceptable approach for policy makers and bureaucrats (Kant CK & Plumber D., 2012). The large scale implementation of harm reduction (OST/NSEPs) to have a wide range of service coverage for the PWID is yet to be introduced with more political support and understanding (MoHP, 2016). Nonetheless the political support and leadership seems positive about the HIV prevention (including harm reduction and HCV prevention) where they speak publicly and favorably with the statement coming from government ministers and high officials from sub national level in programs such as the World AIDS Day celebration, World Hepatitis Day, Global Fund for AIDS TB and Malaria (GFATM) board meetings (NCPI, 2014).

3.1.1 Policy Development:

There has been no policy developed for HCV yet in Nepal. The key policies on national HIV response contain a supportive implicit component of HCV within itself but fail to explain strategic planning on how to control and prevent the HCV especially in PWID (MoHP, 2016). Evidence has shown that policy on harm reduction with a different strategy, different ways of implementation have been proven to be effective (Uchtenhagen, 2010). But in the context of Nepal, they are not there yet. There are some planned targets, some implicit strategy in HIV policy for HCV. Nepal does not have a national policy and treatment guidelines for treatment of HCV, but it started endorsing the HCV treatment guidance in 2014 which is based upon the 'Guidance on care for adolescents and adults living with HCV Genotype 1 or 3 in Nepal 2014' (MoHP, 2015). Table 3 shows some of the main policy responses to HIV that has the component of HCV

Table 3. National HIV Response Policies

Main Policies	Components Disscussed Briefly
1.Nepal HIV Investment Plan (2014-2016)	1.Plan for providing HCV treatment /OST/NSEP
2.National Health sector Strategy (2015-2020)	2.HCV Serological Test(Free of cost Basic Services)
3.National HIV strategic Plan (2016-2021)	3.Challenges with hepatitis C prevention ,treatment and care/ OST / $NSEP$

Source: DoHS, 2016

The national guideline on Opioid Substitution Therapy (OST-2014) was approved by Ministry of Home affairs in 2014 (MoHP, 2015). Nepal has developed policy on use of clean needles and syringes by PWID (NCPI, 2014). Table 4 shows the Nepal policy and practice approach to harm reduction.

Table 4. Nepal Harm Reduction approach in policy and practice

Explicit supportive reference to harm reduction in national policy documents	V
At least one needle and syringe programme operational	\checkmark
At least one opioid substitution programme operational	\checkmark
At least one drug consumption room	×
OST in at least one prison	×
NSP in at least one prison	×
Source: HRI, 2016	

3.1.2 Funding:

Investment plan available for the harm reduction intervention since 2014 seems increasing (Table 5) except for hepatitis C treatment that appears to be fluctuating (MoHP, 2013). But because of the foreign aid dependency, it raises a major concern about the sustainability of these programs in the future. For example, out of total funding for HIV response in Nepal 90% of the funding comes from Global fund while the Nepalese's government contribution is only 10% for the HIV related activities (MoHP, 2016). Table 5 illustrates the funding plan of the harm reduction and HCV program in Nepal. But how much was it spent in reality? There were no reports available to know the actual disbursement from this planning.

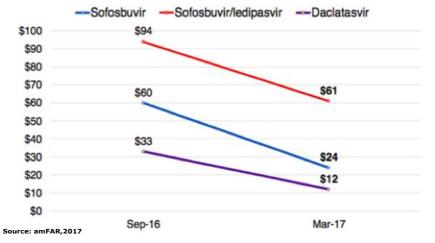
Table. 5 Nepal HIV Investment plan 2014-2016 for PWIDs and HCV treatment

Intervention	2014	2015	2016
People who inject Drugs (PWID)	2,948,852	3,913,859	5,160,773
Needle & Syringe Exchange Program(NSEP)	2,312,435	3,181,923	4,384,169
Oral Substitution Therapy (OST)	636,417	713,936	776,604
Hepatitis C treatment Package(HIV-HCV coinfection	1,315,641	654,179	1,064,604
* (Currency in US Dollars)			ollars)

Source: MoHP, 2013

According to amfAR, for the government purchasing of Indian generic HCV medicine; the price has reduced to 36 US dollar per month on March 2017 (amfAR, 2017) (Fig. 8).

Fig .8 Price reduction in Indian Generic HCV treatment for government purchase



With this purchasing price of USD 108/cure, the drug cost for treating all currently known HCV+ PWID in Nepal is estimated to be 2.36 million US dollar³. This estimate is based on the estimated number of HCV cases and drug users in Nepal. As explained earlier, a conservative estimate of 41.9% prevalence rate was used, so the actual costs may be higher. Also not all diagnostic tests were included. Nepal heavily depends upon funds from the external sources (Bilateral, Multilateral and INGOs) such as Global Fund and GIZ to run the harm reduction program [OST/NSEP] (MoHP, 2015; MoHP, 2016; HRI; 2016). Furthermore with the Global Fund support government has initiated to provide hepatitis C treatments for the HIV-HCV co-infected patients since 2015 (MoHP, 2015). However, it does not include the HCV mono-infection patients who carries the bigger burden of disease and are predominantly PWID.

3.2 Research And Evaluation

A study was conducted in 2015 with the objective of understanding the prevalence of viral hepatitis in PWID in three regions in Nepal with the support from GIZ while performed by Central for Molecular Dynamics Nepal (MoHP, 2015). There are few studies done for the Nepal in the context of HIV-HCV coinfection (Poudel et al., 2014; Ojha et al., 2013). Since 2002, Nepal has been conducting IBBS among the key population in several regions of the country (MoHP, 2015).

However research and evaluation on how successful or effective the current harm reduction programs are to reduce the HCV incidence in the country have not been conducted yet that can have added value to set, analyse and give the feedback on performance indicator of the harm reduction program (Fig.7). Likewise, there has been no research done for the HCV treatment outcome in the country mainly due to its unavailability.

3.3 Strategic planning and management of programs

There are no log frame and strategic planning document for HCV in Nepal. But there are well-defined programs with priorities, objectives and goal sets for HIV (MoHP, 2016).

3.3.1 Goals and Objectives

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Nepal was the first country in South Asia to introduce harm reduction program containing OST and NSEP long before any other South Asian country. By the technical consultation from the United Nations Drug Control Programme, the government of Nepal started its substance abuse control programme back in 1992, which mainly envisaged revision of narcotics legislation and development of treatment and rehabilitation services for drug users (UNODC, 2007). The National Drug Demand Reduction strategy (1996-99) acknowledged OST (mainly methadone) as a treatment alternative and recommended to have 50 % of hard drug users and chronic addict to be included on OST program in the mental hospital. Table 6 shows some of the strategies put forward for harm reduction in PWID in Nepal. In the health sector support program, the government has made the strategy of the major programme focus on refining access and the quality of medical and psychosocial services for PWID (DoHS, 2016). These strategies in its true meaning in achieving its objective remains theoretical today because of the

 $^{^3}$ It does not include the diagnostic tests or investigation cost such as elastography. Best estimated prevalence rate of 41.9% in PWID in Nepal; estimated number of HCV cases in Nepal = 21,861. Note that prevalence rate might vary and the estimated number of HCV cases could be even higher, as the number of estimated drug users has increased up to 150 thousand in 2016. The total treatment cost is just a proxy and might be under estimated.

low coverage; availability, accessibility and effectiveness of current OST /NSEP in Nepal (MoHP, 2016).

Table 6. Nepal Harm Reduction Strategy for PWID

- 1. Building capacity for the establishment and rapid expansion of harm reduction programs including those for "needle and syringe exchange" and "drug substitution therapy".
- 2. Expanding peer-education training and programming using PWID as the primary facilitators/peer-educators.
- 3. Developing and gradually implementing appropriate support services for PWID (counselling, primary health care, harm reduction based education, legal support).
- 4. Developing guidelines, policies, and capacity for the rehabilitation of people who injecting drugs.

3.3.2 Guiding Principles

Inclusive

Involvement of the representative from the people who inject drugs community in designing harm reduction components such as scaling of OST and comprehensive services have been carried out by the government in Nepal with a human rightsbased approach that reflects on national harm and demand reduction strategy 2008 (UNAIDS, 2009).

Client Centered

The inclusive principles have been displaying in the different comprehensive service packages offered to PWID by the government supported NGO such as SPARSHA Nepal (A key population involved community managed NGO) which provides "ONE-STOP-SHOP" based facility. The ONE -STOP-SHOP based provision includes STI treatment, HTC (HIV Testing and Counselling), NSEP, OST, Directly Observed Treatment, Short-course (TB DOTS), ART, Community Care Center (CCC), Community Home Based Care (CHBC), referral linkages for family planning and other sexual and reproductive health assistances plus HCV clinic for treatment of HIV-HCV co-infection (MoHP, 2015). However, this kind of client centred comprehensive services to PWID remains very limited in Nepal, and by so far no public government hospital that has the harm reduction component is providing it.

Human Rights

Activity such as empowering the PWID by engaging them in the national effort to address the issues related to prejudice and discrimination are slowly showing progress with their social acceptance by the community in Nepal (MoHP, 2015). But used terms like equity for HCV positive population has yet to be practised in its true meaning by the government.

Evidence has shown that during planning and designing of the services, vulnerable people amongst the drug users, for instance, unemployed or school drop out youth, sex workers, transgender and minority group are often neglected (WHO, 2010). In 2016, a drug user supporting NGO called "Recovering Nepal" protested against the government for not engaging the people from injecting drug users community and the direct stakeholders on planning and the drafting of the national hepatitis treatment and guidelines while demanding right for information and right for participation given to them by the new constitution of Nepal (ANUPUD, 2016).

3.3.3 Planning program priorities and performance indicators

3.3.3.1 OST Programs

The first OST program in Nepal was introduced in 1994 in the form of Methadone Maintenance Therapy (MMT) in a psychiatric hospital with the intention of minimising over dose, avoiding relapse and reducing the risk of HIV, hepatitis and other infections in PWID (Shrestha, 2000). There were around 270 patients who were under MMT program (Croft et al.,2001) before it was closed on 2002 because of lack of funds, minimal infrastructures and excessive patient dropout rate (UNODC, 2007).

OST services were reintroduced in 2007 with the funding assistance from UNODC after the pressure from the drug users organisation such as "Recovering Nepal" to the government that opened the services in a tertiary care teaching hospital in Kathmandu (Ambekar et al.,2013). In 2009, a pilot project, which was authorized by Ministry of Home Affairs, GIZ has implemented OST program in Nepal with the collaboration with national and international partners to increase the availability of OST which was finally endorsed in 2014 by MoHP and MoHA as a National OST program for the country (Birdsall and GIZ ,2016).

According to WHO/UNODC/UNAIDS technical guide of the national target-setting framework for setting indicator and indicative targets for drug dependence treatment such as OST has formulated the following (Table 7) as the standard indicator for the OST coverage for injecting drug users to have universal access.

Table 7. OST coverage indicators and indicative targets

Coverage Indicators	Targets		
Develope of animid dependent mapple on OCT	Low: <20%		
Percentage of opioid-dependent people on OST at census data	Medium :>20-<40%		
at census data	High :>40%		
	Low: <20%		
Percentage of Opioid Injectors on OST	Medium :>20-<40%		
	High :>40%		

Source: WHO,2009

(Note: OST for non-injecting opioid-dependent people is also considered in this Guide as transition to injecting among this group is not uncommon and hence treatment for opioid dependence reduces the likelihood of initiation to injecting and can be considered as a prevention strategy.)

The coverage in 2013 for OST program in Nepal was less than twenty percent with 346 (Table 11) people being in the methadone program while the estimate PWID population was 52,174 (CBS,2013;MoHP,2015). There were 640 patients (WHO,2016) in 2014, which indicates that the numbers of people increased in comparison to the previous year but in a very trivial way to have a significant impact in current OST program. The government target plan was to cover only 1152 PWID in OST program in 2014(MoHP,2013). However given the number of injecting drug users in Nepal (52,174) the percentage of coverage level according to WHO/UNODC/UNAIDS technical guide indicator and targets remain below 20% and significantly low (MoHP, 2016).

Nepal is using both methadone and buprenorphine in its OST program while looking forward to introducing the improved use of sublingual buprenorphine

which allows alternate day dosing and reduces the over dose risk (MoHP,2016). The strategic plan for the OST program by the government has decided to expand the OST by tackling the supply and demand problems making it client centred so that the demand can be improved to maximise the coverage with an approach of designing user-friendliness services to stable and unstable client (MoHP,2016).

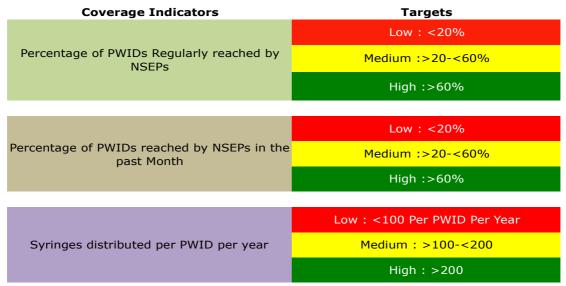
3.3.3.2Needle and Syringe Exchange Program (NSEP)

NSEP was first introduced in Kathmandu, Nepal in 1991 by an organisation called LALS (Life-saving and Life-giving Society) which was later followed by other Asian countries (Costigan, 2003). With the establishment of NSEP in Nepal back in the nineties, the NSEPs have constantly been facing confrontation from the various actors such as local community, police or municipal authorities. Before the sensitization ⁴ for harm reduction program to the general public, police and municipal authorities, LALS confronted numerous challenges from the local community and other key actors in its implementation mainly because the program was visualised as an encouragement for drug use (UNODC,2007).

By 2003 Nepal had eleven NSEPs run districts with the involvement of eighteen NGO but in 2004 NSEPs implemented site reduced to nine mainly because of fund unavailability and lack of technical support whereas government officials claimed that the program was running ineffectively without properly trained outreach staff and some even stated that the needle and syringe were being resold by the clients received through the program (UNODC,2007). With all these challenges, Nepal did learn the lesson that alone NGO run NSEPs cannot sustain over a long term to achieve an effective wide response at the national level to tackle the problem (such as HIV in PWID at that time) and government has to get involved in integrating these programs into primary health care system (Costigan,2003).

WHO/UNODC/UNAIDS technical guide of the national target-setting framework for setting indicator and indicative targets for NSEPs has articulated the following (Table 8) as a standard indicator for the NSEPs coverage for injecting drug users to have universal access.

Table 8. NSEPs Coverage Indicator and Indicative targets



Source: WHO, 2009

⁴ Enhancement of response on importance of minimising the transmission of the infectious disease such as HIV and hepatitis

Data from MoHP shows that number of PWID who have been reached by the harm reduction prevention program such as NSEP has dropped from 11,832 in 2012/13 to 6570 (< 20% coverage) in 2013/14 (MoHP,2015). These reflections can be overwhelming regarding prevention of blood borne disease such as hepatitis C when every year the numbers of drug users including PWID are increasing.

Nepal has included key population such as PWID as high priority in its National HIV strategic planning 2016-2021, which envisaged increasing the number of sterile needle and syringe distributed with an expanded coverage to PWID while endorsing WHO strategy to halt and reverse the HIV epidemic among PWID in Asia Pacific (WHO,2010; MoHP,2016).

HCV transmission, which is mostly through the sharing of needles amongst the PWID, harm reduction program such as NSEPs are put in place as a component from the National HIV strategic planning 2016-2021 where community-based intervention for PWID are implemented through outreach worker in collaboration with local NGOs to reach these target population for the distribution of needle and syringes (MoHP, 2016).

3.3.3.3 HCV Prevention and Treatment Services

Around the globe, HCV is mainly concentrated in people who inject drugs (WHO, 2016a). According to IBBS survey, Nepal also has the major burden of HCV in the PWID. There are different HCV prevention activities as seen in Table 9 formulated by the government for combatting the infection.

Table 9. Hepatitis C Infection Prevention Activities

- 1) Demand Generation Activities for HCV testing
- 2) Community meetings to educate on HCV, Including prevention and treatment Message
- 3) Government and community engagement on HCV

Source: MoHP, 2013

HCV serological test is offered as basic service which is given free of cost according to government health sector strategy 2015-2020. However routine screening test for HCV for the high-risk group such as inmates, sex worker, PWID has not been documented yet. The government of Nepal decided to start providing treatment for hepatitis C for HIV and hepatitis C co-infected patient with the financial aid from the Global Fund (MoHP,2015). However, it does not include the mass of the population who are mono-infected PWID and dominates the greatest burden of disease furthermore remaining as the key source of infection. There are no comprehensive and specific strategies on how to increase prevention and treatment approach for HCV predominantly in PWID from the government though HCV component is mostly amalgamated in the country National HIV strategic plan 2016-2021 without well-defined target, vision, goal and objective (MoHP,2016).

The WHO/UNODC/UNAIDS technical guide of the national target-setting framework for setting indicator and indicative targets for diagnosis and treatment of viral hepatitis has stated the following (Table 10) as a standard indicator for the HCV response in injecting drug users to have universal access.

Table 10. Indicators and indicative targets for diagnosis and treatment of HCV

Coverage **Target** Low: <5% Percentage of HCV-positive PWIDs receiving treatment Medium: > 10 - < 15% for HCV High: > 15%

Source: WHO, 2009

With the overall prevalence of 41.9% in PWID, there are estimated to be 21,861 HCV patients in Nepal.The government has planned to treat 1000 patient (only HIV-HCV coinfected) by 2020-21 (MoHP,2016). According to WHO technical guide, with 1000 patients, the percentage of HCV positive receiving treatment for HCV stays low (below 5% coverage). With this planning, Nepal will not achieve WHO medium (let alone high) coverage levels.

One of the major challenges for Nepal to roll out the HCV treatment remains with the financial constraints. However, availability and affordability of the new groundbreaking DAA (such as Sofosbuvir+Daclatasvir) for country like Nepal has become accessible with Nepal being added to the list of eligible countries for a voluntary license agreement for generic drugs purchasing in considerably less amount of money comparing to European and Western world (amfAR 2016;WHO 2016a).

3.3.3.4 Coordination and Networking

After years of prudence and challenges between MoHA and MoHP for management of the harm reduction program, coordination and the networking between the two main bodies was successfully established from the network of "Champions" such as local civil society group, doctors of psychiatry department at TUTH and international expertise of GIZ (Birdsall and GIZ,2016). The responsibility of the harm reduction program such as for OST; the licensing, purchasing and supply chain management is taken by MoHA whereas OST program implementation in the country is coordinated by MoHP.

Although there is no existence of punitive law in country for instance detention centers for PWID, death penalty for drug offence (WHO,2016b) policies such as the Narcotic Control Drug Act, which restricts the drug use and interchange of needles, and syringes hinders in the coordination between MoHP and MoHA (NCPI,2014). For example, if a drug user has obtained needle/syringe from a prevention program and caught on the way by the police will be harassed and detained in custody (Youth Vision, 2014).

3.4 Responsible Organizations to achieve Strategic Goal

3.4.1. Law Enforcement

Restrict Supply:

Under the administration of Ministry of Home Affairs, Nepal Police Narcotic Control Bureau (NCB) as per jurisdiction of narcotic drug control act with the objective of controlling illicit supply and use of narcotic drugs has been primarily working in Nepal to restrict the supply of drugs such as trafficking of pharmaceutical drugs (NCB,2016).

With the increased smuggling of pharmaceutical drugs from India to Nepal, the majority of the PWID in Nepal are injecting the pharmaceutical drugs such as diazepam, buprenorphine and Phenergan (Ojha et al., 2014).

In 2015, as a trafficked pharmaceutical drug NCB confiscated 25,056 ampules of diazepam and 18,950 ampules of buprenorphine in the country, which was trafficked through the open border of India with the market price of seized drug being 1,674,948 US Dollar (NCB,2016). Although the NCB rigours effort to intensify the checks and screen along the open Indo-Nepal border trafficking of the pharmaceutical drugs is challenging to control and still happening (**Picture**) which reflects the rising number of PWID who uses pharmaceutical drugs every year in Nepal(CBS,2013). Collaboration with the Indian government for controlling illicit drug trafficking is limited and has not been prioritised.

Picture: A drug trafficker of the Indian nationality arrested by Nepal Police at the entry point of capital Kathmandu on july 3, 2017 with 250 ampules of Diazepam, 169 ampules of Phenergan and 150 ampules of Buprenorphine.



Source: OnlineKhabar news portal, 3 July 2017.

Law enforcement agencies in Nepal view drug addiction as a crime (NCB,2016) rather than a problem that needs a medical attention which deters in running efficient and wide range coverage program such as NSEPs since drug users are often beaten, scolded and interrogated by police for using the drugs or having needle and syringe in their pocket (Youth Vision,2014).

3.4.2 Health Care System and NGOs

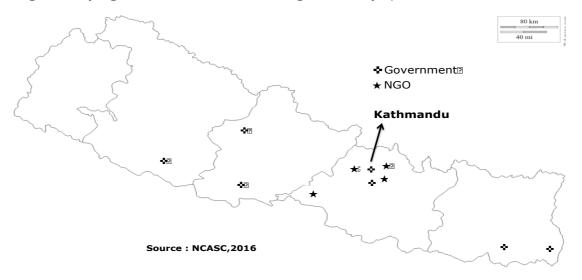
Reduction of the drug demands and the HCV transmission activities are facilitated by government hospital and local NGOs that are running either with government support or with the external donor funding in Nepal. These government hospital and NGOs undertake the responsibility of primary, secondary and tertiary prevention (MoHP,2016). Harm reduction program in Nepal is very much centralised.11 OST government supported sites are mainly located in central, or zonal hospitals (NCASC,2016). The government hospital services are often very time consuming and often lack essential medical supplies (Subedi,2011; Paudel et al.,2012).60 NSEP sites are distributing most of the needles /syringe with or without OST component and the distribution within itself are meagre in number (MoHP,2015). It raises questions on accessibility, acceptability, health impact and cost implication of these harm reduction services that have been running in the Nepal health care system for quite some time.

Reduce Demand:

OST Interventions

Through the funding support from Global Fund, currently, the government of Nepal is running OST program in eleven sites (seven government hospital and four NGO run sites) over the Nepal with the assistance from the Save The Children (NCASC,2016).Fig. 9 displays the OST location in different parts of Nepal.

Fig. 9 OST program location in different regions of Nepal, 2016

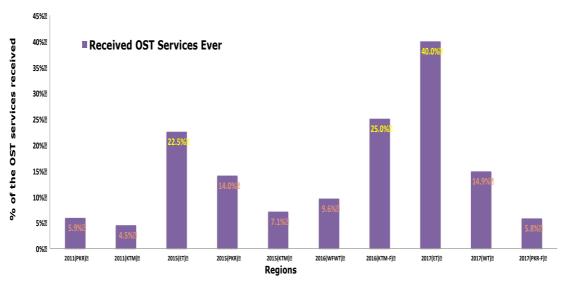


The primary task of service provider being clinical assessment, diagnosis, prescribing medical treatment, dispensing OST and referral to other health services as needed (Ambekar et.al,2010). The clinical care unit prescribes the treatment such as methadone and buprenorphine to the drug users to reduce the craving for the drug under their monitoring and supervisions so that drug demand of the person who uses drugs could be reduced. Social support unit, which is mainly run by the other NGOs perform the key function of identifying potential clients, counselling, referral to social services, ensuring adherence, improving access to OST program and psychosocial intervention (Birdsall and GIZ,2016). There are NGOs like Youth Vision that also runs the OST program in their four functional sites with funding from the other sources (Youth Vision, 2014).

The current functional HCV strategy of government and local NGOs are very much aligned with national HIV strategy. It contributes in tackling with HCV by reducing the risk of transmission. However with the evolving figures of mono-infected HCV frequency from IBBS survey for PWID across the region; effectiveness, accessibility and coverage of harm reduction program (OST&NSEPs) remains ambiguous.

Nepal has scaled up the OST program in the past few years by increasing the number of OST sites [Table 11] (HRI,2016) but client low retention to OST program as of setback such as daily visit to OST sites (accessibility), not getting service in time, service provider behavior remains a problem in delivering the services(Youth Vision,2014).OST program faces challenges such as low coverage and acceptance, no robust strategic coordination, scarce harmonised medical and communal facilities, and lacking female-friendly services (MoHP,2015).Figure 10 shows the OST coverage in different regions of Nepal.

Fig. 10 OST services received by PWIDs during IBBS from the year 2011-2017 in different regions of Nepal



Source : IBBS (2011ab, 2015abc, 2016ab, 2017abc) * PKR: Pokhara; KTM : Kathamndu; ET: Eastern Terai; WFWT:Western to Far Western Terai; KTM-F: Female ; WT : Western Terai ; PKR-F: Female

The OST coverage was documented between 4.5% to 40% for the PWID. The highest PWID endemic concentrated zone such as Kathmandu valley, OST coverage was found to be 4-7% (<20% is Low as the WHO indicator to achieve universal access (Fig.10).

Until July 2016, targeted intervention for PWID reflects coverage of 819 people on methadone and 528 on buprenorphine in the country (NCASC,2016) which in a positive note did manage to get close to the target of 1536 set by the government for the year 2016 (MoHP,2013).Nepal Prison Management Acts forbids the provision of the OST coverage to the drug user inmates (NCPI,2014). Table 11 shows the number of OST sites, number of people 5 on OST and the coverage rate.

Table 11. Number OST sites and total number of people enrolled in the OST program per Year

Indicator Titles	2012	2013	2014	2015/16
Number of OST Sites	3	6	15	15
Number of people on OST(Coverage)	538 (1.03%)	346 (0.7%)	640 <mark>(1.2%)</mark> Methadone(M):519 Buprenorphine(B):121	1347 (2.7%) M:819 B:528

^{*} Denominator taken as total people who Inject drugs in Nepal

Source: MoHP,2015; NCASC,2016

A publication from 2013 suggested that according to the WHO target setting guidelines the OST program in Nepal should be scaled up in a manner to tailor for 12,000 PWID with a national cost scaled up the program to achieve the universal access target (Ambekar et al.,2013).

Studies had shown that effectiveness of NSEP on reducing HCV infection was greater when NSEP were combined with OST as a strategy of full harm reduction

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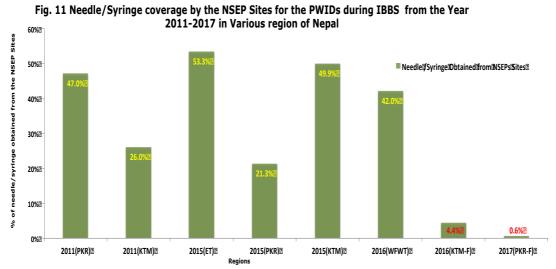
⁵ It includes the injectors and non-injector Opiates users. Size estimation of opiate users (injectors and non- injectors) is ongoing.

interventions rather than NSEP or OST alone (Fernandes et al.,2017). Nepal number of OST and NSEP combined sites remain inadequate to have a full harm reduction coverage level.

The author did not manage to find any available data and reports on the effectiveness of OST program in Nepal. Although a study done amongst 153 drug users in Kathmandu showed that after their rehabilitation (detoxification with abstinence), half of them relapsed and could not remain drug-free within one month (NCACS,2010). During an interview with a physician providing the OST to the patient in one of the OST, sites stated that patient does relapse who are in OST and needs to be reintroduced in the program (Birdsall and GIZ,2016). It reflects that a sound mechanism with performance indicator integrated with target indicators to know the effectiveness of the OST program in Nepal is required to tailor the program according to the necessities of the patient.

NSEP Interventions

There are altogether 60 NSEP sites running in 28 districts by Save The Children under GFATM and NCASC from the pooled fund and by UNODC through their implementing partners with a targeted intervention of NSEP for PWID (MoHP, 2015;WHO,2016b). Although Nepal has embraced and scaled up NSEPs service and sites (Table 12) (HRI, 2016), the percentage of PWID reached by NSEPs according to IBBS surveys and WHO indicator rests between Low to Medium. There are no data available for the percentage of PWID reached by NSEPs in the past month but the data for percentage of PWID who used non-sterile needle/syringe in the past month range between 3-7%(IBBS 2011ab,2015abc, 2016ab,2017abc).Fig. 11 shows the coverage of the NSEPs in different regions of Nepal.



Source : IBBS(2011ab,2015abc,2016ab,2017abc) * PKR: Pokhara; KTM : Kathamndu; ET: Eastern Terai; WFWT:Western to Far Western Terai; KTM-F: Female ; WT : Western ; PKR-F: Female

The needle and syringe exchange program coverage level was as high as 53% in PWID to as low as 0.6% for FWID in some region (Fig.11) (>20-<60% is medium as per WHO indicator for universal access). The number of needles and syringes distributed to PWID has improved compared to past decade, which was 20,000-25,000/month in 2007 to 1,521,054/month in 2016 (UNODC,2007; NCASC,2016). But the trend of distribution has been declining since 2013 while no specific reason was stated for the decrease in needle and syringe being distributed (Table 12). According to NCASC data from 2016 (1,521,054), the needle/syringe distributed per PWID per year with 52,174 PWID being in the country was estimated to be 29 needle-syringe on average(<100 is Low as per WHO Guide). Table 12 reflects the data on the number of needle and syringe distributed per year since 2013.

Table 12. Targeted intervention of NSEP for people who inject drugs

Indicator Titles	2013-2014	2014-2015	2105-2016
Districts covered	23	23	28
Total needle /syringe exchanged or provided	1,731,095	1,663,213	1,521,054

Source: NCASC,2016

20122

The number of needles/syringes distributed to per PWID in 2012 was 36 per person(UNAIDS,2014; WHO,2016b). Nepal coverage is very low for the needle and syringe distribution per person who injects drugs while comparing it with the WHO NSEPs coverage indicator for syringe distributed per PWID per year (Table 8). Fig. 12 demonstrates the number NSEP sites and needle and syringe distributed per PWID per year by NSEPs in Nepal according to the government.

Fig. 12 Number of scaled up NSEP sites and distribution of needle/syringe per PWID per Year (2012-2014) in Nepal

Number of NSEPs Sites

Number of Needle Syringe Distributed per IDUs per year by NSEPs

602

442

202

102

2013

20142

The reason for such a low coverage and distribution of needle/syringe in Nepal can be inferred as the NSEPs still seen as encouraging up people for taking drugs (WHO,2010) while country's existing laws, regulation and policies such as Narcotic Control Drug Act restricts exchange of needles and syringes (NCPI, 2014). These impediments pose a significant barrier in commencing the prevention program such as NSEPs for harm reduction to reduce the transmission of infectious disease like HCV. However, to an extent, NSEPs are tolerated, and the special exemption is given by the government to the service provider. WHO estimates that the number of needle syringe distribution required for the prevention of HCV are expected to be much greater than what WHO has formulated in their NSEPs coverage indicator and indicative targets [Table 8] (WHO,2009). Nepal existing laws, regulation and drug policy such as 1976 Narcotics Control Drug Act, which has not been amended since 1992 holds a strong law enforcement emphasis poses barriers for NSEP (NCPI,2014).

HCV Treatment:

Source: MoHP, 2015

One of the arguments for not providing HCV treatment to PWID is the fear that they will get reinfected again (Aspinall et al.,2013; Lindenburg et al.,2011). So is it worth it? With the Drug relapse, there are chances that PWID who receive the

⁶ WHO has based the target upon studies in developed country settings investigating the levels of syringe distribution and impact on HIV transmission. Note that the levels required for the prevention of HCV are likely to be much higher than those presented in the targets. Pharmacy sales of needle syringe are not available easily. In most cases only, data on the number of syringes distributed via NSEPs are more accessible.

hepatitis C treatment can get reinfected if they continue with the risky behaviour such as needle sharing.

However, according to a study conducted in hepatitis C virus reinfection following treatment among people who use drug showed that HCV re-infection amongst the injecting drug users is low during and after the treatment even if the individual continues injection drug use (Grady et al., 2013).

Evidence has shown that HIV negative drug users with HCV infection can be treated successfully in a multidisciplinary setting despite active drug or alcohol use and psychiatric diseases. Therefore, drug user population access should be increased to HCV therapy using an integrated approach (Lindenburg et al., 2011). The availability and affordability of HCV treatment for the mono-infected PWID in Nepal require an answer(MoHP, 2013). Entire HCV monoinfected PWID are left behind in the government planning.

Treatment as a prevention for HCV is still not envisaged in Nepal although a government supported NGO has started treating 150 HIV-HCV co-infection patients since 2015(MoHP,2015). Evidence has displayed that by treating the HCV positive patient and achieving the sustained virologic response has an association that is not only limited to clearing the viral infection but it can improve clinical outcomes in a longer run, economic benefits and better health-related quality of life.A systematic review on hepatitis C treatment showed that after the HCV treatment and sustain virologic response(SVR), the risk of developing liver related mortality(Relative risk [RR] 0.03-0.2), hepatocellular carcinoma(RR 0.1-0.25) and overall mortality(RR 0.1-0.3) significantly decreased in comparison to the patient who did not receive the treatment. The medical cost was 13 fold lower, and health utility values were higher in those who achieved the SVR after the treatment (Valentine et al., 2015).

However, despite these evidence the government HCV treatment investment plan fund (MoHP,2013) have only included few HCV positive patients (predominantly HIV-HCV coinfected and no HCV monoinfected) in the treatment plan for the future in Nepal.

Treatment of HCV is evolving with new drugs (such as RG 101, a hepatocyte targeted N-acetylgalactosamine conjugated anti-miR-122 oligonucleotide), which might be more effective and achieve SVR in a shorter time in the future (Meike H van der Ree et al.,2017).

3.3.3 Civil Society



Advocacy

A Civil society such as Recovering Nepal, the national organisation of drug users that was established in 2001 and other civil groups actively play a role in the securing the human rights, justice and equity for the drug users. These civil societies consistently advocate for the evidence based and access to free treatment, attention and care for the drug users and involvement of them in planning, decision-making and drafting of program related to drug users such as harm reduction program or HCV intervention (Birdsall and GIZ,2016). They continuously raise their voice to make the government hear about the need and demand of the drug users, for instance, police brutality against people who use drugs, rehabilitation services and social welfare to reintegrate drug users back in the society (Youth vision, 2014). Government of Nepal has been involving civil society in developing and implementing the community level services as that of the HIV or HCV prevention (MoHP,2016) but instances like drafting of the HCV

guidelines without their involvement led them to protest against the government in the street showing their dissatisfaction and concerns (ANUPUD, 2016).

3.5 Monitoring and evaluating the Performance indicator

Nepal does have a monitoring and performance indicator evaluation plan for HIV in its strategic planning with service provider periodic reporting on the epidemiological trend, sentinel surveillance and IBBS studies organised by National Center for AIDS and STD Control (MoHP,2016).Lately from 2015 IBBS studies for PWID has also started reporting on the prevalence of HCV while OST and NSEPs coverage has been documented in IBBS since 2009. However, monitoring and evaluation for program performance indicator, patient drop out from the harm reduction programs are mostly missing to understand the current effectiveness and coverage level of harm reduction programs in the country. There was no known detailed evaluation mechanism found to reflect on needed adaptation on strategic planning of intervention and for the policy makers to envision the magnitude of the HCV and harm reduction problem (Fig.7).The absence of such informing mechanism seems to be creating knowledge gap amongst the policy maker for designing more evidence based central operational policy regarding the harm reduction and HCV treatment for the country.

Chapter IV: Discussion

The results suggest that the high prevalence may be attributed to issues on all levels. Below the main themes per level will be discussed related to each other.

In level 1, after analysing the findings, the main hurdles are observed on the level of political commitment. The HCV investment plan and harm reduction strategy are formalised, but the funding and implementation of these programs are not clear. There is no formalised Hepatitis-C policy. PWID are perceived by the government as challenging and neglected population. HCV seems a lower priority on the political agenda than HIV.

Nepal Narcotic Control Drug Act does not permit needle exchange. Harm reduction programs are not entirely scaled-up and are focused on centralised hospital services. Narcotic drug control policy is neutral about the NSEP program but has promoted the OST program since 2014. Better harm reduction coverage might be achievable if the Act and Policy are revised.

In level 2, lack of research and absence of monitoring and performance indicators for harm reduction program hampers improvements in service delivery to drug users. It indicates the low visibility of the harm reduction program outcome and hinders the planning and restructuring of the interventions. For the resources that have been put in place, the performance indicator must show the results of the interventions. The dearth of such an evaluation process results in a poor understanding of the HCV epidemic. So we don't know what is (not) working, why it is not working, what needs to be adapted and reformed, and whether the programs are placed strategically in the right place for the right people at the right time. These questions need a precise answer from the Nepalese government to reduce the HCV epidemic as a public health threat.

In level 3, there are several problems with planning the HCV response in Nepal. Key data (such as prevalence, incidence, mortality, etc.) are unavailable to interpret and conduct the critical analysis. Some data are outdated. NGO data are not accessible, and there is no size estimation for PWID. The objectives of HCV and harm reduction are still not clear. PWID carry a significant burden of HCV in Nepal. The risky behaviour such as needle sharing is still one of the leading causes

of HCV transmission amongst PWID in Nepal.Distribution of clean needle/syringes remains very low per PWID per year.

Guiding principles such as human rights, equity, inclusiveness, and client-centredness are included in the harm reduction programs carried out by the government of Nepal.But there is no overarching principle for the HCV and harm reduction response.Limited availability of comprehensive client-centered services, police brutality against the PWID and limited ownership of the programs given to the PWID community remains a challenge to address HCV response in the country.

It is surprising to note in figure 3 that HIV+ PWID are not spreading HIV infection as much as the HCV+ PWID, as the HCV prevalence increases faster than HIV.Does this reflect a deficiency of the strategic planning for HCV program to minimise its prevalence? Or is the HIV program strategy of "treatment as prevention" effective? Why is this effect not observed with HCV?

It looks like HIV harm reduction strategies work better than HCV.One possible explanation could be that HCV is more infectious (a much smaller quantity of blood necessary to transmit infection) than HIV.Whatever the reason, the government has not prioritised the HCV epidemic with explicit policy, planning and program.

In Level 4 & 5, the coordination between law enforcement agencies and MoHP needs more collaboration. Practices such as beating, detention and interrogation of drug users are frequent in Nepal. It poses significant obstacles to organise the NSEP. Sensitization of the law enforcement agencies on considering drug addiction as a necessity for medical attention rather than a crime remains vital to delivering the harm reduction program. Illicit drug trafficking across the porous Indo-Nepal border remains a significant challenge for the law enforcement agencies. With the trend of drug users doubling almost every six years and the resulting illicit drug trafficking, it seems like drug addiction problem and its related morbidity and mortality is going to be worse in future for Nepal if no sound policy and strategies to control it are put in place.

Harm reduction services and its coverage in Nepal for people who inject drugs remains low to a medium level such as OST and needle/syringe distribution services for averting and halting the epidemic of hepatitis C.The health care system for harm reduction and HCV program in Nepal are yet to be decentralised. There is no harm reduction program at district and primary health care level. Many of the government health care facility is located in central, or zonal hospitals. It creates inconvenience in accessibility and acceptability for PWID to use the services. HCV high-risk group screenings are not planned strategically and are not in the place yet. One of the possible interventions would be to decentralise the full-scaled harm reduction program to the district hospital, and primary health care centre under constant monitoring, evaluation and research of the program with the necessary restructuring of the services as per see during the process. The existing human resources, for example, health care worker working in the district hospital and PHCC needs to be trained for decentralised large-scale harm reduction program.

Nevertheless, the availability and accessibility for Nepal to get the generic HCV drug for a price as low as 36 US dollar and the efficacy of the new DAA treatment with a side effect significantly lower than the Peg-INF/RBV can help to achieve the high adherence and treatment success rate even better than outcome that has been observed in Aspinall et al. review.It can help towards reducing the HCV prevalence rate and associated morbidity and mortality in the country while following the footway of WHO to eliminate viral hepatitis by 2030 as a public

health threat. There are new treatments for HCV under study and research is ongoing on treatments which are of even shorter duration and higher effectiveness. Nepal has to keep itself informed about these new developments in the field of HCV.

In a broader context for the role of NGO, there was hardly any data available. It is still unclear that how significant is the current role of NGOs and what kind of role they could have for drug use and HCV control programs in the future. HIV programs are vertical in Nepal, and there is no clear clarification either if HCV program is going hand in hand. It is clear that HIV single policy with amalgamated HCV component within itself is not sufficient to change and improve the HCV response in health care system of the country. It has to be aligned with each other with their specific targets, indicator, goals and objective.

Finally, there is a need for more collaboration and coordination between different stakeholders such as MoHP, civil society, and PWID representative community. PWID are often discriminated and stigmatized by the community in every part of society, which could have had lead towards not giving the appropriate attention to this key population by the government and service providers resulting in few programs and minimal service coverage for prevention, treatment, and harm reduction needs which eventually is driving the spread of HCV amongst PWID in Nepal.

There might be some biases in this study. One of them could be the underestimating the cost and overestimating the HCV prevalence (prevalence study sample not representative for the whole country. Carried only amongst the people with health care seeking behaviour). The other one might be there are NGO data missing for HCV cases.

Chapter V: Conclusion

The elements of HCV problems are fundamental for Nepal to address as soon as possible in order to reduce the HCV incidence and prevalence in the country to be in alignment with WHO Strategy of Global Health Sector Strategy (GHSS) on viral hepatitis that aims at reducing the new infections by 90%, mortality by 60% and elimination of viral hepatitis as a public health threat by 2030. There is a necessity for Nepal to have a central HCV comprehensive policy if it wants to align itself with WHO path on the elimination of viral hepatitis. Nonetheless, commitment from politicians who are responsible for policymaking and fund allocation for such kind of activities, which in their opinion has an unfavourable public understanding, remains the key to success.

Current Narcotic Control acts bring difficulties in enabling more responsive harm reduction program to PWID. These laws need to be looked into thoroughly and require revision. Nepal has to envisage and work towards full implementation of a structural level harm reduction program tailored to distribute >200 needles/syringes per PWID per year with a large-scale combination of NSEP and OST program having a high coverage and decentralisation of the services. It is feasible in its context with already available health workers and services on the ground such as district hospital and primary health care centres to reduce the HCV burden in the country.

To address the illicit drug trafficking, Nepal needs to take these issues as a serious matter and address it to the Indian government for more rigorous efforts in border control to minimise the trafficking of drugs from India to Nepal.Nepal does not have a production line for HCV drugs. Nepal does not currently collaborate and coordinate with Indian government or private sector for a large volume purchasing agreement of less expensive generic HCV drugs.

Treatment of HCV as "health for all" and as constitutional human rights seem to be inevitable to be integrated with the structural level program to achieve reduction of HCV infection. It needs to be conveyed close to the drug user community to let them have the responsive, non-judgmental, safe and reliable access. New treatments for HCV are evolving from the scientific world. Currently, policies do not include the current state of science let alone include a vision on these new changes for the future HCV intervention.

Likewise, drug users are currently not sufficiently involved and mobilised by an interactive process of Behavior Change Communication (BCC) at district or primary levels. There is a potential that they can help the drug user community to reduce the drug related harm, incidence and prevalence of the HCV by giving them a sense of ownership of the program that they are involved with.

Effectiveness and accessibility of harm reduction programs are currently not assessed by appropriate evaluation and feedback to policy makers. Research on what is working and what might need a restructuring while delivering the service in the future is scarce.

Chapter VI: Recommendation

- 1. The government should amend the narcotic control drug act to allow the exchange of needles in harm reduction programs.
- 2.A future HCV policy developed by the government should take into account the concept of UN like "Leave no one behind" for the HCV program under the memo of health for all, human rights and equity.
- 3.DoHS should start screening and make tests available for all groups at high risk of HCV infection, such as PWID and imprisoned people.
- 4.The Government should integrate OST with NSEP into a national harm reduction programme and allow the decentralization of the services.
- 5.DoHS should train service providers to provide care for PWID using non-judgmental attitude.
- 6.The government should create a central multidisciplinary technical working group involving primary care physicians, HCV experts, psychiatrists, nurse counsellors, civil society, social workers, and PWID to amplify consistency and stability of harm reduction and HCV treatment programs at primary care level.
- 7.The government should liaise with the Indian government on sourcing and purchasing of less expensive generic HCV treatments, and negotiate cooperation in border control of illicit narcotic drug trafficking.
- 8.MoHP is advised to keep themselves up to date with new evolving changes in the field of hepatitis C treatment. A two yearly revision of existing policy and treatment guidelines is necessary in the light of rapid developments on HCV treatment.
- 9.MoHP to promote hepatitis research on the retrospective study of morbidity/mortality and sequelae (for liver cirrhosis or HCC), prevention (effectiveness of NSEP and OST program) and treatment of hepatitis to inform policy makers on future need and change for HCV program.

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