The effectiveness of the Stockholm needle exchange programme.

Does the Stockholm needle exchange programme control HIV, Hepatitis B, and Hepatitis C in intravenous drug users?

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Abstract

BACKGROUND:
The needle exchange programme (NEP) started in Sweden in 1986 in Lund and shortly after in Malmo. The first NEP in Stockholm opened in spring 2013. The NEP is a service aimed at intravenous drug users (IDU) from 18 years old, with a goal of preventing the blood borne diseases, such as HIV, Hepatitis B (HBV), and Hepatitis C (HCV). With the on going HIV and Hepatitis epidemics, numerous countries around the world have adopted control strategies, such as the NEP to halt the spread of HIV, HBV, and HCV. The objective of this study was to examine if the needle exchange programme has decreased the incidence of HIV, HBV, and HCV in Sweden over a six-year period.

METHODS:
Data for incidence and prevalence was extracted from the yearly reports of the Stockholm's needle exchange programme from 2013 to 2018 and the yearly reports of the public health agency in Sweden from 2013 to 2018. The data was collected for Stockholm, and compared to Västra Götaland, and the whole of Sweden.

RESULTS:
The incidence of HIV was zero in 2013 and 2015 in the NEP. The incidence of HBV decreased to zero in 2013 in the NEP. There is an increased incidence of HCV in the NEP.

CONCLUSION:
The NEP has a protective effect through its combination of needle exchange, opiate substitute therapy, counselling, and vaccinations in reducing and stabilising incidences of the infections, in some instances to zero, as well as providing surveillance and treating infections.

Key words: Needle exchange programme (NEP), Intravenous drug users (IDU), Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV),

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INTRODUCTION

BACKGROUND

The needle exchange programme (NEP) started in Sweden in 1986 in Lund and shortly after in Malmo (Riksdagen.se, 2019). The first NEP in Stockholm opened in spring 2013 (Petersson, 2019). The NEP is a service aimed at intravenous drug users (IDU) from 18 years old, with the goal of preventing blood borne diseases associated with drug use, such as HIV, Hepatitis B (HBV), and Hepatitis C (HCV). NEP distributes clean needles in exchange for used, offers support in breaking drug addiction by counselling, opiate substitute therapy, and social support. NEP also provides vaccinations, midwife consultation, distribution of condoms, naloxone, which is an anti-overdose agent, and general healthcare. (Petersson, 2019; Socialstyrelsen.se, 2019). Today, it is estimated that 13 million people around the world are IDU. Ten percent of the world's HIV infections are due to intravenous drug use. In addition, 67 % of IDU are infected with HCV and 2.2 million have a co- infection of HIV and HCV (World Health Organization, 2019).

With the on-going HIV and hepatitis epidemics, numerous countries around the world have adopted control strategies, such as NEP, to halt the spread of the blood borne infections. It has been argued that if the NEP had been implemented earlier, it would have reduced the number of HIV infections and reduced the cost of treating the infectious, where some are life long treatments (Lurie & Drucker, 1997). Lurie and Drucker (1997) argue that if USA had implemented the NEP earlier, 15 % of their HIV infections could have been reduced, which would have resulted in a 33% overall reduction of HIV, saving 244-538 million dollars. This suggests that the NEP is a cost effective treatment in regard to preventative measures being cheaper than treatment.

Comparing the efficacy of NEP verses HIV counselling revealed that countries that had higher level of counselling showed a significantly larger reduction in HIV infections, compared to countries that had a higher use of the NEP and lower counselling rates (Amundsen et al., 2003). This suggests that counselling can be incorporated in reducing HIV and hepatitis infections rather than be replaced by NEPs, where the focus is mainly on needle exchange (Amundsen et al., 2003).

A Meta analysis conducted by Mir et al (2018) concluded that more research is needed in order to observe the effectiveness of the needle exchange programme, as different articles in the Meta analysis had different outcomes. Confounders that affect results when investigating the effectiveness of the programme, such as, risky sexual behaviour, can affect the overall results if they are not adjusted for in the analysis. However, although more research should be conducted, Mir et al (2018) concludes that the NEPs are important in controlling HIV, in combination with counselling and education, which emulates the Amundsen et al (2013) study, that NEPs should not replace traditional methods but rather be used in combination.

Heroin users have increased substantially over the last ten years (Cotter, Stier, and Aronsohn, 2018). Seventy five percent of HCV infections are attributed to drug injection making NEPs being more critical than ever (Cotter, Stier, and Aronsohn, 2018). Furthermore Cotter, Stier, and Aronsohn (2018) argue that NEP reduces HCV transmission and risk behaviours, as well as reducing health care costs. In addition, there is conclusive evidence that shows that the NEPs are effective in reducing HIV and hepatitis. Moreover, 2 to 6.7 million dollar can be saved with the implementation of the NEPs, which is concurred by Lurie and Drucker (1997), who argue that the NEPs are cost effective in controlling HIV transmissions.

On the other hand, O'Riordan, Khan, and Mazulis (2019) argues that there is no direct evidence that suggest that NEPs are effective, highlighting that there has not been any randomised control trials conducted to test the effectiveness of the programme. Furthermore, the cost of operating the NEPs has increased simultaneously with the number of acute HCV infection among young people, between the ages of 20 to 30 over the years. However, O'Riordan, Khan, and Mazulis (2019) highlights that there is a significant improvement in reducing the HCV transmission due to the combination of opioid substitute therapy, counselling, and needle exchange as compared with programmes where only needle exchange is used. Cotter, Stier, and Aronsohn (2018) and O'Riordan, Khan, and Mazulis (2019) agree that the NEPs should be used in combination with counselling and opioid substitute therapy to maximise the effect of the programme.

A study was conducted at a Swedish needle exchange programme that examined the prevalence and incidence of HIV, HBV and HCV of IDU who had attended the NEP between 1997-2005 by a follow-up blood test. It concluded that the needle exchange programme had a protective effect in HIV transmission but highlighted that this can be due to the low prevalence of HIV in Sweden (Blomé et al., 2010).

The results showed that the HBV transmission was significantly reduced due to the NEP offering other services such as vaccination e.g. HBV vaccine. Despite the reduced transmission of HIV and HBV, HCV continues to increase in IDU (Blomé et al., 2010).

Control of HCV has proven to be challenging, which is in accordance with previous meta-analysis and review articles, however there remains difficulties in conducting a randomised control trial, in order to get a ”true” value of the effectiveness of the NEP. The NEP has shown to contribute positively by reducing HBV infections and offering other types of services, such as cervical cancer screening to a vulnerable population, who would otherwise have difficulties accessing these services.

STUDY PURPOSE

The NEP is an evidence-based approach and is recommended by WHO and the UN (World Health Organization, 2019). The public health agency in Sweden recommends the use of needle exchange programs in order to reach high risk groups such as, person who inject drugs, in order to control and monitor blood borne diseases (Folkhalsomyndigheten.se, 2019). As mentioned previously, other studies have pointed at low number of experiments that measure the effectiveness of the NEPs.

With the increased drug abuse in the world, and the on-going battle in controlling HIV and hepatitis, it is important to examine the incidence of HIV, HBV, and HCV over a longer period of time, in order to determine if the NEPs are effective in reducing or stabilising the incidence, thus showing if the NEPs is efficient enough and contributes to the battle in controlling the blood borne disease.

AIM

The objective of this study is to examine if the needle exchange programme has decreased the incidence of HIV, HBV, and HCV in Stockholm, Sweden over a six-year period.

RESEARCH QUESTION

Does the needle exchange programme decrease the incidence of HIV, HBV, and HCV in people who inject drugs?

METHOD:

Data for incidence and prevalence was extracted from the yearly reports of the Stockholm's needle exchange programme (NEP) (Petersson, 2019) and the yearly reports of the public health agency in Sweden from 2013 to 2018 (Folkhalsomyndigheten.se, 2019)

The data was collected for Stockholm, and compared to Västra Götaland, and the whole of Sweden. The region Västra Götaland is located in South West of Sweden, mainly surrounding Gothenburg. Västra Götaland was selected because it is the second largest populated region after Stockholm and it did not have a needle exchange programme during the studied period.

STUDY POPULATION

Between 2013 and 2018 the Stockholm needle exchange programme had 3281 individual visitors using their services. 3245 persons were enrolled during the study period and were included in this study.

THE NEEDLE EXCHANGE PROGRAMME STOCKHOLM

All individuals admitted to the NEP were included in the analysis. All individuals who were enrolled in the programme were tested in order to determine if they had an HIV, HBV, or HCV infection at the initial stages of the programme. They were further tested every 3 to 6 months to determine if an infection had been acquired or not. Persons visiting the needle exchange programme but not enrolled were not included in this study. The number of people that had contracted HIV, HBV or HCV at the end of the year where included in order to reveal the incidence within the study population attending the needle exchange programme. The number of people testing positive at the initial stages of their enrolment were included in order to reveal the prevalence of HIV, HBV, and HCV among those who attended the programme. The data did not account for loss of follow up and assumes that all participants were tested throughout all the years. There was no data available for incidence of HBV in the NEP in 2014, 2016, and 2017 and for HCV in 2016 and 2017.

PUBLIC HEALTH AGENCY SWEDEN

Data on the overall incidence of HIV, HBV, and HCV for the entire population was collected for each year from the public health agency. Incidences on HIV, HBV, and HCV were collected for Stockholm, Västra Götaland, and the whole of Sweden. There was no data available for incidence of HIV in Stockholm and Västra Götaland in 2014 and 2018 and HBV and HCV in Stockholm, Västra Götaland, and Sweden in 2018.

The data was compiled and plotted in excel using a scatterplot in order to visualise the incidence rate during the studied period. Incidence values are plotted at a log scale in order to be able to compare properly the higher values in the NEP study population with the lower incidence values in the regional and country wide populations. Changes in the incidence over time are shown with linear and exponential trend lines. In order to measure a significant decline, a linear regression test was conducted where applicable. Values of $P \leq 0.05$ are considered significant.

RESULTS:

Table 1: The number of person enrolled in the NEP who were HIV negative, HIV positive, acquired HIV during the programme, prevalence, and incidence.

Year	**Nr. enrolled**	**HIV –**	**HIV +**	**HIV new case**	**Prevalence**	**Incidence**
2013	963	887	76	0	0.07892004	0
2014	634	632	1	1	0.00315457	0.00158228
2015	495	494	1	0	0.0020202	0
2016	393	374	15	4	0.04834606	0.01069519
2017	392	379	10	3	0.03316327	0.00791557
2018	368	354	12	2	0.03804348	0.00564972

Table 2: The number of person enrolled in the NEP who were HBV negative, HBV positive, acquired HBV during the programme, prevalence, and incidence.

Year	***Nr. enrolled***	***HBV-***	***HBV +***	***HBV new case***	***Prevalence***	***Incidence***
2013	963	950	13	0	0.01349948	0
2014	634	-	15	-	-	-
2015	495	489	2	4	0.01212121	0.00817996
2016	393	-	4	-	-	-
2017	392	-	6	-	-	-
2018	368	364	3	1	0.01086957	0.00274725

Table 3: The number of person enrolled in the NEP who were HCV negative, HCV positive, acquired HCV during the programme, prevalence, and incidence.

Year	Nr. enrolled	HCV -	HCV +	HCV new case	Prevalence	Incidence
2013	963	235	722	6	0.75597092	0.02553191
2014	634	85	515	34	0.8659306	0.4
2015	495	102	356	27	0.77373737	0.26470588
2016	393	-	269	-	-	-
2017	392	-	253	-	-	-
2018	368	177* (85)	191	92	0.76902174	0.51977401

()- Overall number of people not infected with HCV at the yearly review.

**- Number of people at risk of being infected.*

The HCV+ are persons with an active HCV infection.

HIV

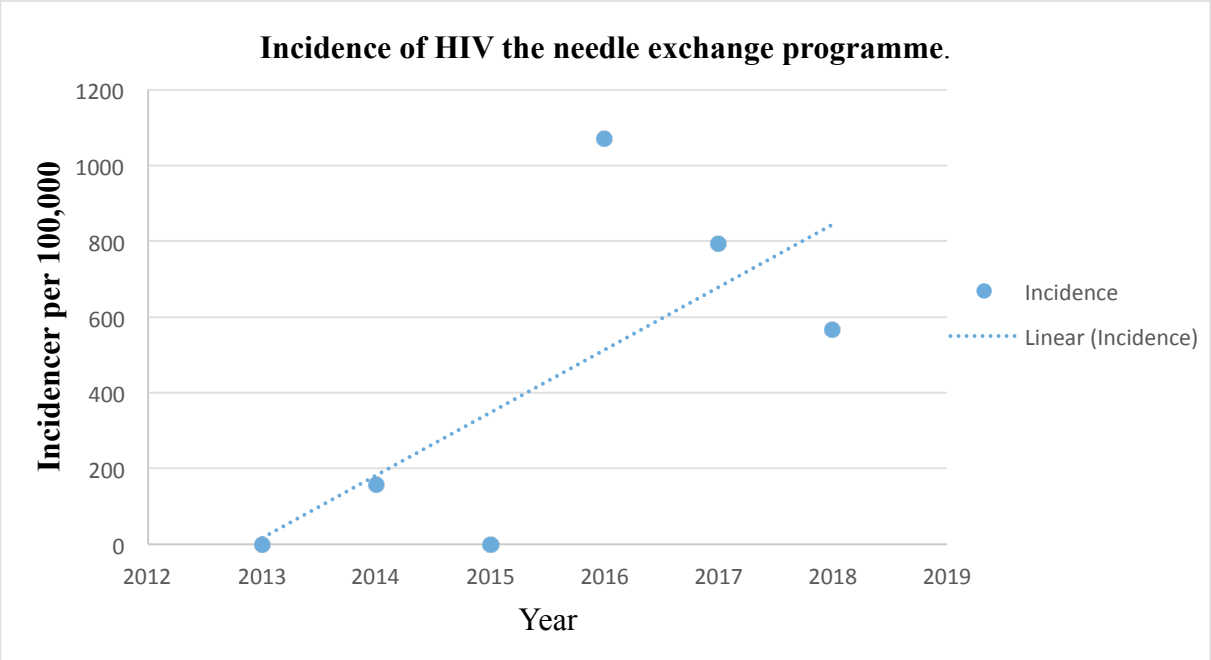

Figure 1: Incidence of HIV in intravenous drug users (IDU) in the needle exchange programme (NEP) between 2013-2018.

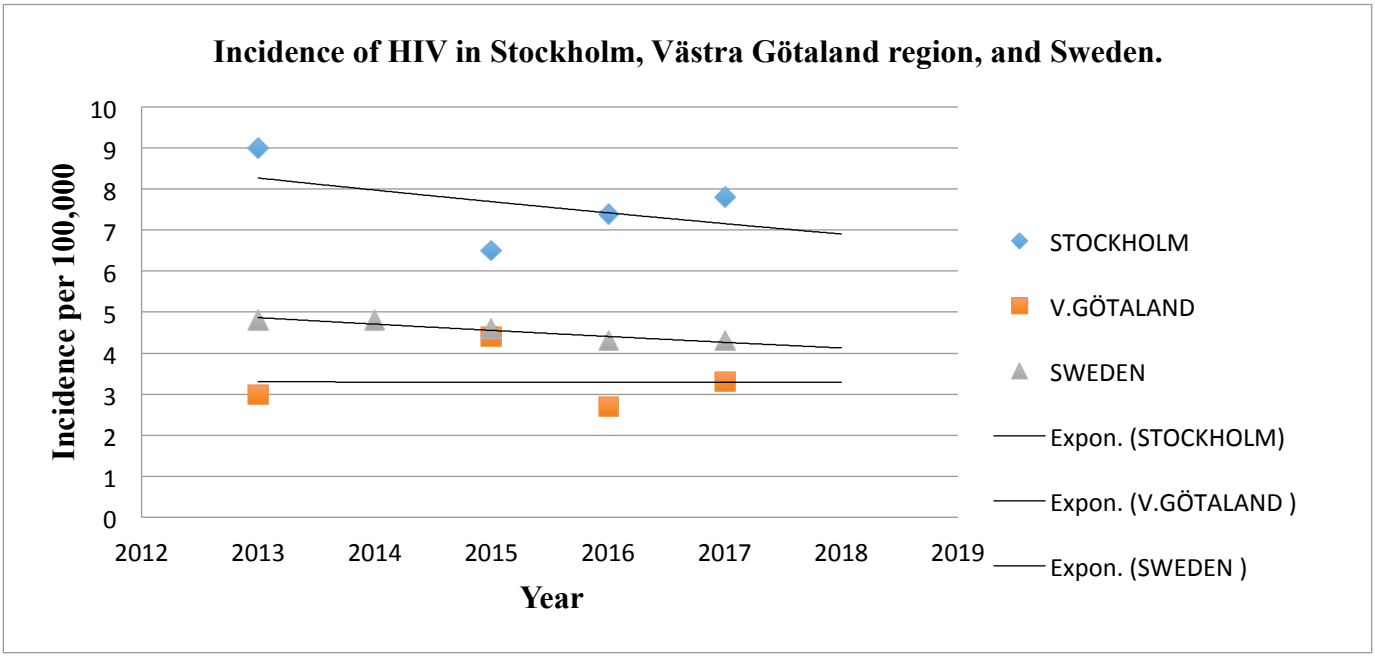

Figure 2:Incidence of HIV in Stockholm, Västra Götaland region, and Sweden. between 2013-2017.

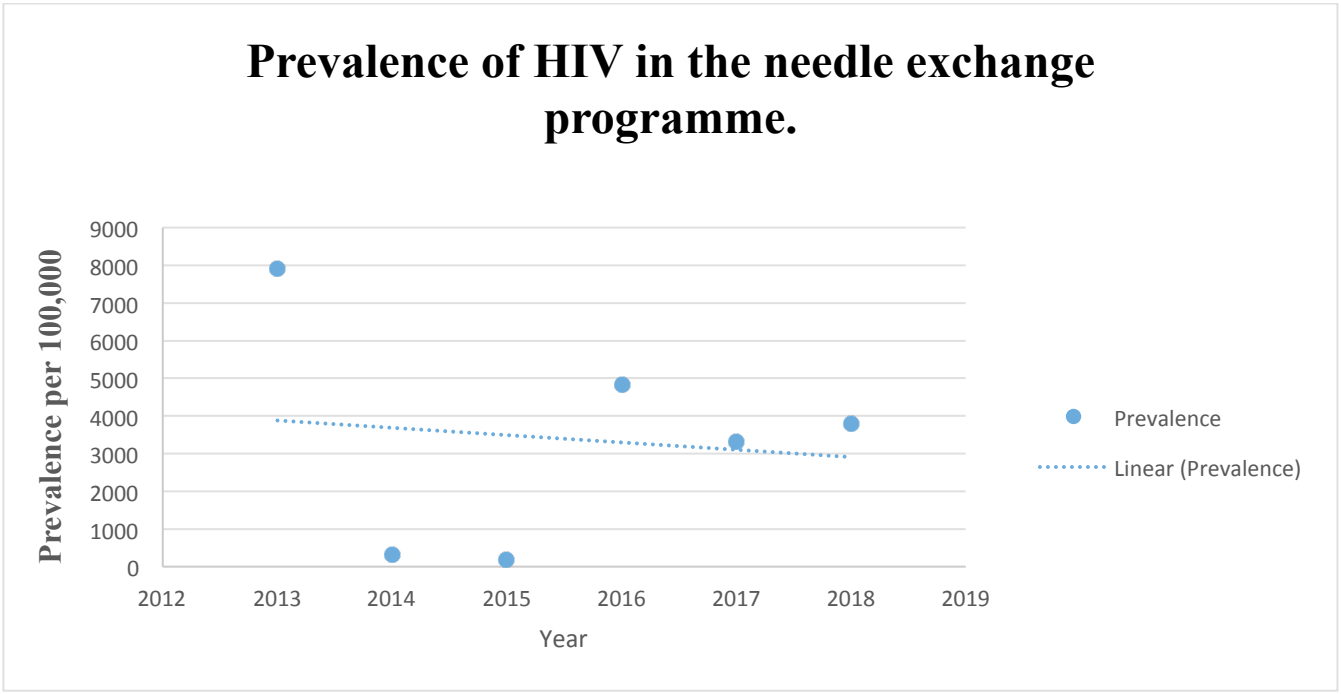

Figure 3: Prevalence of HIV in intravenous drug users (IDU) in the needle exchange programme (NEP) between 2013-2018 in Stockholm.

The incidence of HIV decreased to zero in 2013 and 2015 in the needle exchange programme (NEP) (*Figure 2*). The NEP has had an overall higher incidence of HIV compared to Stockholm, Västra Götaland and Sweden (*Figure 1 and Figure 2).* The NEP has had a lower

incidence of HIV below the Stockholm and Västra Götaland and the whole of Sweden in 2013 and 2015 *(Figure 1 and Figure 2).*

The incidence of HIV is higher in Stockholm region than in Västra Götaland and the whole of Sweden (*Figure 1*). The trend lines show a slow decline in HIV incidence in Stockholm region and the whole of Sweden but a stable incidence in Västra Götaland region *(Figure 1).* Though, the trend line shows an increase in HIV incidence in the NEP *(Figure 2).*

A high prevalence is seen in 2013 at the start of the programme as compared to the following years. The trend line shows a steady decline in prevalence of HIV in the NEP *(Figure 3).*

HEPATITIS B (HBV)

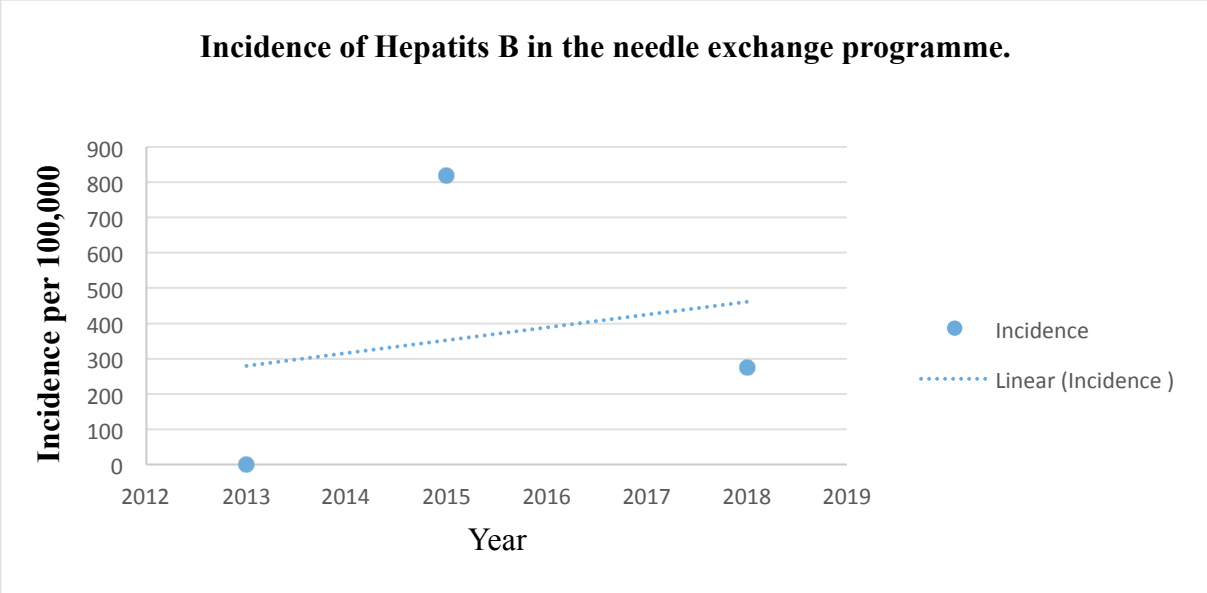

Figure 4: Incidence of Hepatitis B (HBV) in intravenous drug users (IDU) in the needle exchange programme (NEP) between 2013-2018 in Stockholm.

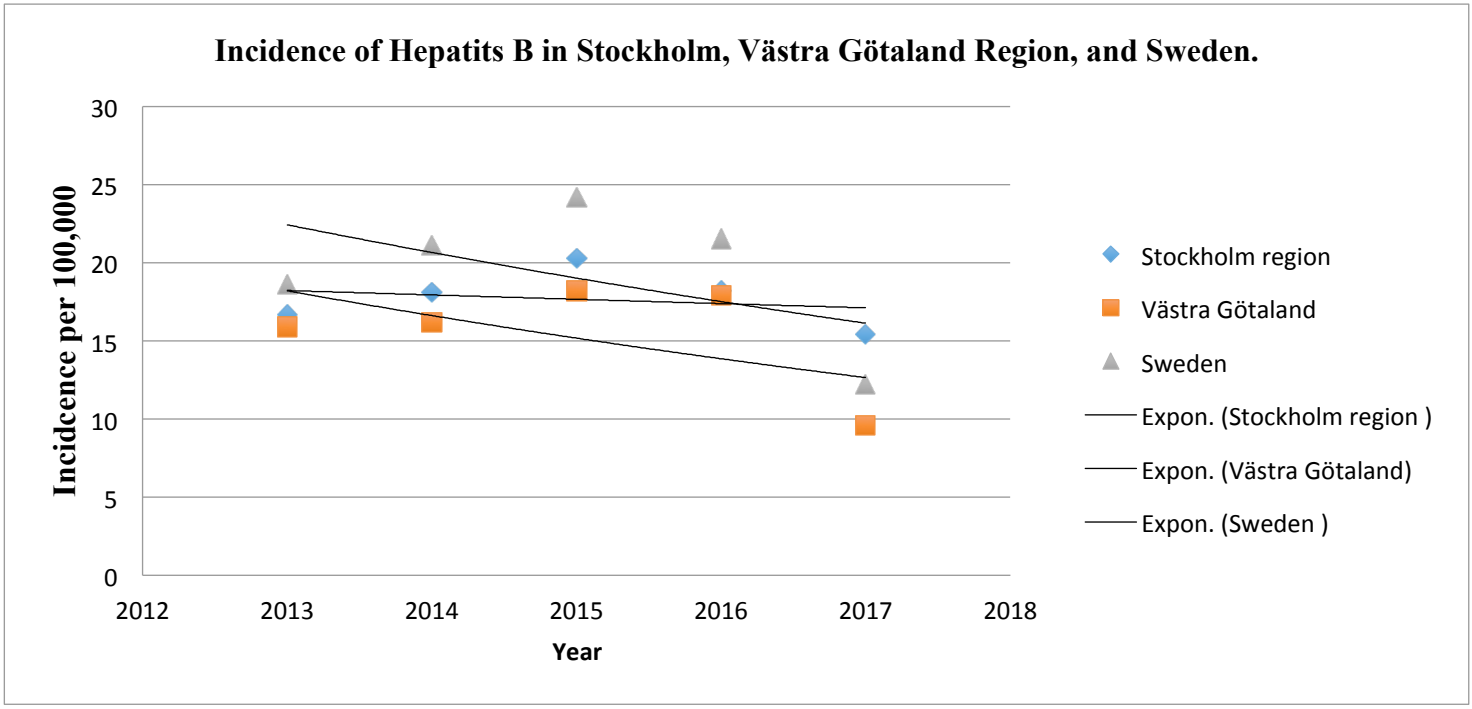

Figure 5: Incidence of Hepatitis B (HBV) in Stockholm, Västra Götaland region, and Sweden between 2013-2017

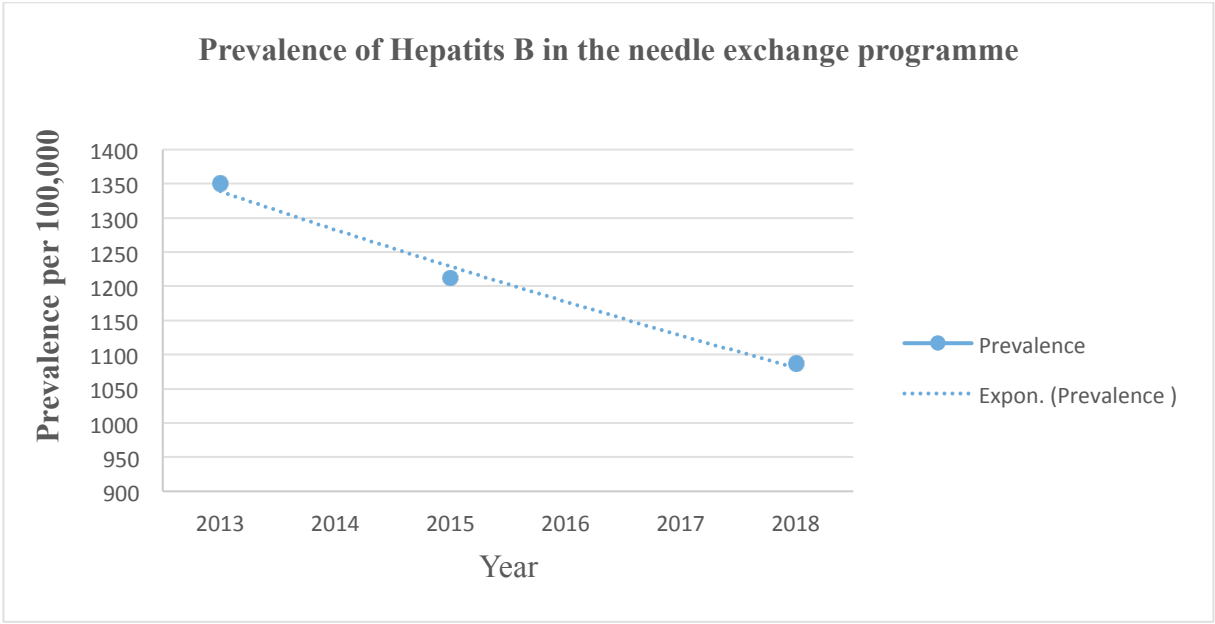

Figure 6: Prevalence of Hepatitis B (HBV) in intravenous drug users (IDU) in the needle exchange programme (NEP) between 2013-2018 in Stockholm.

The incidence of HBV was zero in 2013 and increased in 2015 *(Figure 4)*. The HBV incidence has been the highest in the whole of Sweden but is on a steady decline. The incidence in Stockholm has been stable throughout the years, whereas the incidence has been the lowest in Västra Götaland region and is on steady decline *(Figure 5)*. Notably, the incidence of HBV was on an overall decline in 2017 in all there geographical areas *(Figure 5*). Overall, the exponential trend analysis shows a tendency towards a decline in incidence. However, more data on the incidence in NEP is needed for more conclusive results.

The trend analysis is showing a decrease in HBV prevalence in the NEP population *(Figure 6)*. In 2014, the prevalence of HBV was much higher as compared to the prevalence the prior and following years (*Figure 6)*. There is no statistical significance in the decline in prevalence over the years (P value= 0.05696).

HEPATITIS C (HCV

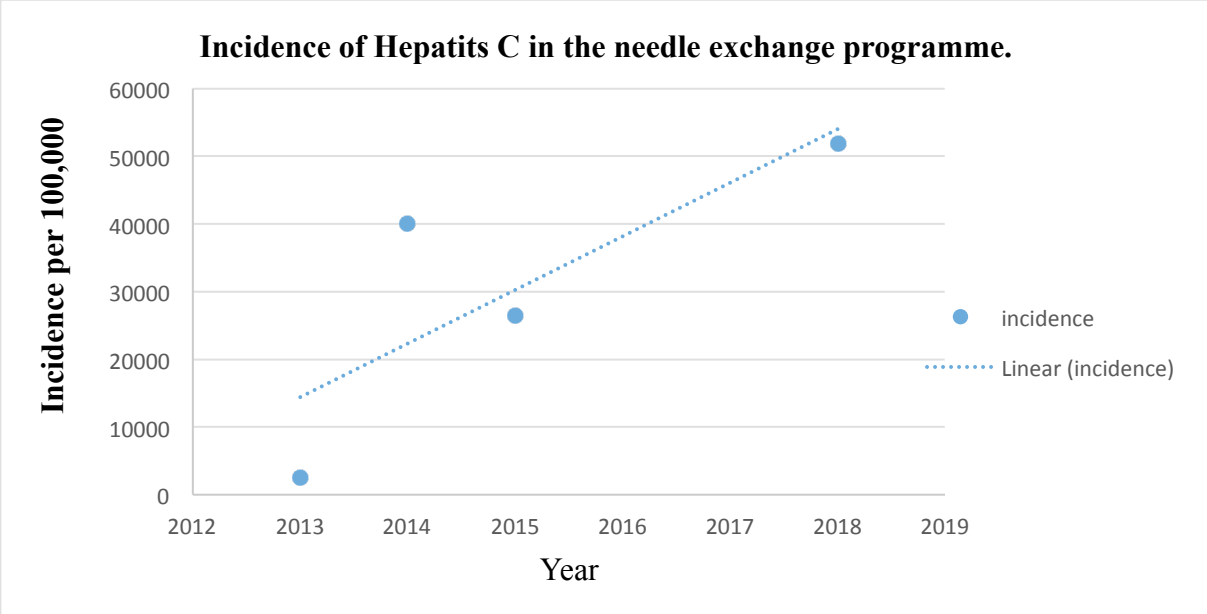

Figure 7: Incidence of Hepatitis C (HCV) in intravenous drug users (IDU) in the needle exchange programme (NEP) between 2013-2018 in Stockholm.

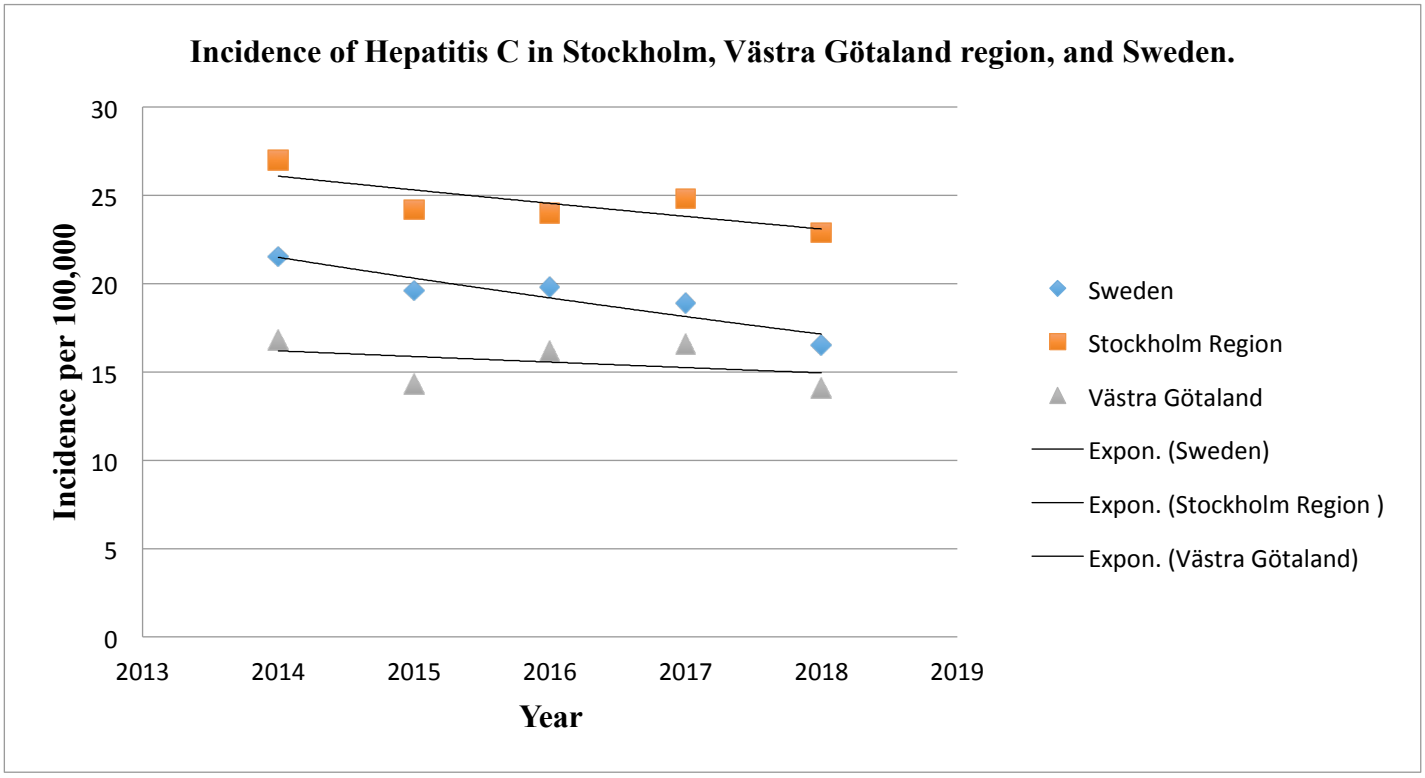

Figure 8: Incidence of Hepatitis C (HCV) in Stockholm, Västra Götaland region, and Sweden between 2013-2018 in Stockholm.

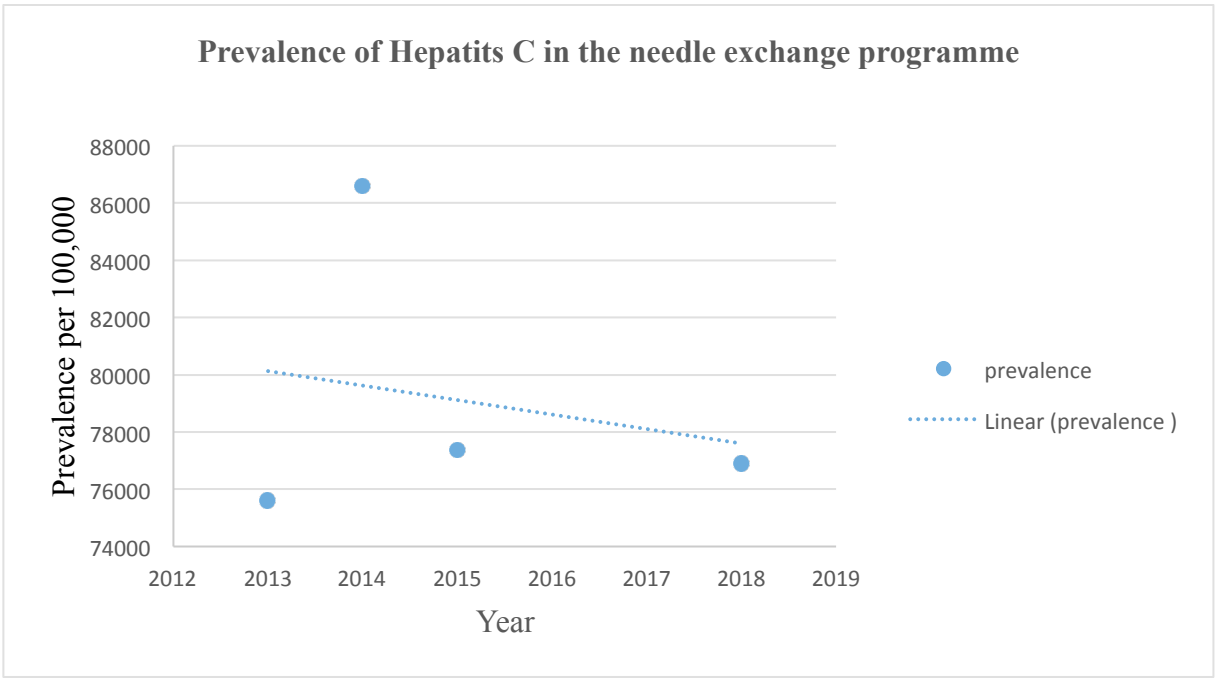

Figure 9: Prevalence of Hepatitis C (HCV) in intravenous drug users (IDU) in the needle exchange programme (NEP) between 2013-2018 in Stockholm.

Although data is missing for 2016 and 2017, the trend analysis shows a sharp increase of HCV in the NEP *(Figure 7)*. The incidence of HCV is the highest in Stockholm region and the lowest in Västra Götaland region (Figure 8). The trend line shows a steady decline in HCV in Stockholm region and the whole of Sweden but remain stable in Västra Götaland region *(Figure 8)*.

The prevalence of HCV in the NEP shows to be on an overall decline *(Figure 9)*. However, there was no statistical significance in the decline over the years (P value =0.0755). Notably, the HCV prevalence was lower in 2013 when the programme started *(Figure 9)*.

DISCUSSION

The study investigated if the needle exchange programme (NEP) decreases the incidence of HIV, HBV and HCV. It showed firstly, that the incidence of HIV decreased to zero on two separate years and showed a tendency towards stabilising. Secondly, the HBV incidence experienced a year with a zero incidence and a later increase but a decline in prevalence; however, data was missing for conclusive results. Lastly, HCV incidence shows to be increasing though the prevalence is drastically decreasing in the NEP population.

The decrease in incidence for HIV shows that a blood borne disease can be reduced in a population that uses the NEP. But this study cannot prove what factors are responsible for the decrease in incidence; whether it is the NEP or other external factors such as human behaviour, lifestyle or the prevalence and incidence of the disease that particular year.

Notably, the programme started in spring 2013, which can have an overall impact on the zero incidence for HIV and HBV in 2013 as monitoring the incidence of the infection later on in the year increases the risk of losing persons that may have been infected at the beginning of the year.

Between 2008 to 2011, the public health agency in Sweden estimated that circa 8000 people in the whole of Sweden were IDU, where the majority, 1837 people, weew situated in Stockholm (Folkhalsomyndiheten.se, 2015). Despite the increased incidence rate in infections, the prevalence is decreasing for HIV, HBV, and HCV. This means that persons enrolling in the programme each year with infections are decreasing. This can be due to the fact that the programme is better and monitoring, survellencing, and diagnosing IDU with blood borne disease, though there is a decrease in prevalence of HBV and HCV every year, the decline is not significant. However the IDU population is small and although the decline is

not significant, the small decline every year can have an impact on every person who is a high risk of contracting a blood borne disease associated with intravenous drug use, as the programme is reaching a majority of IDU throughout the years (Table 1; Table 2; Table 3).

In order to find the "true" efficacy of the programme that IDU who use the NEP are less likely to contract HIV, HBV, and HCV, case-control studies can be conducted. However, confounding factors that increases a persons risk for contracting blood borne diseases such as risky sexual behaviour will remain, though this can be adjusted for (Noroozi et al., 2017). Although the NEP provides some sexual advice, it may not remove the human component of such risk behaviour. Thus leaving the question if it is possible to find the "true" efficacy of such programme when external factors have a consequential impact on the study. The needle exchange programme has advantages that may not be able to be proven statistically such as vaccination, surveillance, dispensing antiviral drug, and etc., which can indirectly control the incidence of blood borne diseases. For example, the dispensing of antiviral medication for HIV is likely to increase compliance to medication regime thus reducing the viral load and in turn making a person non infectious. IDU are provided social support that may make it easier to focus on battling their drug addiction. The NEP also offers vaccinations to all IDU, which increases full immunity to HBV. This makes a preventative measure easily accessible to a group that has compliance difficulties (Blomé et al., 2017). This concurs with a 2010 study (Blomé et al., 2010), that the decrease in HBV incidence was related to vaccinations being offered to the IDU in the NEP. Areas with NEP showed a decline in HBV infection as compared to areas without the NEP, and emphasised that without the full coverage of vaccinations the epidemiology of HBV would change rapidly (Blomé et al., 2010). This can be a plausible explanation for the peak incidence in HBV infection in 2015 (Figure 3), as it could have been an after effect from the late 2014 HBV outbreak in Sweden (Folkhalsomyndigheten.se, 2014), leading to the immediate implementation of control measure; vaccination, for all risk groups, emphasising on IDU who attend NEP (Folkhalsomyndigheten.se, 2014). Further research can therefore be done on the effects the NEP has on the people who use it and how it contributes to their quality of life rather than research on finding the "true "efficacy.

On the other hand, more research needs to be done in order to identify the factors that decreased the incidence to zero, in order to implement similar strategies in the future. A study concluded that the NEP decreases the transmission rate of HIV and the risk behaviours associated with it, which might be a contributing factor to the zero incidence rate 2013 and

2015, again highlighting that the NEP is effective in decreasing the incidence in IDU (Kåberg et al., 2019). Nevertheless, the results show a continued incidence of HIV within the IDU enrolled in the NEP which can be due to the fact that WHO recommends that 200 syringes per year be distributed to each IDU in order to decrease the incidence of infectious diseases, but as of 2017, only 160 syringes per year were distributed at the NEP in Stockholm, consequently, not reaching the full coverage for an effective control measure (World Health Organization, 2013; Petersson, 2019).

A study conducted in Iran showed that IDU enrolled in the NEP were less likely to engage in risky behaviour that increased the transmission of HIV, and perhaps other blood borne diseases (Noroozi et al., 2017). It highlighted that persons exchanging needles at the programme not only were less likely to borrow or lend their needles to others but also used condoms more frequently and consistently, therefore concluding that the programme had a protective effect against the acquisition of HIV (Noroozi et al., 2017). The trend analysis for HCV shows a persistent high incidence. The sharing of needles is the major route of transmission for HCV infections in the western world. This might explain the higher incidence and prevalence of HCV as compared to the rest of the blood borne diseases, as HCV is more prevalent in IDU than HIV and HBV. (Kåberg et al., 2019). Kåberg et al (2019) highlights the importance of the NEP in controlling, treating, and decreasing the incidence of HCV in IDU population despite the consistent high incidence rate. They argue that the programme provides a good surveillance tool and health service in order to identify IDU with HCV and offer treatment to a group who are usually unaware of their status. Furthermore, it highlights the importance of including the NEP in the control measures with opiate substitute therapy, and counselling in order to reduce reinfections in IDU who have successfully been treated thus contributing the WHO goals of eliminating HCV (Kåberg et al., 2019).

The NEP in Stockholm was started in 2013 and data for previous years is not available. However, the incidence of HIV, HBV, and HCV is likely to have been faintly higher, as previous studies and this study has highlighted that the programme contributes to the decreased incidence in IDU attending the NEP.

The NEP has a protective effect through its combination of needle exchange, opiate substitute therapy counselling, and etc., in reducing and stabilising incidences of the disease, in some instant to zero, as well as providing surveillance and treating infections. The continued rise in incidence can be due to other factors out of the NEP control, such as human behaviour and prevalence of a disease. Though studies have highlighted that the use of the

NEP reduces the risk behaviour, it does not eliminate them hence leading to the continued incidences of certain infections within this IDU.

There is a challenge in conducting a randomized control case studies in order to test the "true" efficacy of the NEP as this will require to either, firstly deny one group access to a recommended control strategy in tackling elimination of HIV, HBV, and HCV thus being unethical, depending on where the study takes place. Secondly, finding a similar control group in the population that mirrors the control group, which can pose as a challenge as the studied population, is hard to reach and follow up. Suitable control group could however be found in a city that does not have the NEP to avoid conflicting data and risk denying a risk group preventative measures.

LIMITATION

3242 persons were included in the study but there was no data on how many persons left the programme or were not followed up. Therefore the study assumes that all subjects were tested regularly. The lack of data for some years created challenges in reaching a conclusive result for HBV infection. This can call the accuracy and precision of the results into question thus questioning its validity. However, given that this is a challenging group to study and the difficultness of finding the "true" value of the effectiveness of the programme, the level of accuracy and precision may not be as of importance given that an effect is observed in the studied population. Nonetheless, previous studies have concurred that the programme contributes to the reduced incidences of blood borne diseases thus showing that the programme is more effective rather than non- effective.

STRENGTH

Previous studies that have examined the incidence and prevalence of HIV, HBV, and HCV, have studied or collected the data from a specific time frame. However, this study has examined the incidence for every year and analysed the direct effects the NEP has that specific year. The study highlights the important role the NEP has in reaching this population group and that it contributes to the reduced incidence. The study shows that a control programmes that offers a form of "incentive" can have a higher chance of reaching a risk group that would otherwise be hard to follow up or even reach. It shows that incidence can be reduced, even to zero, and control strategies such as vaccination can be easier to administer. Low economically developed countries that experience high incidence of diseases and infections, which ultimately has a significant impact on the health economy or quality of life,

can implement similar programmes. This will presumably become more cost effective and reduce the disease burden thereby enhancing the quality of life of its citizen.

CONCLUSION

The NEP contributes to the reduction in incidence of HIV and HBV but remain difficult to decrease the HCV incidence in persons who use drugs. However, further research is needed to investigate the "extra" measures that were implemented during the years the incidences were at zero, but also the experiences of IDU who use the NEP, in order to determine the impact and usefulness it has on their quality of life.

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