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Factors Associated with Compliance Among Methadone Maintainence Treatment Patients at Health Clinics in Port Dickson, Malaysia

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Abstract: Methadone Maintenance Treatment (MMT) is effective in reducing opiate use, Human Immunodeficiency Virus risk behaviors, and related crime. Compliance is significant component to indicate the success of the program. However, studies related to compliance are lacking. This paper seeks to determine the client's compliance level towards MMT and identify its associated factors. This is a retrospective cross-sectional study involving 106 respondents undergoing Methadone therapy in Port Dickson, Malaysia government health clinics. Data were obtained from questionnaires with the help of medical and pharmacy records. Overall client's compliance level is satisfactory at 67.0%. There is an association between good compliance and educational level, income, hepatitis C, Tuberculosis, liver function, Methadone induction dose, alcohol, and substance abuse (p<0.05). The determinants of Methadone compliance were 20mg and lower Methadone induction dose (AOR = 3.344, 95%CI = 1.205-9.279, *p*=0.020) and infrequent substance abuse (AOR = 13.306, 95%CI = 4.286-41.313, *p*<0.001).

Keywords: Determinants; Methadone Maintenance Therapy; Compliance; Government; Clinics.

INTRODUCTION

One of the public health issues in Malaysia is drug addiction. Knowing this Ministry of Health Malaysia had implemented National Harm Reduction Program. The components of this harm reduction program include Methadone Maintenance Treatment (MMT), Needle and Syringe exchange program (NSEP) and condom distribution (Norsiah et al., 2016). Methadone is a μ-opioid receptor agonist that has been recognized in reducing substance use, drug-linked risk activities and crimes. MMT is widely regarded as corrective therapy, rather than curative treatment for opioid addiction. Besides, it had no or only limited efficacy in treating dependence on other drug substances (Joseph et al., 2000). Malaysia started to provide MMT to opioid dependence patients in government facilities since 2005. The objective of MMT is to increase the quality of life of substance dependents by reducing relapse improving their physical and mental health, reducing the risk of infectious disease and escalate the

psychosocial functioning (Malini et al., 2018). The successfulness of MMT can be measured using compliance which is a significant element to show the therapeutic effect and control of the program. The utmost applicable way to evaluate the compliance level is through simple self-administered questionnaires (Sharifa et al., 2009).

Compliance to MMT can be related with several factors. Among the most main factors are sociodemographic, factors related to therapy process, factors related to previous history of addiction, and factors related to effect of therapy. All these elements would control the client's compliance and some variables can be connected to each other. Client who are older, attained higher education level, secured full time job, minimal health problems, assured with therapy, process, having good rapport with service provider, stay longer in therapy, less risk behavior for HIV infection and good social function were anticipated to comply with the therapy (Sharifa et al., 2009).

Nevertheless, minimal attention is paid to MMT compliance and its associated factors, especially in Port Dickson, Negeri Sembilan. The aim of this study is threefold.

  i.   To determine the client's compliance level towards MMT in Port Dickson government clinics

  ii.   To identify the socio-demographic characteristics of MMT in Port Dickson government clinics

  iii. To determine predictors associated with compliance of MMT in Port Dickson government clinics

The findings of this research may expand our understanding on compliance to MMT and   suggest a model to improve the compliance.

METHODOLOGY

1. Study design, sample selection and variables

This was a retrospective cross-sectional study involving 106 clients who received the MMT in Port Dickson government clinics for duration of 3 months in year 2020. Port Dickson is a coastal town in Port Dickson District, Negeri Sembilan, Malaysia and have five government health clinics namely clinic Port Dickson, clinic Pasir Panjang, clinic Bukit Pelandok, clinic Linggi and clinic Lukut that offer MMT services. The respondent was selected universally based on inclusion and exclusion criteria. Inclusion criteria in this study were Malaysian citizen, understand Malay or English language, and consented for this research. Those clients with mental health issues, and who recently (less than 2 months) enrolled into MMT programme (to avoid stabilization period which take two to six weeks) were excluded.

Most of the data were based on patient case notes. Additionally, they were also asked to complete a simple questionnaire to obtain their latest data and capture any missing information from the medical records. The independent variables were socio-demographic status (age, sex, ethnic, marital, education, occupation, household income), health status (chronic illness, HIV/AIDS, Hepatitis C, B, liver function, Tuberculosis), and addiction history (induction and maintenance Methadone dose, alcohol, smoking, substance abuse). The dependent variable would be good or poor compliance. Good compliance defined as (Sharifa et al., 2009; Ghani et al., 2019).

i. Not missing Methadone dose more than 3 times consecutively past 3 months.

ii.No positive result of any substance in urinalysis performed randomly past 3 months.

2. Data analysis

Data were analyzed using SPSS version 21.0 using descriptive (frequencies, percentages, means and standard deviations) and analytical analysis were used for descriptive statistics. The chi-square test was used to recognize factors associated to MMT compliance. Predictors for MMT compliance were determined using multiple logistic regression analysis. Statistical significance was set at $p < 0.05$.

3. Ethical Consideration

Approval for this study was obtained from District Health office and respective health clinic in charge person for the Methadone Maintenance Treatment (MMT) programme. Informed consent was obtained from all the participants prior to inclusion in the study. Strict standards for protecting the privacy and confidentially of the respondents during data collection were followed too.

RESULTS

The response rate for this study was 100% which a total of 106 clients who fulfilled the inclusion criteria responded in this study. The socio-demographic profile of the respondents which include age, gender, race, marital status, educational level, employment status and household income are shown in Table I. The mean age of the respondents was 41.5± 10 years. The reported study had the youngest respondent at age 23 and the oldest respondent at 66 years. Majority of the respondents aged between 40 to 49 years old (32.1%). All the respondents are male (100.0%) and no female respondent registered in the MMT clinic in Port Dickson.

It is apparent from table below that majority of the respondents were Malay (87.7%) followed by Chinese (7.5%) and Indian (4.7%). Almost half of the respondents were married (50.0%) and their highest educational attainment were till secondary school (65.1%). Of the 106 respondents who responded this study, 76.4% were employed and half of them (57.5%) have a household income more than RM1200 to support themselves and family.

Table I. Socio-demographic profile of respondents (n=106)

Variables	Frequency (n)	Percentage (%)
Age		
Mean 41.5±10.0(Min 23.0, Max 66.0 years old)		
20-29 years old	10	9.4
30-39 years old	33	31.1
40-49 years old	34	32.1
50-59 years old	22	20.8
60-69 years old	7	6.6
Gender		
Male	106	100.0

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162

ICRRD Qual. Ind. Res. J. 2021, 2(4), 160-174

Female	0	0.0
Race		
Malay	93	87.7
Chinese	8	7.5
Indian	5	4.7
Marital Status		
Single	45	42.5
Married	53	50.0
Widowed/Separated	8	7.5
Educational Level		
No formal education/Primary School	28	26.4
Secondary School	69	65.1
Tertiary School (College/University)	9	8.5
Employment Status		
Employed	81	76.4
Unemployed	25	23.6
Household Income		
Less than RM1200	45	42.5
More than RM1200	61	57.5

Data from Table II shows that 66(62.3%) respondents have at least one non-communicable chronic diseases like Diabetes or Hypertension. Meanwhile communicable disease like HIV/AIDS, Hepatitis B, Hepatitis C and PTB which were prevalent among IVDU only were asked in this study. This study reveal that the prevalence of Hep C among the Methadone client were 46.2%, Hepatitis B 7.5%, HIV/AIDS 16.0% and history of PTB 13.2%. Our study also revealed that majority of the respondent (n=85, 80.2%) have a normal liver function.

The median dose of Methadone induction dose was 20.0mg which minimum dose was 10.0mg and maximum dose was 45.0mg. Three quarter of the respondent (75.5) were started with 20-29mg induction dose. Meanwhile looking into maintenance dose, maximum dose given at 100mg while minimum at 20.0mg which similar to induction dose. Most of the respondent settled at the dose 40-59mg (39.6%) and 20-39 (37.7%). This study also provides evidence that a total of 43(40.6%) clients have been visiting regularly for Methadone therapy in the current setting for more than 5 years.

The findings of present study suggest that only a minority 12(11.31%) of the respondents addicted to

tobacco heavily (>30 cigarettes per day) while remaining 39(36.87%) respondents' smokes between 11-30 cigarettes per day and a half of them 55(51.9%) smokes minimally (< 11 cigarettes per day). Looking into frequency of alcohol intake, only 2(1.9%) respondents admitted taking alcohol frequently (>3 times a week), while 15(14.2%) regularly (2-3 times a week) and 89(84.0%) infrequently (nil or once a week). It is apparent from this study that 80(75.53%) clients from a total of 106 respondents took substance/illicit drug infrequently only. Meanwhile the remaining 26 (24.5%) take regular (2-3 times per week) any form of substance/illicit drug to be lifted.

Table II. Respondent's health status (n=106) Respondent's addiction history (n=106)

Variables	Frequency (n)	Percentage (%)
History of Non-communicable Chronic Illness		
Yes	40	37.7
No	66	62.3
HIV/AIDS		
Positive	17	16.0
Negative	89	84.0
Hepatitis C		
Positive	49	46.2
Negative	57	53.8
Hepatitis B		
Positive	8	7.5
Negative	98	92.5
History of Pulmonary Tuberculosis (PTB)		
Yes	14	13.2
No	92	86.8
Liver Function		
Normal	85	80.2
Abnormal	21	19.8
Methadone Induction Dose		
Median 20.0±6.3mg (Min 10.0 mg, Max 45.0mg)		
10-19mg	8	7.5
20-29mg	80	75.5

30-39mg	13	12.3
40-49mg	5	4.7

Methadone Maintenance Dose

Median 40.0±18.0mg (Min 20.0mg, Max 100.0mg)

20-39mg	40	37.7
40-59mg	42	39.6
60-79mg	19	17.9
>80mg	5	4.7

Duration of MMT in Current Setting

Median 5.0±2.99, Min 1.00, Max 13.00

≤ 5 years	63	59.4
> 5 years	43	40.6

Alcohol Intake

Infrequent (nil or once a week)	89	84.0
Regular (2-3 times a week)	15	14.2
Frequent (>3 times a week)	2	1.9

Substance Abuse

Infrequent (nil or once a week)	80	75.5
Regular (2-3 times a week)	26	24.5
Frequent (>3 times a week)	0	0.0

Cigarettes Smoking

Highly Dependent (>30 cigarettes per day)	12	11.3
Moderately Dependent (11-30 cigarettes per day)	39	36.8
Minimally Dependent (<11 cigarettes per day)	55	51.9

Table III below demonstrates the compliance toward Methadone which were measured based on two indicators. Only a minority of five respondents (4.7%) reported to have missed Methadone dose three times consecutively past three months. Meanwhile from the 106 Methadone clients in Port Dickson government clinics, 76(71.7%) clients have shown negative for urine for drug test which was carried out randomly during the clinic visit. This shows that the prevalence of good compliance towards Methadone was 67.0%.

Table III. Respondent's compliance towards MMT (n=106)

Variables	Frequency (n)	Percentage (%)
Compliance		
Poor	35	33.0
Good	71	67.0
Any Missing Methadone Dose More Than 3 times Consecutively Past 3 Months		
Yes	5	4.7
No	101	95.3
Urine for Drug Positive Past 3 Months		
Yes	30	28.3
No	76	71.7

The Chi-square results test between compliance among the Methadone clients and associated socio-demographic factors are presented in Table IV. There was an association between compliance and education level ($\chi^2=5.035$, df=1, p=0.025) and household income ($\chi^2=4.616$, df=1, p=0.032). Nevertheless, there were no associations between compliance and age group ($\chi^2=0.586$, df=1, p=0.443), race ($\chi^2=1.156$, df=1, p=0.282), marital status ($\chi^2=0.603$, df=1, p=0.437), and employment status ($\chi^2=1.785$, df=1, p=0.182).

Other findings drawn from this study were, there was an association between Methadone compliance and Hepatitis C, history of Pulmonary Tuberculosis, and liver function ($p<0.001$). However, there were no association between Methadone compliance and History of chronic illness, HIV/AIDS status, and Hepatitis B status ($p>0.05$).

Compliance in this study is significantly associated with substance abuse/illicit drug use ($\chi^2=30.025$, df=1, $p<0.001$). Similarly, there were an association between compliance and Methadone induction dose ($\chi^2=9.305$, df=1, p=0.002) and alcohol intake ($\chi^2=6.096$, df=1, p=0.014). Nevertheless, there were no significant associations between Methadone compliance and Methadone maintenance dose, duration of MMT in current setting, and cigarettes smoking ($p>0.05$).

Table IV. Association between compliance and socio-demographic, health history and addiction factors (n=106)

Variables	Compliance		Test statistics		
	Poor	Good	Chi square	df	*p* value
	n (%)	n (%)			
Association between compliance and socio-demographic					

Age Group (years)

< 42	21(36.2)	37(63.8)	0.589	1	0.443
≥ 42	14(29.2)	34(70.8)			

Race

Malay	29(31.2)	64(68.8)	1.156	1	0.282
Non-Malay	6(46.2)	7(53.8)			

Marital Status

Married	22(36.1)	39(63.9)	0.603	1	0.437
Non-married	13(28.9)	32(71.1)			

Education level

Lower level	29(29.9)	68(70.1)	5.035	1	0.025*
Higher level	6(66.7)	3(33.3)			

Employment Status

Unemployed	11(44.0)	14(56.0)	1.784	1	0.182
Employed	24(29.6)	57(70.4)			

Household Income

Less than RM 1200	20(44.4)	25(55.6)	4.616	1	0.032*
More than RM 1200	15(24.6)	46(67.0)			

Association between compliance and health history

History of chronic illness

No	20(30.3)	46(69.7)	0.583	1	0.445
Yes	15(37.5)	25(62.5)			

HIV/AIDS

Positive	7(41.2)	10(58.8)	0.609	1	0.435
Negative	28(31.5)	61(68.5)			

Hepatitis C

Positive	21(42.9)	28(57.1)	3.998	1	0.046*
Negative	14(24.6)	43(75.4)			

Hepatitis B

Positive	5(50.0)	5(50.0)	1.128	1	0.288
Negative	31(31.6)	67(68.4)			

History of Pulmonary Tuberculosis (PTB)

Yes	8(57.1)	6(42.9)	4.245	1	0.039*
No	27(29.3)	65(70.7)			

Liver Function

Normal	24(28.2)	61(71.8)	4.439	1	0.035*
Abnormal	11(52.40	10(47.6)			

Association between compliance and addiction history (n=106)

Methadone Induction Dose

<20	15(22.4)	52(77.6)	9.305	1	0.002*
≥20	20(51.34)	19(48.7)			

Methadone Maintenance Dose

<40	17(31.5)	37(68.5)	0.118	1	0.732
≥40	18(34.6)	34(65.4)			

Duration of MMT in Current Setting

≤ 5 years	21(33.3)	42(66.7)	0.007	1	0.934
> 5 years	14(32.6)	29(67.4)			

Alcohol Intake

Infrequent	25(28.1)	64(71.9)	6.096	1	0.014*
Frequent	10(58.8)	7(41.2)			

Substance Abuse

Infrequent	15(18.8)	65(81.3)	30.025	1	<0.001*
Frequent	20(76.9)	6(23.1)			

Cigarettes Smoking

Highly Dependent	3(25.0)	9(75.0)	0.393	1	0.531
Low Dependent	32(34.0)	62(66.0)			

*Significant at *p*<0.05

The results of the logistic regression for Methadone compliance are summarised in Table V below. Clients with infrequent substances abuse use were 31 times more likely to be compliant to Methadone compared to their counterpart (OR =31.654, 95% CI =6.449-145.7011, p<0.001). Similarly, Methadone clients with lower education level were 18 times more probably to be compliance compared to those with higher education level (OR = 18.936, 95% CI = 1.743-205.701, p=0.016). Meanwhile clients with lower than 20mg Methadone induction dose were five times (OR = 4.896, 95% CI = 1.373-17.461, p=0.014) to be more compliant compared to client with higher than 20mg Methadone dose. This study also shows that there was no association between Methadone compliance and household income, Hepatitis C, Liver function, history of PTB, and alcohol intake (*p*>0.05).

Table V. Simple logistic regression between compliance and socio-demographic, health history and addiction factors

Factors	B	SE	Wald	df	OR	95% CI	p value
Education Level							
Lower level	2.941	1.217	5.840	1	18.936	1.743-205.701	0.016*
Higher level					Reference		
Household Income							
Less than RM 1200	1.140	0.650	3.067	1	3.127	0.875-11.181	0.079
More than RM1200					Reference		
Hepatitis C Status							
Negative	1.208	0.720	2.817	1	3.348	0.816-13.728	0.093
Positive					Reference		
Liver Function							
Normal	1.194	0.733	2.657	1	3.301	0.785-13.876	0.103
Abnormal					Reference		
History of PTB							
Negative	0.386	0.900	0.184	1	0.680	0.116-3.970	0.668
Positive					Reference		

Methadone Induction Dose

	B	SE	Wald	df	OR	95% CI	p value
<20	1.588	0.649	5.994	1	4.896	1.373-17.461	0.014*
≥20				Reference			
Alcohol Intake							
Infrequent	1.322	0.864	2.378	1	3.787	0.697-20.582	0.123
Frequent				Reference			
Substance Abuse							
Infrequent	3.423	0.795	18.521	1	30.654	6.449-145.701	<0.001*
Frequent				Reference			

*Significant at $p<0.05$

Multiple logistic regression was used as the analysis of the determinants of Methadone compliance among the clients. A number of 7 independent variables (education level, household income, hepatitis C, liver function, methadone induction dose, alcohol intake, substance abuse) with a p-value less than 0.25 (Hosmer et al, 2000) were included into preliminary model selected from the bivariate analysis. All the variables were analysed using 'ENTER', 'FORWARD-LR' and 'BACKWAR-LR'. The 'ENTER' method was selected as it produced the most number of significant Methadone compliant determinants. There was no multicollinearity and Hosmer-Lemeshow goodness of fit Chi-squared test showed the model is fit ($\chi2=2.973$, df = 7, $p=0.566$). The Negelkerke's R^2 was 0.415 which indicates that 41.5% of the variation in Methadone compliant was explained by these variables which included in this logistic model. Therefore, the final predictive model of Methadone compliance among the MMT client in Port Dickson government clinics is:

Log (Probability of developing depression)

-1.721 + 1.207(20mg and lesser Methadone induction dose) + 2.588(infrequent substance abuse)

Table IX indicates the analysis of multiple logistic regression for determinants of Methadone compliance. Clients with 20mg and lesser Methadone induction dose are three times (AOR = 3.344, 95%CI = 1.205-9.279, $p=0.020$) more likely to be compliant to Methadone compared clients with 20mg and more Methadone induction dose. Meanwhile clients with infrequent substance abuse are 13 times (AOR = 13.306, 95%CI = 4.286-41.313, $p<0.001$) more likely to be Methadone compliant compared to clients with frequent substance abuse.

Table IX. Multivariate logistic regression examining compliance on MMT among respondents

Factors	B	SE	Wald	df	OR	95% CI	p value
Methadone Induction Dose							

<20	1.207	0.521	5.377	1	3.344	1.205-9.279	0.020
≥20				Reference			
Substance Abuse							
Infrequent	2.588	0.578	20.048	1	13.306	4.286-41.313	<0.001*
Frequent				Reference			

*Significant at $p<0.05$

Nagelkerke R^2 is 0.415

DISCUSSION

MMT is one of the current initiatives in Malaysia to combat the drug addiction epidemic. MMT is one of the current programs in this country to control the drug addiction menace. Sixty-seven percent of respondents showed good compliance which is satisfactory. Good compliance rate is necessary to ensure the success of this Methadone Therapy Program which was implemented under the Harm Reduction Programme in 2005. The compliance rate in our study lesser compared to similar study conducted in Selangor Primary care center in 2007 which was 86.1% (Sharifa et al., 2009). Geographical barrier, and accessibility to MMT service in relation to transportation can be one of the explaining the differences in the compliance level.

Meanwhile a total of 35(33%) respondents showed poor compliance towards the MMT in this study. Methadone compliance varies globally according to country. Different countries reported different range of compliance. United States reports only 17% (Raffa et al., 2007). while in United Kingdom 58% patients did not adhere the treatment (Haskew et al., 2007). In the meantime, in Asia, study findings in China proposes that the proportion of MMT clients having poor compliance were from 36.3% to 88.2% (Zhou et al., 2017; Shen et al., 2016). Differences across the regions happens because compliance subjected to different variables related to socio-demographic, socio-economic, health, and social aspects. Another thing is policy in which rules and regulation pertaining to MMT services set by each Ministry of Health in respective country can differ. In Malaysia, MMT service is given for free in government facility under the provincial healthcare program.

Patients with educational level and stable income found to have a significant positive association with Methadone compliance. It is postulated that being educated and in an employment reduced the harmful cues to opioid misuse and patients are more motivated to comply with Methadone therapy (Norsiah et al., 2016). Other variables that associated with MMT compliance in this study were, hepatitis C, Tuberculosis, liver function. Those with infectious disease usually not compliant to MMT because internal and external factors beyond their control. They might encounter various barriers to healthcare and optimal treatment as result of social instability related to infectious disease, and pervasive stigma experienced by this population (Reddon et al., 2014). However, this contrary to findings in this study.

There is an association between compliance and infectious disease like Hepatitis, Tuberculosis. There are few explanations for this. First, enrolling in MMT allow for more frequent contact with the health-

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171

ICRRD Qual. Ind. Res. J. 2021, 2(4), 160-174

care system and related programmes. This ensure co-administration of infectious disease medications with daily dispensed methadone which promotes compliance (Berg et al., 2009). Second, MMT's stabilising effect may make supportive counselling and other interventions more effective in addressing compliance difficulties including co-occurring mental illness and other psychosocial co-morbidities (Spire et al., 2007). Third, enrollment in MMT may create better chances for monitoring and adjustment of infectious medicine and compliance related issues (Uhlmann et al., 2010). Fourth, those with infectious disease, their data are kept private and confidential with the engagement in MMT clinic (Lin et al., 2015), this improves the compliance because reducing the associated stigma. This study finding cannot explain why liver function is related to MMT compliance. Future clinical exploration is required to understand what may influence this.

Determinants of good compliance in this study were lower Methadone induction dose and infrequent substance abuse. There are two types of methadone dosage given to patients; methadone induction and maintenance dosing. The induction dose is the dose administered during the induction phase, which is the first 2 weeks of therapy. The maintenance phase usually commences after 2 weeks of induction phase. An initial dose of 20-30 mg is usually safe and effective. The mean induction dose was 20.0mg (S.D ± 6.3) followed by a mean maintenance dose of 40.0mg (S.D ± 18.0) in this study. This research finding document a strong association between induction dose and compliance. This is inconsistent with previous study by Marienfeld et al. (2015) and Shen et al. (2016), lower methadone dose was found to be linked to poor compliance. World Health Organization (WHO) recommends the minimum recommended dose of methadone is 60 mg per day, with the majority of patients requiring up to 120 mg per day (World Health Organisation, 2008). There is minimal data on the actual methadone dose for MMT client however it has been discovered that in many Asian nations, the dosage is still below these limits (Reid et al., 2014). Lower doses may result in improved subjective effect control and effective cross-tolerance in terms of compliance. Separately, another Malaysian study done in University Malaya explained why the local population requires lower dosing. The author summarized the main reason is that the better quality of Methadone used in Malaysia that gives the desired effect (Gill & Habil, 2007). The other possible reason is the different genetic make-up among Asians, as compared to the Caucasian population.

Those with infrequent substance abuse more likely to compliant to MMT. Given the chronic nature of opioids use disorder, compliance plays a major role for substance abuser. Clients with history of substance abuse are given methadone on daily basis with adequate doses because the duration of drug effect and withdrawal symptoms. Therefore, compliance to MMT is critical because infrequent substance abuser who miss even a one MMT dose will suffer withdrawal syndrome and are most likely to take other opioids for symptom relief.

There are few limitations to this study that should be addressed. First, MMT compliance were measured based on self-reported data, which could be prone to recall and social desirability response bias. Second, our findings were limited in their generalizability to MMT patients in Port Dickson because of the sampling method. Furthermore, causal relationships between MMT compliance and its determinants were not possible to establish because of cross-sectional design. Finally, some clinical and services-related factors such as quality of services and patients' satisfaction were not included in this study, which required further studies to fulfill the gap of knowledge in compliance of MMT program.

CONCLUSION

Overall client's compliance level is satisfactory at 67.0%. Educational level, income, hepatitis C, Tuberculosis, liver function, Methadone induction dose, alcohol, and substance abuse were associated with compliance to Methadone. Lower Methadone maintenance dose and infrequent substance abuse was found to have a positive influence in good compliance to methadone therapy. This finding could be beneficial in terms of future patient's selection and Methadone retention rate. In general, MMT compliance in Port Dickson government health clinics was found to be effective, however there are areas for improvement that need rectification.

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CONFLICTS OF INTEREST

There are no financial issues or interest of conflicts to declare.

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