

MALAYSIAN METHADONE TREATMENT OUTCOME STUDY (MyTOS):

**REVIEW OF METHADONE MAINTENANCE THERAPY IN MALAYSIA
(2005-2014)**

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ETHICS AND REGULATORY CONSIDERATIONS

a. Independent Ethics Committee

This was mixture of an observational and evaluation of an approved program that had started since 9 years before the study. Its conduct was unlikely to impact on safety and well being of the human subjects involved. However the protocol was still subjected to review by the Independent Ethics Committee (IEC) of the Ministry of Health (MOH) and was approved on 15th May 2014 (NMRR-13-1270-18045).

b. Patient Information and Consent

Written consent was obtained from all study respondents for all sections.

c. Patient Data Protection

Subjects' anonymity was maintained at all times as no identifiable personal information on individuals was captured. This was to respect the privacy and confidentiality rules in accordance with applicable regulatory requirements. All electronic data processed were identified by patient number only, thereby ensuring that the patient's identity remained unknown.

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SUMMARY

Introduction

Malaysia started to provide Methadone Maintenance Treatment to opioid dependence patients in government facilities since 2005. The implementation of this program was as part of the National Harm Reduction Program. This study was conducted to evaluate the Methadone Maintenance Program in Malaysia over a 10 year period (2005-2014) from various perspectives: patients, staffs and infrastructures.

Methodology

A cross sectional two stage systematic stratified random sampling study using retrospective record and questionnaires, conducted in 103 Ministry of Health's health clinics and hospitals from October 2014-December 2014.

Result

The response rate was 93.5% with 3254 respondents selected. They were mainly male, the Malays with a mean age of 39.6 years old, 37.3 % (n=1234) were still on treatment, 17.1% had transferred out, 29.1% had defaulted, 8.6% had died and 7.6% were terminated. The mean duration on MMT was 3.8 years; the mean current methadone dose was 54.8 mg, 60% had takeaway dose, 5.1% required split dose mainly due to drug interactions with HAART and Rifampicin and 29.1% had constipation. Their cardiovascular risks were sedentary life and smoking. For mental health problems, 23.3% had symptoms of depression, 33.2% had symptoms of anxiety while 16.2% have symptoms of stress. For alcohol use, prevalence of current drinker was 8.8% and ever drinker was 9.5%. There were significant improvement in quality of life in all four domains, employment, health status and social functioning; reduction in HIV, Hepatitis B & C transmission, crime, incarceration, drug use and HIV risk. MMT was perceived by patients positively. Staff attitude needs improvement. The overall infrastructure was adequate.

Conclusions & Recommendations

MMT program in Malaysia was found to be effective, hence, must be expanded. There are areas for improvement that need rectification.

Keywords : Malaysia, Methadone Treatment Outcome Study (MyTOS).

TABLE OF CONTENTS

TABLE OF CONTENTS.....	x
LIST OF TABLES.....	xii
INTRODUCTION.....	1
CHAPTER 1: OUTCOME OF MMT	5
GENERAL OBJECTIVE	5
SPECIFIC OBJECTIVES:	5
METHODOLOGY AND SAMPLING DESIGN	5
RESULTS.....	7
CHAPTER 2: CHARACTERISTICS OF PATIENTS ON MMT	12
GENERAL OBJECTIVE:	12
SPECIFIC OBJECTIVES:	12
METHODOLOGY AND SAMPLING DESIGN	12
RESULTS.....	16
CHAPTER 3: EFFECTIVENESS OF MMT	27
GENERAL OBJECTIVE:	27
SPECIFIC OBJECTIVES:	27
METHODOLOGY AND SAMPLING DESIGN	27
RESULTS.....	31
CHAPTER 4: PERCEPTION OF PATIENTS TOWARDS MMT.....	36
GENERAL OBJECTIVE	36
SPECIFIC OBJECTIVES.....	36
METHODOLOGY	36
RESULTS.....	39
CHAPTER 5: STAFFS' ATTITUDE TOWARDS MMT.....	41
GENERAL OBJECTIVE	41
SPECIFIC OBJECTIVES.....	41
RESULTS.....	43
CHAPTER 6: INFRASTRUCTURE & IMPLEMENTATION POLICIES	51
GENERAL OBJECTIVE	51
SPECIFIC OBJECTIVES.....	51
METHODOLOGY	51
RESULT	53

CHAPTER 7: DISCUSSION.....	60
DISCUSSION.....	60
CHAPTER 8: CONCLUSIONS & RECOMMENDATIONS	65
CONCLUSIONS & RECOMMENDATIONS	65
REFERENCES.....	68

LIST OF TABLES

Table 1.1: Socio-demographic characteristics of study respondents	8
Table 1.2: Socio economic status of study respondents	9
Table 1.3: Status of patients on MMT.....	9
Table 1.4: Status of patients on MMT according to urban and rural.....	10
Table 1.5: Distribution of patients on MMT in hospital and health clinics.....	10
Table 1.6: Status of patients on MMT in hospital and health clinics.....	10
Table 2.1: Socio-demographic characteristic of respondents	16
Table 2.2: Methadone dose among respondents	18
Table 2.3: Take away doses among respondents	19
Table 2.4: Cardiovascular risk factors among respondents	23
Table 2.5: Current alcohol use among respondents by AUDIT	25
Table 3.1: Employment status and ability to own house before and after MMT	31
Table 3.2: Blood Borne Virus (BBV) infection status before and after MMT.....	32
Table 3.3: Seroconversion of Blood Borne Viruses (BBV) after joining MMT.....	32
Table 3.4: Status of liver enzymes before and after MMT	32
Table 3.5: History of incarceration (imprisoned & involuntary rehabilitation centre) before and after MMT.....	33
Table 3.6: Comparison of mean frequency for locked-up, imprisoned and sent to involuntary rehabilitation	33
Table 3.7: Comparison of mean score for quality of life (WHOQOL).....	34
Table 3.8: Comparison of mean score of Opiate Treatment Index (OTI) before and after	34
Table 5.1: Staff Socio demography & background information	43
Table 6.2: Availability of basic infrastructure	54
Table 6.3: Availability of HIV/ Hepatitis management program	55
Table 6.4: Safety measures at the methadone clinic	56
Table 6.5: Knowledge on indication and implementation of MMT	57
Table 6.6: Compliance according to service recommendation	57
Table 6.7: Implementation according to Standard Operating Procedures	58

LIST OF CHARTS

Chart 2.1: Duration on methadone treatment among respondents.	18
Chart 2.2: Distribution of current methadone dose among respondents compared with recommendation by the World Health Organization	19
Chart 2.3: Split methadone dose among respondent	20
Chart 2.5: Reported side effects among respondents	21
Chart 2.6: Reported medical illness known by respondents	22
Chart 2.7: Mental health status of respondents according to DASS score	24
Chart 4.1: Perception of clients on their treatment and staff	39
Chart 5.1: Perception towards drug addiction, methadone & NSEP program	44
Chart 5.2: Understanding on principles of MMT	45
Chart 5.3: Knowledge regarding policies in MMT.....	46
Chart 5.4: Perception towards patients on MMT	47
Chart 5.5: Knowledge on safety of methadone	48
Chart 5.6: Knowledge on local issues regarding MMT.....	49
Chart 6.1: Distribution of staffs in MMT service in selected study sites	54
Chart 6.3: Availability of naloxone as rescue measures	56
Chart 6.4: Selection criteria for allowance of take away dose	58

ABBREVIATIONS

AADK	-	Agensi Anti Dadah Kebangsaan
AIDS	-	Acquired Immune Deficiency Syndrome
AMO	-	Assistant Medical Officers
AUDIT-M	-	Alcohol Use Disorder Identification test-Modified
BP	-	Blood Pressure
C&C	-	Cure & Care Clinic
CCSC	-	Cure & Care Service Centers
CCTV	-	Closed- circuit television
COPD	-	Chronic Obstructive Pulmonary Disease
CVA	-	Cerebrovascular Accident
CVD	-	Cardiovascular Diseases
DASS	-	Depression Anxiety Stress Scale
HAART	-	Highly Active Anti-Retroviral Therapy
HEP	-	Hepatitis
HIV	-	Human Immune Deficiency Virus
IHD	-	Ischaemic Heart Disease
IVDU	-	Intravenous Drug Users
MATOD	-	Medication Assisted Therapy of Opiate Dependence
MMT	-	Methadone Maintenance Therapy
MOH	-	Ministry of Health Malaysia
MREC	-	Malaysian Research Ethics Committee
NADA	-	National Anti-Drug Agency
NGO	-	Non-Government Organizations

NSEP	- Needle & Syringe Exchange Program
OTI	- Opiate Treatment Index
PSU	- Primary Sampling Unit
SAC	- Staff attitude and satisfaction
SD	- Standard Deviation
SE	- Standard Error
SPO2	- Peripheral capillary oxygen saturation
SPSS	- Statistical Package for the Social Sciences
SSU	- Secondary Sampling Unit
STIs	- Sexually Transmitted Illnesses
UNAIDS	- United Nations Program on HIV/AIDS
WHO	- World Health Organization
WHOQOL	- World Health Organization Quality of Life
WHOQOL- BREF	- A shorter version of WHOQOL

INTRODUCTION

Opioid use is a global issue affecting around 16 million people, or 0.4 per cent of the population aged 15-64 worldwide with high prevalence of opiate use reported in Asia (0.4%) and Europe (0.5%) and the prevalence of opiate user in East and South East Asia was 0.2%(1). It was reported that the cumulative number of registered substance abusers in Malaysia between 1988 and 2006 were 300,241 and 60.7% of them were opioid abusers (2). In 2013, there were 20 877 drug users detected by the National Anti-Drug Agency and 75% of them were opiate user(3).

The treatment of opioid dependence patients became crucial due to the close relationship of opioid dependence and HIV prevalence. UNAIDS reported in 2014, the global HIV prevalence was 0.8%. It was estimated that there were 36.9 million people living with HIV, including 2.6 million children. Cases of HIV in Malaysia increased exponentially every year with the first case detected in 1986 and a total 101 672 HIV cases detected by December 2013 (4).

The prevalence of HIV in Malaysia in the year 2000 was 24.8 per 100 000 population and about three quarters of HIV transmission at that time was due to sharing infected needles for drug use (5). The total number intravenous drug users in Malaysia were estimated around 170 000 and prevalence of HIV among them was 22.1% (4). The epidemic was seen as an important threat to the country. In 2003, the number of HIV among Malaysian citizen was projected to reach 300 000 by 2015 if effective intervention to curb the HIV epidemic was not taken (6).

Malaysia started to provide Methadone Maintenance Treatment to opioid dependence patients in government facilities since 2005. The implementation of this program was as part of the National Harm Reduction Program (7).

The components of harm reduction include MMT, needle & syringe exchange program (NSEP) and condom distribution. The two main components that started in 2005 were MMT and NSEP while the third component was incorporated into both programs. It was started in October 2005 with ten MMT centers (eight governments and two in private sectors) and

three NSEP services. NSEP was conducted by Non-Government Organizations (NGO) that received funds from Ministry of Health Malaysia (MOH).

The MMT program has expanded and included the other agencies such as prisons and the National Anti-Drug Agency (NADA) premises over the years. In NADA, the program was implemented in Cure & Care Clinic (C&C) and Cure & Care Service Centres (CCSC). By December 2013 there were 811 MMT centres (446 government facilities and 365 private setting) in this country that provided treatment for total of 65,259 opioid dependence patients (33444 in government facilities and 31, 805 in private settings) with 18 600 active patients (8).

After 8 years of implementation, the outcome has been indirectly seen as reduction in new HIV case among drug users as well as reduction in HIV prevalence in the country (9). Due to almost simultaneous implementation of other harm reduction elements such as Needle Syringe Exchange Program (NSEP), it was uncertain about the effectiveness of MMT program in this country as there was no nationwide evaluation of the program specifically looking at various other outcome measures.

There were issues related to the MMT program such as the patients on MMT, staffs and infrastructure. Most of the issues were curbed and intervened. Several guidelines were produced by MOH to improve the services. The most prominent issues were related to handling patient's behavior.

Despite the various issues related to implementation of harm reduction measures, the prevalence of HIV in Malaysia in 2013 has reduced to 11.4 per 100 000 populations (8). The percentage of HIV registered patients due to intravenous drug use was also reduced from 75% in 2005 to 55% in 2009 (9). It was also found that among more than 20 000 registered patients on MMT, 66% were actively working in a salaried job (9). This indicates that MMT services can significantly stabilize an individual's lifestyle, helping the person to maintain social commitments and become a contributing member of society.

A meta-analysis found good outcome on retention, opioid abuse and criminality among the opioid dependence patients on methadone maintenance treatment compared with those who were not on treatment (10). A study by Gossop et al (11) found that there was no

difference in outcome between methadone treatments at primary health care settings compared to treatment in the specialist drug clinic. A 1 year cohort study in Ireland found older patients, single, living in their own home and on higher dose of methadone had fewer breaks in methadone treatment (12).

There were some small scale evaluations on MMT program in this country that reflected some success in this intervention (13) (14) (15) (16) (17) (18) (19) (20). However, there was no nationwide evaluation of this intervention looking at various outcome measures in Malaysia compared with other countries (21) (22) (23) (24) (25). After many years of implementation, it is timely to evaluate the program in term of several areas such as the effectiveness of the program in the country, the outcome of the treatment, the attitude of the staffs working in a Methadone Maintenance Program and adequacy of methadone program facilities in the country. Perception of patients on methadone treatment is also an important area to explore. Therefore a large scale multi-centre study was seemed necessary to examine the outcome and effectiveness of this nationwide programme.

This study was conducted to evaluate the Methadone Maintenance Program in Malaysia over a 10 year period (2005-2014) from various perspectives: patients, staffs and infrastructures as recommended by the WHO (26). The report of this study is prepared in several chapters as below:

Chapter 1: Outcome of MMT

Chapter 2: Characteristics of patients on MMT

Chapter 3: Effectiveness of MMT

Chapter 4: Perception of patients towards MMT

Chapter 5: Staffs' attitude towards MMT

Chapter 6: Infrastructure & Implementation policies

Chapter 7: Discussion

Chapter 8: Conclusions and Recommendations

CHAPTER 1

OUTCOME OF MMT

CHAPTER 1

GENERAL OBJECTIVE

To evaluate the outcome of the MMT programme in Ministry of Health Malaysia

SPECIFIC OBJECTIVES:

- i. To describe the socio demographic characteristic of patients on MMT.
- ii. To evaluate main treatment outcome in terms of current status.

METHODOLOGY AND SAMPLING DESIGN

A. Patients on methadone treatment

Study Design

Cross sectional study using retrospective record

Sample Size

Sample sizes were calculated using Sample Size Calculation Formula for a prevalence study.

$$n_{srs} = \frac{z_{\alpha}^2 P(1 - P)}{e^2}$$

The sample size calculation would consider all criteria as specified below:

1. Expected prevalence of HIV among IVDU (P): 30%
2. Standard error (e): 0.05
3. Confidence Interval of 95%.
4. Design effect of 2

The sample size was calculated using an appropriate formula for a survey and it was determined on the basis of the ability to estimate prevalence of the health conditions

specified in this study with adequate or acceptable precision. The sample was then inflated to cater for estimated design effect and non-response.

For this study, the required optimum sample size was 3500 respondents with 1900 respondents from urban and 1600 respondents from rural. The sample size was inflated to consider for the estimated design effect and 25% non-response. The allocation of sample to the state, urban and rural was done proportional to the population size. The list of selected healthcare facilities is tabulated in Appendix I.

Study population

All patients on MMT program in Ministry of Health facilities.

Study setting

Selected healthcare facilities (health clinic and hospitals)

Study period

The study was carried out from October until December 2014.

The data collection process was preceded by a pilot study at Tampin Health Clinic three months prior to evaluate the validity of the study questionnaire created by the investigators (socio demography, medical and legal history).

Sampling design

The design of the study was a multistage stratified cluster sampling. It was stratified by urban and rural. The primary sampling unit (PSU) was the health facilities (clinic /hospital) while the secondary sampling unit (SSU) was the eligible respondents in the selected health facilities. There were 55 sites out of 155 urban facilities and 48 sites out of 98 rural facilities, giving a total of 103 healthcare facilities. Forty respondents were randomly selected from their medical record from each of the selected health care facilities.

Inclusion criteria

- i. Registered in MMT program for at least 1 year
- ii. Literate
- iii. Not suffering from acute illness
- iv. Consented for the study

Exclusion criteria

- i. No consent.
- ii. Intoxicated on the day of the interview.

Study instruments

Questionnaire booklet for respondents

Data collection:

Information was extracted from medical records.

Study analysis

Data was exported to statistical software Statistical Package for the Social Sciences (SPSS version 16.0) for analysis. The data were checked and cleaned. Descriptive analysis was done to describe the prevalence for various parameters.

RESULTS

In this study, there were 3500 samples randomized. There were 221 medical records undetected and 3279 records sample data were available for analysis and referred as respondents' records (93.6% response rate). Out of 3279 records, relevant information cannot be obtained from 25 medical records, hence were identified as missing. Therefore, only 3254 respondents' baseline information at recruitment were identified and analyzed.

i. Socio-demography

Table 1.1: Socio-demographic characteristics of study respondents

Socio demographic Characteristic	Count	%
<i>Sex (n=3254)</i>		
Male	3223	99.0
Female	31	1.0
<i>Age group at baseline (n=3254)</i>		
18-29	452	15.9
30-39	1314	43.9
40-49	999	32.3
50-59	425	17.3
>= 60	64	3.7
<i>Ethnicity (n=3254)</i>		
Malay	2862	85.9
Chinese	261	9.3
Indian	116	4.3
Others	15	0.2
<i>Marital Status(n=3254)</i>		
Married	1420	42
Widowed	36	1.0
Divorced	230	7.6
Separated	16	0.5
Cohabiting	3	0.1
Never Married	1549	48.8
<i>Religion (n=3254)</i>		
Islam	2869	85.9
Christianity	76	2.4
Buddhist	215	8.0
Hindu	72	2.6
Sikh	5	0.2
None	13	0.4
Others	4	0.1

The mean age was 39.6 years old (min=18 years, max=72 years, SD=9.4).

Table 1.2: Socio economic status of study respondents

Socio-demographic Characteristic	Count	%
<i>Employment Status (n=2823)</i>		
Yes	2088	73.9
No	735	26.1
<i>Household Income (RM)(n=1768)</i>		
<800	415	23.0
800 – 1000	446	24.5
>1000 – 2000	566	32.6
>2000 – 5000	259	14.9
>5000	82	4.9
<i>Accommodation (n=3254)</i>		
Yes	2596	79.8
No	658	20.2

ii. Status Of MMT Treatment

a. General status

Table 1.3: Status of patients on MMT

Status	Count	Estimated population	% Prevalence	95% CI	
				Lower	Upper
Dead	251	2373	8.6	6.8	10.8
Defaulted	984	8030	29.2	26	32.4
Transferred	546	4831	17.5	14.6	20.8
Active	1234	10243	37.1	33.7	40.7
Terminated voluntarily	221	1972	7.1	4.9	10.3
Terminated involuntarily	18	138	0.5	0.2	1.1

b. Status of patients on MMT by locality

Table 1.4: Status of patients on MMT according to urban and rural

Status	Urban			Rural		
	Percentage	95% CI		Percentage	95% CI	
		Lower	Upper		Lower	Upper
Dead	9.5	7.3	12.3	5.5	4.0	7.5
Defaulted	27.8	24.2	31.7	33.5	28.2	39.2
Transferred	18.3	14.8	22.4	14.9	11.4	19.4
Still on follow-up	36.4	32.3	40.8	39.5	34.7	44.4
Terminated Voluntarily	7.5	4.8	11.6	5.9	3.5	9.9
Terminated Involuntarily	0.4	0.2	1.3	0.7	0.2	2.4

iii. Status of patients on MMT by facilities

Table 1.5: Distribution of patients on MMT in hospital and health clinics

	Count	Estimated population	% Prevalence	95% CI	
				Lower	Upper
Health Clinics	2296	18332	66.5	52.7	77.9
Hospitals	958	9255	33.5	22.1	47.3
Total	3254	27587	100		

Table 1.6: Status of patients on MMT in hospital and health clinics

Status	Health Clinic			Hospital		
	Percentage	95% CI		Percentage	95% CI	
		Lower	Upper		Lower	Upper
Dead	8.5	6.3	11.4	8.7	6.1	12.4
Defaulted	27.9	23.8	32.4	31.5	27.5	35.8
Transferred	14.9	12.1	18.3	22.6	17.6	28.5
Still on follow-up	39.5	34.7	44.6	32.4	29.3	35.8
Terminated Voluntarily	8.5	5.7	12.5	4.4	1.8	10.2
Terminated Involuntarily	0.6	0.2	1.5	0.3	0.1	1.7

CHAPTER 2

CHARACTERISTICS OF PATIENTS ON MMT

CHAPTER 2

GENERAL OBJECTIVE:

To study the characteristic of the active respondents in the MMT program in Ministry of Health facilities in Malaysia.

SPECIFIC OBJECTIVES:

- i. To describe socio demographic characteristics of active respondents
- ii. To study the methadone treatment (pattern & side effects encountered)
- iii. To describe the health status of the active respondents in terms of:
 - a. Known medical illness among the active respondents
 - b. Cardiovascular risk
 - c. Mental health status
 - d. Alcohol use

METHODOLOGY AND SAMPLING DESIGN

Study Design

Cross sectional study among all respondents who were still on methadone treatment at selected study sites.

Sample Size

The sample size was calculated using Epicalc 2000 sample size calculator.

A single proportion calculation was done based on listed outputs which were:

- Health status of active respondents
- Cardiovascular risks
- Alcohol use status
- Mental health status

Study population

All registered patient who is still active in MMT program in Ministry of Health facilities during the study period.

Study setting

Selected healthcare facilities (health clinic and hospitals) in Malaysia.

Study period

The study was carried out from October until December 2014.

The data collection process was preceded by a pilot study at Tampin Health Clinic three months prior to evaluate the validity of the study questionnaire created by the investigators (socio demography, medical and legal history).

Sampling design

The design of the study was a multistage stratified cluster sampling. It was stratified by urban and rural. The primary sampling unit (PSU) was the cluster of health facilities (clinic /hospital) while the secondary sampling unit (SSU) was the eligible patients in the selected health facilities. There were 55 sites out of 155 urban facilities and 48 sites out of 98 rural facilities, giving a total of 103 healthcare facilities. Forty patients were randomly selected from each of the selected health care facilities, where only the active patient was analysed.

A total of 1234 of active patient was taken as study respondents.

Inclusion criteria

- i. Registered in MMT program for at least 1 year
- ii. Literate
- iii. Consented for the study

Exclusion criteria

- i. No consent
- ii. Intoxicated on the day of the interview
- iii. Suffering from acute illness

Study instruments

- i. Questionnaire booklet for patient
- ii. Anthropometric measurement using weighing scale and measurement for height using stadiometer. Body Mass Index (BMI) was calculated based on Malaysian Clinical Practice Guideline for Obesity (27)
Blood pressure measurement set
- iii. Chemistry analyzer and virology test

Questionnaire for respondents comprised of:

- i. Socio demography
- ii. History: Legal , treatment, medical
- iii. Validated Malay version of Alcohol Use Disorder Identification test (AUDIT-M) (28)
- iv. Cardiovascular screening tool for local use(CVD screening)
- v. Validated Malay version of Depression Anxiety Stress Scale (DASS) (29)

Data collection:

- i. Interview using structured questionnaires
- ii. Extracting required information from medical records.
- iii. Laboratory investigations: random blood sugar, random cholesterol, liver function test, HIV, Hepatitis B and C.

Study analysis

Data was exported to statistical software Statistical Package for the Social Sciences (SPSS version 16.0) for analysis. The data were checked and cleaned. Descriptive analysis was done to describe the prevalence for various parameters.

RESULTS

i. Socio-demographic characteristics of respondents.

Table 2.1: Socio-demographic characteristic of respondents (n=1234).

Socio-Demography	Respondents	
	n	%
<i>Locality</i>		
Urban	655	53.1
Rural	579	46.9
<i>Type of facility</i>		
Hospital	283	22.9
Health clinic	951	77.1
<i>Sex</i>		
Male	1,223	99.1
Female	11	0.9
<i>Age</i>		
18-29	175	14.5
30-39	504	41.7
40-49	347	28.7
50-59	154	12.7
>=60	29	2.4
<i>Ethnicity</i>		
Malay	1,118	90.6
Chinese	79	6.4
Indian	30	2.4
Others	7	0.6
<i>Religion</i>		
Islam	1120	90.8
Christian	8	0.6
Buddhist	69	5.6
Hindu	28	2.3
Sikh	1	0.1
None	5	0.4
Others	3	0.2

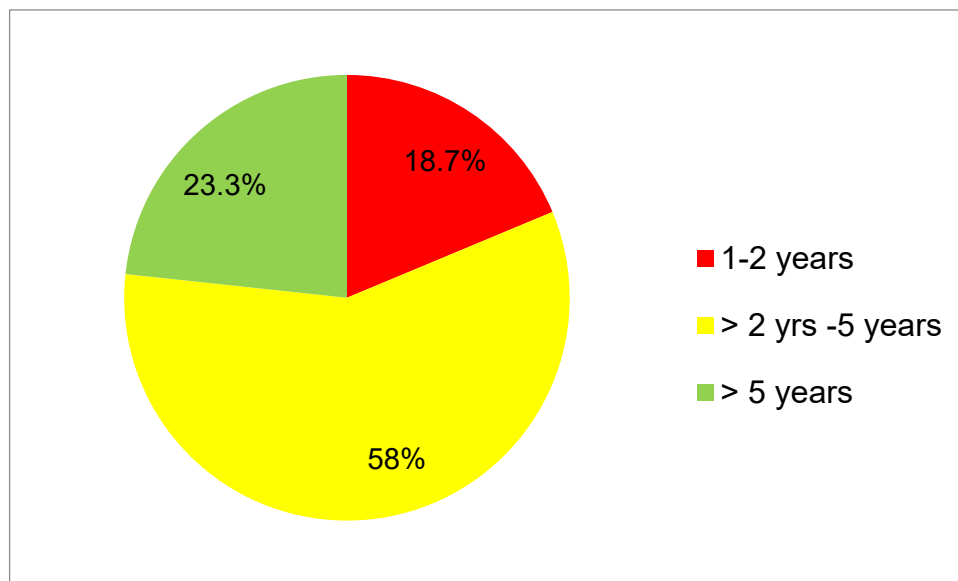
Socio-Demography	Respondents	
	n	%
<i>Current Marital Status</i>		
Never married	493	40
Married	631	51.1
Widow/ Widower/ Divorcee	108	8.7
Co-habiting	2	0.2
<i>Current Employment Status</i>		
Employed	1097	88.9
Not employed	137	11.1
<i>Current Household Income</i>		
< RM800	226	19.8
RM 800 – RM 1000	251	22
RM > 1000 – RM 2000	383	33.6
RM > 2000 – RM 5000	211	18.5
> RM 5000	70	6.1
<i>Current Personal Income</i>		
No income	154	13.1
< RM800	283	24.0
RM 800 – RM 1000	270	22.9
RM > 1000 – RM 2000	399	33.9
RM > 2000 – RM 5000	65	5.5
> RM 5000	7	0.6

The mean age of the respondents was 39.2 years old (min =19 years, max=69 years old, SD= 9.3).

ii. **Methadone treatment**

a. **Duration on treatment**

Chart 2.1: Duration on methadone treatment among respondents. (n=1143, missing data=91)



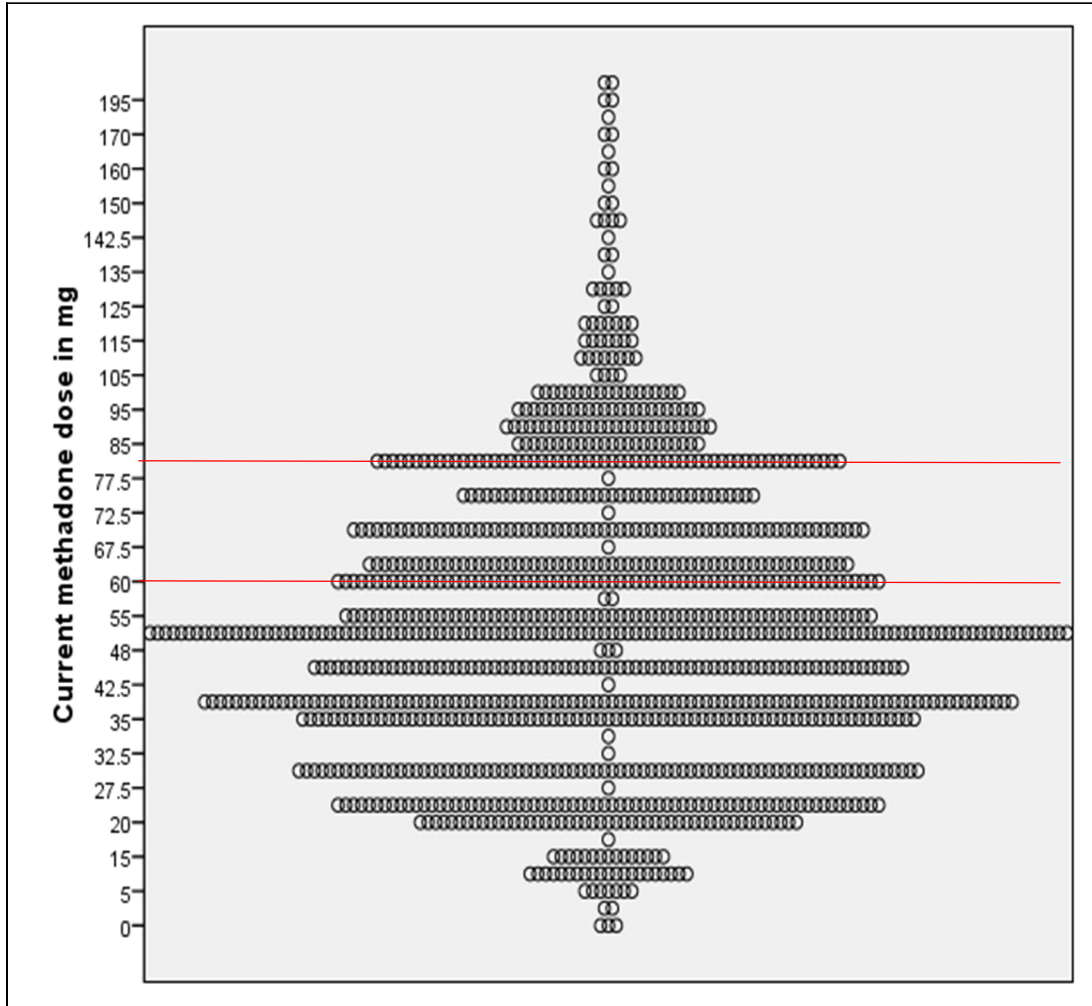
The mean duration on methadone treatment was 3.8 years (min=1 year, max=9 years, SD= 1.8).

b. **Dosage**

Table 2.2: Methadone dose among respondents (n= 1174, missing data=60)

Data	Current dose	Maximum dose level ever consumed while in treatment program
<i>Mean</i>	54.8 mg	66.8 mg
<i>Minimum</i>	2.5 mg	Not Applicable
<i>Maximum</i>	200 mg	220 mg

Chart 2.2: Distribution of current methadone dose among respondents compared with recommendation by the World Health Organization



Note: WHO recommendation for maintenance dose is between 60-80 mg

c. Take away dose

Table 2.3: Take away doses among respondents (n=1209, missing data=25)

Take-away Dose	n	Percent (%)
Yes	727	60.1
No	482	39.9

The mean number of take away doses was 3.26 days (min= 1 day, max= 50 days, SD= 4.1).

d. Split dose

Chart 2.3: Split methadone dose among respondent (n= 1201, missing data=33)

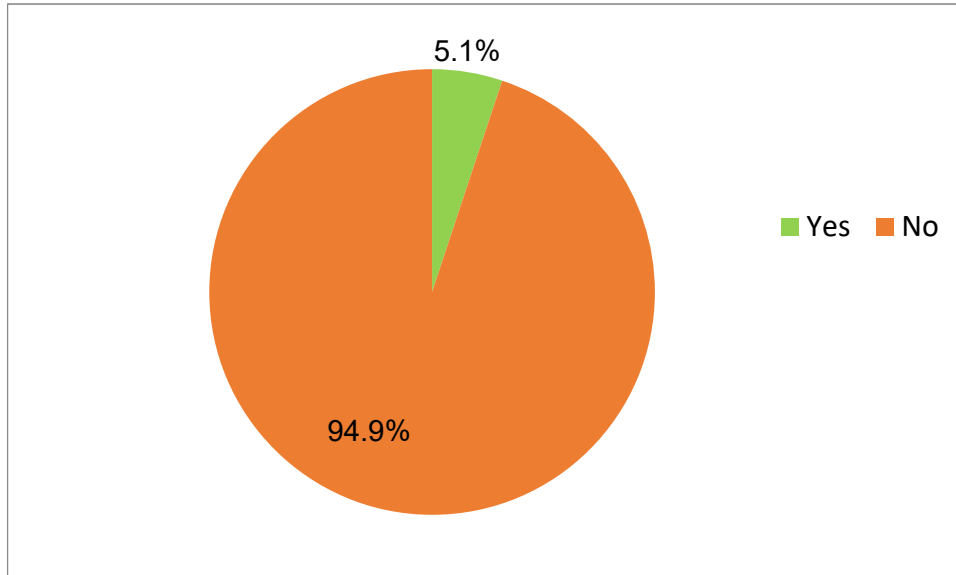
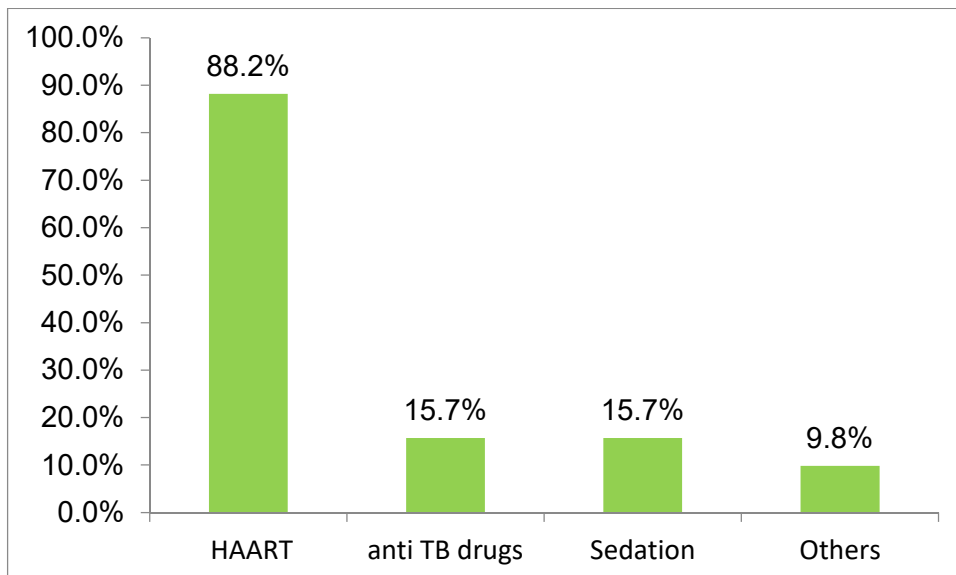
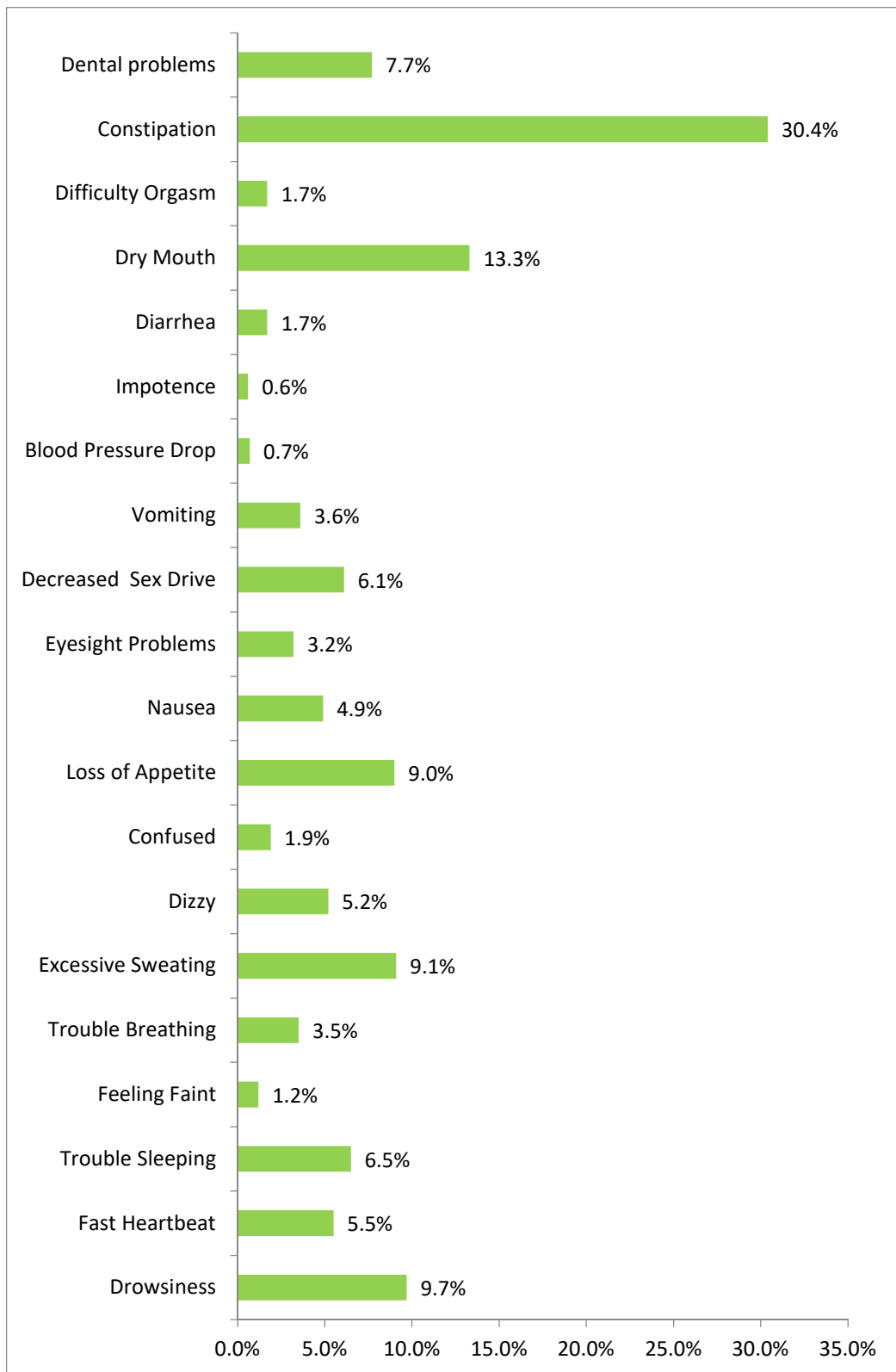


Chart 2.4: Reason for splitting methadone dose (n=61)



e. Methadone Side effects

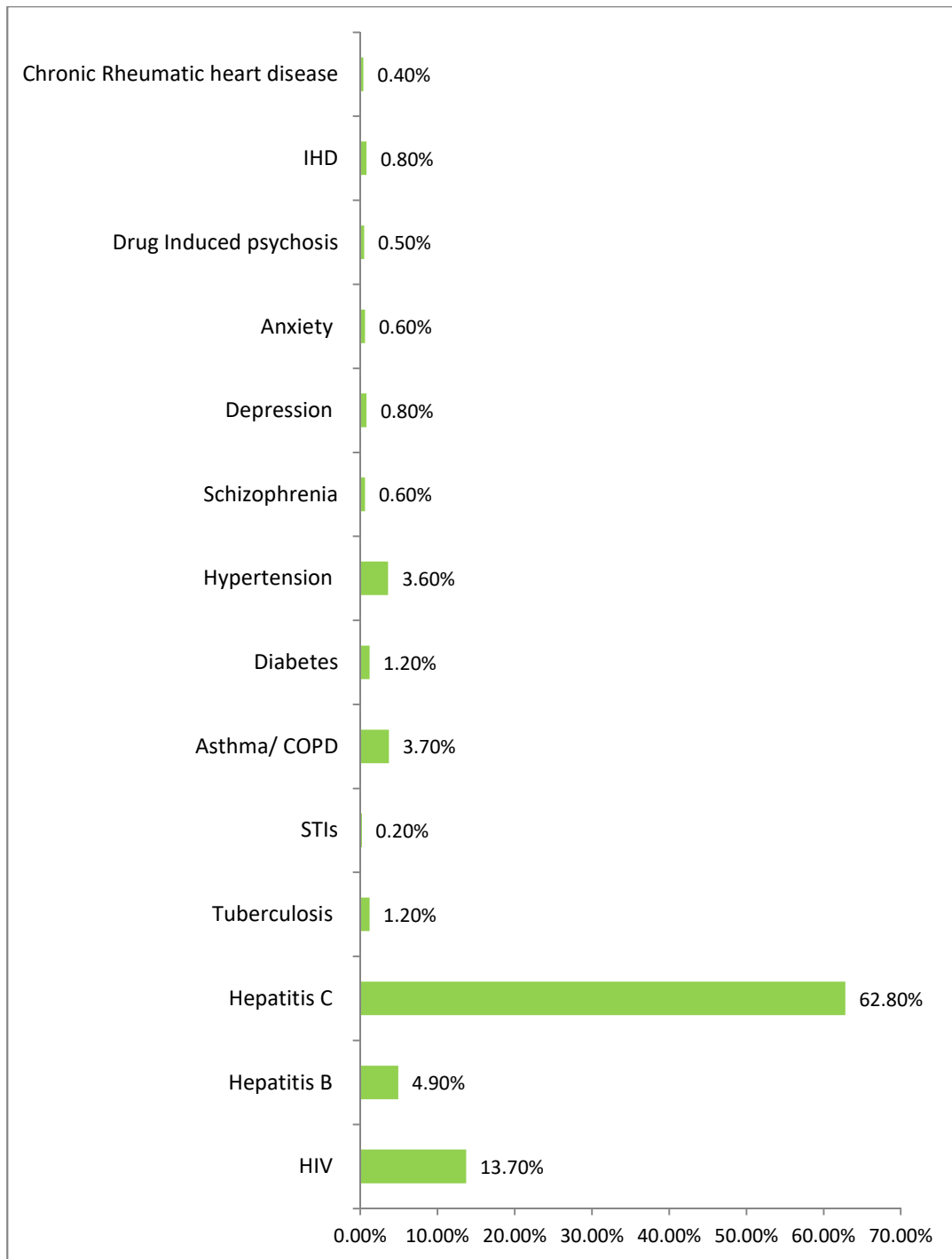
Chart 2.5: Reported side effects among respondents (n=1222, missing data=12)



iii. Health status

a. Medical Illnesses Known By Respondents

Chart 2.6: Reported medical illness known by respondents (n=1234)



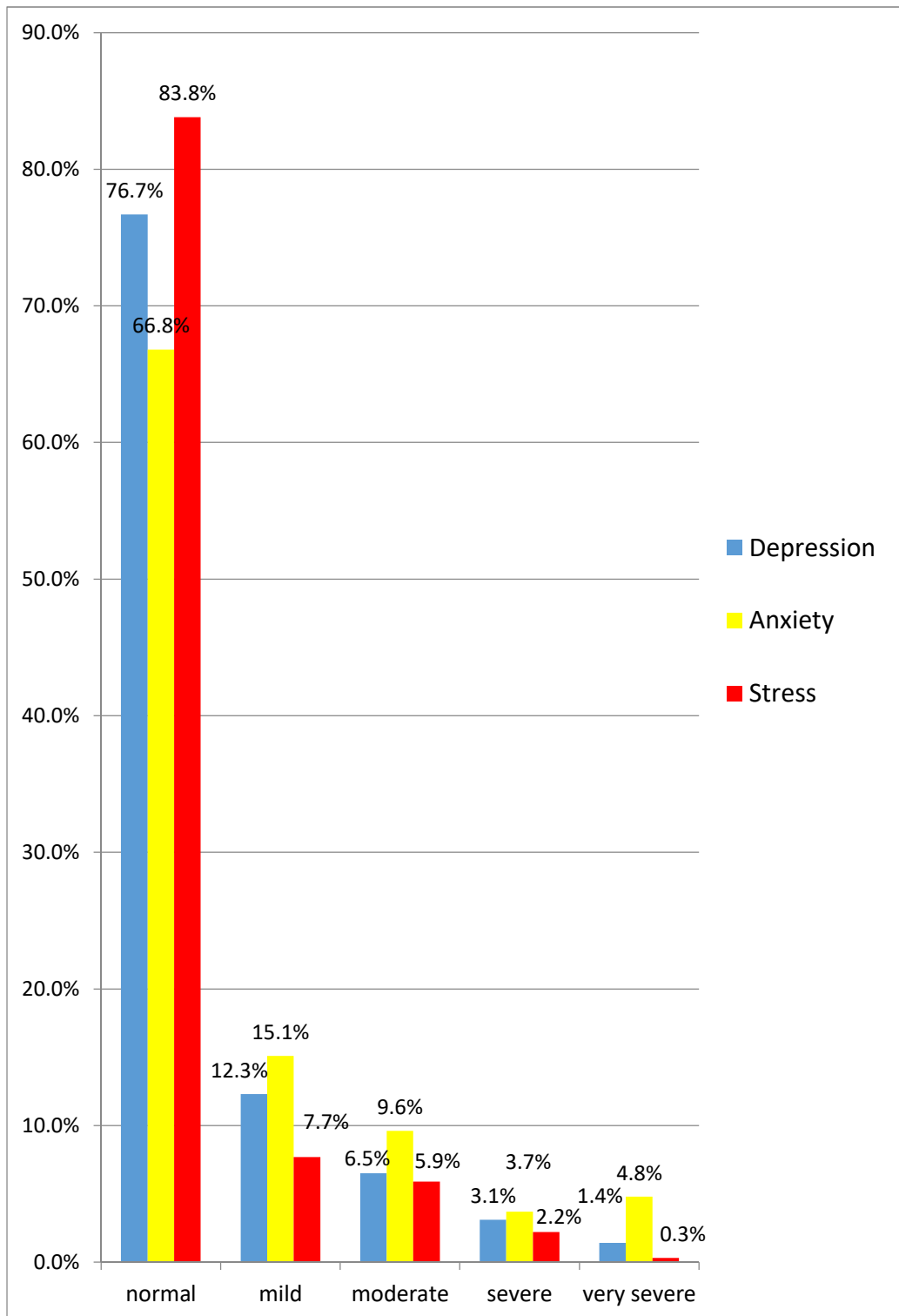
b. Cardiovascular Risk

Table 2.4: Cardiovascular risk factors among respondents (n= 1169, missing data=65)

Risks factors	n	Percentage (%)
<i>1. Family history of CVA and IHD</i>	178	14.6
<i>2. Family history of Diabetes Mellitus</i>	384	33.6
<i>3. Smoking</i>	883	72.2
<i>4. Drinking alcohol (ever & current)</i>	111	9.5
<i>5. Not exercising more than 5 x per week</i>	954	82.0
<i>6. Body Mass Index (BMI) (n=1034)</i>		
< 18 kg /m ²	1	0.1
18.0 - < 23.0 kg/m ²	581	56.2
23.0 - 27.4 (Pre-obese/ overweight)	316	30.6
27.5 - 34.9 (Obese I)	121	11.7
35.0 - 39.9 (Obese II)	12	1.2
≥40.0 (Obese III)	3	0.3
<i>7. Elevated blood pressure (n=1169)</i>		
Normal (< 140 /90 mmhg)	963	82.4
Abnormal (≥ 140/90mmhg)	206	17.6
<i>8. Diabetes mellitus (n=1094)</i>		
Normal (<7)	905	82.7
Borderline (7.0-11.0)	175	16.0
Abnormal (>11)	14	1.3
<i>9. Hypercholesterolaemia (n= 896)</i>		
Normal (<5.2 mmol/l)	709	79.1
Abnormal (>5.2 mmol/l)	187	20.9

c. Mental Health Status

Chart 2.7: Mental health status of respondents according to DASS score (n= 1175, missing data = 59)



d. Alcohol Use Among Study Respondents

Table 2.5: Current alcohol use among respondents by AUDIT (n=1180, missing data=54)

Drinking pattern	n	%
1. <i>Drinking alcohol in the past 12 months</i> (Current drinker)	95	8.1
2. <i>Category of drinking by risk score</i>		
a. 0-7 (zone 1: low risk)	62	65.3
b. 8-15 (zone 2: moderate risk)	26	27.4
c. 16-19 (zone 3: severe risk)	4	4.2
d. ≥ 20 (zone 4: very severe risk)	3	3.2
3. <i>Binge drinking</i>		
a. Never	61	64.2
b. Less than once a month	23	24.2
c. Once a month	6	6.3
d. Once a week	3	3.2
e. Every day or almost everyday	2	2.1

Alcohol use among Methadone patients were not much different between those from rural or urban area (urban =57.9%, rural =42.1%, P=0.167). The age group with highest use was those between 30-39 years old and 40 to 49 years old, (34.3% and 27.3%) respectively.

The prevalence of drinker were highest among Indian (41.4%), followed by Chinese (27.3%) and Malay (6.0%).

CHAPTER 3

EFFECTIVENESS OF MMT

CHAPTER 3

GENERAL OBJECTIVE:

To assess effectiveness of MMT programme in reducing HIV transmission and other related parameters.

SPECIFIC OBJECTIVES:

To evaluate the impact of MMT programme with regards to:

- i. Employment status
- ii. Ability to own accommodation
- iii. Blood borne virus infection
- iv. LFT
- v. Incarcerations
- vi. Quality of life
- vii. Substance use
- viii. Crime
- ix. Health status
- x. HIV risk
- xi. Social functioning

METHODOLOGY AND SAMPLING DESIGN

Study Design

Quasi experimental study design

Sample Size

Sample sizes were calculated with Epicalc 2000 sample size calculator using two main proportion or two mean difference based on the listed output:

- i. Employment status
- ii. Ability to own accommodation
- iii. Blood borne virus infection
- iv. LFT
- v. Incarcerations
- vi. Quality of life
- vii. Substance use
- viii. Crime
- ix. Health status
- x. HIV risk
- xi. Social functioning

Based on the smallest mean difference and highest SD or smallest difference of proportion of score before and after intervention; the optimum sample size calculated were 200.

Study population

All registered patient who is still active in MMT program in Ministry of Health facilities during the study period.

Study setting

Selected healthcare facilities (health clinic and hospitals) in Malaysia.

Study period

The study was carried out from October until December 2014.

Data collection

The data collection process was preceded by a pilot study at Tampin Health Clinic three months prior to evaluate the validity of the study questionnaire created by the investigators (socio demography, medical and legal history).

Sampling design

The design of the study was a multistage stratified cluster sampling. It was stratified by urban and rural. The primary sampling unit (PSU) was the cluster of health facilities (clinic /hospital) while the secondary sampling unit (SSU) was the eligible patients in the selected health facilities. There were 55 sites out of 155 urban facilities and 48 sites out of 98 rural facilities, giving a total of 103 healthcare facilities. Forty patients were randomly selected from patients' record from each of the selected health care facilities, where only the active patient was analysed to look for the effectiveness of the methadone program.

A total of 1234 of active patient was taken as study respondents.

Inclusion criteria

- i. Registered in MMT program for at least 1 year
- ii. Literate
- iii. Not suffering from acute illness
- iv. Consented for the study

Exclusion criteria

- i. No consent.
- ii. Intoxicated on the day of the interview.
- iii. Suffering from acute illness

Study instruments

- i. Questionnaire booklet for patient
- ii. Anthropometric measurement using weighing scale and stadiometer for weight and height measurements.

- iii. Blood pressure measurement set.
- iv. Chemistry analyser and virology test

The questionnaire used in this study was on:

- i. Socio demography
- ii. Legal, treatment and medical histories.
 - a. Legal:
 - i. Incarceration – defined as detention of those who were caught by police for any offenses and was locked up or sent to prison or compulsory drug rehabilitation centres
 - ii. Re-incarceration – defined as re-imprisonment or those who were found guilty by the court and involuntarily placed in drug rehabilitation centres
- iii. WHO Quality of Life (WHOQOL- BREF)

The World Health Organization Quality of Life (WHOQOL) project was initiated in 1991. The aim was to develop an international cross-culturally comparable quality of life assessment instrument. It assesses the individual's perceptions in the context of their culture and value systems, and their personal goals, standards and concerns. The WHOQOL instruments were developed collaboratively in a number of countries worldwide, and have been widely field-tested.

The validated WHOQOL-BREF Malay version (30) instrument comprises 26 items, which measure the following broad domains: physical health, psychological health, social relationships, and environment. The WHOQOL-BREF is a shorter version of the original instrument that may be more convenient for use in large research studies or clinical trials. The raw scores were transformed into per hundred using the recommended conversion table (31).

- iv. Opiate Treatment Index (OTI)

The Opiate Treatment Index (OTI) is a structured interview designed to provide a measure of the effectiveness of drug treatments. The OTI measures 6 treatment outcomes; drug use, HIV risk-taking behavior, social functioning, criminality, health status and psychological functioning. The OTI in its completeness from takes 20-30 minutes to complete. In some studies, only selected components of the instrument are administered. The drug use questions allow the calculation of a quantity/frequency

estimate (Q score), through the addition of consumption amounts on the two previous days and dividing these values by the time intervals between days (32).

Note: Important elements in evaluation of effectiveness in of MMT were based on recommendations in several outcome studies (33)(24)(21)(34).

Data collection

Data was collected via;

- i. Direct interview using structured questionnaires
- ii. Self-administered questionnaire
- iii. Extracting required information from medical records.
- iv. Laboratory investigations: random blood sugar, random cholesterol, Liver Function Test, HIV, Hepatitis B and C.

Study analysis

Data was exported to statistical software Statistical Package for the Social Sciences (SPSS version 16.0) for analysis. The data were checked and cleaned. Descriptive analysis was done to describe the prevalence for various parameters. Chi square test and paired t test were used for further analyses.

RESULTS

i. Employment Status

ii. Ability To Own Accommodation

Table 3.1: Employment status and ability to own house before and after MMT

Variables (n=1234)	Baseline		Current	
	Yes n (%)	No n (%)	Yes n (%)	No n (%)
Employment	941 (76.3)	293 (23.7)	1097 (88.9)	137 (11.1)
Ability to own house	348 (28.2)	886 (71.8)	418 (33.9)	816 (66.1)

iii. Blood Borne Viruses Infection

Table 3.2: Blood Borne Virus (BBV) infection status before and after MMT

BBV	n	Baseline		Current	
		Positive	Negative	Positive	Negative
		n (%)	n (%)	n (%)	n (%)
HIV	1200	162 (13.5)	1038 (86.5)	168 (14.0)	1032 (86.0)
Hep B	1183	59 (5.0)	1124 (95.0)	62 (5.2)	1121 (94.8)
Hep C	1088	686 (63.1)	402 (36.9)	703 (64.6)	385 (35.4)

Table 3.3: Seroconversion of Blood Borne Viruses (BBV) after joining MMT

BBV	Seronegative to seropositive	Seropositive to seronegative
HIV	6 (0.5%)	NA
Hepatitis B	4 (0.3%)	1 (0.1%)
Hepatitis C	29 (2.7%)	12 (1.1%)

v. Liver Function Test (LFT)

Table 3.4: Status of liver enzymes before and after MMT (N=988, missing data=246)

Status	Before MMT	After MMT
Normal	883(88.5%)	872 (87.4%)
Abnormal	115 (11.5%)	126 (12.6%)

vi. Incarceration

Table 3.5: History of incarceration (imprisoned & involuntary rehabilitation centre) before and after MMT

History	Before MMT n (%)	After MMT n (%)
<i>Locked –up(n=868)</i>		
Yes	506(58.3)	218(25.1)
No	362(41.7)	650(74.9)
<i>Imprisoned(n=846)</i>		
Yes	482 (57)	77 (9.1)
No	364 (43)	769 (90.9)
<i>Involuntary rehabilitation centre(n=831)</i>		
Yes	229 (27.6)	13 (1.6)
No	602 (72.4)	818 (98.4)
<i>Incarceration(imprisoned & Involuntary rehabilitation centre)(n=1234)</i>		
Yes	736 (59.6)	93 (7.5)
No	498 (40.4)	1141 (92.5)

Table 3.6: Comparison of mean frequency for locked-up, imprisoned and sent to involuntary rehabilitation

Types of incarceration	Mean ± SD		Mean difference ± SE	95% CI		t	P
	Before	After		Min	Max		
Locked up (N=868)	2.33 ± 3.41	0.38 ± 0.77	1.95 ± 0.11	1.73	2.18	17.25	<0.001
Imprisoned (N=846)	1.45 ± 2.07	0.12 ± 0.44	1.33 ± 0.07	1.19	1.47	18.44	<0.001
involuntary rehabilitation centre (N=831)	0.52 ± 1.12	0.03 ± 0.24	0.50 ± 0.04	0.42	0.57	12.47	<0.001

vi. Quality of Life (World Health Organization's Quality of Life, WHOQOL)

Table 3.7: Comparison of mean score for quality of life (WHOQOL)

Variable n= 905	Mean \pm SD		Mean difference \pm SE (before vs after)	95% CI		t	P
	Before	After		Min	Max		
Physical	54.42 \pm 15.00	67.18 \pm 14.63	-12.76 \pm 0.58	-13.89	-11.61	-21.90	<0.001
Psychological	51.06 \pm 15.65	66.54 \pm 14.81	-15.48 \pm 0.61	-16.67	-14.29	-25.4	<0.001
Social	52.79 \pm 17.54	65.87 \pm 17.14	-13.07 \pm 0.66	-14.38	-11.77	-19.65	<0.001
Environmental	50.36 \pm 14.52	64.48 \pm 15.25	-14.12 \pm 0.56	-15.21	-13.03	-25.38	<0.001

vii. Substance Use based on Opiate Treatment Index

Table 3.8: Comparison of mean score of Opiate Treatment Index (OTI) before and after

Items n= 779	Mean \pm SD		Mean difference \pm SE (before vs after)	95% CI		t	P
	Before	After		Min	Max		
Heroin	2.70 \pm 2.38	0.003 \pm 0.06	2.69 \pm 0.08	2.53	2.86	31.62	<0.001
Other opiate	0.05 \pm 0.43	0.00 \pm 0.00	0.05 \pm 0.02	0.02	0.08	3.01	0.002
Alcohol	0.04 \pm 0.58	0.00 \pm 0.04	0.04 \pm 0.02	0.00	0.08	1.99	0.046
Marijuana	0.01 \pm 0.26	0.00 \pm 0.00	0.01 \pm 0.00	0.00	0.03	1.36	0.17
Tranquilizer	0.50 \pm 0.68	0.00 \pm 0.00	0.05 \pm 0.02	0.00	0.10	2.02	0.14
Amphetamine	0.02 \pm 0.24	0.00 \pm 0.00	0.02 \pm 0.00	0.00	0.36	2.24	0.03
HIV Risks	6.22 \pm 7.24	2.65 \pm 4.27	3.56 \pm 0.23	3.12	4.00	15.77	<0.001
Social functioning	12.21 \pm 6.01	9.80 \pm 5.43	2.41 \pm 0.20	2.01	2.81	11.88	<0.001
Crime	0.30 \pm 1.10	0.03 \pm 0.28	0.30 \pm 0.03	0.24	0.37	9.11	<0.001
Health score	3.94 \pm 4.50	2.22 \pm 3.09	1.73 \pm 0.13	1.47	1.98	13.37	<0.001

CHAPTER 4

PERCEPTION AMONG PATIENTS TOWARDS MMT

CHAPTER 4

GENERAL OBJECTIVE

To assess perception towards treatment among patients on MMT

SPECIFIC OBJECTIVES

- i. To identify perception towards treatment goal
- ii. To know perception towards staff's capability in running MMT service
- iii. To evaluate perception towards rules and regulations in treatment center

METHODOLOGY

Study design

Cross sectional study among all respondents who were still on methadone treatment at selected study sites.

Sample size

The sample size was calculated using Epicalc 2000 sample size calculator. A single proportion calculation was done based on perception towards treatment.

Study population

All registered patients who were still active on MMT program in Ministry of Health facilities during the study period.

Study population

All registered patient who are still active on MMT program in Ministry of Health facilities during the study period.

Study setting

Selected healthcare facilities (health clinic and hospitals) in Malaysia.

Study period

The study was carried out from October until December 2014.

The data collection process was preceded by a pilot study at Tampin Health Clinic three months prior to evaluate the validity of the study questionnaire created by the investigators (socio demography, medical and legal history).

Sampling design

The design of the study was multistage stratified cluster sampling. It was stratified by urban and rural. The primary sampling unit (PSU) was the cluster of health facilities (clinic /hospital) while the secondary sampling unit (SSU) was the eligible patients in the selected health facilities. There were 55 sites out of 155 urban facilities and 48 sites out of 98 rural facilities giving a total of 103 healthcare facilities. Forty patients were randomly selected from each of the selected healthcare facilities, where only the active patient were analysed.

A total of 1234 of active patient were taken as study respondents.

Inclusion criteria

- i. Registered in MMT program for at least 1 year
- ii. Literate
- iii. Consented for the study

Exclusion criteria

- i. No consent.
- ii. Intoxicated on the day of interview.
- iii. Suffering from acute illness.

Study instruments

Treatment Perception Questionnaire (TPQ)(26). It is a brief, 10 item scale designed to measure client satisfaction with treatment for substance abuse problems. The questionnaire is designed to be self-administered by clients of substance abuse treatment services. The study questionnaires (process and outcome), participant instructions and response scales were translated into the national language (Malay) by bilingual translators who were health professionals with experience in research interviewing. The translated version was validated for face validity. Both the original TPQ version in English and also the translated version were given to respondents and they are allowed to choose either language according to their proficiency.

The Treatment Perception Questionnaire (TPQ) contains two five-item subscales concerning client perceptions of staff and of the treatment programme. The first subscale concerns beliefs about staff understanding of clients' problems, agreement about treatment objectives, availability for discussion, ability to motivate and professional competence. The second subscale assesses client perceptions of aspects of treatment programme operation: communication about treatment decision-making, treatment expectations, therapeutic content, time in treatment and programme rules and regulations.

To minimize response bias, the TPQ contains five positively and five negatively worded items. These items are scored on a five-point scale (strongly disagree to strongly agree, weighted 0-4). Score weights for negatively worded items are reversed (ie. strongly agree = 0 and strongly disagree = 4). Scoring of the TPQ is achieved by summing the item weights across the 10 items. If preferred, the two subscales can be scored individually to examine response patterns on the staff and programme subscales separately.

Data collection

Self-administered anonymous questionnaire.

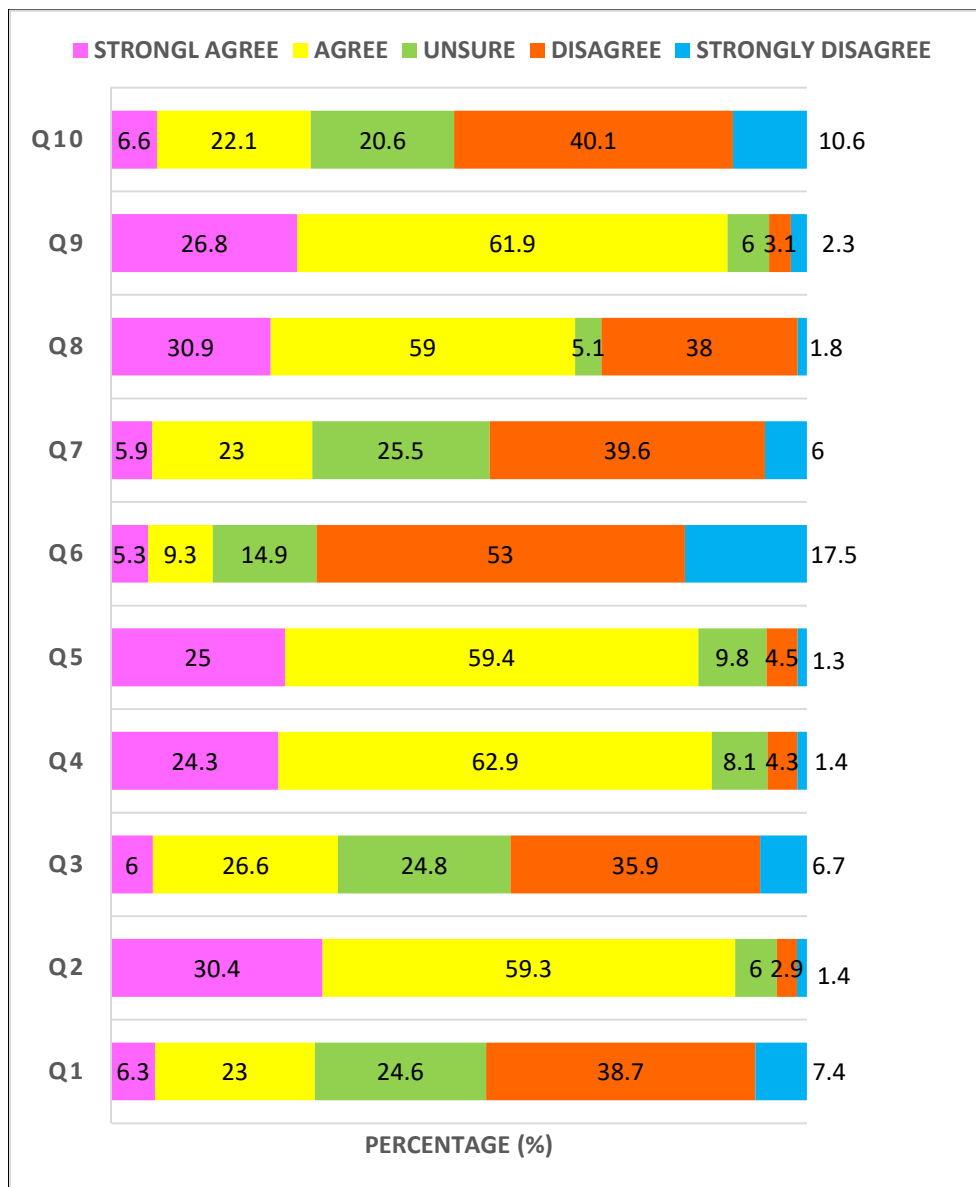
Study analysis

Data was exported to statistical software Statistical Package for the Social Sciences (SPSS version 16.0) for analysis. The data was checked and cleaned. Descriptive analysis was done to describe prevalence for various parameters.

RESULTS

i. Perception on treatment and staff

Chart 4.1: Perception of clients on their treatment and staff



Q1:staff do not understand on the type of assistance required by clients)	Q6: do not like all the treatment sessions attended
Q2: explained clearly about the treatment	Q7: not enough time to solve problems
Q3: had different opinion regarding aim of therapy	Q8: staff have done a good job
Q4: staff who are always ready to listen	Q9: received assistance that was needed
Q5: staff give motivation to solve problems	Q10: do not like some of the rules/laws regarding therapy

CHAPTER 5

STAFF'S ATTITUDE TOWARDS MMT

CHAPTER 5

GENERAL OBJECTIVE

To assess staff's attitude towards Methadone Maintenance Therapy (MMT).

SPECIFIC OBJECTIVES

- i. To determine socio demographic profiles of staffs handling MMT.
- ii. To identify attitude towards drugs addiction & harm reduction.
- iii. To assess understanding on principles of MMT.
- iv. To determine knowledge regarding policies in MMT.
- v. To identify perception towards patients on MMT.
- vi. To evaluate knowledge on safety of methadone.

Study design

Cross sectional study among staff handling Methadone Maintenance Therapy

Sample size

Estimated four staff handling MMT per 103 selected sites

Study population

All staffs handling MMT in Ministry of Health's health care facilities.

Study setting

Selected healthcare facilities (health clinic and hospitals)

Study period

The study was carried out from October until December 2014.

Sampling design

The design of the study was as in Chapter 1. There were 55 sites out of 155 urban facilities and 48 sites out of 98 rural facilities giving a total of 103 healthcare facilities. Four staffs per site among selected sites were offered to participate in the study.

Inclusion criteria

- i. Consented for the study
- ii. Working in MMT service for at least 6 months
- iii. Not suffering from acute illness

Study instruments

Questionnaire on Staff Attitude and Satisfaction (CAS) (26)

The CAS includes instructions how to rate the responses to the statements made in the questionnaire. The interviewer should check with staff that the instructions are well understood and should assert the confidentiality of the response, confirming that no information will be passed to programme management or to other staff.

Staff attitude and Satisfaction Questionnaire (CAS)

The CAS is a self-administered, five-scale, 44-item instrument that ascertains staff attitudes towards methadone maintenance treatment, methadone maintenance patients, medical knowledge about methadone and satisfaction with the work environment.

Additional 10 questions were prepared based on local issues in Malaysia.

Data collection

Self-administered anonymous questionnaire

Study analysis

Data was exported to statistical software Statistical Package for the Social Sciences (SPSS version 16.0) for analysis. The data was checked and cleaned. Descriptive analysis was done to describe prevalence for various parameters.

RESULTS

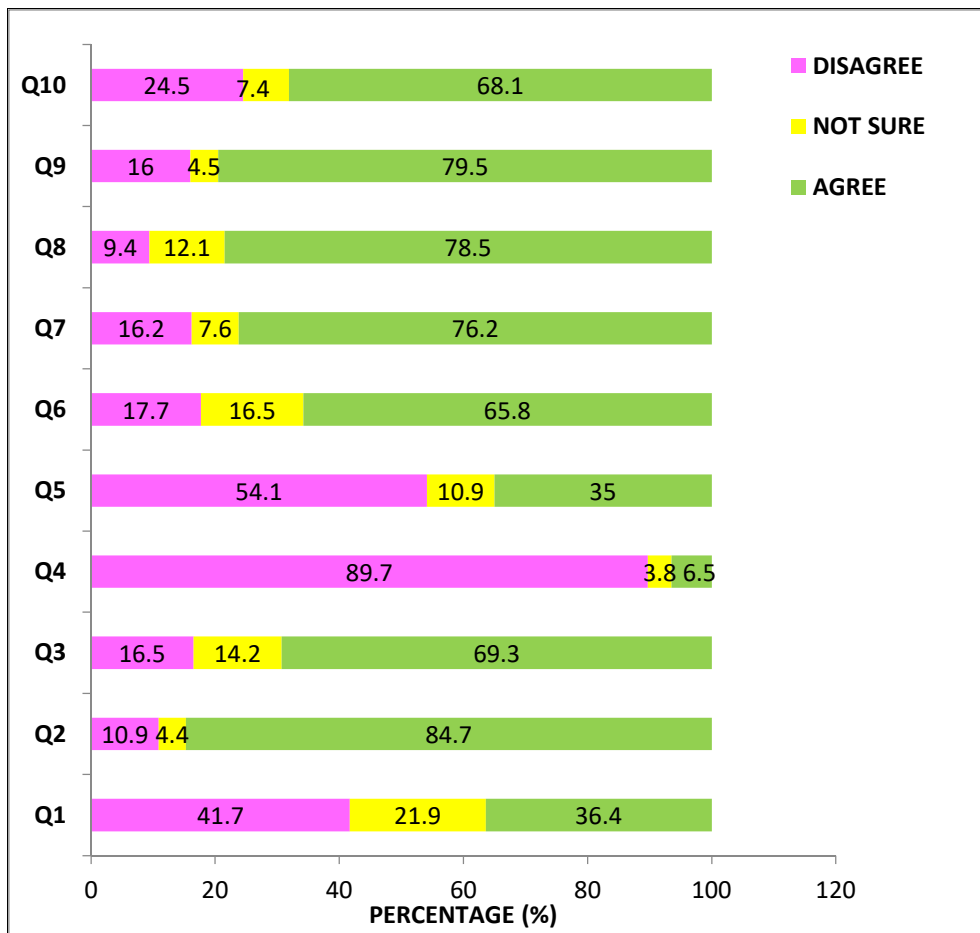
i. Socio demography

Table 5.1: Staff Socio demography & background information (n=341)

Variable	n	%
<i>Location (n=341)</i>		
Urban	188	55.1
Rural	153	44.9
<i>Types of facilities (n=341)</i>		
Hospital	68	19.9
Clinic	273	80.1
<i>Categories of respondents (n=325, missing= 16)</i>		
Doctors		
Psychiatrist	3	0.9
Family Medicine Specialist	8	2.5
Public Health Physician	2	0.6
Medical Officer	90	27.7
Pharmacists		
	98	30.2
Paramedics		
Assistant Medical Officers	76	23.4
Nurses	23	7.1
Others (clerk / general worker)	25	7.7
<i>Gender (n=324, missing data=17)</i>		
Male	183	56.5
Female	141	43.5
<i>Age Category*</i>		
20-29	171	54.3
30-39	98	31.1
40-49	33	10.5
50 & above	13	4.1
<i>Duration of service in Health department</i>		
1-5 years	143	46.7
6-10 years	101	33
11- 15 years	27	8.8
16-20 years	18	5.9
>20 years	17	5.6
<i>Duration of service in MMT unit</i>		
< 1 year	50	15.9
1 to < 2 years	95	30.2
2 to < 5 years	128	40.6
5 years & above	42	13.3
<i>Had received training in MMT</i>		
Yes	222	71.4
No	89	28.6

ii. **Attitude towards drugs addiction & harm reduction**

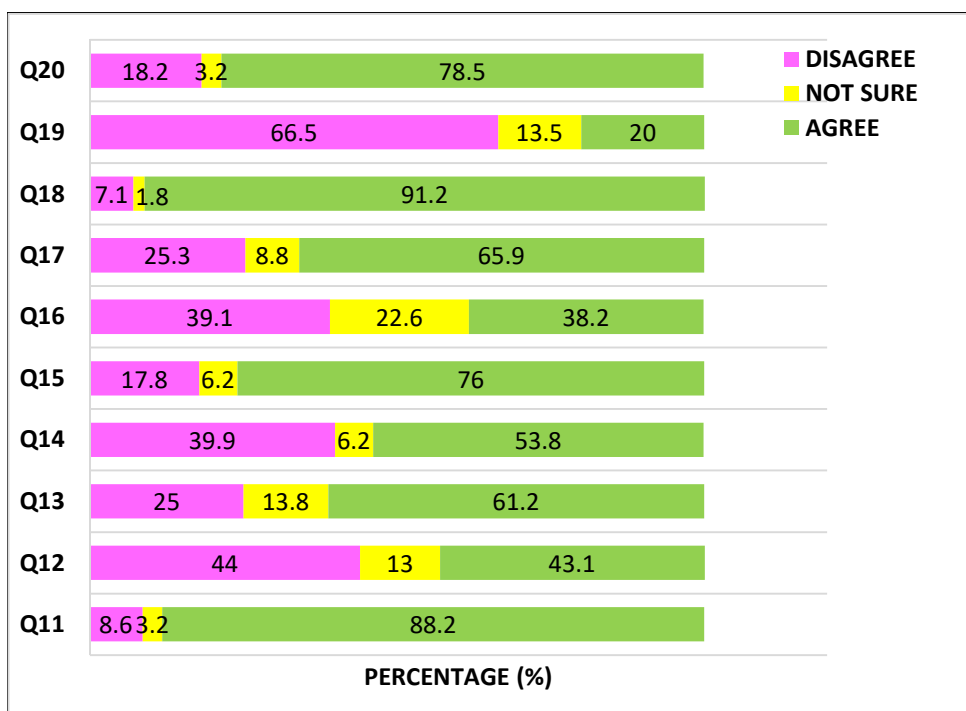
Chart 5.1: Perception towards drug addiction, methadone & NSEP program



Q1: Modern society is too tolerant towards drugs addicts	Q6: Methadone/Buprenorphine do more than substitute one drug for another.
Q2: Adults convicted of selling drugs to minors should be jailed for life	Q7: Needles/ syringe exchange should be established in all cities known to have significant number of injecting drug users.
Q3: Persons convicted of sales of illicit drugs should not be eligible for parole.	Q8: Methadone/buprenorphine maintenance greatly reduce the health, social and legal consequences of narcotic addiction.
Q4: Marijuana should be legalized.	Q9: Drug addiction is a vice.
Q5: People who become addicted to heroin have only themselves to blame.	Q10: Drug addicts are weak people who cannot resist the temptation to use drug

iv. Understanding on principles of MMT

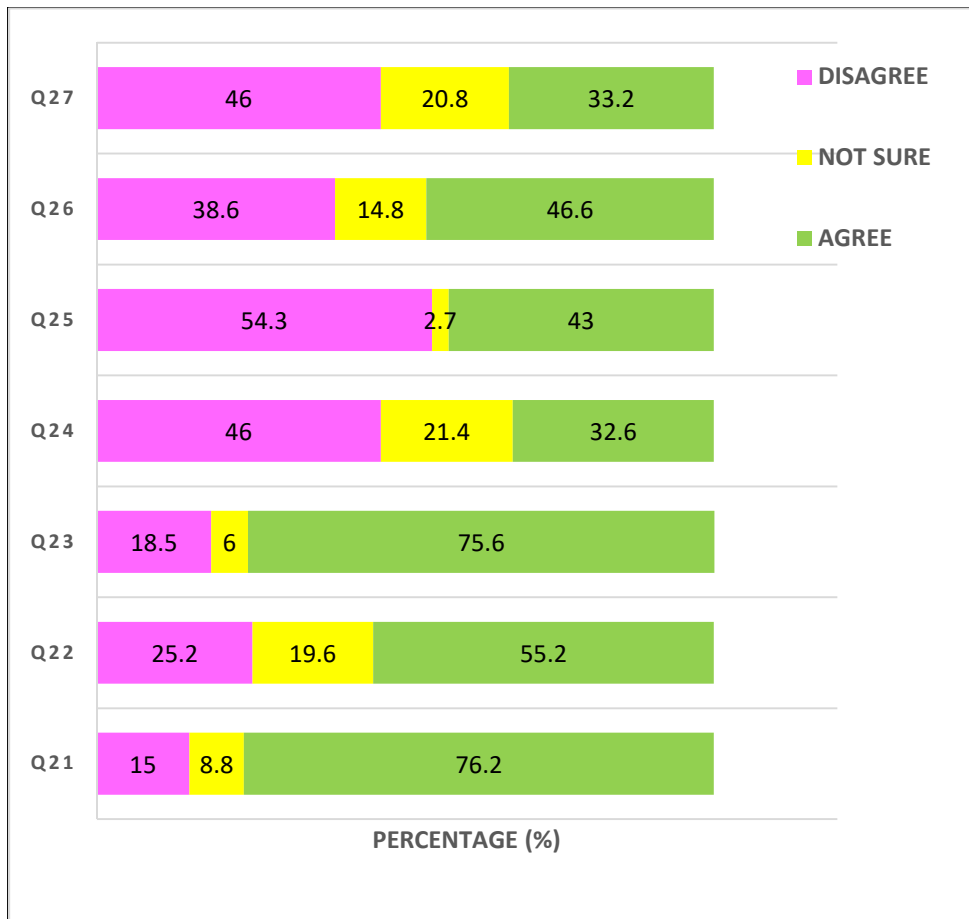
Chart 5. 2: Understanding on principles of MMT



Q11: Abstinence from all narcotics should be the principle goal of treatment with methadone or buprenorphine.	Q16: It is unethical to maintain addicts on Methadone/Buprenorphine indefinitely.
Q12: Methadone/Buprenorphine patients who continue to use drugs should have their doses of Methadone /Buprenorphine reduced.	Q17: Methadone/Buprenorphine patients who repeatedly fail to keep counselling appointments should be gradually withdrawn off methadone/buprenorphine.
Q13: No limits should be set on the amount of time a patient can be on methadone /Buprenorphine maintenance	Q18: After a period of stable methadone or buprenorphine maintenance, patient should be encouraged to start a gradual withdrawal from methadone /buprenorphine
Q14: A patient should be tapered off Methadone/Buprenorphine once he/she has stopped using heroin.	Q19: Methadone/buprenorphine treatment should be time limited (e.g. less than 6 months or less than a year).
Q15: Patient should be given only enough Methadone / buprenorphine to prevent withdrawal.	Q20: Maintenance patient who ignores repeated warnings to stop using heroin should be expelled from treatment.

v. Knowledge regarding policies in MMT

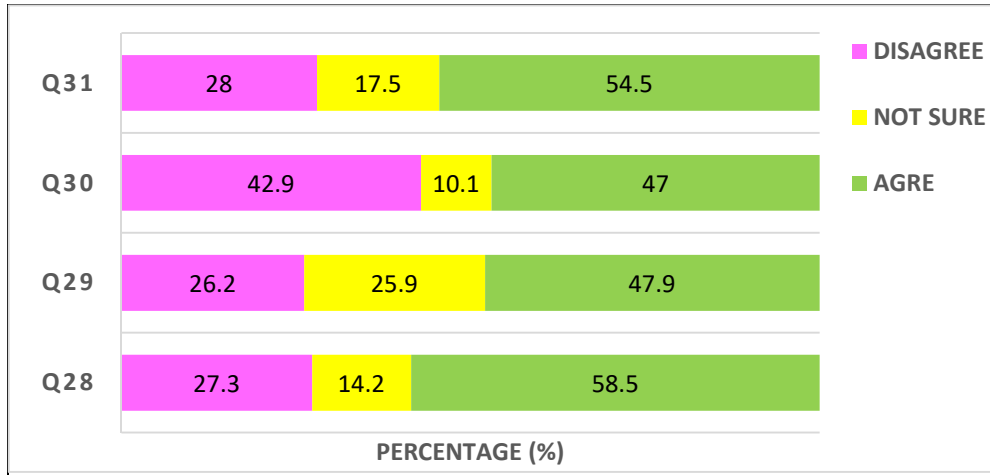
Chart 5.3: Knowledge regarding policies in MMT



Q20: Methadone/buprenorphine should be expanded to all heroin addicts who want methadone or buprenorphine can received it.
Q21: Heroin addicts should be given long term maintenances only after short term maintenance has been unsuccessful
Q22: Methadone/buprenorphine patients who continue to use illegal drug should be discharged to make way for others more likely to benefit from the treatment.
Q23: Heroin addicts should be given methadone/buprenorphine maintenance only after alternative treatments have been unsuccessful
Q24: Patient caught selling or trading their methadone/buprenorphine doses should get fewer take home doses.
Q25: Patients on high methadone/buprenorphine doses should get fewer take home doses than patients on low doses.
Q26: Methadone/buprenorphine client who complaint about their program should be encouraged to leave

vi. Perception towards patients on MMT

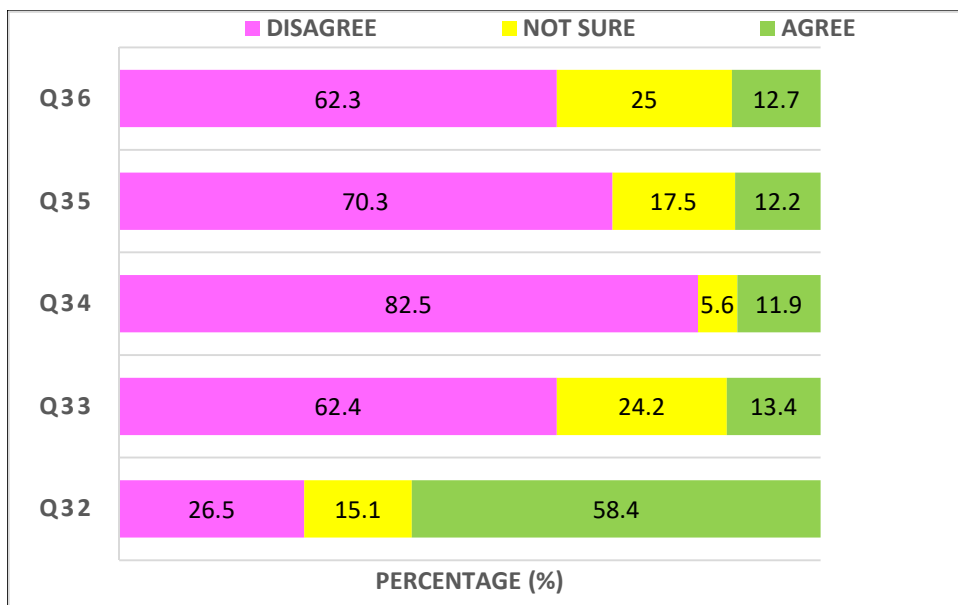
Chart 5.4: Perception towards patients on MMT (n=336, missing data = 5)



Q28: Many patients here just want a break from hustling (they do not really want to stop heroin addiction).
Q29: Many patients here are sincerely working towards their recovery.
Q30: Many patients here are generally uncooperative.
Q31: Most heroin addicts use drugs because they have to not because they want.

vii. Knowledge on safety of methadone

Chart 5.5: Knowledge on safety of methadone



Q32: Methadone/buprenorphine maintenance can cause liver damage.
Q33: Methadone/buprenorphine is more dangerous than heroin to the unborn child.
Q34: Stable dose of methadone or buprenorphine significantly interfere with the ability to drive a car or operate machinery.
Q35: Methadone/buprenorphine maintenance increases the severity of pre-existing depression.
Q36: Methadone/buprenorphine maintenance can cause kidney damage.

viii. Knowledge on local issues regarding MMT

Chart 5.6: Knowledge on local issues regarding MMT



Q37:MMT patients who ignore repeated warning to stop heroin should be gradually withdrawn from the program	Q42:The MMT programme should aim all their client to total abstinence of heroin
Q38:MMT patient who continue to abuse non- opioids drug (benzodiazepine) should have their methadone dose reduced	Q43:The MMT clients should not be allowed for take away more than 3 days
Q39:If repeated warning of non-prescription use of benzodiazepine are ignored, the patient should be discharge from the MMT programme	Q44:The MMT programme allows easier drug trafficking in clinic compound
Q40:MMT’s main aim is to reduce the harmful effects of opioids and IV drug uses and not for abstinence	Q45:The clinic running MMT programme should be under police surveillance
Q41:The MMT programme will exposed the clinic to the bad behaviours of the MMT clients like stealing the clinic belonging	Q46:The people running the MMT programme should be rotated to avoid any occupational related hazards

CHAPTER 6

INFRASTRUCTURE AND IMPLEMENTATION OF MMT

CHAPTER 6

GENERAL OBJECTIVE

To evaluate adequacy of infrastructure and implementation of Methadone Maintenance Therapy (MMT) services.

SPECIFIC OBJECTIVES

- i. To identify availability of basic requirements to run MMT services
- ii. To assess knowledge on existing policy and Standard Operating Procedures (SOP)
- iii. To determine compliance towards existing policy and Standard Operating Procedures (SOP)

METHODOLOGY

Study Design

Cross sectional study

Sample size

As illustrated in Chapter 1, there were 55 sites out of 155 urban facilities and 48 sites out of 98 rural facilities giving a total of 103 healthcare facilities involved in the study. One In Charged person on MMT service from selected health clinics was offered to be study respondent.

Study population

All In-Charged staffs on overall MMT service in Ministry of Health facilities that provide methadone treatment during the study period.

Study setting

Selected healthcare facilities (health clinics and hospitals) in Malaysia.

Study period

The study was carried out from October until December 2014

Sampling design

The design of the study was multistage stratified cluster sampling. It was stratified by urban and rural. The primary sampling unit (PSU) was the cluster of health facilities (clinic /hospital) while the secondary sampling unit (SSU) was the eligible respondents in the selected health facilities. There were 55 sites out of 155 urban facilities and 48 sites out of 98 rural facilities giving a total of 103 healthcare facilities.

Inclusion criteria

Consented

MMT service started for at least 1 year

Exclusion criteria

Not consented

MMT service started less than 1 year

Study instrument

Questionnaire booklet derived from recommendation by the World Health Organization (WHO) (26).

Part 1 - Infrastructure – done by researcher group and based on local criteria (35) (36)

Part 2 - PC2 – Checklist for service description (maintenance treatment)

Part 3 - PC3- Checklist for service description (HIV/Hepatitis prevention and management)

PC2 and PC 3 are self-administered instruments for the service director or designated staff and need not be translated if the person answering the questionnaires is sufficiently fluent in the English language.

Data collection

Self-administered questionnaire that was filled up by the In Charge person of the MMT service.

Study analysis

Data was exported to statistical software Statistical Package for the Social Sciences (SPSS version 16.0) for analysis. The data was checked and cleaned. Descriptive analysis was done to describe prevalence for various parameters.

RESULT

i. Availability of basic infrastructure

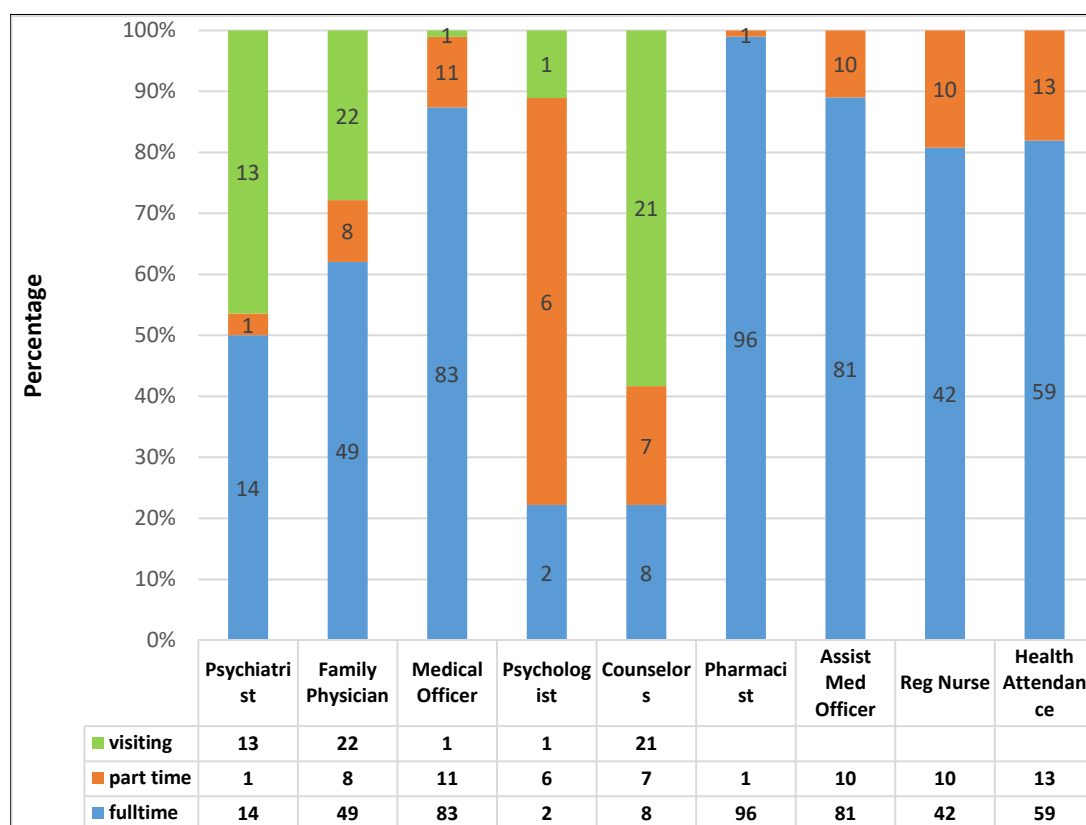
Table 6.1: Location and type of facilities (n=103)

Characteristic	Location And Type Of Facilities	n	%
<i>Location</i>	Urban	55	54.5
	Rural	48	45.5
<i>Type of facilities</i>	General Hospital	11	10.7
	District Hospital	10	9.7
	Health Clinics	82	79.6
<i>Availability of specialist</i>	Hospital with psychiatrist	17	16.5
	Hospital without psychiatrist	4	3.8
	Health clinic with specialist	24	23.3
	Health clinic without specialist	58	56.3

Table 6.2: Availability of basic infrastructure (n=103)

Infrastructure	n	%
Renovation of infrastructure	88	85.4
Reasonable space to run the MMT services	78	75.7
Methadone dispensing machine or device	55	53.4
Sink with clean water supply	96	93.2
Dispensing counter or station	98	95.1
Clean water for drinking	102	99.0
A place for patient to rest for observation after induction	79	76.7
Examination couch	46	44.7
Client friendly dispensing counter	90	87.4

Chart 6.1: Distribution of staffs in MMT service in selected study sites



Note: Fulltime- In house & dedicated to MMT, Part time-In house but also multitask for other services, Visiting- Coming from other hospitals or clinic

Chart 6.2: Availability of supporting services (n=103)

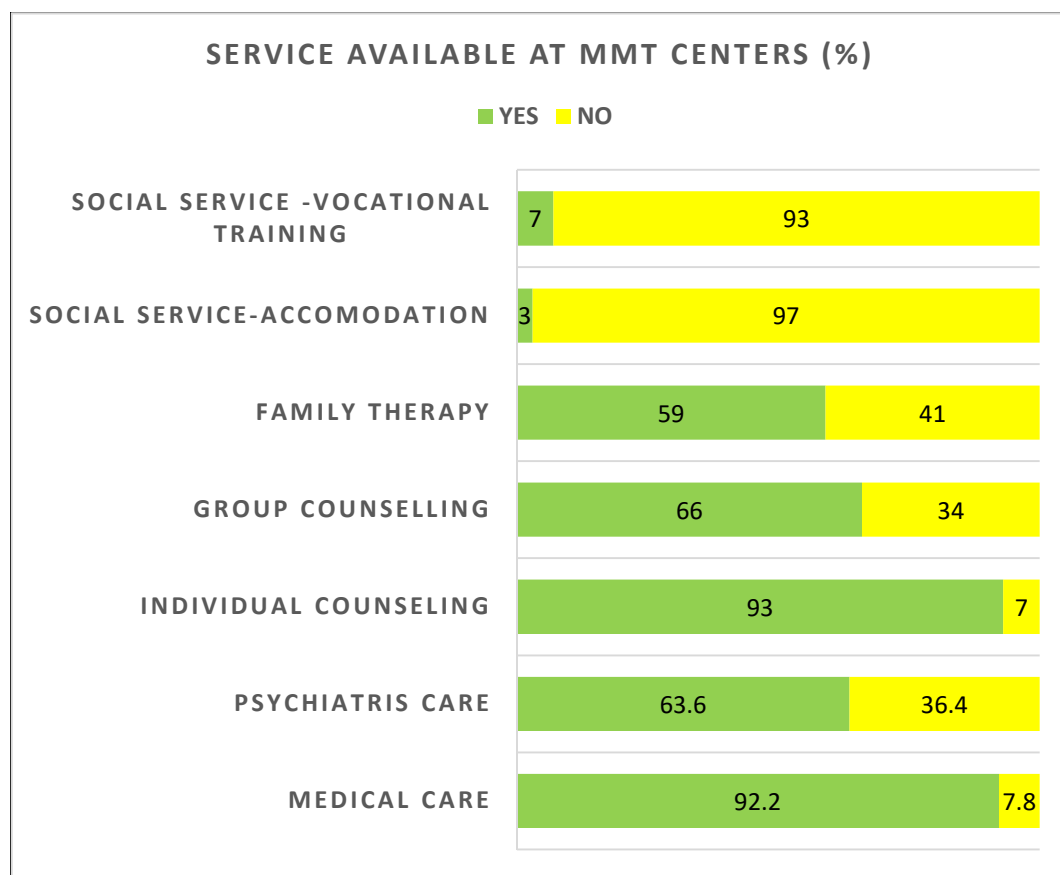


Table 6.3: Availability of HIV/ Hepatitis management program (n=103)

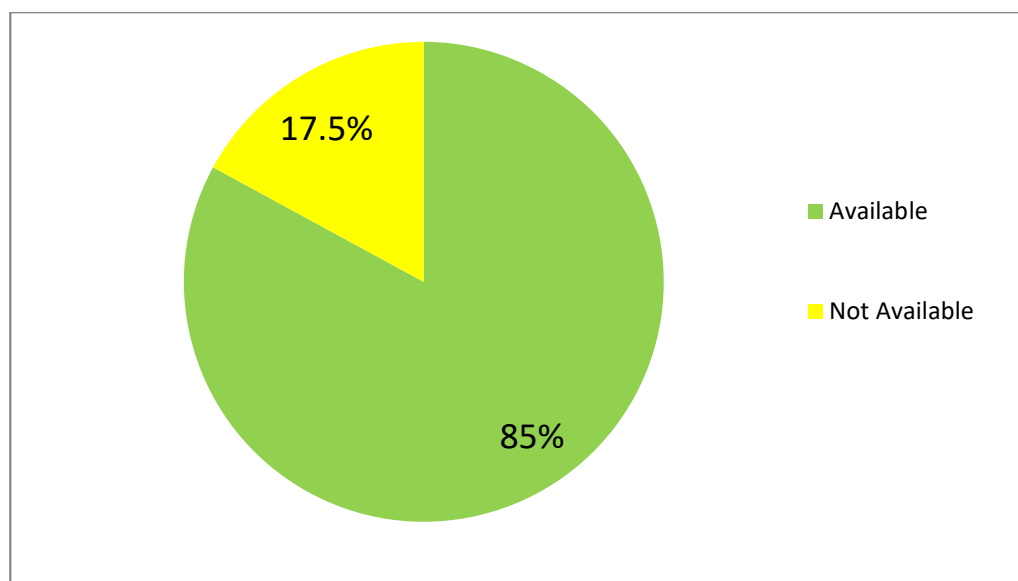
TESTING		n	%
SCREENING			
1.	Routine testing for HIV seropositivity	102	99
2.	Routine testing for Hep B seropositivity	98	95.1
3.	Routine testing for Hep C seropositivity	99	96.1
PREVENTION			
1.	Routine vaccination for Hep B seronegative clients	0	0
2.	Availability of free syringes/needles	41	40.6
3.	Availability of free condoms	70	68.6
4.	Counseling on HIV/HEP available	95	93.1
MANAGEMENT			
1.	Anti-retroviral medication available	85	82.5
2.	Networking with infectious specialist : internal specialist available	45	43.7
3.	Networking with infectious specialist : external specialist	69	67.6

ii. **Safety measures at MMT delivery sites (n=103)**

Table 6.4: Safety measures at the methadone clinic (n=103)

Item	n	%
A first aid kit is available or easily accessible for emergency treatment (within the building)	71	68.9
There is an exit door for the dispenser and the patients in case of emergency	83	81.4
Security guard services	49	47.6
CCTV	14	13.7
Grill/screen/partition between dispenser and patients	19	18.8

Chart 6.3: Availability of naloxone as rescue measures (n=103)



iii. Knowledge on existing policy and Standard Operating Procedures

Table 6.5: Knowledge on indication and implementation of MMT (n=103)

Items	Correct answer	
	n	%
Minimal age for MMT (≥18yrs)	80	77.7
Minimal duration of opiate dependency	61	59.2
Consent from relative is not needed	51	49.5
MMT only for Malaysian citizen	87	84.4
MMT only for voluntary patients	92	89.3
Not related with failure in previous treatment	66	64.1
No maximum methadone dose limit per patient	32	31.1
Patient can contribute in determining sufficient methadone dose	51	49.5

iv. Compliance towards existing policy and Standard Operating Procedures

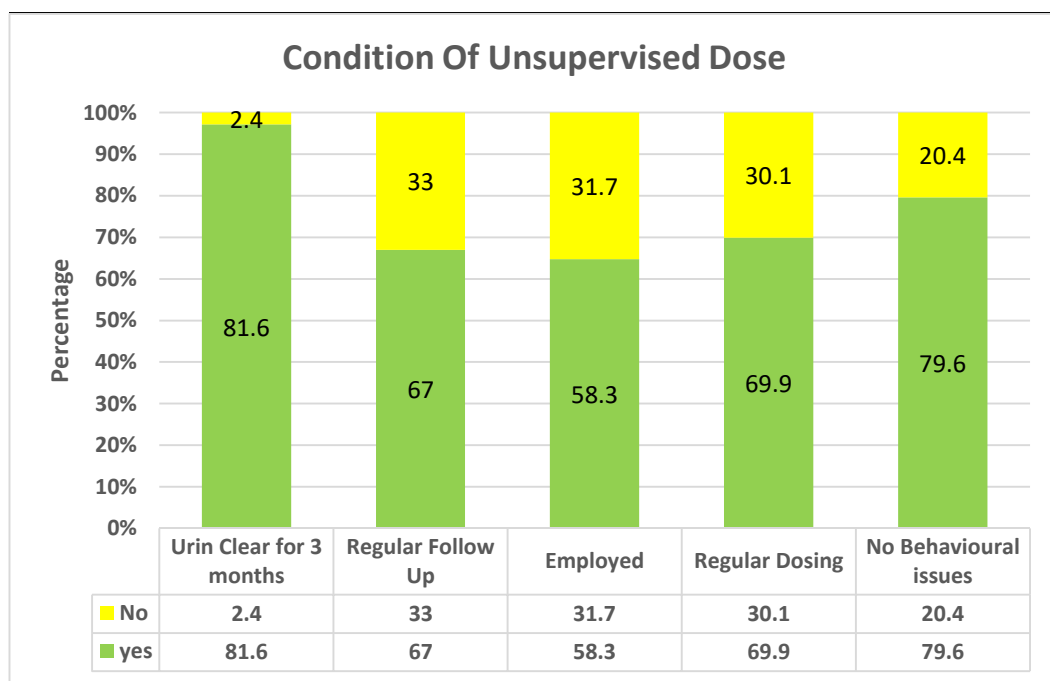
Table 6.6: Compliance according to service recommendation (n=103)

	n	%
Renovation before MMT services started		
YES	47	45.6
NO	56	54.4
Renovation after MMT services started (n = 55)		
YES	41	39.8
NO	14	60.2
Written local standard available		
YES	47	45.6
NO	56	51.4
The Centre has been officially inspected to meet the standard BEFORE starting the MMT service		
YES	50	48.5
NO	53	50.1
The Centre has been officially inspected to meet the standard AFTER starting the MMT service		
YES	64	62.1
NO	38	36.9

Table 6.7: Implementation according to Standard Operating Procedures (n=103)

Items	n	%
1 Urine drug test monitoring	94	91.2
2 Frequency of urine drug test for monitoring		
a. Daily	4	4.3
b. 1-3X per week	13	13.8
c. 1-3X per month	60	63.8
d. Less than 1-3X per month	17	18.1
3 Availability of measures to ensure genuine urine sample taken	89	86.4
4 Supervision of methadone ingestion	102	99
5 Allowance of 1 take away methadone dose	86	83.5
6 Allowance of more than 1 take away methadone dose	62	60.2

Chart 6.4: Selection criteria for allowance of take away dose (n=103)



CHAPTER 7

DISCUSSION

CHAPTER 7

DISCUSSION

The population of the study was mainly males with the majority in their 30's and single. The characteristics were almost similar with previous local studies (20) (16) (18) (14) (13). Similar characteristics were seen in Macao (35) and Taiwan (36). In Australia, the mean age was slightly lower (29.5 years old) and more female patients (36%) were on MMT (21). In this study, although the majority were employed, their monthly household incomes were below the Malaysian poverty level, which was less than RM760.00 in Peninsular Malaysia (37). As more treatment centres opened, more respondents transferred to their preferred centre, which normally located nearer to their accommodation or working place. There was no significant difference between transfers out cases from urban and rural. Considering transferred out respondents still on methadone treatment, there were 54.6% of respondents still in treatment program during the study. Almost a third had defaulted treatment hence require further evaluation. Their difficulties to retain in treatment need to be addressed well to ensure sustainability of the treatment program.

The number of deceased while on treatment was 8.6%. This finding is slightly lower than a study conducted on a 4 year cohort in a district in Malaysia (38) that reported 10.3% death out of 165 patients on MMT and the cause of death in the study was due to motor vehicle accident (29.4%), AIDS (29.5%), Hepatitis C complication (29.4%), myocardial infarction (5.9%) and unknown (5.9%). There were 206 deaths among patient on MMT reported in Victoria, Australia between the year 2001-2005 (39) and the deaths were due to overdose (66.5%), natural disease (11.5%), external injuries (21.3%) and uncertain (0.5%). A meta-analysis found the 2 commonest cause of death among people who inject drug were HIV/AIDS and overdose (40).

There were more treatment centres conducted in health clinics compared with hospitals with a ratio of two third in health clinics and a third in hospitals. The findings were in line with recommendation from a study by Gossop et al that primary care clinics can provide MMT as well as in addiction specialist clinic (11) and a local study (16).

More than half of the respondents had been treated for more than 5 years. The mean methadone dose was 54.8 mg which was slightly below the recommended range of 60-80 mg by the WHO (41) and a few other studies (42) (43) (44) (35). A local study in 2010 reported a much lower mean methadone dose of 37.5 mg but with high retention rates and improvement on quality of life (16). An early methadone review in 1973 in the United State (45) described maintenance methadone dose as either high dose (80-120 mg) or low dose (20-60mg).

This study found the commonest side effects were constipation (30.4%) followed by dry mouth (13.3%). These two problems were among known side effects (45). Decrease in libido

was reported among 6.1% of them. A study in Iran reported 8.3% of sexual dysfunction (46). Another study in Malaysia found erectile dysfunction was related to age and not related to methadone dose or duration of treatment (47). In terms of cardiovascular risk, smoking and not exercising were the two most common cardiovascular risk factors noted among them. Smoking was noted in two third (72.2%) of them. A local study found 100% of newly recruited patients for MMT smoked cigarette (16). Higher prevalence of smokers among illicit drug users not on treatment were reported elsewhere: 86% in Australia (21) and 97% in the USA (48). The majority of the respondents had normal blood pressure, blood sugar and cholesterol level. Detection of abnormal blood sugar that requires further confirmation due to suspicion of diabetes was almost similar to the prevalence of diabetes in 17.5% Malaysian reported in the National Health Morbidity Survey, Malaysia 2015 (49).

The majority of the respondents had a normal mental assessment. Among those with some form of psychiatric co morbidity, anxiety was noted to be commonest problem in contrast to a study among MMT patients in China, where depression was noted to be higher than an anxiety (44). When compared with IVDUs not on opiate based-treatment, the prevalence of psychiatric comorbidity was much lower. A local study found, among newly joined involuntary drug rehabilitation centre, 27.9% had anxiety and 39.8% had depression (50). Another study in the UK reported prevalence of psychiatric comorbidity among illicit drug users not on treatment was as high as 69% (40).

Concurrent alcohol use among drug users caused high psychiatric comorbidities. A study in the USA found 38% prevalence of Alcohol Use Disorder among illicit opiate primary users (51). In this study, comorbidity of recent alcohol consumption in the past 12 months was seen in 8.1% of respondents, while 9.5% reported ever using alcohol throughout their life. The prevalence of current alcohol use was slightly higher than among the general population in Malaysia which was 7.7% (49). A similar trend was noted for drinking categories according to risk groups. When compared with findings in the Malaysian National Health Morbidity Survey 2015 (49), the prevalence among ethnic group was similar and in terms of binge drinking, the study respondents showed lower binge drinking (35.8% of current drinker) habit than the general population in Malaysia (59.4% of current drinker). A local study among IVDUs not on MMT found 77% had lifetime alcohol use and 37% were current drinker (50). In England and Wales in 2009-2010, the proportion of recent drug users reporting concurrent harmful alcohol use was at least 90 % (52).

The respondents showed improvement in terms of capability to be employed and to own a house as seen in other studies (53) (54) (55) (42). In fact, being employed was found to be one of several predictors of opioid abstinence and treatment retention (56). The MMT program in Malaysia is proven to be effective in halting transmission of blood borne viruses such as HIV, Hepatitis B & Hepatitis C. It is a known fact that the prevalence of HIV among drug users in Malaysia has reduced over the years since the implementation of harm

reduction strategies (8). This study has shown a direct effect of methadone treatment in reducing or preventing HIV and other blood borne virus transmission as also seen in other studies (57) (16) (58) (59). Slight increments seen after MMT could be due to respondents were in window period when recruited in the treatment program. Hepatitis C showed the highest number of sero-conversion to seropositive (64.6%) as it is a known fact that hepatitis C is more contagious (60) Hepatitis C is potentially causing an extra health burden to patients due to limited accessibility to eradication therapy. People with Hepatitis C die on average 22 years younger than those without the infection (61). A local study found almost a third of death among patients on MMT was due to Hepatitis C complication (38). This study found a small number of the respondents became sero-negative for hepatitis C without any eradication intervention.

There was not much derangement in liver enzymes after joining MMT. The program also has proven to be effective in reducing incarceration as seen in other studies (62) (16) (42) (63). Despite no alteration in the existing drug law in Malaysia, MMT program is seen to be able to prevent respondents from repeating drug use. Significant reduction of in re incarceration among respondents who were either imprisoned or sent to involuntary drug rehabilitation centre is a huge success. Indirectly the program has shown to be cost effective in reducing cost of incarceration in the country.

Apart from the parameters above, MMT program in Malaysia had significantly showed improvement in respondents' quality of life in all four domains as also seen in other local studies (17) (13) (20) (14). The use of illicit drugs, especially opiate had shown to be significantly reduced. Cigarette smoking habit also showed significant reduction. Apart from that, patients also had been screened for other communicable and non-communicable diseases and intervened similarly as other patients who were not on methadone treatment. Patients in MMT in this study experienced improvement in their general health, social functioning and significant reduction in HIV risks and crime. The findings are similar to other studies (42) (19) (21).

In terms of perception towards MMT, mostly, the clients gave a positive outlook to the treatment program including staff and other assistance provided. However, quite a significant number felt staff had insufficient time to solve their problems. The overall satisfaction to MMT is similar to recent studies in Malaysia (53) (64). A study in Malaysia also found patients identified methadone treatment, psychosocial programs, religious instruction, and recreational activities as important factors contributing to treatment success in addressing both health and addiction needs(64). Similar findings were noted in nationwide evaluations in France (65).

In general, most of methadone treatment centres in Malaysia were equipped with basic requirements to run MMT services as recommended (26). Most of treatment centres had

renovated the infrastructure to some extent in order to meet the basic safety requirement. Only about half had methadone dispensing machine which is a bit costly. The rest survives with the ordinary syringing method. About a third of the methadone dispensing site did not provide a place for patients to rest for observation after induction. Less than half of treatment centres did not provide an examination couch in the dispensing area as most of the centres were actually part of main clinics' building where other treatment services are provided. Almost all treatment centres provide client friendly dispensing counter without any grill/screen/partition between dispenser and patients. Less than half of treatment centres were provided with security guard services and very few had safety monitoring via CCTV. In terms of knowledge among staffs on existing policy and Standard Operating Procedures, there were areas that need improvement. Staff perception towards MMT is similar by an evaluation in France (65). Similarly, measures to improve monitoring and supervision need to be uplifted in order to ensure a good treatment outcome and success of this program.

CHAPTER 8

CONCLUSIONS & RECOMMENDATIONS

CHAPTER 8

CONCLUSIONS

The methadone maintenance treatment program as Medication Assisted Therapy of Opiate Dependence (MATOD) that started since a decade ago was found to be successful. More than half of patients were still on treatment. The treatment program was noted to be effective in reducing drug use, risk of getting HIV & other blood borne viruses' infection, crime and incarceration. The program had also protected sero-negative patients from getting new infection and had improved quality of life and general health. Patients were noted to feel satisfied with the treatment program; however, there were areas for improvement in terms of staffs' attitude towards the program and the adequacy of existing infrastructure especially on safety measures.

RECOMMENDATIONS

1. The methadone maintenance therapy program should be continued and further expanded.
2. There are a few areas that need to be improved:
 - a. Stigma among staffs on methadone therapy – More awareness program should be conducted for staffs
 - b. Staffs' understanding on aims of methadone therapy and principles of treatment – Guideline on methadone therapy need to be updated.
 - All staffs involve in MMT should be trained to follow the Malaysian guideline.
 - A standard training manual for the country need to be developed.
 - All doctors prescribing methadone should be accredited.
 - c. Staffs' skill in handling psychosocial issues.
 - Each facility should be equipped with at least a counselor or develop a good network with other agencies that can provide psychosocial interventions.
 - d. Human resource:
 - The team should comprised of dedicated staffs for the program which at least include a doctor, a pharmacist, paramedics and

supporting staffs who would provide the service for at least 2 years.

e. Infrastructure and facilities :

- In order to provide good service, the premise should be easily accessible, enough space and rooms (consultation room, dispensing room, secure storage room, space for urine & blood collection)
- Basic clinical equipment must be made available (emergency trolley, examination couch, BP set, thermometer, SPO2 analyzer, oxygen tank) and naloxone.

f. Safety:

Methadone dispensing facility must be a safe environment for staffs to work by providing:

- Escape routes on occasion of unexpected aggression.
- Provision of security guard during service hours.
- Provision of CCTV at the premise will be an advantage.
- Training on handling difficult patients.

g. Patients:

- All patients should have comprehensive medical assessment including screening for communicable diseases such as blood borne viruses, sexually transmitted diseases & tuberculosis and non-communicable diseases such as diabetes, hypertension, dyslipidemia and mental health conditions.
- Alternatives to existing opiate replacement therapy such as buprenorphine should be made available for patients with HIV infection on HAART treatment and tuberculosis on rifampicin due to potential drug interaction effect.
- Codependency with other substances among patients need to be tackled, hence, it is timely to provide one stop center for addiction services methadone treatment facilities in Malaysia.

h. Monitoring & Evaluation of the program to ensure a sustainable success:

- National level task force on harm reduction should meet at least twice a year to ensure the program in moving towards the right direction.
- Continuous evaluation of collected data at national level
- There is a need to have a national registry for all MMT patients in the country

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APPENDIX 1: LIST OF SELECTED SITES

a. Urban

State	Selected sites
Perlis	Hospital Tuanku Fauziah
Kedah	Klinik Psichiatri Hosp.Alor Setar
Kedah	Klinik Kesihatan Pendang
Kedah	Klinik Kesihatan Guar Cempedak
Kedah	Klinik Kesihatan Bandar Alor Setar
Kedah	Klinik Kesihatan Padang Serai
Pulau Pinang	Hospital Pulau Pinang
Pulau Pinang	Hospital Bukit Mertajam
Pulau Pinang	Klinik Kesihatan Jalan Perak
Pulau Pinang	Klinik Kesihatan Sg Dua (Timur Laut)
Pulau Pinang	Klinik Kesihatan Sg Dua (SPU)
Perak	Hospital RPB Ipoh
Perak	Hospital Slim River
Perak	Klinik Kesihatan Jelapang
Perak	Klinik Kesihatan Taiping
Perak	Klinik Kesihatan Bagan Serai
Selangor	Hospital Tanjung Karang
Selangor	Klinik Kesihatan AU2, Keramat
Selangor	Klinik Kesihatan Bt 9, Cheras
Selangor	Klinik Kesihatan Seri Kembangan
Selangor	Klinik Kesihatan Telok Panglima Garang
WPKL	Hospital Kuala Lumpur
WPKL	Klinik Kesihatan Jinjang
WPKL	Pejabat Kesihatan Kepong
N.Sembilan	Hospital Tuanku Jaafar
N.Sembilan	Klinik Kesihatan Mantin
N.Sembilan	Klinik Kesihatan Senawang
N.Sembilan	Klinik Kesihatan Gemas
N.Sembilan	Klinik Kesihatan P.Dickson
Melaka	Hospital Melaka
Melaka	Klinik Kesihatan Ayer Molek
Melaka	Klinik Kesihatan Cheng
Melaka	Klinik Kesihatan Peringgit

State	Selected sites
Melaka	Klinik Kesihatan Tengkeru
Johor	Hospital Permai
Johor	Hospital Kota Tinggi
Johor	Klinik Kesihatan Larkin
Johor	Klinik Kesihatan Pontian
Johor	Klinik Kesihatan Segamat
Pahang	Hospital Jengka
Pahang	Klinik Kesihatan Chini
Pahang	Klinik Kesihatan Rompin
Pahang	Klinik Kesihatan SG Tekam Utara
Pahang	Klinik Kesihatan Mempaga
Terengganu	Hospital Hulu Terengganu
Terengganu	Hospital Besut
Terengganu	Hospital Setiu
Terengganu	Klinik Kesihatan Marang
Terengganu	Klinik Kesihatan Seberang Takir
Kelantan	Hospital Raja Perempuan Zainab II (1)
Kelantan	Hospital Tanah Merah
Kelantan	Klinik Kesihatan Bandar Pasir Mas
Kelantan	Klinik Kesihatan Gua Musang
Kelantan	Klinik Kesihatan Bandar Tumpat

b. Rural

State	Selected sites
Perlis	Klinik Kesihatan Kuala Perlis
Kedah	Klinik Kesihatan Sik (KKIA)
Kedah	Klinik Kesihatan Kuala Ketil
Kedah	Klinik Kesihatan Serdang
Kedah	Klinik Kesihatan Naka
Kedah	Klinik Kesihatan Lubuk Merbau
Pulau Pinang	Hospital Balik Pulau
Pulau Pinang	Klinik Kesihatan Tasek Gelugor
Pulau Pinang	Klinik Kesihatan Bayan Lepas
Pulau Pinang	Klinik Kesihatan Penaga
Pulau Pinang	Klinik Kesihatan Kubang Semang
Perak	Klinik Kesihatan Gunung Semanggul
	Klinik Kesihatan Karai
	Klinik Kesihatan Changkat Lada
	Klinik Kesihatan Sauk

State	Selected sites
Perak	Klinik Kesihatan Lawin
Perak	Klinik Kesihatan Kuala Kurau
Selangor	Hospital Tengku Ampuan Jemaah
Selangor	Klinik Kesihatan Taman Medan
Selangor	Klinik Kesihatan Sungai Air Tawar
N.Sembilan	Hospital Tuanku Ampuan Najihah
N.Sembilan	Klinik Kesihatan Kuala Pilah
N.Sembilan	Klinik Kesihatan Tampin
N.Sembilan	Klinik Kesihatan Jelebu
N.Sembilan	Klinik Kesihatan Palong 4,5,6
Melaka	Klinik Kesihatan Kuala Sg Baru
Melaka	Klinik Kesihatan Padang Sebang
Melaka	Klinik Kesihatan Jasin
Melaka	Klinik Kesihatan Umbai
Melaka	Klinik Kesihatan Selandar
Johor	Klinik Kesihatan Masai
Johor	Klinik Kesihatan Bandar Tenggara
Johor	Klinik Kesihatan Tenglu
Johor	Klinik Kesihatan Parit Jawa
Johor	Klinik Kesihatan SG.Mati
Pahang	Klinik Kesihatan Maran
Pahang	Klinik Kesihatan Pekan Awah
Pahang	Klinik Kesihatan Jengka 2
Pahang	Klinik Kesihatan Purun
Pahang	Klinik Kesihatan Chemomoi
Terengganu	Klinik Kesihatan Kuala Besut
Terengganu	Klinik Kesihatan Ketengah Jaya
Terengganu	Klinik Kesihatan Ajil
Terengganu	Klinik Kesihatan Seri Langkap
Kelantan	Klinik Kesihatan Wakaf Baru
Kelantan	Klinik Kesihatan Bachok
Kelantan	Klinik Kesihatan Bandar Kuala Krai
Kelantan	Klinik Kesihatan Pengkalan Chepa
Kelantan	Klinik Kesihatan Selising



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