



## CHAPTER III

### METHODOLOGY

This was a cross-sectional study designed to develop and test an instrument to measure quality of life in Thai patients at least two months after a myocardial infarction. The qualitative and quantitative approach was employed. Internal consistency reliability, content validity, constructs validity, criterion related validity, and norms were examined.

This chapter describes the methods to be used including steps of quality of life instrument development, population, sample, setting, protection of human subjects, and the data collection procedures. Instruments are described and the procedures for data analysis are included.

#### **Steps of quality of life instrument development**

##### **Step1. Construct definition and content of the quality of life instrument in Thai patients with post myocardial infarction**

1.1 The literature review was done by researching both Western and Thai data bases: Ovid, CINAHL, EBSCO, ProQuest, SCIENCE @ DIRECT, Google, Mahidol university library, Thailand; using key words: quality of life, well-being, health status, happiness, satisfaction, myocardial infarction, coronary disease, heart disease, heart attack, instrument development, measurement, tool, and psychometric testing. The existing knowledge of QOL from Thai and western countries was synthesized to understand the concept and theories of QOL in patients with MI to determine how to develop an interview guide for in-depth interviews.

1.2 In-depth interview was done by using an interview guide.

1.2.1 The settings used to interview were the Chest Disease Institute and Mission Hospital because they had patients with post MI and gave permission the researcher conducting the interview.

1.2.2 The samples who participated in this phase were coronary artery disease patients, post myocardial infarction, and double or triple vessels disease patients. The inclusion criteria were: diagnosis of myocardial infarction of at least two months ago, treated by medicine or / and intervention age over 35 years, and willing to participate in this study. Exclusion criteria were: critical complications such as arrhythmia, heart failure or psychosis. The researcher reviewed the records from the registration office to determine what individuals met inclusion criteria. The total participants in this interviewing phase were seventeen. The demographic characteristics of these participants are presented in Table4.

**Table4. Demographic characteristics of the participants in interviewing phase**

(N=17)

Demographic Characteristic	Frequency	Percent
Age (Range from 45-74)		
45-51	4	23.5
52-58	4	23.5
59-65	6	35.4
66+	3	17.6
Sex		
Male	12	70.6
Female	5	29.4
Marital Status		
Single	1	5.9
Marriage	14	82.4
Widow	2	11.7
Region		
Buddhism	14	82.4
Christ	1	5.9
Islam	2	11.7
Education		
Primary school	7	41.3
Secondary school	3	17.6
Diploma	3	17.6
Bachelors and higher	4	23.5
Occupational status		
Full time	3	17.6
Part-time	4	23.5
Not work	10	58.9
Incomes		
5,000 and less baht/month	3	17.6
5,001-10,000 baht/month	3	17.6
10,001-15,000 baht/month	6	35.4
15,001-20,000 baht/month	5	29.4

**Table4 . (Continued)**

Demographic and Characteristic	Frequency	Percent
<b>Incomes</b>		
5,000 and less baht/month	3	17.6
5,001-10,000 baht/month	3	17.6
10,001-15,000 baht/month	6	35.4
15,001-20,000 baht/month	5	29.4
<b>Economic status</b>		
Enough	13	76.5
Not enough	4	23.5
<b>Duration of illness</b>		
Less than 2 months	1	5.9
2-6 months	1	5.9
6-12 months	5	29.4
more than 1 year	6	35.4
<b>Treatment</b>		
Medicine	14	82.4
Medicine and intervention	3	17.6

From Table4, The participant's age ranged from 45-74 years with a mean of 59.05 (SD= 8.00). The majority of participants were male (70.6%), married (82.4%), and Buddhist (82.4%). Educational background of participants had various levels: primary level (41.3%), Bachelors and higher (23.5 %). Most of the participants did not work (58.9%) and the incomes were varying from 5,000-20,000 baht per month which were enough for living (76.5%). They had had disease for more than six months (64.8%) and were treated with medicine (82.4%).

1.2.3 The interviewing of potential participants were approached when they had a regularly scheduled visit in the out-patient clinic and in the clinical wards for patients who were readmitted. The researcher introduced herself and clearly explained the purpose of the study, and the risks and benefits of participation. After accepting to be a participant, the researcher interviewed a participant with an in-depth interview method by using a question guideline and tape recording. In-depth interviews were to be conducted with seventeen Thai patients who had experienced a MI from Chest Disease Institute and Mission Hospital. During the 45-60 minutes interviews, the participants were to be asked about their conceptualization of QOL.

### 1.3 Data analysis

1.3.1 After the interview, data from the tape recorder was transcribed line by line, and open coding. Data analysis was done by content analysis. Content analysis is a research technique to systematically examine descriptive data or the set of techniques that are used to identify patterns, categories, and/or themes in recorded language (Walz, Strickland and Lenz, 2005). The categories of the construct emerged. There were eight themes and 82 statements presented in Table5.

**Table5. Themes and Statements Derived from In-Depth Interview (N = 17)**

Statements	Case 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	T	
1. Able to do things by oneself	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	17
2. Able to do activities of daily living	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	17
3. Unable to do activities of daily living						/		/							/				3
4. Able to work but decreased in quantity	/		/	/	/	/		/		/				/	/				9
5. Can do any activities as usual	/	/			/		/			/	/	/	/	/	/	/	/	/	12
6. Able to eat food	/						/		/	/	/		/	/	/	/	/	/	10
7. Sleep	/						/	/	/	/	/		/	/	/	/	/	/	11
8. Able to urinate or pass faeces	/									/									2
9. Limited in some activities	/						/		/	/	/	/		/	/	/	/	/	10
10. Limitations and feel restrained						/		/						/	/				4
11. Decrease in active ability	/			/	/		/		/				/	/	/	/	/	/	10
12. Able to do what one has done as before	/						/			/	/	/	/	/	/	/	/	/	10
13. Feel tired when walking back and forth		/				/		/							/				4
14. Able to walk without feeling tired	/						/			/	/				/	/	/	/	7
15. Cannot walk anywhere						/		/											2
16. Taking medicine regularly	/				/		/	/	/	/	/	/	/	/	/	/	/	/	13
17. Practice according to the physician	/					/	/	/		/	/	/	/	/	/	/	/	/	12
18. Avoiding symptom stimulant	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	17
19. Increased carefulness	/	/	/		/		/	/		/	/	/			/	/	/	/	12
20. living carefully	/	/	/		/		/	/		/	/	/			/	/	/	/	12

**Table5. (Continue)**

Statements	Case 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	T
21. Self practice according to treatment with reason and belief	/				/					/	/	/	/			/	/	8
22. No chest pains	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	17
23. No complications	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	17
24. No difficulty breathing	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	17
25. Not tiredness	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	3
26. Weakness						/												1
27. Not being a burden for other people	/	/			/		/		/	/	/	/	/		/	/	/	12
28. Accepts the disease and their status	/	/	/		/		/		/	/	/	/	/	/	/	/	/	14
29. Tries to accept their status	/	/	/		/		/		/	/	/	/	/	/	/	/	/	14
30. Psychological comfort	/	/			/		/			/	/	/				/	/	9
31 Feel frustrated due to limitations of activity or doing things one wants			/	/		/		/	/	/	/				/			8
32 Stress			/	/		/		/										4
33. Discouragement			/	/	/	/		/							/			6
34. Frustration when cannot do some activities			/	/		/		/	/	/	/				/			8
35. Anxiety about incurable disease		/	/	/		/												4
36. Having their own will power because they would like to get well and stay with their children as long as possible		/	/				/	/	/	/	/	/						8
37. Not confused				/	/						/							3
38. Frustration due to limitation of eating food			/				/		/						/	/	/	6
39. Hopelessness					/	/		/										3

**Table5. (Continue)**

Statements	Case 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	T
40. Being depressed			/	/		/									/			4
41. Sad due to their own heart disease						/		/										2
42. Fear of death due to delayed treatment								/							/			2
43. Fear of suffering from disease			/												/		/	3
44. Trust in their religion		/			/					/	/	/	/	/	/	/	/	10
45. Prayer, worship	/	/			/					/	/	/	/					7
46. Adherence to their religion	/	/	/		/	/	/	/	/	/	/	/	/	/	/	/	/	16
47. Belief in karma		/		/	/	/							/	/	/			7
48. Able to work as usual				/			/		/			/	/	/	/			7
49. Able to earn their livelihood				/		/	/		/				/	/	/	/		8
50. Unable to earn their livelihood		/			/		/								/	/	/	6
51. Living with out changing						/		/										2
52. Meeting with friends		/			/				/	/	/	/	/	/	/	/	/	11
53. Having social activities: enter priesthood ceremony, wedding, house warming		/							/	/	/	/	/	/				7
54. Not involved in social activities, parties or doing activities with neighbors		/							/	/	/	/	/	/				7
55. Social relationships make life to be more valuable and not valueless	/				/				/		/							4
56. Visits by their neighbors									/	/		/		/				4
57. Supported by their relatives or neighbors						/			/	/								3
58. Enough money for treatment expenses	/	/	/		/		/	/	/	/	/	/	/	/	/	/	/	15
59. Enough money for treatment and no financial problems	/	/	/		/		/		/	/	/	/						9
60. Enough money for daily expenses		/							/		/	/	/	/	/	/		8
61. Not enough money for expenses related to treatment			/		/		/											3



Table5. (Continue)

Statements	Case 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	T
62.Enough money for any expenses	/		/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	16
63. Have financial problems in living			/		/	/												3
64. Not enough income due to being unable to work				/		/		/							/			4
65. Must have money				/		/								/				3
66.Unable to get money for caring for their family				/		/												2
67.Satisfaction about their family	/	/	/		/		/	/	/	/	/	/	/					11
68.Having good relationships in their family	/	/	/		/	/	/	/	/	/	/	/	/					12
69. Will power from family		/	/				/	/	/	/	/	/						8
70. Poor relationships in family					/													1
71. Would like to have caring from their children	/				/	/	/	/	/	/	/	/		/	/	/	/	13
72. Caring from their family	/	/		/		/	/	/	/	/		/	/	/	/	/	/	14
73. Caring from their children and couples	/	/		/		/	/	/	/	/								8
74.Go to the hospital with their child	/	/	/		/		/	/	/		/	/				/	/	11
75. Happy family, love among siblings, forgiving and supporting	/	/						/	/	/	/	/		/	/	/	/	11
76. Their children and couple are not suffering	/		/	/		/	/			/	/	/			/			9
77. No troubles in family		/	/	/			/		/	/	/	/						8
78.Join activities with family	/	/	/				/	/	/	/					/	/	/	10
79.Have good children and not quarrelsome								/	/		/	/						4
80. Be a burden for family																		5
81.Family members have stress	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	13
82.Will power from their siblings									/	/								2

**Table 6. Themes and statements derived from in-depth interview (N = 17)**

Themes	Statements
1. Physical and function	<ol style="list-style-type: none"> <li>1. Able to do things by themselves</li> <li>2. Able to do activities in daily living</li> <li>3. Unable to do activities in daily living</li> <li>4. Able to work but decreased in quantity</li> <li>5. Can do any activities as usual</li> <li>6. Able to eat food</li> <li>7. Sleep</li> <li>8. Able to urinate or pass faeces</li> <li>9. Limited in some activities</li> <li>10. Limitations and restrained</li> <li>11. Decrease in active ability</li> <li>12. Able to do what they have done as before</li> <li>13. Feel tired when walking back and forth</li> <li>14. Able to walk without feeling tired</li> <li>15. Cannot walk anywhere</li> </ol>
2. Self care	<ol style="list-style-type: none"> <li>1. Taking medicine regularly</li> <li>2. Practice according to the physician</li> <li>3. Avoiding symptom stimulant</li> <li>4. Increasing their own alertness</li> <li>5. Being careful in living</li> <li>6. Self practice according to treatment with reason and belief</li> </ol>
3. Symptoms	<ol style="list-style-type: none"> <li>1. No chest pains</li> <li>2. No complications</li> <li>3. No difficulty breathing</li> <li>4. No tiredness</li> <li>5. Weakness</li> </ol>

Table 6 (continue)

Themes	Statements
4. Psychological aspect	<ol style="list-style-type: none"> <li>1. Not being a burden for other people</li> <li>2. Accepting the disease and their status</li> <li>3. Trying to accept their status</li> <li>4. Psychological comfort</li> <li>5. Feel frustrated due to limitations of activity or doing things they want</li> <li>6. Stress</li> <li>7. Discouragement</li> <li>8. Frustration when unable do some activities</li> <li>9. Anxiety about incurable disease</li> <li>10. Having their own will power because they would like to get well and stay with their children as long as possible</li> <li>11. No confusion</li> <li>12. Frustration due to limitation of eating food</li> <li>13. Hopelessness</li> <li>14. Being depressed</li> <li>15. Sadness due to their own heart disease</li> <li>16. Fear of death due to delayed treatment</li> <li>17. Fear of suffering from disease</li> </ol>
5. Spiritual aspect	<ol style="list-style-type: none"> <li>1. Trust in their religion</li> <li>2. Prayer, worship</li> <li>3. Adherence to their religion</li> <li>4. Belief in karma</li> </ol>

**Table 6 (continue)**

Themes	Statements
6. Social aspect	<ol style="list-style-type: none"> <li>1. Able to work as usual</li> <li>2. Able to earn their livelihood</li> <li>3. Unable to earn their livelihood</li> <li>4. Living with out changing</li> <li>5. Meeting with friends</li> <li>6. Having social activities: entering priesthood ceremony, weddings, house warming</li> <li>7. Not involved in social activities, parties or doing activities with neighbors</li> <li>8. Social relationships make life more valuable and not valueless</li> <li>9. Visits by their neighbors</li> <li>10. Supported by your relatives or neighbors</li> </ol>
7. Economics aspect	<ol style="list-style-type: none"> <li>1. Enough money for treatment expenses</li> <li>2. Enough money for treatment and no financial problems</li> <li>3. Enough money for daily expenses</li> <li>4. Not enough money for expenses related to treatment</li> <li>5. Enough money for any expenses</li> <li>6. Have financial problems in living</li> <li>7. Not enough income due to being unable to work</li> <li>8. Must have money</li> <li>9. Unable to get money for caring for their family</li> </ol>

**Table 6 (continue)**

Themes	Statements
8. Family aspect	<ol style="list-style-type: none"> <li data-bbox="591 345 1013 378">1. Satisfaction about their family</li> <li data-bbox="591 418 1156 451">2. Having good relationships in their family</li> <li data-bbox="591 491 933 524">3. Will power from family</li> <li data-bbox="591 564 982 597">4. Poor relationships in family</li> <li data-bbox="591 637 1213 670">5. Would like to have caring from their children</li> <li data-bbox="591 710 945 743">6. Caring from their family</li> <li data-bbox="591 783 1125 816">7. Caring from their children and couples</li> <li data-bbox="591 856 1105 889">8. Going to the hospital with their child</li> <li data-bbox="591 929 1275 1041">9. Happy family, love among siblings, forgiving and supporting</li> <li data-bbox="591 1081 1048 1114">10. Their children are not suffering</li> <li data-bbox="591 1154 920 1187">11. No troubles in family</li> <li data-bbox="591 1227 982 1260">12. Join activities with family</li> <li data-bbox="591 1300 1171 1333">13. Have good children and not quarrelsome</li> <li data-bbox="591 1373 982 1406">14. Being a burden for family</li> <li data-bbox="591 1446 1013 1479">15. Family members have stress</li> <li data-bbox="591 1519 1044 1552">16. Will power from their siblings</li> </ol>

1.3.2 Content validity for the qualitative data was done with trustworthiness technique by the three experts in qualitative research to confirm the content validity. Some statements had the same meaning to others but they were used with different words such as negative and positive wording. These statements were grouped and avoided redundancy of the meaning. After that, the construct of quality of life in Thai patients with post myocardial infarction was discovered. The three post MI patients reconfirmed the content of the quality of life again. Then, the construct of quality of life instrument in Thai patients with post myocardial infarction had six themes of 68 statements presented in Figure3 and Table 3.

#### The Construct of QOL in Thai Patients with Post MI

From the analysis of the in-depth interview data could be concluded that the construct of quality of life had eight themes:

QOL in Thai Patients with Post MI is the perception or feeling of life satisfaction or life happiness in the construct of 1) physical capacity, 2) physical health, 3) psychological comfort, 4) economic stability, 5) family ties and social engagement, and 6) spiritual health.

The details of these six themes were summarized as follows:

1. Physical capacity refers to the ability to do activities in normal life. This theme consists of three categories:

1.1 Activity of daily living: eating, bathing, dressing, and personal hygiene. The participants with post MI stated that:

*"I must not be a burden, I must help myself, I must walk and I must perform my activities in daily living such as dressing and toileting".( # 17/158-160)*

*“ When I have chest pain and difficulty breathing, I cannot get up, I cannot work. I need someone to be with me in order to be aware of the attack when it occurs promptly”. (# 5/ 152-156).*

1.2 Routine work: housework such as rice cooking, cooking, washing, plant watering, gardening, walking, exercising, and any routine activity as stated by the participants with post MI:

*“My life is changing. I am not able to do anything. I cannot do housework.” (# 15 /12-17)*

*“I cannot help my daughter to cook rice, even though I try it just a little, I feel tired and weak. When I try to help myself to go to the toilet, I cannot do it. Only my daughter can help me to do so.” (# 7 / 125-128)*

1.3 Role duty: job working, ability of working, traveling, social activity. The participants with post MI stated that:

*“ I cannot go out to sell something. When the disease comes I feel tightness in chest then I cannot go. I must use sublingual drug” (# 13/ 56-70)*

2. Physical health refers to physical status which has no symptom or any sign of disease and any dangerous complication, including adapted activity of daily living to maintain good health. This theme consists of two categories:

2.1 Symptoms and complications of heart disease such as:

Symptoms: chest pain, difficulty breathing, tiredness, fatigue, fainting.

*“My sickness was worse, I feel very tired, I cannot work I only sit and lie down. Sometimes, I crawled to the toilet. Today, I was admitted because I felt breathlessness”. (# 7/ 24-25, 27-28).*

Complications: swelling legs, rapid heart beat, cannot lie flat.

*" I feel breathlessness, but not chest pains, on the day I plan to go out for a trip, it is like I cannot breath in and out, it took about 2-3 minutes, it did not get better, then I went to the hospital , finally, the physician found I had water in my lung". (#9 / 26-29).*

2.2 Adapted activity of daily living such as following the health care plan of the health team, proper food intake for heart disease, avoiding the stimulants of heart symptoms, and being careful in living.

*"Today if I want to eat something, I must beware, I must be concerned with what the physician has ordered me to do. I must look after my life. I must make my body strong". (# 10/ 104-107).*

*"I think I must be aware of daily living . If I want to travel far from home, I must be concerned about the place that can facilitate me and be effective enough to support me if I have a heart attack". (#9/ 61-64).*

3. Psychological comfort refers to the psychological status which has no stress from disease, but has satisfaction and happiness in doing favorite activities, including the ability to live happily according to ones role or function. This theme consists of two categories: Feeling Empowered and Feeling Good.

### 3.1 Feeling empowered

*"It is because now I cannot do anything. Before I got sick, I was an active person. I never stopped doing things all day long. Around 4 – 5 am I went to trade goods. But now I must stay in bed like this, my heart has turned blue, irritable, in despair, it is not the same as the time before being sick. It is ineffective". (#15 /133-134).*

### 3.2 Feeling good

*" I think if I have a good heart, I will not take advantage of anyone. When I participated with friends and shared something together I felt happy" (# 2/ 69-70).  
I don't know about the future, but now I an so comfortable, I have*



*money to pay for it. I can live happily, wherever I want to go to I will".*  
(# 2/ 104-105).

4. Economic stability refers to the status of enough money for daily expenses to have a happy life, for the cost of treatment and for all members in his family to live.

*"My life has changed, from someone who can work to having an inability to work. My income has decreased and I need someone to take care of me. My heart feels discourage."* (#7 / 28-30).

5. Family ties and social engagement refers to the good relations within or /and between or/and among family, friends and society.

#### 5.1 Family tie

*"I must be careful, I don't want my family members to know more about where I go. I don't want someone nagging me. Now I don't work hard. I stay home everyday. Somedays I lie down all day and do nothing, but knowbody blames me".*  
(# 4 / 163- 165).

#### 5.2 Social engagement

*" My social life has changed. It means if I want to participate in social activities or go to a party, I can't. Everything has been given up since last January".* # 2 / 317-319.

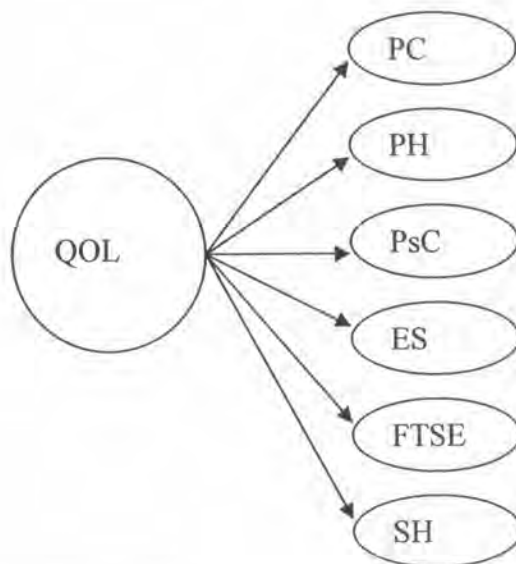
*" We must help each other. We must support each other. If we face any problem we must help, we share feelings. Social life and neighbors are also important as well"*

6. Spiritual health refers to the status which has peace of mind, self control, empowerment, value, and hope including practices according to ones belief and religion.

*" I feel release. It is because I went to join the Dharma society.*

*The Dharma society has many levels. I have to choose to perform good deeds. It is not only going to monk's sermons or praying but also following the Buddha's words" # 13/ 48-50.*

**Figure3.** Six themes of quality of life in Thai patients with post myocardial infarction from qualitative phase1.



QOL = Quality of life

PC = Physical capacity

PH = Physical health

PsC = Psychological comfort

ES = Economic stability

FTSE = Family tie and social engagement

SH = Spiritual health

**Table 7. Six themes and sixty eight items of quality of life in Thai patients with post myocardial infarction from qualitative phase.**

Themes	Statements
1. Physical Capacity	1. You can work 2. Your activity ability is decreased 3. You can walk up 8 in 10 stairs without being tired or feeling tightness in your chest 4. You can walk in on a flat plain for more than 500 meters without chest pains or difficult breathing 5. You can do routine housework: cooking, laundry, house cleaning, plant watering, etc 6. You need help from other people for routine activities 7. You can do activities of daily living by yourself: eating, bathing, dressing, and personal hygiene 8. You are able to care for yourself
2. Physical Health 2.1 symptom and complication	9. You have chest pain 10. You have difficulty breathing 11. You are tired 12. You are fatigued and weak 13. You are light-headed or faint 14. You do not have complications such as some swelling of the legs, arrhythmia
2.2 Adapted activity of daily living	15. You can control your diet properly for heart disease: low salt or low cholesterol diet 16. You can sleep without sleeping pills 17. You can have regular bowel movements 18. You do sweaty exercise at least 3 times a week 19. You can take medicine with each meal correctly and regularly 20. You can sleep 6-8 hours per day 21. You follow the advice from the doctors and nurses. 22. You study about disease to solve problems 23. You live carefully without any dangers in your life: don't do heavy energetic work or don't go to places without prompt treatment for heart disease

**Table 7. (continue)**

Themes	Statements
3. Psychological Comfort	24. You avoid from any stimulant for your heart problems: over glad or sad or stress
3.1 Feeling Empowered	25. You have willpower to care for yourself in this ill condition 26. You accept your illness and your status 27. You are happy to go to any place you want 28. You feel happy to take and help your family 29.. You feel you are being a burden on your family
3.2 Feeling Good	30. You are fearful about symptoms suffering from an increasing severity of the disease 31. You are in fear about death due to delayed treatment 32. You feel frustrated due to inhibitions and limitations in doing your favorite activities: eating fried food, different meats, strong feelings or action movies etc. 33. You are happy to go to any place you want 34. You feel it is hopeless to work for a living 35. You feel happy to take and help your family 36. You feel you are being a burden on your family 37. You are happy to have correct treatment 38. You are sad to have this disease.
4. Economic stability	39. You have continual income from working or your close relatives 40. You have enough money for your living expenses 41. You have enough money for treatment expenses 42. You have enough money to go to receive treatment from the hospital: expenses for traveling, residents, food etc. 43. You have expense problems for extra medicine or unexpected cost expenses 44. You have decreasing income while you are sick 45. You can care for your children and as a couple to live without suffering 46. You have a warm family 47. You have children or are a couple or have family members to help and care for you

**Table 7. (continue)**

Themes	Statements
5. Family tie and social engagement	<p>48. You have to be concerned and cared for by your family</p> <p>49. You feel happy to have a warm family</p> <p>50. Your family are happy</p> <p>51. You feel generosity from your family</p> <p>52. You feel satisfied that your children and your partner is not stressed.</p> <p>53. You are proud to have good children.</p> <p>54. You are happy to stay with your child as long as possible</p> <p>55. You are happy to join in with your family activities</p> <p>56. You are not comfortable about family stress</p> <p>57. You feel comfortable about the caring from your sibling</p> <p>58. You have close contact with your sibling, friends, and relatives</p> <p>59. You have a good relationship with your neighbors</p> <p>60. You are concerned to join in social activities</p>
6. Spiritual health	<p>61. . You join in social activities sometimes: entering the priesthood ceremonies, wedding ceremonies, housewarmings, funeral ceremonies, etc.</p> <p>62. You hope to work or do activities as well as you did before</p> <p>63. You feel that life has value</p> <p>64. You feel that your mind is at peace and strong</p> <p>65. You feel psychological comfort when reading or listening to your religious prayers</p> <p>66. You believe that your illness is a planned part of life and planned before</p> <p>67. You are happy when you pray or worship or intone</p> <p>68. You live along with your religious doctrine</p>

## **Step2. Generating and judging measurement**

### 2.1 Generating items

Items were generated based on the meaning, the construct, and the qualitative data about quality of life in Thai patients with post MI. The new Thai QOL instrument was using five levels Likert type scales which generally ask respondents to indicate their level of agreement with a declarative statement; the degree or extent to which what is expressed in the statement is true of a belief, attitude, or characteristic of the respondent; or the frequency of a behavior. And it also possible to label each scale point as well as scale endpoints. Good Likert items should state the opinion, attitude, belief, behavior, or characteristic being assessed in clear terms and use the appropriate wording scale points. Careful item judging can be very helpful in this regard (Netemeyer, et.al., 2003).

There are no hard and fast rules for the size of an initial item pool. Single facet constructs will require fewer items than will complex multifaceted constructs. In general though, a larger number is preferred, as overinclusiveness is more desirable than underinclusiveness (Netemeyer, et.al., 2003). Sixty eight items of Thai QOL instrument were generated in all six themes from data that was grounded from in-depth interview (see more detail in Appendix D).

Theme 1. Physical capacity (PC) consisted of 8 items.

Theme 2. Physical health (PH) consisted of 16 items.

Theme 3. Psychological comfort (PsC) consisted of 14 items.

Theme 4. Economic stability (ES) consisted of 9 items.

Theme 5. Family tie and social engagement (FTSE) consisted  
of 14 items.

Theme 6. Spiritual health (SH) consisted of 7 items.

The quality of life instrument in Thai patients with post myocardial infarction was designed to measure frequency and quantity of the quality of life by using 5 levels Likert scale: 5 = all the time, 4 = most of the time, 3 = sometimes, 2 = a little of the time, 1 = hardly any of the time; and 5 = the most, 4 = most, 3 = moderate, 2 = a little, 1 = very little. Likert scale is widely used in instruments measuring opinions, beliefs, and attitudes.

## 2.2 Judging measurement

The content of the new quality of life instrument in Thai patients with post myocardial infarction was confirmed by the degrees to which experts agree about the themes and facets of the content. In this study, the validity of content of the new instrument was done only by face validity because the content of quality of life was defined by the post myocardial infarction.

### Face Validity

All items were considered by thirteen experts: two experts in quality of life, three experts in development instrument, one coronary disease physician, one rehabilitation physician, one clinical nurse specialist, two cardiac teachers, one social science expert, and two medical nursing teachers. The experts were asked to review the sixty eight items with the definition and the meaning of each constructs of quality of life and rate them on 4-point ordinal scales from 1 (not relevant to conceptual definition) to 4 (extremely relevant to conceptual definition). In addition, the experts were asked to determine whether any areas had been omitted from the instrument, whether the theme of quality of life had adequately sampled, and whether any suggestions for item improvement were given. The judging of the items for this instrument was assessing the level of the agreement among the experts and the qualitative data. Content validity index cannot be done in this study because the

definition and the construct of the quality of life were derived from the patients but all items were judged with 80% of the expert's agreement.

Revision and correction of all items were conducted prior to testing for reliability. The six items were deleted because of redundancy or not congruence with the theme as the expert suggestion or opinions during the content validity test. For instance: "you cannot do routine activities by yourself" and "you can help yourself", "you think that illnesses with heart disease means you need to have money", "you cannot work for a living even though you have a place to work for living", "you feel discomfort when your family members are stressed", and "you are proud of your good children".

The second draft of the quality of life instrument in Thai patients with post myocardial infarction had sixty two items in six domains. It was presented in Table 5.



**Table 8 The sixty two item statements of the QOL instrument in Thai patients with post MI after face validity**

Theme and Category	Item No	Item Statements
Theme1. Physical Capacity	1	You can do some little work in the house
	2	Your active ability is decreased
	3	You can walk up 8 in 10 stairs without being tired or tightness in your chest
	4	You can walk on a flat plain for more than 500 meter without chest pain or difficulty breathing
	5	You can do routine housework: cooking, laundry, house cleaning, plant watering, etc
	6	You can do activities of daily living by Yourself: eating, bathing, dressing, and personal hygiene
Theme2. Physical Health		
2.1 Symptom and Complication	7	You have chest pain
	8	You have difficulty breathing
	9	You are tired
	10	You are fatigued and weak
	11	You are light-headed or faint
	12	You feel tired and cannot breath when lying down
	13	You have some swelling of the legs
	14	You have irregular heart beats

**Table 8 (Continued)**

Theme and Category	Item No	Item Statements
2.2 Adapted Activity of Daily Living	15	You can control diet properly for heart disease: a low salt or low cholesterol diet
	16	You can sleep without sleeping pills
	17	You can have regular bowel movements
	18	You have sweaty exercise at least 3 times a week
	19	You can take medicine each meal correctly and regularly
	20	You can sleep 6-8 hours per day
	21	You can take care of yourself correctly and properly for your heart disease by studying about it.
	22	You live carefully without any dangers in your life: don't do heavy energetic work or don't go to places without prompt treatment for heart disease
	23	You avoid any stimulant for your heart problems: elation or sadness or stress
Theme3. Psychological comfort		
3.1 Feeling Empower	24	You have willpower to care for yourself in this ill condition
	25	You accept your illness and your status
	26	You are satisfied with the treatment
	27	You have anxiety about a disease which is unable to be treated
	28	You feel discouraged in your life
	29	You feel sad to have heart disease
	30	You are fear the symptoms and suffering from an increased severity of the disease
	31	You are fear death due to delayed treatment

**Table 8 (Continued)**

Theme and Category	Item No	Item Statements
<b>Theme3. Psychological comfort</b>		
<b>3.2 Feeling Good</b>	32	You feel frustrated due to inhibitions and limitations in doing your favorite activities: eating fried food, different meats, strong feeling or action movies etc
	33	You are satisfied with your physical ability which you can do.
	34	You are happy to go to any place, you want
	35	You feel it is hopeless to work for a living
	36	You feel happy to take and help your family
	37	You feel you are being a burden on your family
	<b>Theme4. Economic Stability</b>	38
39		You have continual income from working or your close relatives
40		You have enough money for your living Expenses
41		You have enough money for the treatment Expenses
42		You have enough money for going to receive treatment from the hospital: expenses for traveling, resident, food etc.
43		You have expense problems for extra Medicine or unexpected cost expense
44		You have decreasing income while you Are sick
45		You can take care of your children and as a couple to live without suffering

**Table 8 (Continued)**

Theme and Category	Item No	Item Statements
Theme5. Family tie and social engagement	46	You have a warm family
	47	You have children or partner or family members to help and care for you
	48	You have to be concerned and cared for by your family
	49	You join in your family activities: eating food, traveling, shopping
	50	You have close contact with your sibling, friends, and relatives
	51	You have good relationships with your neighbors
	52	You are satisfied to join in social activities
	53	You join in social activities sometimes: entering the priesthood ceremonies, wedding ceremonies, housewarmings, funeral ceremonies, etc.
	62	You are happy to live with your children or family as long as possible, even though you have heart disease
	Theme6. Spiritual health	54
55		You feel that life has value
56		You feel an unstable life after you had heart Disease
57		You feel that your mind is at peace and Strong
58		You feel psychological comfort when reading or listening to your religious prayers
59		You believe that your illness is a planned Part of life and planned before
60		You are happy when you pray or worship or intone
61		You live along with your religious doctrine

From Table 5, there were 6 themes presented within 62 items. Theme 1. Physical Capacity had 6 items, Theme2. Physical Health had 17 items and composed of 2 categories: Symptom and Complication 8 items, and Health maintenance 9 items, Theme3. Psychological comfort had 14 items and composed of 2 categories: Feeling Empower 8 items, and Feeling Good 6 items, Theme4. Economic stability has 8 items, Theme5. Family ties and social engagement had 9 items, Theme6.had 8 items. The QOL instrument in Thai patients with post MI was used a Likert scale which was one of the most common item formats. It had five levels: all of the time, most of the time, sometimes, a little of the time, and hardly any of the time. Likert scaling is widely used in instruments measuring opinions, beliefs, and attitudes.

The sixty two items of TQOL instrument were tested for reliability by 30 patients with post MI and the Cronbach's alpha coefficient was 0.928.

### **Step3. Designing and conducting studies to develop a scale**

The objectives of this step were: testing a pool of items as an item trimming and initial validity testing procedure, and conducting multiple studies for scale development. Construct validity was tested by exploratory factor analysis (EFA). Criterion related validity was tested by Pearson correlation. Reliability was tested by Alpha Cronbach. Establishing norms or standardization score

### **Population**

The population for this study includes all individuals in Thailand who were diagnosed as having a MI at least two months prior to participating in this study.

### **Sample**

All purposive samples were obtained of individuals who had experienced MI at least 2 months prior to data collection. A two month time frame was selected because participants would still be in the period of convalescence. Participants would be selected if they met the following inclusion criteria: a) a diagnosis of MI in the past two months, b) were notified that they had a MI, c) received medication only for the treatment of their MI, and d) living at home. Participants would be excluded if they had critical conditions or serious complications such as severe heart failure, dangerous arrhythmias, or psychoses. Participants were excluded if they had surgical intervention following their MI.

### **Sample size**

The purpose of this study was to develop a new instrument to measure health-related quality of life in Thai patients who had experience of MI. Because of the new instrument, no data about the scale's variance is available and we cannot conduct a power analysis. The sample size was based on criteria of factor analysis, a statistic used to analyze data. Dixon (2001: 300) suggested the minimum ratio of participants per item that is desirable to generalize from the sample to a wider population should be 10:1. Bryant & Yamold (1998: 99-136) suggested that the ratio of subject and variable in factor analysis at least was 5:1. The sample size of this study was calculated from the 10 participants per item. It has 62 items, in which case the sample size should be 620 participants.

## Setting

The settings for data collection took place in the out patient coronary artery disease clinics from eleven government hospitals in Thailand: Siriraj Hospital, Ramathibodi Hospital, King Chulalongkorn Memorial Hospital, Maharaj Chiangmai Hospital, Khon Khan Hospital, Prince Songklanakarin Hospital, Rajvithei Hospital, Vachirapayabarn Hospital, Pramongkuitkloa Hospital, and Bhumipol Hospital. These hospitals serve as tertiary care centers for coronary artery disease patients from various provinces in Thailand. Because of the low number of the revisiting post MI patients and the limited time of study, data collection by mail took place. The name list of post MI patients from the eleven hospitals was taken from intensive units and the researcher phoned each participant to ask permission for participation in this study to do the questionnaires. After permission, a set of questionnaires was sent according to the participants' addresses and they sent them back to the researcher in one week.

## Instruments

Three instruments were used in this study. They are: (1) SF36 version2 in Thai version (2) MacNew Heart Disease Health Related Quality of Life Questionnaire, (3) Quality of Life Instrument in Thai Patients with Post Myocardial Infarction (TQOL)..

### 1. SF36 version2 in Thai version:

The SF36 version2 in Thai version was invoiced the license from the Quality Metric Company. The SF36 is a widely-used generic instrument consisting of 36 items that measure eight domains of quality of life: physical functioning, role limitation due to physical health problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health. Summed scores are

computed for each domain using developed algorithms. Scores range from 0-100 with higher scores indicating higher quality of life. Internal consistency reliability ranges from .73 to .96. Validity has been supported by its ability to discriminate between different physical and mental health morbidity groups (Ware Sherbourne, 1992). Reliability of SF36 version 2 in Thai version was tested by 30 patients with post MI and the Cronbach's alpha coefficient was 0.926.

## 2. MacNew HRQOL Questionnaire:

MacNew HRQOL Questionnaire was the first time it was used as a specific QOL instrument in Thailand. It was used generally as a standard instrument in heart disease quality of life measurement in the U.S.A. and Europe. Back translation process was done systemically under supervision of Dr. Neil Oldridge who had authority in this instrument. The researcher used this instrument for specific criterion related to validity of the new instrument because there was no specific standard quality of life instrument for patients with post myocardial infarction and the MacNew HRQOL Questionnaire was matched with the new one in type of the measure, specific heart patients, and a standard instrument. Even though, it was not proved for a standard instrument in Thailand, it could support the new instrument for the precise instrument. This was also a limitation of this study.

### Translation process of MacNew HRQOL Questionnaire

The process of translation and back translation process of MacNew HRQOL Questionnaire was guided by MacNew Collaboration study. It also allows for the assessment of internal consistency (Cronbach's alpha) to gauge reliability of the translated version. This technique has been suggested to be the minimum required



standard to determine equivalence of an instrument across different languages (Maneesriwongul & Dixon, 2004). The processes were as followed:

1. MacNew HRQOL Questionnaire was translated from English to Thai by two bilingual translators: one is in the health profession and the other is not in the health profession.

2. The MacNew HRQOL Questionnaire, translated from English to Thai instruments were back translated to English by two other bilingual translators: one is in the health profession and the other is not in the health profession.

3. Both translated from English to Thai and back translated from Thai to English. The MacNew HRQOL Questionnaire was sent to Dr. Neil Oldridge, the MacNew HRQOL authority. There was some recommendations and advice to make the instrument better.

4. A translated from English to Thai of MacNew HRQOL instrument was back translated from Thai to English again by another new bilingual translator who is not in the health profession. The last back translated MacNew HRQOL instrument was sent to Dr. Neil Oldridge again. After the acceptance of the translated MacNew HRQOL instrument, a Thai version of MacNew HRQOL instrument was validated for the conceptual equivalence, clarity, and suitable language by twelve experts. The scores of conceptual equivalence range from 83.31% to 100%, clarity range from 58.31% to 100%, and suitable language range from 41.71% to 100%.

MacNew Heart Disease Health-Related Quality of Life instrument. The MacNew Heart Disease Health-Related Quality of Life instrument consists of 27 items that assess three domains of health-related quality of life. There are 13 items assessing physical limitations, 14 items assessing emotional functioning, and 13 items

that assess social functioning. Items are rated from 1 (None of the time) to 7 (All of the time). Mean scores are computed for each domain. Higher scores indicated higher quality of life. The scale has been used in more than 5200 patients with heart disease. Internal consistency reliability ranges from .73-.95 across different cultures and translations. Face and content validity were established during development. Construct validity has been determined by negative relationships with both symptom experiences and disease severity (Hofer, Lim, Guyatt & Oldridge, 2004). Reliability of Thai version of MacNew HRQOL Questionnaire was tested by 30 patients with post MI and the Cronbach's alpha coefficient was 0.936.

### 3. The Quality of Life Instrument in Thai patients with post MI

The Quality of Life Instrument in Thai patients with post MI was first developed from the Qualitative method. Seventeen participants were interviewed by in-depth method and content analysis was done by four qualitative experts. The first draft of the instrument has 68 items in 6 dimensions: physical functioning, physical health, psychological comfort, economic stability, family and social relationship, and spiritual health. After revision according to the experts' recommendations, content validity index was done by thirteen experts. Revision and correction of the whole instrument was adjusted properly, the final instrument has 62 items in 6 dimensions and 2 sub-dimensions. Items were rated from 1 (Hardly any of the time or Very little) to 5 (ALL of the time or The most). Items were summed so that higher scores indicated higher health-related quality of life. Reliability was tested by 30 patients with post MI and the Cronbach's alpha coefficient was 0.928.

### **Protection of Human Subjects**

This study received approval from the Chulalongkorn University Institutional Review Board. Each of the eleven tertiary government hospitals must provide human subject approval. Potential subjects were approached and invited to participate in the study at the out patient clinic visit two months following the MI. The overall purpose of the study, the risks and benefits, and the time required for participation were explained. Participants were assured of anonymity and confidentiality. They were informed that they could discontinue their participation at any time. Signed consent was obtained (see Appendix A).

Confidentiality was maintained by omitting their names from the data. Only a code number was placed on the questionnaires. There was no known risk of participating in the study. It took approximately 1 hour to complete the questionnaires. There was no cost for participating and participants would not receive an incentive fee for participation.

### **Data Collection**

This study was approved from the IRB committee and the president of the hospital of twelve hospitals. The researcher trained the research assistants about the method of collecting data. Then the researcher went to collect data accompanied by research assistants. They reviewed the records from the registration office to determine which individuals met inclusion criteria. The date of the two-month follow-up appointment was obtained at this time. Potential participants were approached when they had a regularly scheduled visit in the out-patient clinic. The researcher and research assistants introduced themselves and clearly explained the purpose of the study, and the risks and benefits of participation. After obtaining informed consent,

participants completed questionnaires in the waiting area of the clinic following the regularly scheduled appointment with the physician. Participants received a thank you for their contribution of time and meaningful information following completion of the questionnaires.

According to a small number of participants of each collecting time, a researcher corrected this problem with a method of collecting data by mail. Names of Patients with post MI from the intensive care unit record were phoned to ask permission to participate in this study. After accepting to be a participant, a set of questionnaires including a letter asking to participate in this study, information and consent sheets, five questionnaires and an envelop with stamp and researcher's address which was ready to be sent back in one week after receiving the mail. A researcher and research assistants used this method for all eleven hospital.

### **Data Analysis**

Data was entered into SPSS-PC database. All data would be analyzed by using SPSS version 14.0. Reliability and validity data for the existing measures would also be computed.

#### **1. Descriptive statistics**

Demographic characteristics of the participant (age, gender, marital status, education, occupation) were summarized using descriptive statistics. Descriptive statistics included means, standard deviation, range, frequency, and percent, as appropriate.

Descriptive statistics would also be computed for all scales, including the new quality of life instrument, the MacNew Health-Related Quality of Life instrument,

and the SF36. Descriptive statistics included mean, standard deviation, range, skew, and kurtosis.

## **2. Reliability**

Scale reliability is the proportion of variance attributable to the true score of the latent variable. There were several methods for computing reliability, but they all share this fundamental definition and based on the computational method one uses. In this study, two methods were used to estimate reliability, item analysis and Cronbach's alpha.

### **Item Analysis**

Item analysis is the process used to remove items that have low interitem correlations. The removal of these items increases the homogeneity and internal consistency estimates of reliability. Increasing the average interitem correlation by culling poor items can be powerful (Ferketich, 1999). During item analysis, several pieces of data should be evaluated to determine whether to retain or delete an item including the interitem correlation matrix, corrected average interitem correlation coefficient, correct item-total correlation coefficient, and information about the alpha estimate if an item is dropped from the scale. Freketich (1999) recommends that items be deleted if the item-total correlation is  $<.30$  or  $>.70$  with no significant changes in coefficient alpha. Items less than  $.30$  indicate that the items are not related to other items to a great deal. Items greater than  $.70$  indicated that items are redundant.

### **Internal Consistency Reliability**

Internal consistency reliability is defined as the homogeneity of the items comprising a scale. The internal consistency reliability (or coefficient alpha) is one of the most important indicators of a scale's quality. It estimates the homogeneity of a measure composed of several items or subparts. The reliability of each subscale of the

new instrument will be estimated using Cronbach's alpha. A value of .70 will be considered an acceptable level of internal consistency (Knapp, 1995; Nunnally, 1978).

Internal consistency reliability is used to the extent that all subparts measure the same characteristic. This approach to reliability assesses an important source of measurement error in multi-item measures. This method measures consistency within the instrument.

### **3. Validity**

The validity of the new quality of life instrument for Thai patients following a MI was assessed in multiple ways. Statistical analyses will be conducted to assess criterion-related and construct validity.

#### **Criterion-Related Validity**

Criterion-related validity is used to demonstrate the accuracy of a measure by comparing it with another measure which has been demonstrated to be reliable and valid. In this study, the MacNew Health-related Quality of life, a disease-specific measure, and the SF-36, a generic measure, are being used to demonstrate criterion-related validity with the new quality of life instrument for individuals post myocardial infarction. Criterion validity was assessed by calculating the correlation coefficient between the new QOL instrument and the SF-36, and new QOL instrument and the MacNew HRQOL.

#### **Construct Validity**

Construct validity is directly concerned with the theoretical relationship of a variable (Cronbach & Meehl, 1955). It is used to determine whether the instrument captures proposed theoretical relationships. In this study, factor analysis was used to test the construct validity. Factor analysis is designed on the basis of a conceptual

framework, a measure to assess various dimensions or subcomponents of a phenomenon of interest and wishes to empirically justify these dimensions or factors

A factor is a group of items that belong together. Items can be deleted that don't correlate well enough with a factor. Cronbach's alpha is then computed to assess for internal consistency reliability. There are two types of factor analysis: exploratory factor analysis and confirmatory factor analysis.

Exploratory Factor Analysis analyses the correlation between items of QOL instrument in Thai patients with MI and the factors by using Pearson Product Moment correlation with exploratory factor analysis.

Norms testing, it was done by analysis percentiles score and T-scores of QOL in Thai patients with MI. Then five score levels were assigned from  $T_{50} \pm 10$ . In addition, other methods were able to find norms scores, for instance: score range between score at 75<sup>th</sup> percentile and 25<sup>th</sup> percentile; or range score of  $\text{Mean} \pm \text{SD}$ . In this study, a method of five levels of T-scores was chosen to find the norms score.