Ministry of Health Malaysia

NATIONAL DERMATOLOGY REGISTRY

(DermReg)

Annual Report of the MALAYSIAN PSORIASIS REGISTRY 2007 - 2009

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With contributions from:

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- The Ministry of Health, Malaysia
- Dermatological Society of Malaysia
- Faculty of Medicine, College of Physicians, Academy of Medicine Malaysia
- Datamed Clinical Computing Services Sdn Bhd

ABBREVIATIONS

BB-UVB	Broad-band ultraviolet B
BMI	Body mass index
BSA	Body surface area
CDLQI	Child Dermatology Life Quality Index
CRC	Clinical Research Centre
CRF	Case report form
DermReg	National Dermatology Registry
DLQI	Dermatology Life Quality Index
eCRF	Electronic case report form
eDermReg	DermReg web application
HLA	Human leukocyte antigen
IQR	Interquartile range
MOH	Ministry of Health
MPR	Malaysian Psoriasis Registry
NA	Not available
NB-UVB	Narrow-band ultraviolet B
NHMS	National Health and Morbidity Survey
PI	Principal Investigator
PUVA	Psoralen and ultraviolet A
QoL	Quality of life
RCC	Registry Coordinating Centre
SC	Site Coordinator
SD	Standard deviation
SDP	Sources data providers

ABOUT DermReg

Introduction

DermReg is an ongoing systematic collection, analysis and interpretation of data pertaining to dermatological diseases and services in Malaysia. It is a nationwide project which aims to integrate all dermatological patient registries and databases developed in Malaysia. These registries are essential to the planning, implementation and evaluation of clinical and health services as well as research in dermatology

Objectives of DermReg

General Objective

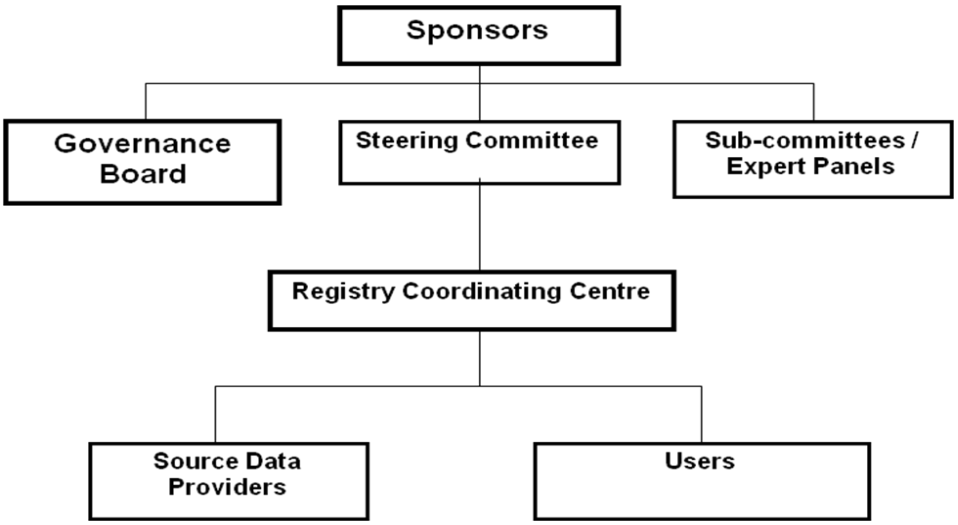
To establish a nationwide systematic prospective collection of data pertaining to skin diseases and dermatological services, in order to study the natural history, outcome and quality of life issues of skin diseases, as well as the effectiveness, safety and accessibility of various treatment modalities.

Specific Objectives:

1. Determine the socio-demographic profile of patients with skin diseases
2. Determine the burden of skin diseases in the population
3. Describe the natural history of skin diseases
4. Identify the potential causal and risk factors of skin diseases
5. Describe the clinical manifestation of skin diseases
6. Describe the effect of skin diseases on the quality of life
7. Determine the efficacy and cost effectiveness of treatment of skin diseases
8. Monitor the safety and adverse effects of products and services used in the treatment of skin diseases
9. Evaluate accessibility and quality of health services related to skin diseases
10. Stimulate and facilitate basic, clinical and epidemiological research on skin diseases

ORGANISATION OF DermReg

The organizational structure of DermReg consists of sponsors, Governance Board, Steering Committee, Sub-committees or Expert Panels, Registry Coordinating Centre, Source Data Providers (SDP) and users.



SPONSORS

The DermReg is sponsored by:

1. Ministry of Health, Malaysia
    a. Clinical Research Centre, Hospital Kuala Lumpur
    b. Department of Dermatology, Hospital Kuala Lumpur
    c. Head of Dermatology Services, Malaysia
2. The Dermatological Society of Malaysia
3. Faculty of Medicine, College of Physicians, Academy of Medicine Malaysia

GOVERNANCE BOARD

Governance Board of DermReg is a committee established by the sponsors. Its roles are:

- to ensure that the DermReg stay focused on its objectives
- to ensure its continuing relevance and justification

1. Datuk Dr. Roshidah Baba (Chairperson)
   Head of Dermatological Services and Senior Consultant Dermatologist
   Department of Dermatology
   Hospital Melaka

2. Dr. Koh Chuan Keng
   President of the Dermatological Society of Malaysia, and
   Consultant Dermatologist
   Koh Skin Specialist Clinic

3. Dr. Steven Chow Kim Weng
   President of the College of Physicians, Academy of Medicine Malaysia, and
   Senior Consultant Dermatologist
   The Skin Centre, Kuala Lumpur

4. Dr. Goh Pik Pin
   Director of the Clinical Research Centre Network
   Ministry of Health

STEERING COMMITTEE

Steering Committee for Malaysian Psoriasis Registry (MPR)

No.	Name	Institution
1.	Dr. Chang Choong .Chor (Chairman)	Hospital Kuala Lumpur
2.	Dr. Choon Siew Eng	Hospital Sultanah Aminah, Johor Bahru
3.	Dr. Pubalan Muniandy	Hospital Umum Sarawak
4.	Dr. Tang Jyh Jong	Hospital Permaisuri Bainun, Ipoh
5.	Dr. Chan Lee Chin	Hospital Pulau Pinang
6.	Dr. Najeeb Ahmad Mohd Safdar	Hospital Tuanku Jaafar, Seremban
7.	Dr. Steven Chow Kim Weng	The Skin Clinic, Kuala Lumpur
8.	Dr. Mohd Noh Idris	Klinik Kulit Md Noh, Kuala Lumpur

REGISTRY COORDINATING CENTRE

The **DermReg Registry Coordinating Centre (RCC)** is based at the Department of Dermatology, Hospital Kuala Lumpur. It coordinates the data collection among the source data providers, and collaborates with the Clinical Research Centre (CRC) that provides epidemiological and statistical support.

Registry Manager	Cik Noor Addillah bt Shueef

Technical Support Personnel

Epidemiology Officer	Dr. Jamaiyah Haniff Clinical Epidemiology Unit, CRC
Biostatisticians	Ms Premaa A/P Supramaniam Ms Tassha Hilda bt Adnan CRC
Clinical Data Manager	Ms Teo Jau Shya ClinResearch Sdn Bhd
Database Administrator	Ms Lim Jie Ying Datamed Clinical Computing Services Sdn Bhd

SOURCE DATA PROVIDERS (SDP)

Source data providers (SDP) are centres that contribute data to the registries.

Source Data Providers for Malaysian Psoriasis Registry (MPR)

No.	Source Data Provider	Investigator
1.	Hospital Kuala Lumpur	Dr. Chang Choong Chor
2.	Hospital Pulau Pinang	Dr. Chan Lee Chin
3.	Hospital Sultanah Bahiyah, Alor Setar	Dr. M. Balakrishnan
4.	Hospital Tuanku Fauziah, Perlis	Dr. M. Umaselvam
5.	Hospital Sultanah Fatimah, Muar	Dr. Kader Mohamad
6.	Hospital Tuanku Jaafar, Seremban	Dr. Najeeb Ahmad Mohd Safdar
7.	Hospital Queen Elizabeth, Kota Kinabalu	Dr. Zaigham Mahmood
8.	Hospital Sungai Buloh	Dr. Azahzuddin Hamzah
9.	Hospital Tengku Ampuan Afzan, Kuantan	Dr. Ong Cheng Leng
10.	Hospital Permaisuri Bainun, Ipoh	Dr. Agnes Heng Yoke Hui
11.	Hospital Umum Sarawak, Kuching	Dr. Pubalan Muniandy
12.	Hospital Tengku Ampuan Rahimah, Klang	Datin Dr. Saraswathy Devi Sinniah
13.	Hospital Melaka	Dr. Che Salmi Yusoff
14.	Prince Court Medical Centre	Dr.Gangaram Hemandas
15.	Hope Skin & Laser Centre, Gleneagles Intan Medical Centre	Dr. Allan Yee Kim Chye
16.	Hospital Sultanah Aminah, Johor Bahru	Dr. Choon Siew Eng

OFFICIAL WEBSITE OF DermReg

http://www.acrm.org.my/dermreg/

ABOUT MPR

Introduction

Psoriasis is a common skin disease characterized by inflamed scaly patches and plaques. It runs a chronic relapsing course with variable degree of severity, and causes significant physical, psychosocial and economic impact on the patient. Being incurable, it may lead to poor patient compliance especially in treatment which will further compromise the overall management of the disease.

The Malaysian Psoriasis Registry (MPR) is a skin disease clinical registry. It is a prospective, ongoing systematic collection of data pertaining to patients who have psoriasis. The main reason for setting up a psoriasis registry is to have more accurate data on the various aspects of psoriasis in Malaysia. This would help in assessing the true magnitude of the problem in Malaysia, including the demographic data, types of psoriasis, its severity, aggravating factors, any associated joint and nail involvement and the various types of therapies commonly used. Having a psoriasis registry should also help in research work and more importantly in improving the overall management of the patients.

Objectives

The MPR has the following objectives:

- Primary objective:
  To obtain more accurate data on various aspects of psoriasis in Malaysia.

- Secondary objectives:
  1. To determine the socio-demographic profiles of patients with psoriasis.
  2. To determine the disease burden attributed to psoriasis.
  3. To provide information for planning of medical services, facilities, manpower and training related to the management of psoriasis.
  4. To stimulate and facilitate research on psoriasis and its management.

Scope of MPR

The MPR is intended to be a truly national population based disease and treatment registry. Hence it seeks the participation of all providers of dermatological services in both the public and private sectors in Malaysia.

The MPR collects:

- Demographic data
- Clinical data including patients' history and clinical examination findings
- Quality of life measure i.e. Dermatology Life Quality Index (DLQI)
- Modalities of treatment used

Outcomes of interest include:

- Course of the disease
- How the disease affects quality of life
- Disease improvement with treatment
- Association with any other diseases

Inclusion criteria:

1. All patients who are clinically diagnosed to have psoriasis by a registered dermatologist or by a medical practitioner under the supervision of a dermatologist are included. Confirmation of diagnosis by histopathologic examination is optional.

Exclusion criteria:

1. Patients whose diagnosis is in doubt are excluded.

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EXECUTIVE SUMMARY

Stock and Flow
During the period from October 2007 to December 2009, a total of 4,445 patients with psoriasis from 16 dermatology centres (14 government and 2 private centres) were notified to the registry.

Demographic Characteristics of Patients
Male-to-female ratio was 1.29:1. Ethnic distribution: Malay 48.5%, Chinese 24.3%, Indian 17.8%, other ethnic groups 9.0%. Mean age at notification was 43.3 ± 17.3 years (range 0 - 97 years). Most patients (99.0%) were Malaysian citizens.

Medical History
Mean age of onset of psoriasis was 33.5 ± 16.7 years (range 0 – 87 years). Family history of psoriasis was present in 19.8% of the patients. Positive family history was more common among patients with younger onset (aged 40 and below) compared to those with later onset of disease: 22.7% vs 14.1%. Among those who had positive family history, family members affected were either of their parents in 42.0%, siblings in 35.7% and children in 11.7%.

49.6% of the patients reported one or multiple factors which aggravated their psoriasis. The commonest aggravating factors were stress (67.2%), sunlight (36.5%) and infection (18.8%).

Comorbidities
In adult psoriasis patients aged 18 and above, the common comorbidities were overweight 35.4%, obesity 22.1%, hypertension 24.6%, diabetes mellitus 17.4%, hyperlipidaemia 15.9%, and ischaemic heart disease 5.6%. In patients aged below 18, the commonest comorbidity was bronchial asthma (3.8%) followed by diabetes mellitus (1.3%).

Clinical Presentation
The commonest clinical type of psoriasis was plaque psoriasis (85.3%). This was followed by guttate psoriasis (4.7%), erythrodermic psoriasis (2.6%), pustular psoriasis (1.5%) and flexural psoriasis (0.5%). The majority of patients (61.3%) had body surface area involvement of 10% or less.

Psoriatic arthropathy was reported in 16.1% of patients. The commonest clinical pattern was oligo-/monoarthropathy (41.7%) followed by rheumatoid-like symmetrical polyarthropathy (33.8%) and distal hand joints arthropathy (27.8%).

About two-third (59.8%) of patients had nail changes related to psoriasis. Among patients who had nail disease, common nail changes were pitting (71.5%), onycholysis (51.9%), discoloration (38.4%) and subungual hyperkeratosis (15.5%). Total nail dystrophy occurred in 6.7% of patients with nail disease.

Treatments received in the past 6 months
The majority of patients (74.4%) used only topical treatment. The most popular mode of topical treatment was topical steroids (80.9%), followed by tar preparation (79.3%) and emollients (74.8%). Phototherapy was used in 3.9% of patients. Narrowband UVB (NB-

UVB) was the commonest mode of phototherapy used (69.6%). Systemic therapy was given in 21.1% of patients. The most frequently used systemic therapy was methotrexate (14.9%), followed by acitretin (4.8%), sulphasalazine (1.4%), systemic steroids (1.3%), cyclosporine (1.0%), biologics (0.4%) and hydroxyurea (0.3%).

Quality of Life

Measurement of quality of life using Dermatology Life Quality Index (DLQI) or Child DLQI (CDLQI) was performed in 3,612 adult patients (aged 17 and above) and 233 children/adolescent patients (aged 5 to 16). The mean DLQI score was 8.5 ± 6.5 for adult patients and the mean CDLQI was 7.3 ± 5.5 for children/adolescent patients.

INTRODUCTION

Psoriasis is a common skin disease characterised by inflamed scaly patches and plaques. It runs a chronic relapsing course with variable degree of severity, and causes significant physical, psychosocial and economic impact on the patient. Being incurable, it may lead to poor patient compliance especially in treatment which will further compromise the overall management of the disease.

The main reason for setting up a psoriasis registry is to have more accurate data on the various aspects of psoriasis in Malaysia. This would help in assessing the true magnitude of the problem in Malaysia, including the demographic data, types of psoriasis, its severity, aggravating factors, any associated joint and nail involvement and the various types of therapies commonly used. Having a psoriasis registry should also help in research work and more importantly in improving the overall management of the patients.

The Malaysian Psoriasis Registry (MPR) is a skin disease clinical registry. It is a prospective, ongoing systematic collection of data pertaining to patients who have psoriasis. Preliminary work on the MPR started in 1998 by a group of dermatologists, which culminated in the First Malaysian Psoriasis Symposium on the 17th May 1998. This registry consists of information on patients with psoriasis in Malaysia and is under the umbrella of the National Dermatology Registry (DermReg). A case report form was developed and data collection started as a pilot project in March 2000. A preliminary report of the registry (March 2000 to July 2005) was published in the Malaysian Journal of Dermatology in the August 2005 issue.

In 2007, MPR was extensively revised under the guidance of CRC and with the financial support from MOH. A new case report form was introduced and a new centralised electronic database with web application was established to facilitate multi-centre data collection. Preliminary report of the newly revised MPR was published in the Medical Journal of Malaysia in September 2008. The First Annual Report of MPR 2007-2008 was published in the following year.

CHAPTER 1

STOCK AND FLOW

During the period from October 2007 to December 2009, a total of 4,445 patients were notified to the registry. The number of notified patients gradually increased throughout the period (**Figure 1.1**).

A total of 16 dermatology centres (14 government and 2 private centres) participated in the MPR. Department of Dermatology, Hospital Kuala Lumpur notified the highest number of patients. This was followed by Hospital Pulau Pinang and Hospital Umum Sarawak (**Table 1.1**).

The majority of the patients (77.8%) were notified once. A second notification during subsequent follow-up visit was also received in 989 (22.2%) patients. Out of these patients, 735 (16.5%) had one follow-up notification, 215 (4.8%) had two follow-up notifications, and 39 (0.84%) had more than two follow-up notifications (**Table 1.2**).

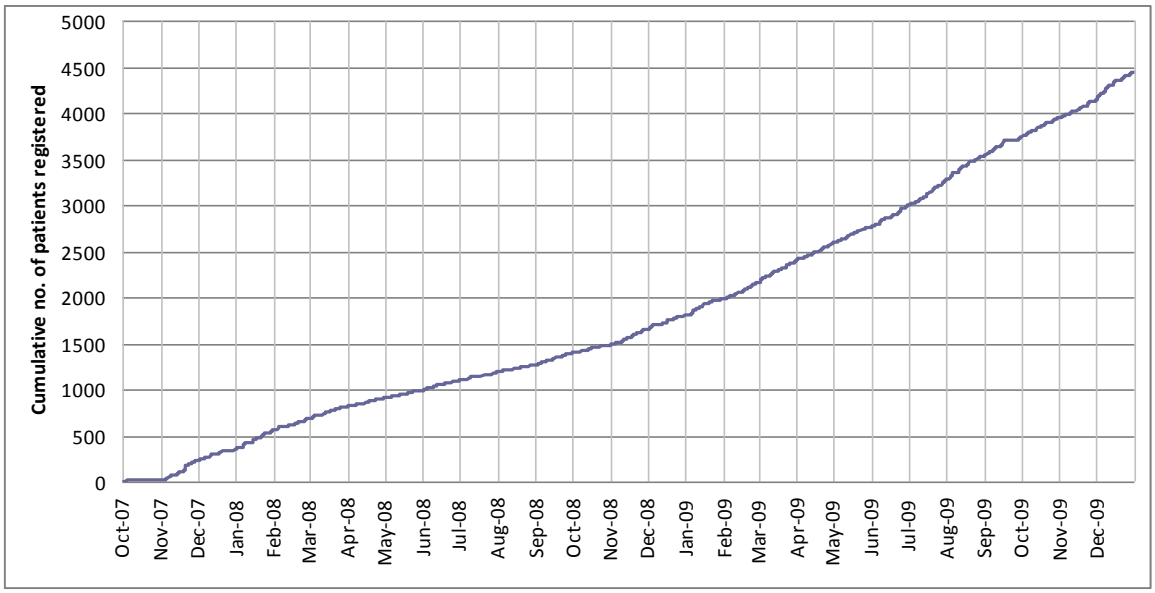


Figure 1.1 Psoriasis patients notified to the MPR.

Table 1.1 Number of psoriasis patients notified in each participating centre

	No. of patients notified			
	2007	**2008**	**2009**	**Total**
Hospital Kuala Lumpur	88	286	371	745
Hospital Pulau Pinang	26	113	497	636
Hospital Umum Sarawak, Kuching	8	257	261	526
Hospital Sultanah Bahiyah, Alor Setar	113	225	100	438
Hospital Tengku Ampuan Rahimah, Klang	0	100	294	394
Hospital Raja Permaisuri Bainun, Ipoh	73	67	188	328
Hospital Queen Elizabeth, Kota Kinabalu	21	116	160	297
Hospital Melaka	0	0	256	256
Hospital Sultanah Fatimah, Muar	7	79	135	221
Hospital Tengku Ampuan Afzan, Kuantan	0	59	138	197
Hospital Sultanah Aminah, Johor Bahru	0	38	151	189
Hospital Tuanku Fauziah, Kangar	3	49	79	131
Hospital Sungai Buloh	9	29	2	40
Gleneagles Intan Medical Centre	0	17	6	23
Hospital Tuanku Jaafar, Seremban	0	18	0	18
Prince Court Medical Centre	0	0	6	6
Total	348	1453	2644	4445

Table 1.2 Distribution of psoriasis patients according to the number of notifications

Year	No.	%
Entry notification	3,456	77.8
Entry and one follow-up notifications	735	16.5
Entry and 2 follow-up notifications	215	4.8
Entry and 3 follow-up notifications	37	0.8
Entry and 4 follow-up notifications	1	0.02
Entry and 5 follow-up notifications	1	0.02
Total	4445	99.94

CHAPTER 2

CHARACTERISTICS OF PATIENTS

There were more males than females (56.4% and 43.6% respectively), with a male to female ratio of 1.29:1. Malays comprised the majority of 48.5%, followed by Chinese 24.3%, Indians 17.8%, Orang Asli 0.1% and other ethnic groups 8.9%.

The mean age at presentation to the clinic was 43.3 ± 17.3 years with a range from 0 to 97 years. The majority were married (68.1%), 27.4% were single, and the rest, either divorced or widowed. (**Table 2.1**)

Table 2.1: Patient demographics

Patient characteristics		**No.**	**%**
Gender	Male	2506	56.4
	Female	1939	43.6
Ethnic distribution	Malay	2157	48.5
	Chinese	1082	24.3
	Indian	789	17.8
	Orang Asli	5	0.1
	Others	397	8.9
	NA	15	0.3
Nationality	Malaysian	4399	99.0
	Non Malaysian	38	0.9
	NA	8	0.2
Marital status	Single	1219	27.4
	Married	3028	68.1
	Divorced	35	0.8
	Widowed	93	2.1
	NA	70	1.6
Age at notification (years)	Mean ± SD (Range)	43.3 ± 17.3 (0 - 97)	

CHAPTER 3

MEDICAL HISTORY

Onset of Psoriasis

Psoriasis may first appear at any age. In the MPR, 66.3% of patients had first symptoms of psoriasis by the age of 40. The mean age of onset in our cohort was 33.5 ± 16.7 years with a wide range from 0 to 87 years. (**Figure 3.1**) The mean interval between onset (as reported by patient) and diagnosis (first diagnosed by physician) was 2.09 ± 4.4 years.

Family History

Psoriasis is a skin disorder with a polygenic mode of inheritance. In our registry, about one-fifth (19.7%) of patients had at least one family member who is psoriasis patient. (**Table 3.1**) Of those with a positive family history, 42.0% had either of their parents affected. Siblings were affected in 35.7% and children in 11.7%. (**Table 3.2**) More patients with positive family history were observed among those with a younger onset of disease (aged 40 and below) compared to those with later onset of disease: 22.7% vs 14.1% (**Table 3.1**).

Aggravating factors of psoriasis

The majority of patients (49.6%) reported one or multiple factors which worsen their psoriasis control. Stress was the commonest aggravating factor (67.2%), followed by sunlight (36.5%) and infection (18.8%). Other identified aggravating factors included trauma (6.5%), drugs (5.7%), smoking (5.0%), alcohol (3.9%), pregnancy (2.7%) and topical treatment (1.7%) (**Table 3.3**).

Analysing the subgroup of patients whom reported infection as an aggravating factor, upper respiratory tract infection (17.5%) appeared to be the commonest infective trigger. (**Table 3.4**) Common medications found to aggravate psoriasis were beta blocker (20.0%), withdrawal of systemic steroids (15.2%), non-steroidal anti-inflammatory drugs (8.0%) and antibiotics (7.2%). (**Table 3.5**)

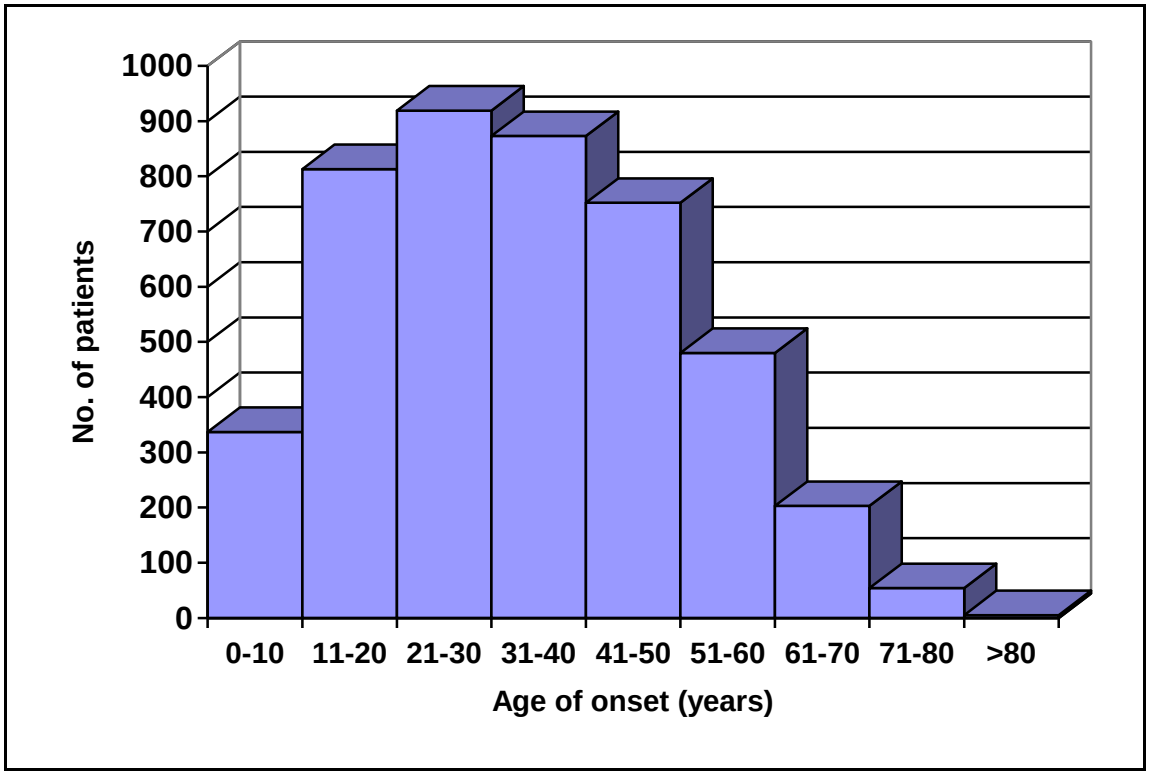


Figure 3.1 Distribution of age of onset

Table 3.1 Positive family history of psoriasis and its relationship with age of onset

		Overall		Age of onset of psoriasis			
				40 & below		Above 40	
		No.	%	N	%	N	%
Family members with psoriasis	Yes	874	19.7	664	22.6	209	14.0
	No	3540	79.6	2258	76.8	1276	85.5
	NA	31	0.7	19	0.6	8	0.5

Table 3.2 Family members with psoriasis

Family member (one or multiple)	No.	%
Father	227	26.0
Mother	140	16.0
Sibling(s)	312	35.7
Children	102	11.7
Others	223	25.5

Table 3.3 Aggravating factors of psoriasis

Aggravating factors (one or multiple)	No.	%
Stress	1469	67.2
Sunlight	797	36.5
Infection	411	18.8
Trauma	143	6.5
Drugs	125	5.7
Smoking	109	5.0
Alcohol	86	3.9
Pregnancy	58	2.7
Topical treatment	37	1.7

Table 3.4 Infections which aggravated psoriasis

Infection	No.	%
Upper respiratory tract infection	72	17.5
Fever / febrile illness	7	1.7
HIV	3	0.7
Chickenpox	2	0.5
Chikugunya	2	0.5
Dengue fever	1	0.2
Viral infection	1	0.2
Boil	1	0.2
Not specified	322	78.3

Table 3.5 Drugs which aggravated psoriasis

Drug	N	%
Beta-blocker	25	20.0
Systemic steroids (withdrawal)	19	15.2
NSAIDs / analgesics	10	8.0
Antibiotic	9	7.2
Traditional medications	6	4.8
Topical tar preparation	3	2.4
Antimalarial drug	1	0.8
Sodium valproate	1	0.8
ACE inhibitor	1	0.8
Daivobet	1	0.8
Dermovate	1	0.8
'Diane'	1	0.8
Antihistamine	1	0.8
Glucosamine	1	0.8
Homeopathy	1	0.8
"Gamat" (Sea cucumber extract)	1	0.8

CHAPTER 4

COMORBIDITIES

Patients with psoriasis were found to have a number of other concomitant diseases. Some of them had been associated with psoriasis in other studies, while others were coincidental. As the spectrum of diseases differs among age groups, adult and children/adolescent patients were analysed separately.

In adult psoriasis patients aged 18 and above, overweight was the most prevalent co-morbidity affecting 36.8% of the subject population, followed by obesity (34.2%), hypertension (24.6%), diabetes mellitus (17.4%), dyslipidaemia (15.9%), ischaemic heart disease (5.6%) and cerebrovascular disease (1.5%). (**Table 4.1**)

Table 4.1: Prevalence of comorbidities in adult psoriasis patients aged 18 and above

Cormorbidity	No.	%
Overweight	1363[#] (1418[*])	36.8[#] (35.4[*])
Obesity	851[#] (1317[*])	34.2[#] (22.1[*])
Hypertension	1003	24.6
Diabetes mellitus	709	17.4
Dyslipidaemia	646	15.9
Ischaemic heart disease	228	5.6
Stroke	60	1.5

[#] according to BMI classification for adult Asians as stated in the Clinical Practice Guidelines on Management of Obesity 2004, Ministry of Health, Malaysia

* according to the WHO International Classification of BMI

In children and adolescents aged below 18 years with psoriasis, the most prevalent comorbidity was overweight or obesity i.e. BMI at or above 85th centile (28.0%), followed by bronchial asthma (3.8%) and diabetes mellitus (1.3%). Other comorbid conditions were much less common. (**Table 4.2**)

Table 4.2: Prevalence of comorbidities in psoriasis patients aged below 18 years

Comorbidity	N	%
Overweight or obesity (BMI≥85th centile)	104	28.0
Bronchial asthma	14	3.8
Diabetes mellitus	5	1.3
Hypertension	3	0.8
Hyperlipidaemia	2	0.5
Down syndrome	2	0.5
Epilepsy	1	0.3
Thalassemia	1	0.3
Atrial defect	1	0.3
Congenital heart disease	1	0.3
Obstructive sleep apnoea	1	0.3

CHAPTER 5

CLINICAL PRESENTATION

Plaque psoriasis was the commonest type of psoriasis (85.3%). This was followed by guttate psoriasis (4.7%) and erythrodermic psoriasis (2.6%). Pustular and flexural/inverse psoriasis were much less common, constituting 1.5% and 0.5% respectively **(Table 5.1**)

Majority of our patients had mild to moderate body surface area involvement. 36.0% of our psoriatic patients had <2% BSA affected, while 40.4% had 2-10% of BSA affected. Severe psoriasis with >10% BSA affected occurred in 20.8% patients, while 2.8% had erythrodermic psoriasis, i.e. >90% BSA involved (**Table 5.2**).

A composite clinical scoring system was used to evaluate the severity of psoriatic lesions in five body regions. A score of 0 to 3 was given for each body region according to the degree of erythema, thickness and scaliness of the skin lesions. The total clinical score may range from 0 to 15. Analysis on severity of lesion noted that most of the moderate to severe lesions (score 2 and 3) located on lower limb (36.4%), trunk (32.5%) and upper limb (28.7%). Half of our psoriatic patients (49.9%) did not have any lesion on the face and neck. If present, lesions on face and neck were generally less severe (score 1 or 2). (**Table 5.3**)

The majority (59.8%) of patients with psoriasis had nail involvement (**Table 5.4**). Among patients who had psoriatic nail disease, most of them had pitting (71.5%). Other common features were onycholysis (51.9%), discoloration (38.4%) and subungual hyperkeratosis (15.5%). Total nail dystrophy was found in 6.7 % of patients with nail involvement. (**Table 5.5**)

Joint disease related to psoriasis was reported in 16.1% of the patients. (**Table 5.6**) Rheumatoid factor was detected in 11.9% of patients with arthropathy who were tested. (**Table 5.7**) The commonest clinical pattern of psoriatic arthropathy was oligo-/monoarthropathy (41.7%). This was followed by rheumatoid-like symmetrical polyarthropathy (33.8%), morning stiffness (31.5%), distal hand joints arthropathy (27.8%), spondylitis (10.2%) and enthesopathy (8.4%). The most severe form of arthropathy, i.e. arthritis mutilans occurred in 4.0% of patients. (**Table 5.8**)

Most of the patients with psoriatic arthropathy experienced joint pain at time of presentation (82.9%). (**Table 5.9**) Joint swelling was present in 31.7%, while joint deformity occurred in 22.2%. (**Table 5.9**) The commonest types of joint deformities were swan neck deformity (17.0%) and Boutonniere deformity (12.6%) and, followed by distal hand joint deformity (7.5%), bamboo spine (3.1%), proximal interphalangeal joint deformity (3.1%), rheumatoid arthritis-like (1.3%) and arthritis mutilans (0.6%). (**Table 5.10**)

Table 5.1 Distribution of psoriasis patients according to the type of psoriasis.

Type of psoriasis	No.	%
Plaque	3793	85.3
Guttate	208	4.7
Pustular	68	1.5
Erythrodermic	117	2.6
Flexural/Inverse	23	0.5
Palmoplantar non-pustular	3	0.1
Others	131	3.0
NA	102	2.3

Table 5.2 Distribution of percentage of body surface area affected in psoriasis patients.

% Body surface area affected (N=3565)	No.	%
<2%	1283	36.0
2 - 10%	1440	40.4
>10% to 90%	743	20.8
>90%	99	2.8

Table 5.3 Distribution of severity of body part affected in psoriasis patients.

Body part	Clinical score									
	0		1		2		3		NA	
	No.	%	No.	%	No.	%	No.	%	No.	%
Scalp	873	19.6	2340	52.6	959	21.6	209	4.7	64	1.4
Face & neck	2220	49.9	1745	39.3	333	7.5	41	0.9	106	2.4
Trunk	1161	26.1	1752	39.4	1271	28.6	173	3.9	88	2.0
Upper limbs	1029	23.2	2049	46.1	1134	25.5	140	3.2	93	2.1
Lower limbs	841	18.9	1897	42.7	1396	31.4	221	5.0	90	2.0

Table 5.4 Distribution of nail involvement in psoriasis patients.

Nail involvement	No.	%
Yes	2659	59.8
No	1742	39.2
NA	44	1.0

Table 5.5 Distribution of nail features in patients with nail involvement

Nail features	No.	%
Pitting	1902	71.5
Onycholysis	1381	51.9
Discoloration	1021	38.4
Subungual hyperkeratosis	413	15.5
Total nail dystrophy	179	6.7

Table 5.6 Distribution of joint disease in psoriasis patients

Joint disease	No.	%
Yes	717	16.1
No	3670	82.6
NA	58	1.3

Table 5.7 Distribution of rheumatoid factor in psoriasis patients with joint disease

Rheumatoid factor	No.	%
Positive	14	11.9
Negative	104	88.1
NA	599	

Table 5.8 Distribution of types of joint disease

Type of joint disease (one or multiple)	No.	%
Oligo-/monoarthropathy	299	41.7
Symmetrical polyarthropathy (rheumatoid-like)	242	33.8
Morning stiffness > 30 mins	226	31.5
Distal hand joints arthropathy	199	27.8
Spondylitis	73	10.2
Enthesopathy	60	8.4
Arthritis mutilans	29	4.0

Table 5.9 Symptoms of psoriatic arthritis

	Status	No.	%
Pain	Yes	594	82.9
	No	87	12.1
	NA	36	5.0
Joint swelling	Yes	227	31.7
	No	456	63.6
	NA	34	4.7
Joint deformity	Yes	159	22.2
	No	523	72.9
	NA	35	4.9

Table 5.10 Distribution of type of joint deformities in patients with joint disease

Type of joint deformity	No.	%
Swan neck deformity	27	17.0
Boutonniere deformity	20	12.6
Distal hand joint deformity	12	7.5
Bamboo spine	5	3.1
Proximal interphalangeal joint deformity	5	3.1
Rheumatoid arthritis-like	2	1.3
Arthritis mutilans	1	0.6
Others	15	9.4
Unspecified	78	49.7

CHAPTER 6

TREATMENTS

Types of treatment for psoriasis received by the patients in the last six months were analysed.

Most patients (97.3%) used some form of topical medications for psoriasis. (**Table 6.1**) The majority of patients (74.4%) used only topical treatment. The most commonly used topical medication was topical steroids (80.9%). This was followed by topical tar preparation (79.3%), emollients (74.8%), keratolytics (54.0%), vitamin D analogue such as calcipotriol (23.1%) and dithranol (1.9%). (**Table 6.2**)

In the last six months prior to notification, 3.9% of patients received phototherapy. (**Table 6.3**) Most of these patients (69.6%) were given narrowband UVB (NB-UVB) while 8.8% were given broadband UVB (BB-UVB). Less popular modalities were oral PUVA (4.7%), topical PUVA (1.8%) and bath PUVA (0.6%). (**Table 6.4**)

Systemic therapy was used in 21.1% of patients. (**Table 6.5**) Methotrexate, being the commonest systemic therapy, was used in 14.9%. This was followed by acitretin (4.8%), sulphasalazine (1.4%), systemic corticosteroids (1.3%), cyclosporine (1.0%), biologics (0.4%) and hydroxyurea (0.3%). (**Table 6.6**) The biologic therapy most frequently used was etanercept (5 patients), followed by efalizumab (4 patients), infliximab (2 patients) and adalimumab (1 patient). The name of the biologic agent was not specified in 4 patients.

Table 6.1 Use of topical therapy in psoriasis patients

Topical therapy	No.	%
Yes	4327	97.3
No	118	2.7
Total	4445	100.0

Table 6.2 Distribution of types of topical therapy

Topical therapy (one or multiple)	No.	%
Topical steroids (other than face and flexures)	3594	80.9
Tar preparation	3523	79.3
Emollient	3324	74.8
Keratolytics	2401	54.0
Vitamin D analogues	1025	23.1
Dithranol (anthralin)	84	1.9
Others	91	2.1

Table 6.3 Use of phototherapy in psoriasis patients

Phototherapy	No.	%
Yes	171	3.9
No	4105	92.4
NA	169	3.8
	4445	100.0

Table 6.4 Distribution of types of phototherapy

Type of phototherapy (one or multiple)	No.	%
Narrowband UVB	119	69.6
Broadband UVB	15	8.8
Oral PUVA	8	4.7
Topical PUVA	3	1.8
Bath PUVA	1	0.6
Others	2	1.2

Table 6.5 Use of systemic therapy in psoriasis patients

Systemic therapy	No.	%
Yes	938	21.1
No	3507	79.9
Total	4445	100.0

Table 6.6 Distribution of types of systemic therapy in psoriasis patients

Type of systemic therapy (one or multiple)	No.	%
Methotrexate	660	14.9
Acitretin	214	4.8
Sulphasalazine	61	1.4
Cyclosporin	43	1.0
Hydroxyurea	14	0.3
Biologics	16	0.4
Systemic corticosteroids	59	1.3
Others	58	1.3

CHAPTER 7

QUALITY OF LIFE

There were a total of 3,612 adult patients (aged 17 and above) and 233 child/adolescent patients who completed the quality of life questionnaires, namely Dermatology Life Quality Index (DLQI) and Child Dermatology Life Quality Index (CDLQI).

The mean DLQI for adult psoriasis patients was 8.5 ± 6.5, and the mean CDLQI for child/adolescent patients was 7.3 ± 5.5.

The responses for each question of the DLQI and CDLQI were tabulated in **Table 7.1 and 7.2** respectively. 1,209 adult patients (33.5%) reported a DLQI of more than 10 indicating severe quality of life impairment due to psoriasis or its treatment (**Figure 7.1**). There were 210 adults (5.8%) who had a DLQI of more than 21 indicating extremely large effect on their quality of life by psoriasis. Nevertheless, 13.9% of adult patients reported no effect at all on their quality of life.

As shown in **Figure 7.2**, "systems and feelings" was the DLQI category most affected by psoriasis in adult patients. 35.5% of patients were affected very much or a lot by the itch and pain as well as embarrassment due to psoriasis. The aspect of life least affected by psoriasis was "personal relationship" in which 85.6% of the adult patients did not have or only have a little effect in this aspect.

In children/adolescents group, 25.3% of patients reported a CDLQI of more than 10 indicating very large or extremely large effect on QoL (**Figure 7.3**). There were four patients (1.7%) who had CDLQI of more than 21, reflecting extremely large effect of QoL. On the other hand, 14.6% child/adolescent patients had no effect at all on QoL.

In child/adolescent patients, the category of CDLQI most affected was "symptoms and feelings" and aspect of life least affected by psoriasis was "personal relationship" in which 83.9% of the children did not have or only have a little effect (**Figure 7.4**). These results are similar to that of the adult patients.

Table 7.1 Responses for DLQI in adult psoriasis patients (age 17 and above)

No.	DLQI Question	No. (%)				
		Very much	A lot	A little	Not at all	Not relevant
1	Over the last week, how itchy, sore, painful, or stinging has your skin been?	352 (8.7)	1015 (25.0)	2217 (54.6)	479 (11.8)	-
2	Over the last week, how embarrassed or self conscious have you been because of your skin?	536 (13.2)	980 (24.2)	1500 (37.0)	1037 (25.6)	-
3	Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	299 (7.4)	732 (18.0)	1363 (33.5)	1547 (38.0)	127 (3.1)
4	Over the last week, how much has your skin influenced the clothes you wear?	268 (6.6)	754 (18.6)	1382 (34.0)	1537 (37.8)	124 (3.1)
5	Over the last week, how much has your skin affected any social or leisure activities?	310 (7.6)	741 (18.2)	1331 (32.8)	1571 (38.7)	111 (2.7)
6	Over the last week, how much has your skin made it difficult for you to do any sport?	320 (7.9)	653 (16.2)	1125 (27.9)	1399 (34.7)	539 (13.4)
7	Over the last week, has your skin prevented you from working or studying?	344 (9.5)	245 (7.0)	770 (21.3)	1584 (43.9)	656 (18.2)
8	Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	155 (3.8)	428 (10.6)	1184 (29.2)	2110 (52.0)	180 (4.4)
9	Over the last week, how much has your skin caused sexual difficulties?	117 (2.9)	212 (5.3)	643 (16.0)	2080 (51.8)	964 (24.0)
10	Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy or by taking up time?	203 (5.0)	631 (15.5)	1339 (32.9)	1681 (41.4)	211 (5.2)

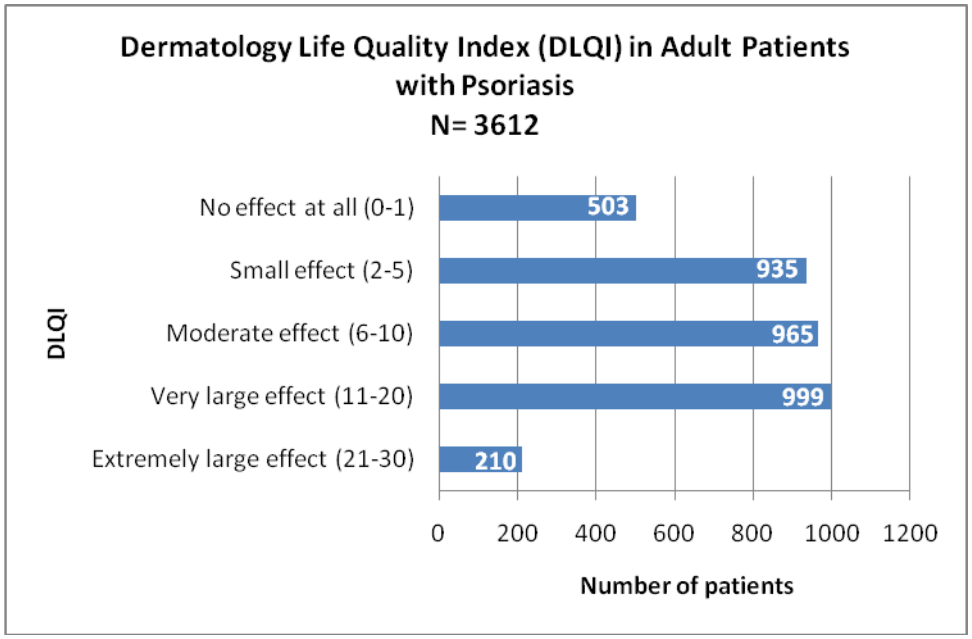


Figure 7.1: Quality of life in adult patients with psoriasis

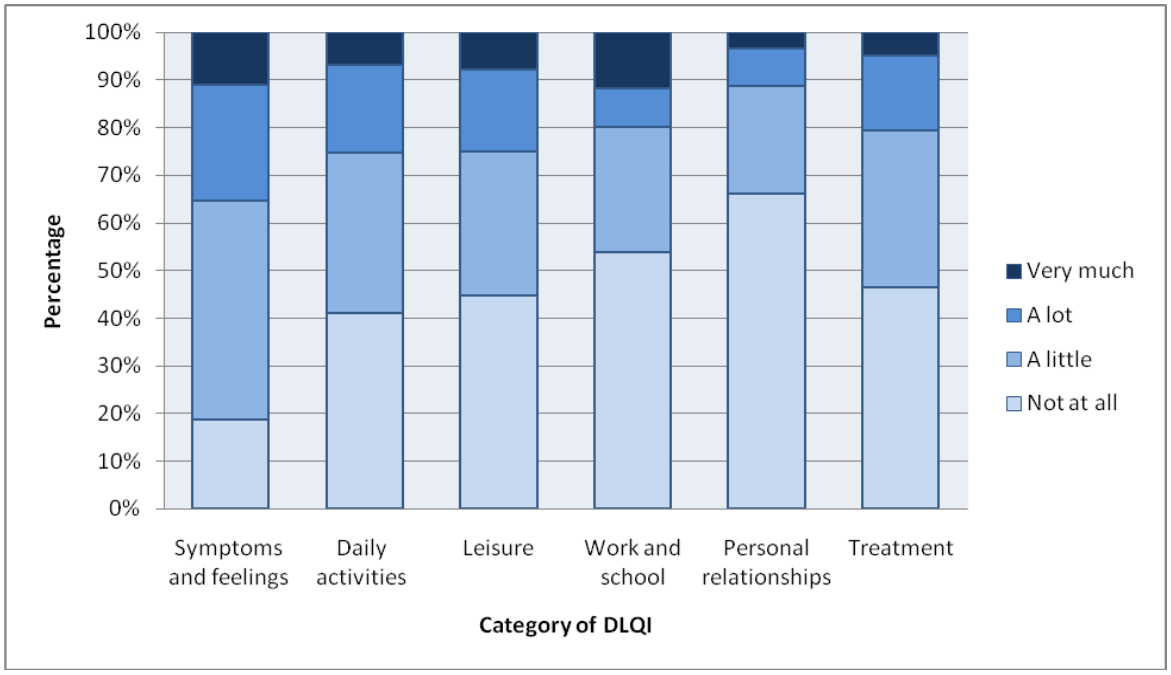


Figure 7.2 QoL impairment in adults psoriasis patients based on category of DLQI

Table 7.2 Responses for CDLQI in child/adolescent psoriasis patients (aged 5 to 16)

No.	CDLQI Question	No. (%)				
		Very much	A lot	A little	Not at all	Not relevant
1	Over the last week, how itchy, "scratchy", sore, painful, or stinging has your skin been?	14 (5.3)	70 (26.4)	157 (59.3)	24 (9.1)	-
2	Over the last week, how embarrassed or self conscious have you been because of your skin?	39 (14.7)	59 (22.3)	111 (41.9)	56 (21.1)	-
3	Over the last week, how much has your skin affected your friendships?	11 (4.2)	31 (11.7)	84 (31.7)	139 (52.5)	-
4	Over the last week, how much have you changed or worn different or special clothes/shoes because of your skin?	12 (4.6)	47 (17.8)	83 (31.4)	122 (46.2)	-
5	Over the last week, how much has your skin trouble affected going out, playing, or doing hobbies?	13 (4.9)	39 (14.7)	92 (34.7)	121 (45.7)	-
6	Over the last week, how much have you avoided swimming or other sports because of your skin trouble?	18 (6.8)	37 (14.0)	74 (27.9)	136 (51.3)	-
7	If school time: Over the last week, how much did your skin problem affect your school work? Or If holiday time: Over the last week, has your skin problem interfered with your enjoyment of the holiday?	7 (2.7)	33 (12.6)	81 (30.9)	141 (53.8)	-
8	Over the last week, how much trouble have you had because of your skin with other people calling you names, teasing, bullying, asking questions or avoiding you?	13 (5.0)	24 (9.2)	65 (24.9)	159 (60.9)	-
9	Over the last week, how much has your sleep been affected by your skin problem?	16 (6.5)	29 (11.8)	71 (29.0)	129 (52.7)	-
10	Over the last week, how much of a problem has the treatment for your skin been?	8 (3.1)	34 (13.0)	89 (34.0)	131 (50.0)	-

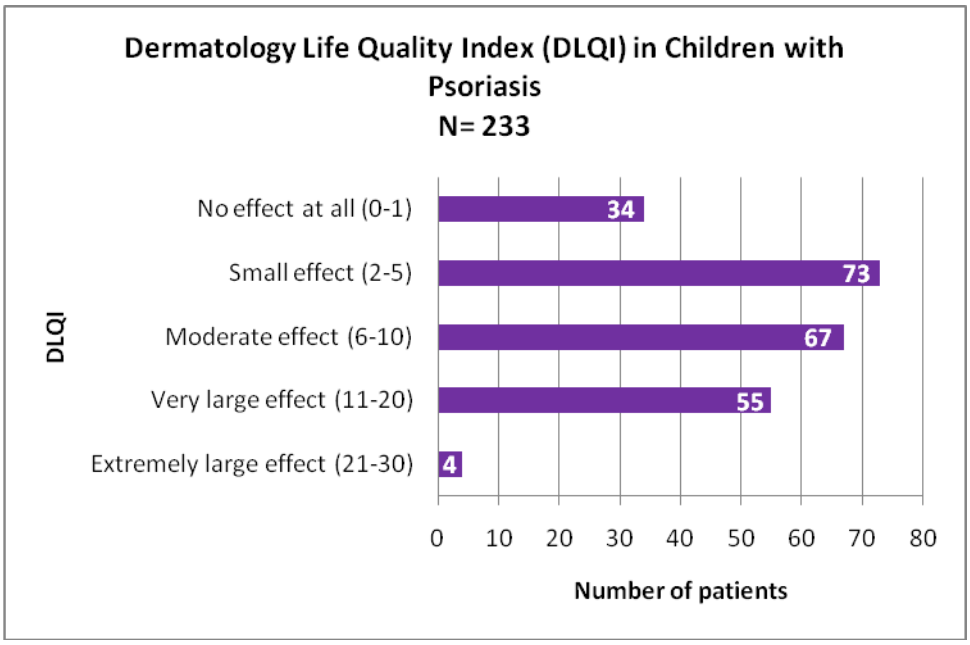


Figure 7.3 Quality of life in children/adolescents with psoriasis.

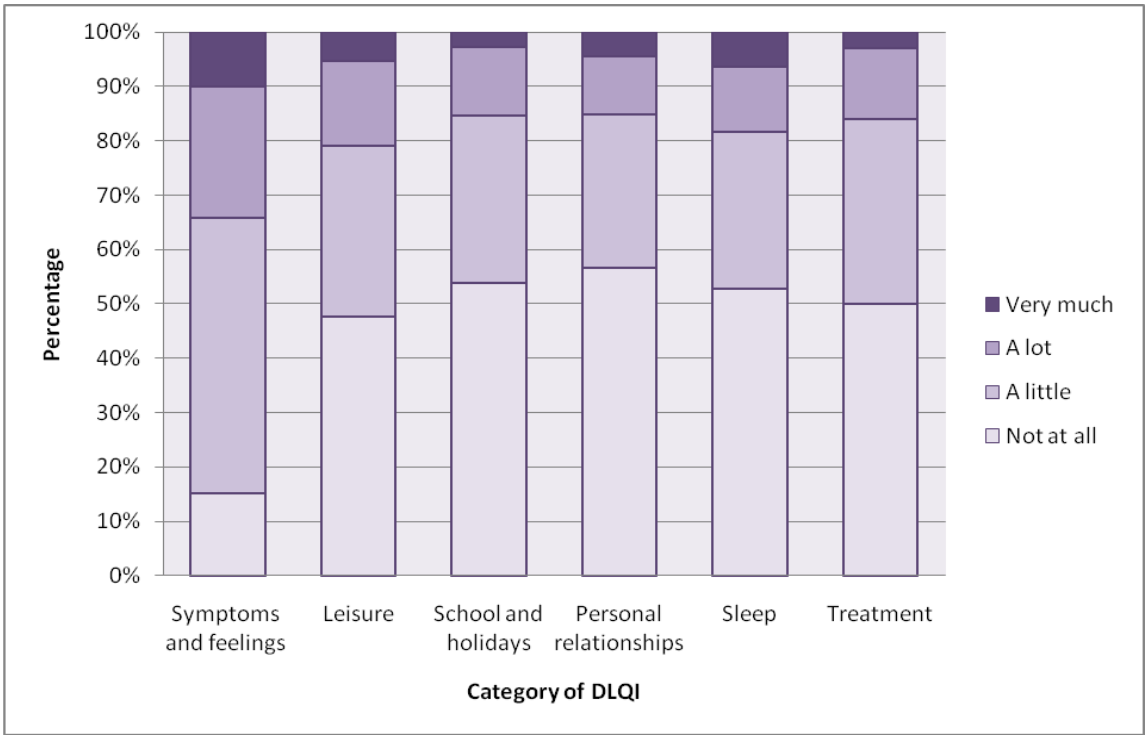


Figure 7.4 QoL impairment in child/adolescent psoriasis patients based on category of DLQI

CHAPTER 8

OUTCOMES

In this registry, follow-up data are to be collected approximately every 6 months. Outcome of patients is assessed by measuring the change in several clinical parameters between the last follow-up visit and the visit at registration. Severity of psoriasis skin lesions are assessed in terms of the extent of lesions, i.e. percentage of body surface area involvement, and lesional characteristics via a clinical skin scoring method for each of the five body regions. Other clinical parameters monitored include severity of joint pain on a visual analogue score (0-10), and quality of life using Dermatology Life Quality Index (DLQI).

From a total of 4,445 psoriasis patients registered in MPR, follow-up data were obtained in 989 patients. The mean duration of follow-up was 12.4 ± 5.7 months, with the longest duration of 29 months. (**Table 8.1**).

Extent of Psoriasis Lesions

The extent of psoriasis lesions is assessed in terms of percentage of body surface area involvement categorised into 4 scales, i.e. <2%, 2%-10%, 10%-90%, and >90% (erythrodermic). A total of 678 patients were evaluated for change in the extent of lesions. Of these patients, 170 patients (25.1%) had improvement by at least one scale, among which 26 (3.8%) had improvement by two scales, and 1 patient improved from BSA>90% to BSA<2%. No improvement was found in 397 patients (58.6%), and 111 patients (16.4%) had worsening by at least one scale (**Figure 8.1**).

Clinical Skin Scores

Clinical skin scores measures the thickness, erythema and scaliness of the psoriasis lesions in each of the five body regions. A score of 0 to 3 is given for each body region. Total Clinical Skin Score is the total of the scores in all five body regions. The overall mean total clinical skin score at baseline was 10.1±2.6, and the mean score at follow-up was 9.43±2.60. This gave an overall improvement in clinical skin score of 0.62±2.68. The improvement in mean score was similar in all subgroups of patients with different intervals of follow-up. This relatively small degree of improvement is not surprising in view of the highly dynamic nature of the course of illness in psoriasis due to the potential influence by various aggravating factors.

Two patients (0.2%) had the most marked improvement in skin scores by 75% or more, and 28 patients (2.9%) had improvement by 50-75%, while 147 patients (15.2%) had 25-50% improvement. 291 patients (30.1%) had modest improvement of less than 25%. No improvement of skin scores were detected in 240 patients (24.8%). Skin scores worsened in 258 patients (26.7%) (**Figure 8.2**).

Joint Pain

From a total of 72 patients who reported to have joint pain, 37 patients (51.4%) had improvement in joint pain as measured by the visual analogue scale. Of these patients, 11 patients (15.3%) had improvement of between 50% and 75%, 20 patients (27.8%) had improvement of between 25% and 50%, and 6 patients (8.3%) had improvement of less than 25%. There was no improvement of joint pain in 12 patients (16.7%), while joint pain worsened in 23 patients (32.0%) (**Figure 8.3**).

Change in Quality of Life

In adult patients aged 17 years and above, we noted an overall improvement in the quality of life. A total of 848 adult patients were evaluated for change in quality of life by DLQI. Of these patients, 187 patients (22.1%) had significant improvement with a reduction of DLQI score by at least 5, whereas 124 patients (14.6%) had significant worsening with an increase in DLQI score by at least 5. (**Figure 8.4**)

A total of 33 patients aged below 17 were evaluated for change in quality of life by DLQI. Of these patients, eight patients (24.2%) had a significant improvement of Child DLQI score by at least 5, while three patients (9.1%) worsened. (**Figure 8.4**)

Table 8.1: Distribution of psoriasis patients according to the duration of follow-up

Duration of follow-up	No.	%
0 to 6 months	218	22.0
7 to 12 months	332	33.6
13 to 18 months	288	29.1
19 to 24 months	148	15.0
25 to 30 months	3	0.3
	989	100.0

Mean duration of follow-up: 12.4 ± 5.7 months (range 0 – 29 months)

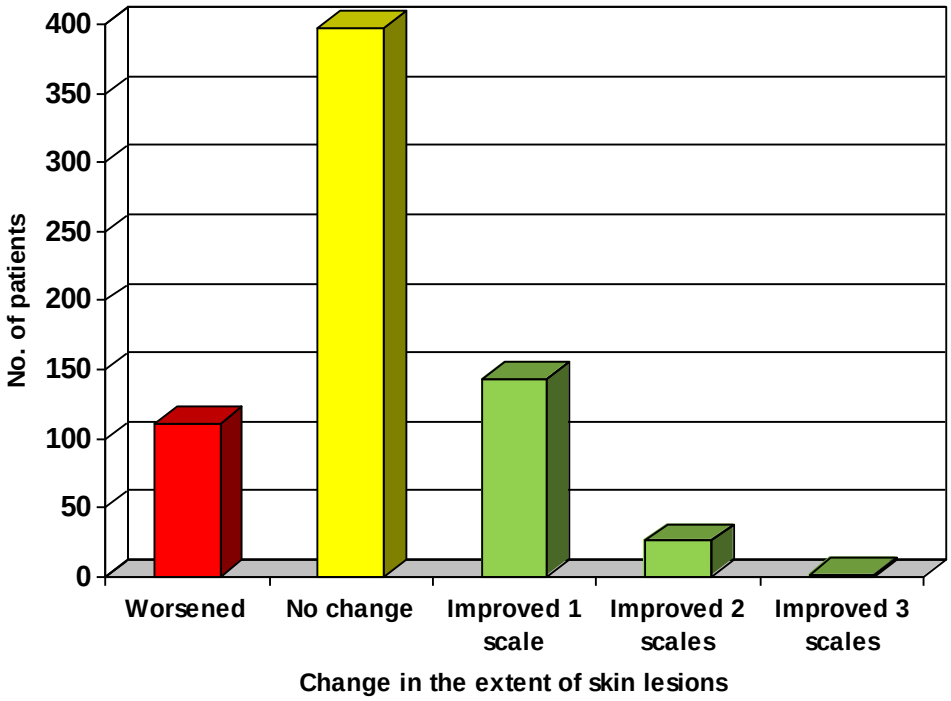


Figure 8.1: Improvement in the extent of skin lesions

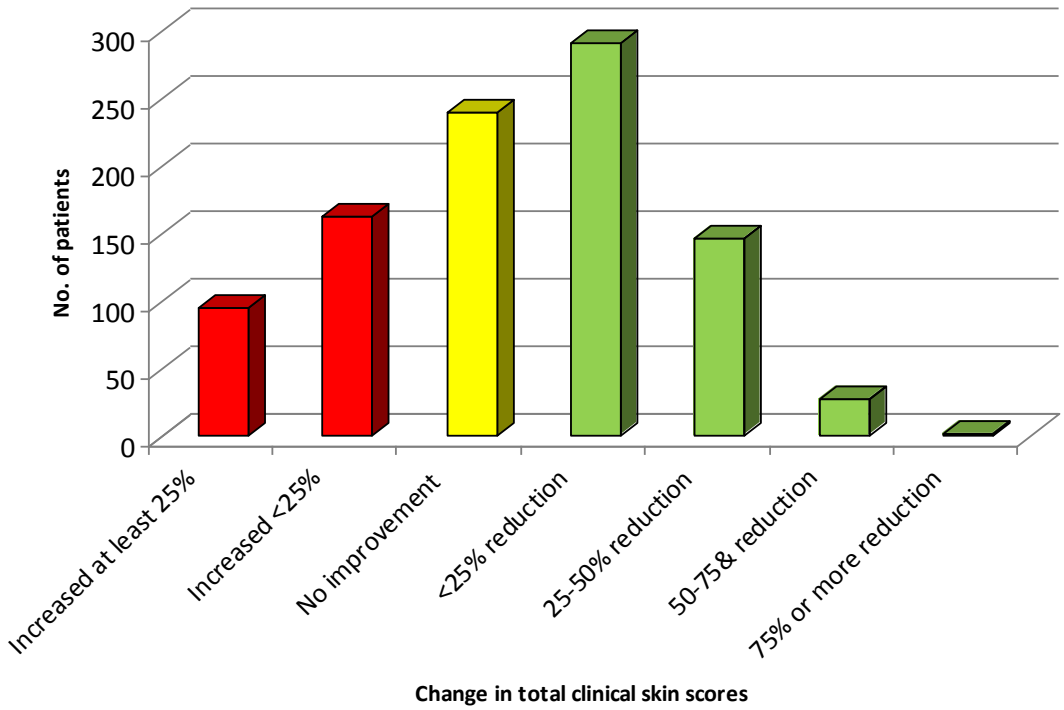


Figure 8.2: Improvement in the total clinical skin scores

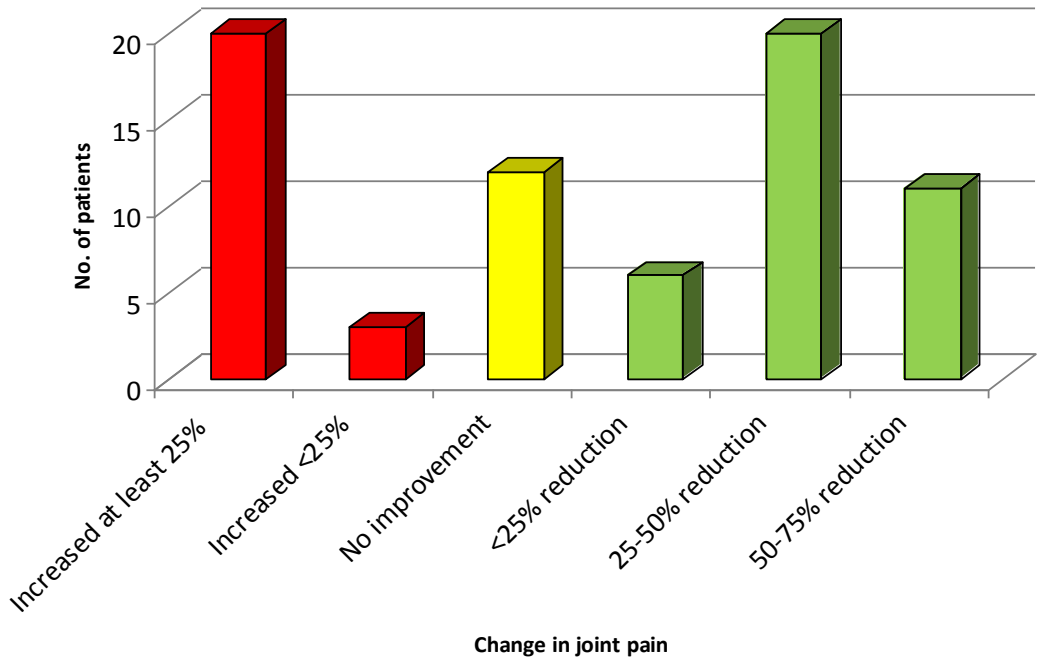


Figure 8.3: Improvement in joint pain

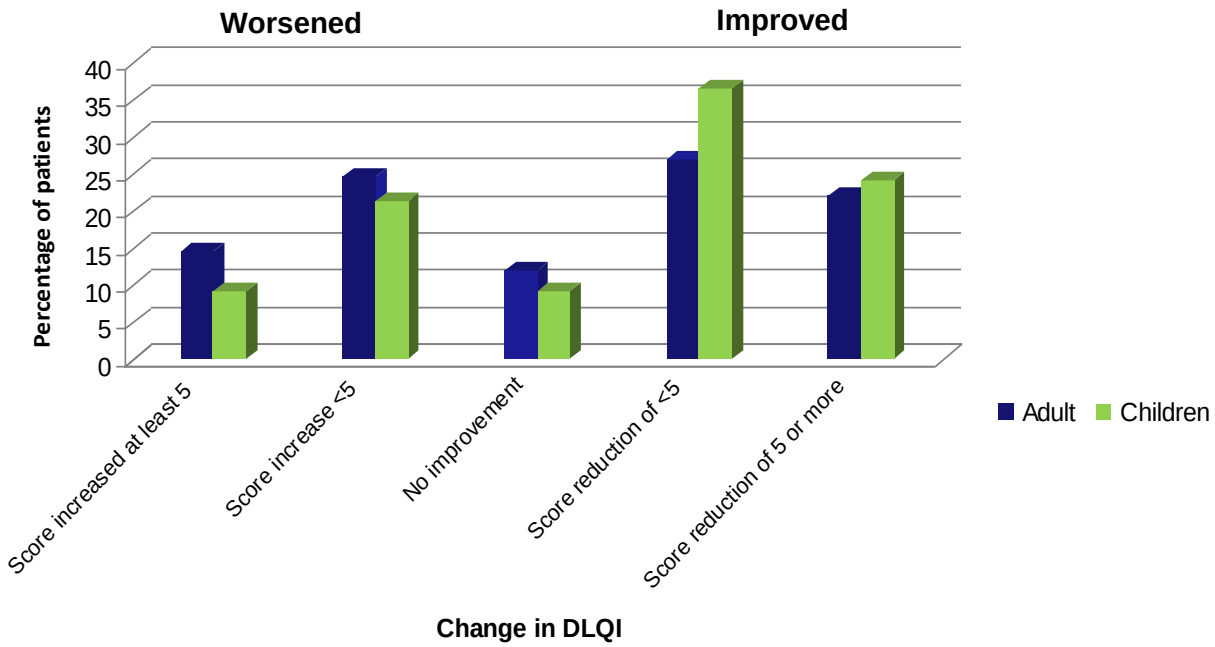


Figure 8.4: Improvement in DLQI and CDLQI

APPENDIX A: CASE REPORT FORM

Malaysian Psoriasis Registry
Case Report Form

CONFIDENTIAL
For Office Use only:
ID: /
Centre

Instruction: Where check boxes [ ] are provided, check (√) one or more boxes. Where radio buttons ◉ are provided, check (√) one button only.

Doctor's Name :	
Name of Institution :	

SECTION 1: DEMOGRAPHIC DETAILS

1. Patient visit date : (dd/mm/yyyy)	/ /
2. Type of visit :	◉ New Case ◉ Follow-Up
3. Name of patient :	
4. NRIC :	MyKad/ MyKid: - - Old IC:
	Other ID document No:
	Specify document type (if others): ◉ Registration number ◉ Mother's I/C ◉ Work Permit ◉ Clinic RN ◉ Passport ◉ Father's I/C ◉ Driver's Licence ◉ Police ID Card ◉ Birth Certificate ◉ Armed Force ID ◉ Hospital RN ◉ Others
5. Address : #	Town / City: State :
6. Contact # number :	Homephone: - H/P: -
7. Gender : #	◉ Male ◉ Female
8. Date of birth : # (dd/mm/yyyy)	/ /
9. Ethnic group : #	◉ Malay ◉ Chinese ◉ Indian ◉ Orang Asli ◉ Others, specify : .....
10. Nationality : #	◉ Malaysian ◉ Non-Malaysian, specify .....
11. Marital status : #	◉ Single ◉ Married ◉ Divorced ◉ Widow ◉ Widower

SECTION 2 : MEDICAL HISTORY

1. Age when # psoriasis started :	
2. Age when # psoriasis diagnosed :	
3. Family # member(s) with psoriasis :	◉ No ◉ Yes → (if YES, please tick ONE or MULTIPLE) ☐ Father ☐ Sibling(s) ☐ Other relative, specify ..... ☐ Mother ☐ Children
4. Aggravating factors :	◉ No ◉ Yes → (if YES, please tick ONE or MULTIPLE of the following) ☐ Infection : ..... ☐ Drugs : ..... ☐ Topical Rx : ..... ☐ Trauma ☐ Stress ☐ Sunlight ☐ Hypocalcaemia ☐ Pregnancy ☐ Smoking ☐ Alcohol
5. Disease burden in the last 6 months :	a) No.of clinic visits due to psoriasis : (enter 0 if none)
	b) No. of days off work due to psoriasis : (enter 0 if none)
	c) No. of hospital admissions due to psoriasis : (enter 0 if none)

6. Other diseases :	a) Ischaemic heart disease :	◉ Yes ◉ No ◉ Unknown	e) Hyperlipidaemia :	◉ Yes ◉ No ◉ Unknown
	b) Cerebrovascular disease (stroke) :	◉ Yes ◉ No ◉ Unknown	f) Other diseases, specify :	◉ Yes ◉ No ◉ Unknown
	c) Diabetes mellitus :	◉ Yes ◉ No ◉ Unknown		
	d) Hypertension :	◉ Yes ◉ No ◉ Unknown		

** Note : Items marked # above need not be entered during follow-up visits.*

Version 1.9 Last updated 11/10/07

page 1 of 4

Malaysian Psoriasis Registry
Case Report Form

CONFIDENTIAL

For Office Use only:
ID: [ ] / [ ]
Centre [ ]

Instruction: Where check boxes [ ] are provided, check (√) one or more boxes. Where radio buttons ( ) are provided, check (√) one button only.

SECTION 3: CLINICAL EXAMINATION

1. (a) Height : [ ][ ][ ] (cm) (b) Weight: [ ][ ][ ] (kg)

2. Pregnant : *(for female)* ( ) No ( ) Yes → Period of gestation : [ ][ ] weeks

3. Type of psoriasis : ( ) Plaque ( ) Guttate ( ) Pustular ( ) Erythrodermic ( ) Flexural / Inverse ( ) Others,specify: .....
(Please select ONE predominant type)

4. Severity : Body surface area involved : ( ) <2% ( ) 2 - 10% ( ) > 10% ( ) Erythrodermic (>90%)

Body part	Grade of severity
Scalp	( ) 0 ( ) 1 ( ) 2 ( ) 3
Face & Neck	( ) 0 ( ) 1 ( ) 2 ( ) 3
Trunk	( ) 0 ( ) 1 ( ) 2 ( ) 3
Upper Limbs	( ) 0 ( ) 1 ( ) 2 ( ) 3
Lower Limbs	( ) 0 ( ) 1 ( ) 2 ( ) 3

Key for grading
Grade 0 : Skin normal or hypo-/hyperpigmented patch only.
Grade 1 : Mild erythema,fine scales, thin plaque, with or without central clearing.
Grade 2 : Moderate erythema or scaling, moderately thick plaque.
Grade 3 : Severe erythema or scaling, very thick plaque

5. Nail involvement : ( ) No ( ) Yes → *(if YES, please tick ONE or MULTIPLE)*
[ ] Pitting [ ] Discoloration [ ] Total nail dystrophy
[ ] Onycholysis [ ] Subungual hyperkeratosis

6. Joint disease : ( ) No ( ) Yes →

a) Rheumatoid factor	( ) Negative	( ) Positive	( ) Not Available
b) Type :-	1. Morning stiffness > 30 minutes	( ) No	( ) Yes
	2. Enthesopathy	( ) No	( ) Yes
	3. Oligo-/ Monoarthropathy	( ) No	( ) Yes
	4. Distal hand joints arthropathy	( ) No	( ) Yes
	5. Proximal hand joints arthropathy (rheumatoid- like)	( ) No	( ) Yes
	6. Spondylitis / Sacroiliitis	( ) No	( ) Yes
	7. Arthritis mutilans	( ) No	( ) Yes
c) Severity:-	1. Pain	( ) No ( ) Yes →	Pain Score (1-10) : [ ][ ]
	2. Swelling	( ) No ( ) Yes	
	3. Deformity	( ) No ( ) Yes →	Please Specify : .....

SECTION 4 : TREATMENT

1. Topical therapy :	a) Tar preparation	( ) No ( ) Yes	e) Keratolytics e.g. salicylic acid	( ) No ( ) Yes
	b) Vitamin D analogues e.g calcipotriol	( ) No ( ) Yes	f) Emollient	( ) No ( ) Yes
	c) Dithranol (anthralin)	( ) No ( ) Yes	g) Others, specify	( ) No ( ) Yes →
	d) Topical steroids (other than face / flexures)	( ) No ( ) Yes		

2. Phototherapy : ( ) No ( ) Yes → *(if YES, please tick ONE or MULTIPLE)*
[ ] BB-UVB [ ] Oral PUVA [ ] Topical PUVA [ ] Others,specify
[ ] NB-UVB [ ] Bath PUVA [ ] Excimer laser .....

3. Systemic therapy :	a) Methotrexate	( ) No ( ) Yes	f) Biologics, specify	( ) No ( ) Yes →
	b) Acitretin	( ) No ( ) Yes	g) Systemic corticosteroids	( ) No ( ) Yes
	c) Sulphasalazine	( ) No ( ) Yes	h) Others, specify	( ) No ( ) Yes →
	d) Cyclosporin	( ) No ( ) Yes		
	e) Hydroxyurea	( ) No ( ) Yes		

SECTION 5: QUALITY OF LIFE

1. Quality of Life :	Please instruct and assist patient in completing the attached DLQI form

***Note : Please ensure that all sections of this form have been completed.*
Kindly submit to :
Malaysian Psoriasis Registry, Department of Dermatology, Hospital Kuala Lumpur, Jalan Pahang, 50586 Kuala Lumpur

Version 1.9 Last updated 11/10/07 *page 2 of 4*

Malaysian Psoriasis Registry
Dermatology Life Quality Index (DLQI)
(For Adults of Age Above 16)

CONFIDENTIAL
For Office Use only:
ID: /
Centre

Instruction: Where check boxes ☑ are provided, check (√) one or more boxes. Where radio buttons ◉ are provided, check (√) one button only.

Objektif kaji selidik adalah untuk memahami setakat manakah masalah kulit anda mempengaruhi kehidupan anda SEPANJANG MINGGU LALU.
The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK.
这份问卷的目的是衡量上周内您的皮肤问题对您的生活造成了多大的影响
Sila tandakan satu kotak (√) untuk setiap soalan / *Please tick "√" one box for each question* 请在每个问题后选择一项打 " √ ".

DLQI Score ☐ *Auto calculated*

Sepanjang Minggu Lalu .... *OVER THE LAST WEEK* 上周内,	Sangat Banyak *Very much* 非常多	Banyak *A lot* 许多	Sedikit *A little* 一点	Tidak Langsung *Not at all* 完全没有	Tidak Berkenaan *Not Relevant* 无关
1) Setakat manakah kulit anda berasa gatal atau sakit ? *Over the last week, how itchy, sore, painful or stinging has your skin been?* 您的皮肤感到痒、触痛、疼痛、刺痛了吗 ?	◉	◉	◉	◉	
2) Setakat manakah anda berasa malu atau segan, disebabkan oleh kulit anda? *Over the last week, how embarrassed or self conscious have you been because of your skin?* 由于您的皮肤问题，您感到尴尬或自卑吗?	◉	◉	◉	◉	
3) Setakat manakah kulit anda menganggu anda daripada pergi membeli belah atau menjaga rumah atau berkebun ? *Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?* 因为皮肤问题，对您购物、做家务、整理庭院影响程度如何?	◉	◉	◉	◉	◉
4 Setakat manakah kulit anda mempengaruhi pakaian yang anda pakai? *Over the last week, how much has your skin influenced the clothes you wear?* 皮肤问题对您穿衣服影响程度如何?	◉	◉	◉	◉	◉
5) Setakat manakah kulit anda mengganggu aktiviti - aktiviti sosial atau masa lapang anda ? *Over the last week, how much has your skin affected any social or leisure activities?* 皮肤问题对您的社交或休闲生活有多大的影响?	◉	◉	◉	◉	◉
6) Setakat manakah keadaan kulit anda menyebabkan anda tidak selesa bersukan? *Over the last week, how much has your skin made it difficult for you to do any sport?* 皮肤问题对您运动有多大妨碍?	◉	◉	◉	◉	◉
7) Adakah kulit anda menyebabkan anda tidak bekerja atau belajar? *Over the last week, has your skin prevented you from working or studying?* 皮肤问题是否让您无法上班或学习? ☐ Ya *Yes* 是 ☐ Tidak *No* 不是 ☐ Tidak Berkenaan *Not Relevant* 无关 "Jika "tidak", setakat manakah kulit anda menjadi masalah semasa kerja atau belajar? *If "No", over the last week how much has your skin been a problem at work or studying?* 如果选择 "不是"，那么上周内您的皮肤问题对工作或 学习有多大影响呢?		◉	◉	◉	
8) Setakat manakah kulit anda menimbulkan masalah dengan teman,rakan baik atau saudara mara anda? *Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives ?* 皮肤问题妨碍了您和爱人、亲密的朋友、亲戚间的交往了 吗?	◉	◉	◉	◉	◉
9) Setakat manakah kulit anda menyebabkan sebarang masalah hubungan seks ? *Over the last week, how much has your skin caused sexual difficulties?* 皮肤问题给您的性生活造成了多大影响?	◉	◉	◉	◉	◉
10) Setakat manakah rawatan kulit anda menimbulkan masalah seperti mengotori rumah anda atau mengambil masa anda? *Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy or by taking up time?* 由于治疗您皮肤的毛病，给您造成了多少麻烦，如把家 里弄得一团糟或占用了您很多时间?	◉	◉	◉	◉	◉

Sila semak sama ada SETIAP soalan telah dijawab. Terima kasih
Please check you have answered EVERY question. Thank you.
请您检查您是否已回答所有问题. 谢谢合作

Version 1.9 Last updated 11/10/07 *page 3 of 4*

Malaysian Psoriasis Registry
Children's Dermatology Life Quality Index (DLQI)
(For age 5 to 16)

CONFIDENTIAL

For Office Use only:
ID: ____ / ____
Centre ____

Instruction: Where check boxes ☑ are provided, check (√) one or more boxes. Where radio buttons ◉ are provided, check (√) one button only.

Objektif kaji selidik adalah untuk memahami setakat manakah masalah kulit anda mempengaruhi kehidupan anda SEPANJANG MINGGU LALU.
The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK.
这份问卷的目的是衡量上周内您的皮肤问题对您的生活造成了多大的影响.
Sila tandakan satu kotak (√) untuk setiap soalan / *Please tick "√" one box for each question* 请在每个问题后选择一项打 " √ "

DLQI Score: ____ Auto calculated

Sepanjang Minggu Lalu .... *OVER THE LAST WEEK* 过去一星期中	Sangat Banyak *Very much* 非常多	Banyak *A lot* 许多	Sedikit *A little* 一点	Tidak Langsung *Not at all* 完全没有
1) Setakat manakah kulit anda berasa gatal atau sakit ? *Over the last week, how itchy, "scratchy",sore or painful has your skin been?* 你皮肤发痒、搔抓、破皮或疼痛的程度是如何?	◉	◉	◉	◉
2) Setakat manakah anda berasa malu, segan, susah hati atau sedih disebabkan oleh kulit anda? *Over the last week, how embarrassed or self conscious, upset or sad have you been because of your skin?* 你因为自己皮肤问题而感到难为情或害羞、苦恼或难过的程度是如何?	◉	◉	◉	◉
3) Setakat manakah kulit anda mempengaruhi persahabatan anda? *Over the last week, how much has your skin affected your friendships?* 皮肤问题对你和朋友交往的影响是如何?	◉	◉	◉	◉
4) Setakat manakah anda menukar atau memakai pakaian atau kasut kerana kulit anda? *Over the last week, how much have you changed or worn different or special clothes/shoes because of your skin?* 你因为皮肤问题而改变穿著不同或特定衣鞋的影响是如何?	◉	◉	◉	◉
5) Setakat manakah masalah kulit anda mempengaruhi anda untuk keluar, bermain atau melakukan hobi anda? *Over the last week, how much has your skin trouble affected going out,playing , or doing hobbies?* 皮肤的问题对你外出、玩耍、或从事休闲嗜好的影响是如何?	◉	◉	◉	◉
6) Setakat manakah anda menjauhi diri daripada berenang atau melakukan sukan lain disebabkan oleh masalah kulit anda? *Over the last week, how much have you avoided swimming or other sports because of your skin trouble?* 你因为皮肤的问题而避免游泳或其他运动的影响程度是如何?	◉	◉	◉	◉
7).Pada minggu yang lalu, *Last week,* 过去一星期 Pada hari persekolahan, setakat manakah kulit anda mempengaruhi kerja sekolah anda? *If school time: Over the last week, how much did your skin problem affect your school work?* 如果是上课时间，皮肤问题影响你学校功课的程度是如何? ATAU *OR* 或 *Pada hari cuti, setakat manakah kulit anda menggangu anda menikmati cuti?* *If holiday time: Over the last week, has your skin problem interfered with your enjoyment of the holiday?* 如果是放假期间，皮肤问题干扰到你享受假期的兴致是如何?	◉	◉	◉	◉
8) Setakat manakah orang menggelar anda dengan nama yang tidak baik, mengejek, menanya soalan-soalan atau menjauhi diri disebabkan oleh kulit anda? *Over the last week, how much trouble have you had because of your skin with other people calling you names, teasing, bullying, asking questions or avoiding you?* 因为皮肤的问题使得别人骂你、嘲笑你、欺负你、问你问题或躲避你，这种困扰程度是如何?	◉	◉	◉	◉
9) Setakat manakah masa tidur anda diganggu kerana masalah kulit? *Over the last week, how much has your sleep been affected by your skin problem?* 你因皮肤的问题而影响到睡眠的程度是如何?	◉	◉	◉	◉
10) Setakat manakah rawatan kulit anda menjadi suatu masalah? *Over the last week, how much of a problem has the treatment for your skin been?* 针对皮肤所进行的治疗对你产生的困扰程度是如何?	◉	◉	◉	◉

Sila semak sama ada SETIAP soalan telah dijawab. Terima kasih
Please check you have answered EVERY question. Thank you.
请您检查您是否已回答所有问题. 谢谢合作

APPENDIX B: DATA MANAGEMENT

The National Dermatology Registry (DermReg) maintains a database that includes patient's demographic data, medical history, comorbidities, clinical presentation, treatments received in the past 6 months and quality of life. Data is stored in SQL Server due to the high volume of data accumulated throughout the years.

Data Sources

SDPs of DermReg comprise of dermatology centres or clinics with dermatologists who participate in the registry throughout Malaysia.

Data Collection

The study involves collection of data on the patient's first visit to the participating centre and thereafter every six monthly on follow-up visits.

A carefully designed Case Report Form (CRF) is employed in the data collection. This is a double-sided single-sheet CRF which consists of a clinical data form and a multilingual Dermatology Life Quality Index (DLQI) form in both adult and children versions. The clinical data form is to be completed by the doctor in-charge while the DLQI form is to be completed by the patient (parent or guardian for young patient) with guidance from trained staff if necessary. Adult DLQI form should be used for patients above 16 years old, while Children DLQI for patients aged 5 to 16. It is not required to fill the DLQI form for patients below 5 years of age.

One set of CRF is to be completed for each new patient during consultation at the first visit to the participating centre. A new set of CRF is to be completed for the same patient every 6 monthly to record the progress of the patient. The CRFs are used as part of the clinical records.

The CRF is to be completed in duplicate. The participating centre retains the duplicate copy in the patient's medical record, while the original copy is to be sent within 2 weeks to the RCC where data are analysed, interpreted and presented in regular reports to be disseminated to the users.

Participation of SDP is entirely voluntary.

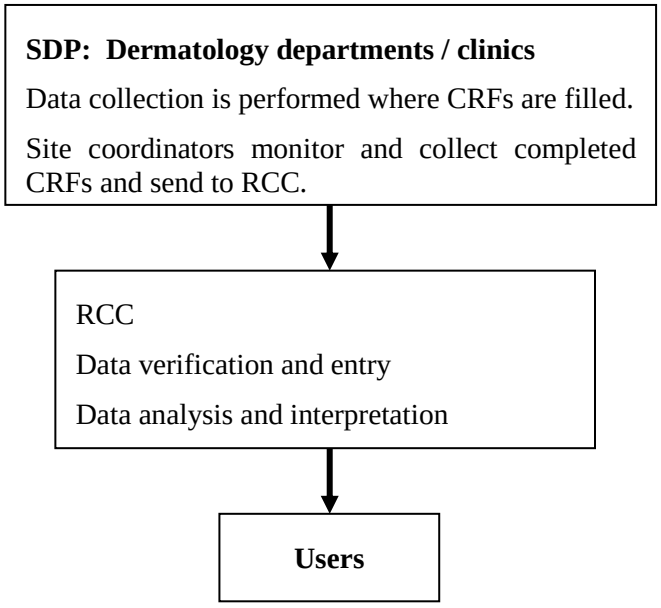
Registry ICT Infrastructure and Data Centre

The operations of the DermReg are supported by an extensive ICT infrastructure to ensure operational efficiency and effectiveness.

The network infrastructure consists of the network layout, placement of relevant hardware equipment, the general flow of data across the network, as well as the network services required for a functional and secure DermReg network infrastructure. DermReg servers are located in a data centre in Cyberjaya in order to provide DermReg with quality assured data hosting services and state-of-the-art physical and logical security features without having to invest in costly data centre setup internally. The physical security features implemented include fire suppression system, access card and biometrics authentication to gain physical access to the data centre, uninterrupted power supply, and backup devices. Logical security features implemented include firewall, antivirus, automated patching, encryption, traffic monitoring and intrusion detection system.

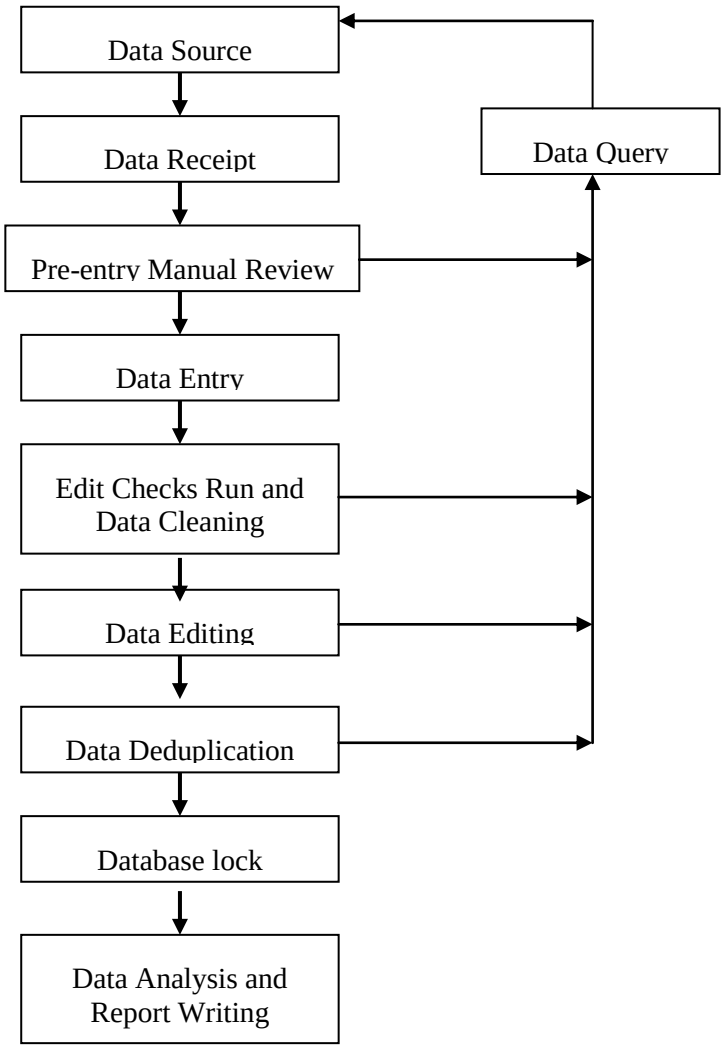
Data Flow Process

Data are collected by doctors in the dermatology departments or clinics. Completed CRFs are then sent to the RCC.



Data received by the RCC are manually reviewed and checked for completeness and error. Data without apparent problems are entered into the registry database. Edit checks are performed periodically to identify potential data errors, such as missing data, non-allowed values, out of range numeric values, inconsistent data and error with deduplication. Data queries that are resolved are then updated to the database.

To ensure complete enumeration and validity of data, a series of tasks as shown in the figure below have to be in place.



SDP Data Reporting, Data Correction and Submission Tracking

Data submitted by SDP are entered into electronic case report form (eCRF) via DermReg Web Application (eDermReg).

There are a number of data security features that are designed into eDermReg such as web owner authentication, two-level user authentication, access control, data encryption, session management to automatically log off the application, audit trail and data backup and disaster recovery plan.

Prior to registering a patient record, a verification process is done by using the search functionality to search if patient exist in the entire registry. This step is done to avoid duplicate records. For patients that exist in the database, SDP only needs to add a new notification with basic patient particulars pre-filled based on existing patient information in the database.

There are a few built-in functionalities at the data entry page that serve to improve data quality. One such function is auto calculation which reduces errors in human calculation. There is also inconsistency check functionality that disables certain fields if these fields are answered in a certain manner. When value entered is not within the specific range, user is prompted for the correct value.

Real time reports are also provided in the web application. The aggregated data reports are presented in the form of tables and graphs manner. These aggregated data reports are typically presented in two manners, one as the centre's own data report and another as registry's overall data report.

Edit checks run and Data cleaning

Edit check was performed periodically by the registry manager to identify missing compulsory data, out of range values, inconsistency data, invalid values and error with de-duplication. Data cleaning is then performed based on the results of edit checks. Data update and data checking of the dataset is performed when there is a query of certain fields when necessary. It could be due to request by user, correction of data based on checking from data query in eCRF or after receiving results from preliminary data analysis. During data standardization, missing data are handled based on derivation from existing data. For example, deriving age from IC, deriving gender from IC and name and inferring race from name. Checking inconsistency of the data also done, for example IC and name shows female but gender is male. Data de-duplication is also performed to identify duplicate records in the database that might have been missed by the SDP.

Legal Aspects and Confidentiality

Data transfer from source data producers is entirely voluntary. There is no legal provision to compel any individual or institution to report or transfer its data to the RCC. The data transferred to RCC is highly sensitive and has to be kept strictly confidential with access only to authorized individual working in the RCC. Strict data protection procedure will need to be put in place, following standard disease registration practice, and in compliance with applicable regulatory guidelines.

Data release policy

One of the primary objectives of the Registry is to make data available to the physicians, policy makers and researchers. The Registry would appreciate that users acknowledge the Registry for the use of the data. Any request for data that requires a computer run must be made in writing (by email, fax, or registered mail) accompanied with a Data Release Application Form and signed Data Release Agreement Form. These requests need prior approval by the Governance Board before data can be released.

APPENDIX C: STATISTICAL METHODS

ANALYSIS SET

This refers to the set of cases included in the analysis. Two analysis sets were defined:

1. **Patient notification between 2007 and 2009**

   There were 4,445 patients in the dataset. The analysis set was use for the analysis in Chapter 1, 2, 3, 4, 5 and 6, which comprises of 348 cases in year 2007, 1,453 cases in year 2008 and 2,644 cases in year 2009. The cases include first notification and up to five follow-up notifications.

2. **Patient outcome between 2007 and 2009**

   There were 989 cases considered for the outcome analysis in Chapter 8.

DATA MANAGEMENT

Data Cleaning

The data from the MPR database were subjected to extensive checking prior to definitive analysis. Errors found or queries raised were checked against the database and/or CRF and corrections were made immediately.

Missing Data

Details on the missing data were issue to Project Manager to clarify the status of the information. Trackable missing information was then incorporated into the dataset but for untrackable and tolerable missing data were included in the analysis and defined as missing.

STATISTICAL METHOD

Descriptive analysis was done in presenting frequencies and percentages of distribution whereas bar and pie charts were used in presenting the figures. For continuous data, the mean, standard deviation, minimum, maximum, median and interquartile range were reported. For standardization in output table, the values of percentages and summary descriptive were limited to one decimal point only. The summaries of data presentation by chapter were described as below:

Stock and Flow

Chapter 1 explained the registry for the distribution of centres reported and distribution of patients according to number of notifications.

Characteristics of Patients

Chapter 2 explained the socio-demographic profiles such as gender, ethnicity, nationality and marital status. Descriptive summary was done for age at visit.

Medical History

Chapter 3 emphasized on the distribution of aggravating factors of psoriasis patients. Crosstabulations were concentrated on the comparison of family members with psoriasis against age of onset.

Comorbidities

Chapter 4 emphasized on the combination of distribution and descriptive summaries of age of onset, several demographic profiles and comorbidities. Figures were presented graphically using bar and stacked bar charts.

Clinical Presentation

Chapter 5 concentrated on the descriptive summaries of pain score. The distribution of psoriasis patients were further analysed on types of psoriasis, body surface area, severity, nail involvement, joint disease, rheumatoid factor, symptoms of psoriatic arthritis and types of joint disease. Crosstabulations performed with several combinations involving age of onset, types of psoriasis, demographic profiles, severities and disease involvements. The graphical presentation were pie chart, bar and stacked bar chart.

Treatment

Chapter 6 presented the distribution of patients with topical therapy, phototherapy, types of phototherapy and systematic therapy. The graphical presenteation were in pie chart, bar and stacked bar chart.

Quality of Life

Chapter 7 solely concentrated on a specific intention, which was on Dermatology Life Quality Index (DLQI). The distribution and crosstabulation figures were presented graphically using bar, stacked bar and line charts.

Outcomes

Chapter 8 explained on the distribution and descriptive summary of the outcome variables. The improvement of lesion extent, skin score, joint score and DLQI score were graphically presented using bar charts.

STATISTICAL SOFTWARE

Stata version 9.0 and SPSS 14.0

APPENDIX D: PARTICIPATING CENTRE DIRECTORY

Hospital Kuala Lumpur Department of Dermatology Hospital Kuala Lumpur Jalan Pahang 50586 Kuala Lumpur. Tel: 03-26155255 Fax: 03-26985927	Investigator: Dr Chang Choong Chor Site- coordinator: -
Hospital Pulau Pinang Dermatology Department, Hospital Pulau Pinang, Jalan Residensi, 10990 Pulau Pinang, Tel: 04-2293333 Fax: 04-2281737	Investigator: Dr Chan Lee Chin Site- coordinator: Dr Tan Wooi Chiang
Hospital Sultanah Bahiyah, Alor Setar Dermatology Department, Hospital Sultanah Bahiyah, Lebuhraya Darul Aman, 05100 Alor Setar, Kedah Tel: 04-7002295 Fax: 04-7323770	Investigator: Dr M. Balakrishnan Site- coordinator: Dr Azlida Che Man
Hospital Tuanku Fauziah, Kangar Dermatology Department, Hospital Tuanku Fauziah, Jalan Kolam,01000 Kangar, Perlis. Tel: 04-9763333 Fax: 04-9768239	Investigator: Dr M. Umaselvam Site- coordinator: Dr Sharifah Farihah Syed Abas
Hospital Sultanah Fatimah, Muar Dermatology Department, Hospital Pakar Sultanah Fatimah, Jalan Salleh, 84000 Muar, Johor. Tel: 06-9521901 Fax: 06-2810560	Investigator: Dr. Hj. Kader b Mohamed Site- coordinator: Dr. Siti Khadijah Abdul Wahid

Hospital Tuanku Ja'afar, Seremban Dermatology Department, Hospital Tuanku Ja`afar, Jalan Rasah 70300 Seremban, Negeri Sembilan. Tel: 06-7623333 Fax: 06-7625771	Investigator: Dr. Najeeb Ahmad Mohd Safdar Site- coordinator: Dr.Prakash A/L Balasubramaniam
Hospital Queen Elizabeth, Kota Kinabalu Dermatology Department, Hospital Queen Elizabeth, Karung Berkunci no 2029 , 88586 Kota Kinabalu, Sabah. Tel: 088-206316 Fax: 088-252823	Investigator: Dr Zaigham Mahmood Site- coordinator: Dr Mervin George
Hospital Sungai Buloh Dermatology Unit Hospital Sungai Buloh, Jalan Hospital, 47000 Sungai Buloh, Selangor Darul Ehsan. Tel: 03-61454333 Fax: 03-61454222	Investigator: Dr. Azahzuddin b Hamzah Site- coordinator: Pn Rohayu Johar
Hospital Tengku Ampuan Afzan, Kuantan Dermatology Department, Hospital Tengku Ampuan Afzan, Jalan Tanah Putih, 25100 Kuantan, Pahang. Tel: 09-5133333 Fax: 09-5142712	Investigator: Dato' Dr Ong Cheng Leng Site- coordinator: Pn Latipah Hj Othman
Hospital Raja Permaisuri Bainun, Ipoh Dermatology Department, Jabatan Dermatologi, Hospital Ipoh, Jalan Hospital 30990 Ipoh, Perak. Tel: 05-2533333 Fax: 05-2531541	Investigator: Dr Agnes Heng Yoke Hui Site- coordinator: Dr Tang Jyh Jong

Sarawak General Hospital Dermatology Department, Hospital Umum Sarawak, Jln Tun Ahmad Zaidi Adruce, 93586 Kuching, Sarawak. Tel: 082-257555 Fax: 082-240767	Investigator: Dr Pubalan Muniandy Site- coordinator: Dr Felix Yap Boon Bin
Hospital Tengku Ampuan Rahimah, Klang Dermatology Department, Hospital Tengku Ampuan Rahimah, 41200 Klang, Selangor. Tel: 03-33723333 Fax: 03-3729089	Investigator: Datin Dr Saraswathy Devi Sinniah Site-coordinator: Dr Norasma bt Roslan
Hospital Sultanah Aminah, Johor Bahru Jabatan Dermatologi, Hospital Sultanah Aminah Johor Bahru, Jalan Abu Bakar, 80100, Johor Bahru, Johor Tel: 07-2226920 Fax: 07-2242694	Investigator: Dr Choon Siew Eng Site- coordinator: Dr Tey Kwee Eng
Gleneagles Intan Medical Centre Hope Skin and Laser Centre, Gleneagles Intan Medical Centre, 282 & 286 Jalan Ampang, 50450 Kuala Lumpur. Tel: 03-42578112 Fax: 03-42576112	Investigator: Dr. Allan Yee Kim Chye Site- coordinator: -
Hospital Sungai Buloh Dermatology Unit Hospital Sungai Buloh, Jalan Hospital, 47000 Sungai Buloh, Selangor Darul Ehsan. Tel: 03-61454333 Fax: 03-61454222	Investigator: Dr Azahzuddin b Hamzah Site- coordinator: Pn Rohayu Johar

Hospital Melaka Jabatan Dermatologi, Hospital Melaka, Jalan Mufti Hj. Khalil, 75400 Melaka. Tel: 06-2822344 Fax: 06-2841590	Investigator: Dr Che Salmi Yusoff Site- coordinator: Dr Ng Si Yuan
Prince Court Medical Centre Prince Court Medical Centre, 39, Jalan Kia Peng, 50450 Kuala Lumpur. Tel: 03- 26100000 Ext 2955 Fax: 03-21600940	Investigator: Dr. Gangaram Hemandas Belani Site- coordinator: -