

PsoReg – The Quality Register for Systemic Psoriasis Treatment

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The introduction of a new generation of drugs for the systemic treatment of psoriasis might be a challenge to the dermatologic community. How do we face this challenge?

We believe that our current instruments are not enough to cope with this challenge. In clinical studies, special risks as well as opportunities in patient subpopulations often remain undetected because study populations are a poor model for real patient populations. The reason is that they differ in, for instance, concomitant diseases and medication as well as age distribution. Furthermore, the trustworthiness of sponsored clinical drug investigations has recently been severely questioned (1, 2). Clinical experience, on the other hand, will not solve the problem either, as no single department will be able to gain sufficient experience within an acceptable period of time.

We therefore suggest that PsoReg, a quality register for systemic psoriasis treatment, should be established to create robust long-term data. PsoReg will ensure long-term evaluation effectiveness and safety profiles of old

versus new generation treatments as well as treatment combinations. The broad collective experience of PsoReg with the large number of unselected patients might even allow identification of both target phenotypes for different treatments and safety concern in small patient subpopulations. Additionally, the impact on the quality of life and cost effectiveness could be analyzed. Although psoriasis is a global disease, its high prevalence in the Nordic countries together with our epidemiological expertise and ability to collaborate makes it our duty to act now.

Point of departure

The outline of this register has been made by a Swedish psoriasis expert group with a broad representation of dermatology departments as well as private practitioners. Furthermore, the medical product agency, the patient organisation (PSO), and the organisation of dermatological nurses (DVSS) were represented. Rheumatology was embodied by a leading expert in psoriasis arthropathy. A board consisting of five dermatologists with special expertise was appointed by the expert group in co-operation with the Swedish Society for Dermatology and Venereology (SSDV) for the comprehensive work with the register. This board represents the University Hospitals of Lund, Göteborg, Stockholm, and Umeå. Umeå is the home of the register. Moreover, a national psoriasis network comprising 228 persons was established which, together with the expert group, represents some 80% of the publicly funded dermatologi-

cal services. Both the SSDV and the rheumatology society (RF) support the establishment of PsoReg. In an ideal world, public authorities would finance such a project. However, in the real world, the authorities concerned offer only a contribution. We therefore invite patient organisations, the participating clinics, and the pharmaceutical industry to help sharing the costs.

PsoReg – a two-way communication in real time

The web-based design of the register is based on a simple idea: in the long run, the register can be successful only if the client is satisfied. This is not achieved only through the understanding that every patient included in the register is a step towards improved psoriasis treatment. In today's world with its constant lack of time, the register must offer an additional practical incentive: to support the management of patients with psoriasis. Several tools are planned such as: static reports on one's own patient population in comparison with the aggregated national population; the possibility to create customised or unit specific reports; patient overviews describing the reporting unit's patient population from a given set of parameters; search functionality in order to identify subsets of patients; on-line statistics; automated controls, e.g. of missing blood tests or further check-ups. The patient, on the other hand, becomes a partner as he/she is actively involved in the data collection. Furthermore, register data on the disease development supports the physician/patient dialogue about

the future therapy strategy. At the end of the consultation, the patient receives a hand-out containing a summary of his register data as well as the time for the next blood test and visit.

Outlook

When we started the work on PsoReg in 2002, we also initiated discus-

sions with representatives from the other Nordic countries. At our latest meeting in September 2004, a breakthrough was made when we agreed on the joint set of questions shown below. Moreover, it was decided that Sweden should develop the architecture of a common core for all the separate Nordic databases, which can then be adapted in accordance with national needs. This is cost-ef-

fective and allows for pooling and comparing the data. In this way, we can create an enlarged platform to strengthen the links between the Nordic countries for the benefit of patients with psoriasis worldwide.

References

1. Davidoff F, DeAngelis CD, Drazen JM, Hoey J, Hojgaard L, Horton R, et al. Sponsorship, authorship, and account-

PsoReg

Security number: 191212121222 | Report | Profile | Overview | Statistics | Search | log-out

Inclusion	Clinic	Treatment	Safety																																																								
National security number: 19-121212-1212 Surname/name: Andersson Anders																																																											
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Previous treatments <table border="1"> <thead> <tr> <th></th> <th>Yes</th> <th>No</th> <th>Unknown</th> </tr> </thead> <tbody> <tr><td>UVB</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>PUVA</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>MTX</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>Retinoids</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>CyA</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>Alefacept</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>Efalizumab</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>Etanercept</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>Infliximab</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>Fumaric acid</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>Hydrea</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>Thioguanine</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> <tr><td>Climate therapy</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr> </tbody> </table>			Yes	No	Unknown	UVB	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	PUVA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	MTX	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Retinoids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	CyA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Alefacept	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Efalizumab	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Etanercept	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Infliximab	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Fumaric acid	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Hydrea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Thioguanine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Climate therapy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Onset of disease (YYYY - MM) <input type="text"/> - <input type="text"/> Following <input type="checkbox"/> Throat infection <input type="checkbox"/> Life crisis <input type="checkbox"/> Medicine / Drugs <input type="checkbox"/> None of the above Comorbidities ICD 10: <input type="text"/> <input type="button" value="->"/>	
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Alternative answers Alcohol

Frequency

- Never
- Once a month or less
- 2-4 times a month
- 2-3 times a week
- 4 times a week or more

Amounts

- 1-2
- 3-4
- 5-6
- 7-9
- 10 or more

Exempel shows an image describing what counts as a drink

ICD 10
A scroll with search function

Inclusion	Clinic	Treatment	Safety
National security number 19-121212-121 Surname/name Andersson Anders			
Clinical type			
<input type="checkbox"/> Plaque psoriasis with guttate lesions <input type="checkbox"/> Pustular psoriasis, general <input type="checkbox"/> Inverse psoriasis <input type="checkbox"/> Plaque psoriasis without guttate lesions <input type="checkbox"/> Pustular psoriasis, palmoplantar (PPP) <input type="checkbox"/> Nail changes <input type="checkbox"/> Erythrodermic psoriasis <input type="checkbox"/> Acrodermatitis continua suppurativa <input type="checkbox"/> Koebner response			
Joint Diseases			
		Yes	No
Psoriasis arthritis		<input type="radio"/>	<input type="radio"/>
Morning stiffness > 30 min		<input type="radio"/>	<input type="radio"/>
Sore joints / swollen joints		<input type="radio"/>	<input type="radio"/>
Pso-skin activity			
As a doctor, to what degree would you determine this patient's psoriasis?			
- Right now			
<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>			
		<input type="radio"/> Improved <input type="radio"/> unchanged <input type="radio"/> worse mild severe	
- Compared to the last appointment			
PASI			
	Area	Erythema	Induration
Head	<input type="text"/>	<input type="text"/>	<input type="text"/>
Trunk	<input type="text"/>	<input type="text"/>	<input type="text"/>
Arms	<input type="text"/>	<input type="text"/>	<input type="text"/>
Legs	<input type="text"/>	<input type="text"/>	<input type="text"/>
Desquamation			
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			
Calculate PASI <input type="text"/>			
Quality of life - Information from the patient			
How uncomfortable was your skin psoriasis last week?			
<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>			
		No discomfort discomfort	
How much pain did you encounter last week due to your joint disease?			
<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>			
		No pain severe	
Optional (DLQI)			
Dermatology Life Quality Index			
<input type="button" value="Save"/> <input type="button" value="Reset"/>			

Clinic/Treatment: As long as the patient receives systemic therapy he will be registered at least four times a year. Lab values will be optional and the assortment will be possible to modify according to the needs of every centre.

Alternative answers PASI

Erythema
Induration
Desquamation

Area

? 0%	? 1 none
? <10%	? 2 some
? 10-29%	? 3 moderate
? 30-49%	? 4 severe
? 50-69%	? 5 maximum
? 70-89%	
? 90-100%	

Inclusion	Clinic	Treatment	Safety
National security number 19-121212-1212 Surname/name Andersson Anders			
Current systemic treatment			
<input type="text"/>		From <input type="text"/> until <input type="text"/> Dose <input type="text"/> mg/ day <input type="text"/>	<input type="button" value="->"/>
<input type="text"/>		From <input type="text"/> until <input type="text"/> Dose <input type="text"/> mg/ day <input type="text"/>	<input type="button" value="->"/>
MTX <input type="text"/> From <input type="text"/> until <input type="text"/> Dose <input type="text"/> mg/ve Total <input type="text"/> mg			
PUVA <input type="text"/> From <input type="text"/> until <input type="text"/> Total dose <input type="text"/> J/cm ²			
Other current medication			
Drug <input type="text"/>	Dose <input type="text"/>	Drug <input type="text"/>	Dose <input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="button" value="->"/>
Current lab samples			
Bloodpressure <input type="text"/> / <input type="text"/>	ALT <input type="text"/> ukat/L	Cholesterol <input type="text"/> mmol/L	
ESR <input type="text"/> mm/h	γ -GT <input type="text"/> ukat/L	Triglycerides <input type="text"/> mmol/L	
CRP <input type="text"/> mg/L	CDT <input type="text"/> U/L	Urine stick prot <input type="text"/>	
MCV <input type="text"/> fL	Procollagen III <input type="text"/> ug/L	Urine stick Ery <input type="text"/>	
HB <input type="text"/> g/L	Crea <input type="text"/> umol/L	Liver biopsy <input type="text"/>	
White cells <input type="text"/> 10E ⁹ /L	CD4 count <input type="text"/> 10E ⁹ /L		
Platelets <input type="text"/> 10E ⁹ /L	Urate <input type="text"/> umol/L		
<input type="button" value="Save"/> <input type="button" value="Reset"/>			

Alternative answers

Current systemic treatment

? None
? Neotigason
? CyA
? Alefacept
? Efalizumab
? Etanercept
? Infliximab
? Fumaric acid
? Hydrea
? Thioguanine

MTX

? None
? With Folic acid
? Without Folic acid

PUVA

? None
? Bath PUVA
? Tabl. PUVA

Urine stick

? No sample
? pos.
? neg.

Liver biopsy

? no sample
? normal
? cirrhosis
? fibrosis
? steatosis

ability. Lancet 2001; 358: 854-856. 921-928.±

2. Als-Nielsen B, Chen W, Gluud C, Kjaergard LL. Association of funding and conclusions in randomized drug trials: a reflection on treatment effect or adverse events? JAMA 2003; 290:

Safety: It will be possible to access this page if side effects occur, or for the follow-up of previously reported side-effects.

Inclusion	Clinic	Treatment	Safety
National security number 19 -121212-1212 Surname/name Andersson Anders			
<div style="border: 1px solid gray; height: 30px;"></div>			
New side effects/Symptoms			
Type	Related to pso. treatment	Action	Intensity
ICD 10	<input type="checkbox"/> probably	<input type="checkbox"/> none	<input type="checkbox"/> impairment unlikely to be permanent
<input type="text"/>	<input type="checkbox"/> possible	<input type="checkbox"/> dose adjustment	<input type="checkbox"/> impairment likely to be permanent
	<input type="checkbox"/> unlikely	<input type="checkbox"/> temporary cessation of treatment	<input type="checkbox"/> hospital care needed
		<input type="checkbox"/> permant cessation of treatment	<input type="checkbox"/> mortal danger
			<input type="checkbox"/> deceased
->			
<input type="button" value="Save"/>		<input type="button" value="Reset"/>	

Earlier reported, but not closed, side effects/symptoms will appear in this area.

ICD 10
A scroll with a search function