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 artropathy. 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 dermatological services. Both the SSDV and the rheumatology society (RF) support the establishement 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

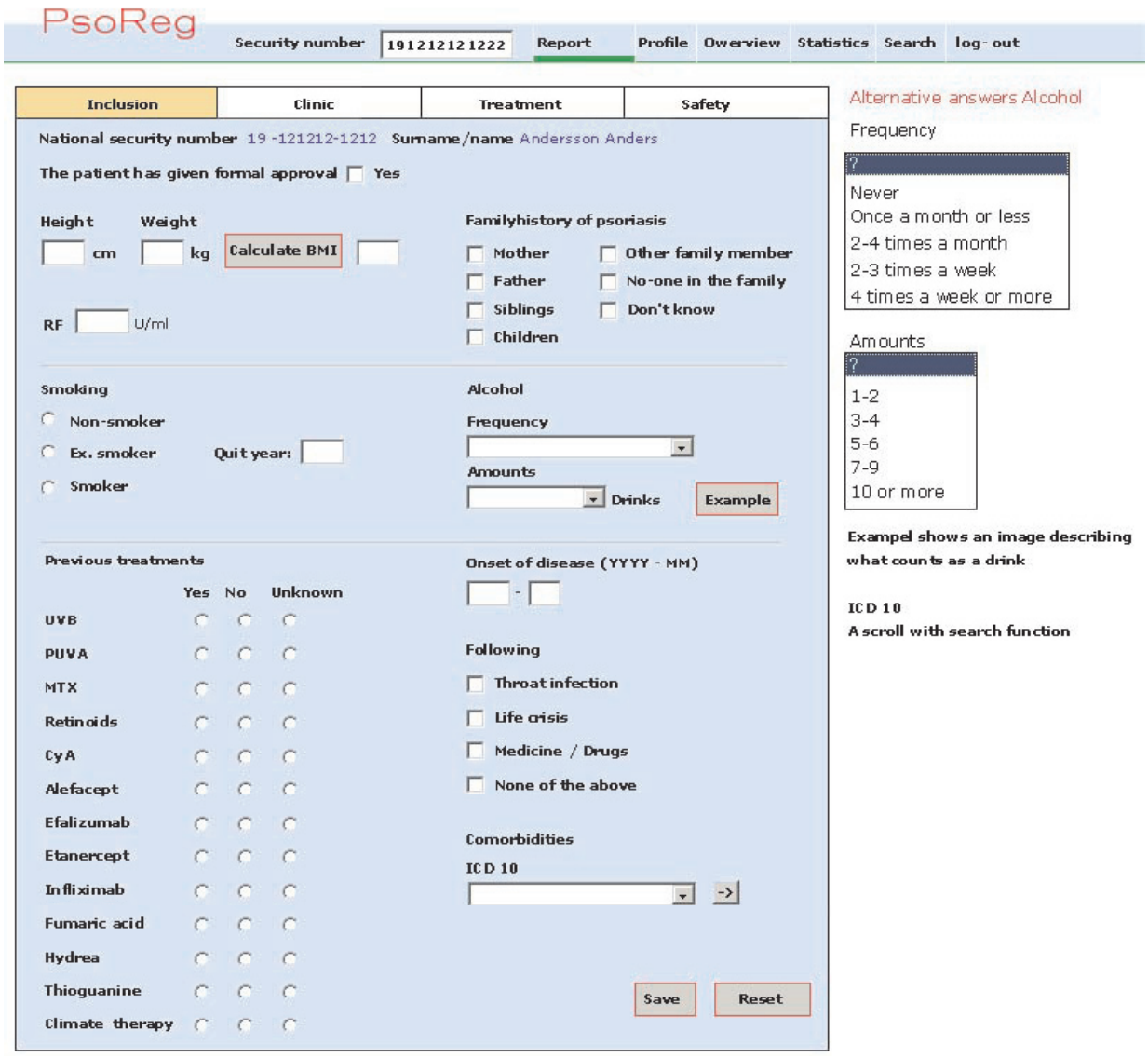
the future therapy strategy. At the end of the consultation, the patient receives a hand-out containing a summary of his register data as well as the time for the next blood test and visit.

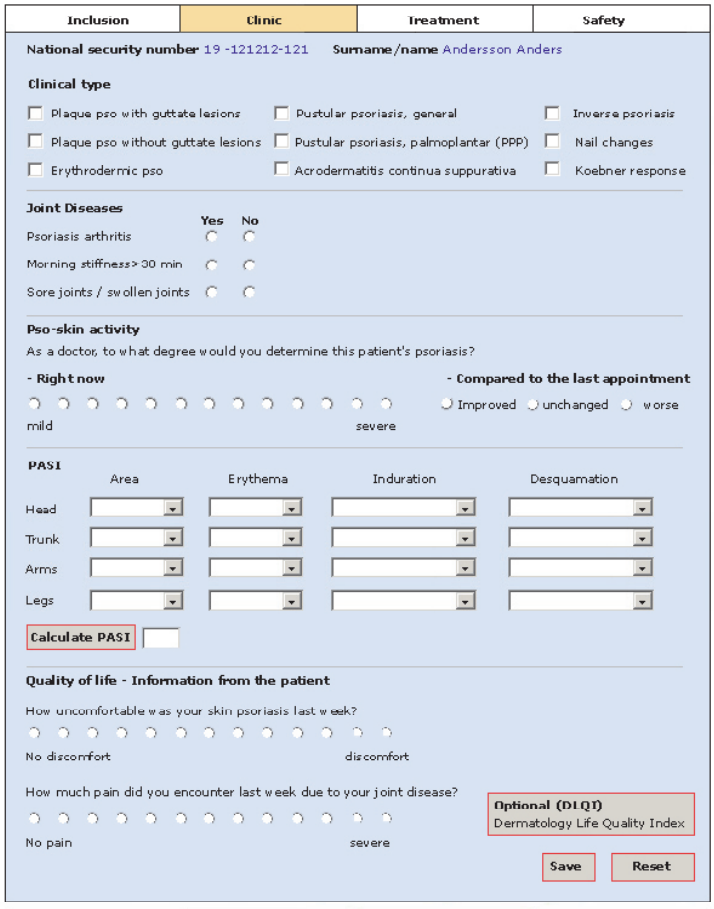
Outlook

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

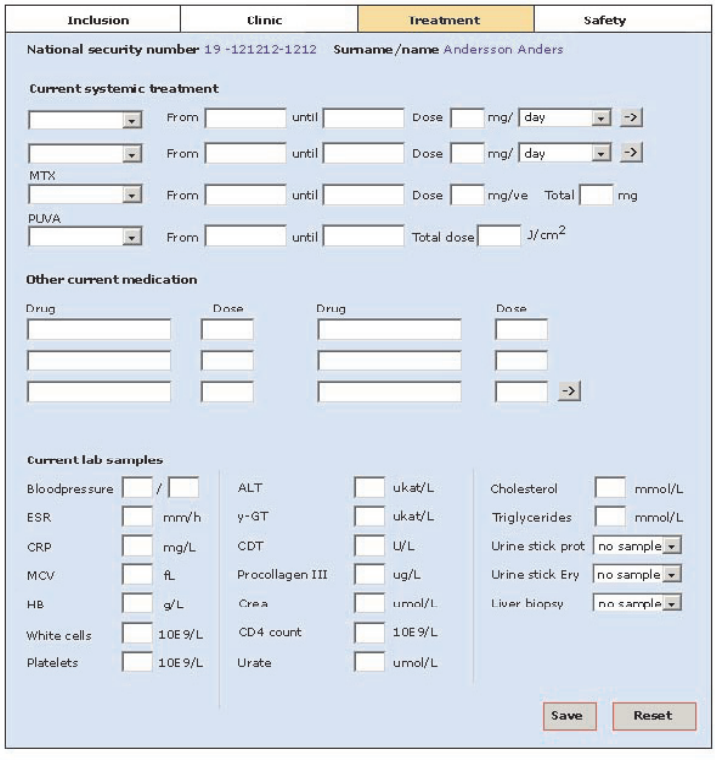




Alternative answers PASI

Erythema
Induration
Area
Desquamation

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



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
Both PUVA
Tabl. PUVA

Urine stick

No sample
pos.
neg.

Liver biopsy

no sample
normal
cirrhosis
fibrosis
steatosis

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.

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

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