Assessment versus Outcome and **Patient Participation**
Psoriasis as an Example

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A discussion paper for members of the Psoriatic Disease Workgroup

Introduction

I have had a major interest in psoriasis since the early 1980s and spent nearly 30 years from 1994 onwards working with my colleague, Professor Christopher Griffiths, in what was one of the world's first dedicated psoriasis clinics.

I attended the very first IDEOM meeting, which was held in Rome ten years ago, and have been keenly interested in its work, for which Alice Gottlieb deserves enormous credit.

Alice and Amanda have very generously allowed me to circulate this short paper outlining my hopes and concerns about the terminology used for assessing psoriasis and its impact on those who have to contend with it.

I do feel that there is still insufficient effort put into encouraging and empowering patients with psoriasis to participate in the management of their disease by entrusting them with simple tools for regular **assessment** of its severity and impact, which can then be shared with their professional carers (not only dermatologists and dermatology nurses but also family physicians where appropriate). Of course, other diseases (including psoriatic arthritis) should be amenable to being monitored in a similar fashion, but I am addressing the disease which I know best.

Assessment versus **Outcome**

The very foundation of **IDEOM** (acronym for **International Dermatology Outcome Measures**) is contained in its title and focuses quite rightly on the important task of assessing whether interventions for psoriasis are effective, safe and affordable.

Over the past thirty years enormous financial resources have been directed at developing and refining the now quite remarkable array of interventions for managing the disease. An essential task of the dermatology community is to judge whether a particular intervention can be recommended for use. This is a matter which involves weighing up effectiveness against both risk of harm and affordability, the latter a component which will vary considerably in different healthcare settings.

Clinical studies have in recent years been largely and generally appropriately funded by the pharmaceutical industry. They have focused on examining whether a particular agent is effective and safe and thus whether it can be recommended for general clinical use. Such studies typically involve repeated severity assessments over a period of 12 weeks followed by a longer surveillance, typically one year. The progress that has been made is truly astounding.

Unfortunately, however, a long-term **cure** of psoriasis is not something that is on the horizon and patients will generally need to continue therapy whilst the underlying driver for the disease remains active, something that is currently impossible to predict for any given patient.

Furthermore, psoriasis is generally not a disease with an **outcome** as such. It will typically wax and wane over time with well-known factors such as stress or infection influencing disease activity. I feel that the demands required for clinical trials have placed too much emphasis on **outcome**, which is designed largely for proof of efficacy of an intervention, rather than on **guiding long-term management**, which requires repeated **assessment** over time in order to be able to monitor whether current treatment is appropriate or needs to be changed. To my mind, not enough thought is given to the difference between the two, with **outcome** often used indiscriminately as a synonym for **assessment**.

Patient participation and empowerment in managing psoriasis

Access to dermatological care is affected by several different factors including, on the one hand, availability of dermatological expertise and adequate funding of dermatology services and, on the other hand, the practicality from the patient's point of view of accessing such expertise, which may be constrained by geographical remoteness, mobility problems or financial constraints.

The increasing use of teledermatology consultations can help, particularly in the monitoring of patients on long-term medication. Telemedicine has its dangers but has the great advantage that it can spare patients a considerable amount of time which would otherwise be needed for hospital or clinic assessments.

Given appropriate tools, many psoriasis sufferers would be perfectly capable of participating in the long-term management of their disease by **assessing** the activity of their psoriasis on a regular basis (e.g. once a month) or more often if severity tends to fluctuate. Using secure electronic transfer, they would then be able to submit updated cumulative reports to their professional carer (dermatologist, family physician etc.) on an occasional basis (e.g. every three months) for inclusion in their patient record.

If, on the other hand, their psoriasis flares, then they can submit an up-to-date assessment which can then be directly compared with their previous assessments and can, if necessary, contact their carer by phone, teleconsultation or in-person attendance for further advice.

Not all psoriasis sufferers would be able to manage such record-keeping but many would, particularly if given a straightforward tool by which to do so. Being entrusted with the long-term monitoring of their own disease can, however, give many patients an important stake in its management.

Self-assessment tools for monitoring psoriasis severity and impact

What tools are available to enable people with psoriasis themselves to monitor systematically its severity over time?

Thirty years ago a self-assessment version of the flawed but widely adopted ***Psoriasis Area and Severity Index (PASI)*** was developed from the original as the **Self-Assessment *Psoriasis Area and Severity Index (saPASI)***. It retains all the well-known flaws of PASI, including failure to recognise that the impact of having psoriasis on the skin of the face or hands has a very different impact from having a similar-sized patch of psoriasis on the skin of the back. With no other contenders at the time, the original PASI had become the standard for assessing psoriasis severity despite its many well-known flaws. The saPASI amplifies those flaws.

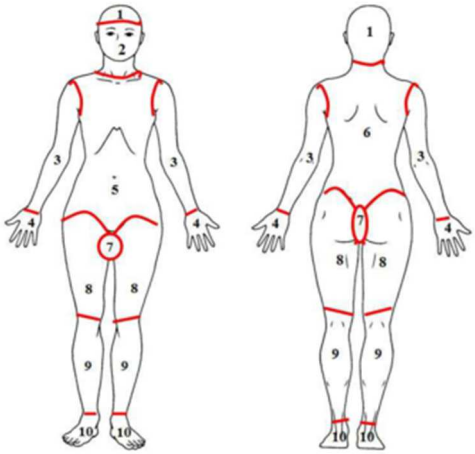
The Dermatology Life Quality Index (DLQI) has been used extensively for many years to complement PASI by providing a summary score of the impact of skin disease on different aspects of a patient's quality of life and to assess whether changes in that impact can be modified by therapeutic intervention. It is presented as a single-sheet questionnaire with a score from 0 to 3 selected by the patient for each of ten questions ranging from symptoms to effects on daily living (see example below). It is not psoriasis-specific.

3.	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant	❒

It can become somewhat tedious for the patient to be presented with the same questions repeatedly, quite often with a majority of the questions (e.g. difficulties with playing sports or having sexual difficulties) being of no relevance to many patients, particularly the elderly.

The Simplified Psoriasis Index (SPI) is a three-domain instrument which was developed in Salford, Manchester, UK, from a prototype published in 2000 as the *Salford Psoriasis Index*. The latter entailed a complex conversion from PASI to derive a score between 0 and 10 for the first of its three domains (current severity).

A completely new method of scoring severity was therefore subsequently developed for the current severity domain of SPI by dividing the body surface into 10 unequal areas, such that half of the weighting for psoriasis extent was assigned to five functionally or psychosocially important sites: 1. Scalp and hairline, 2. Face, neck and ears, 3. Hands, fingers and fingernails, 4. Genital area and anus, 5. Feet, toes and toenails.



Three options are available for scoring each of the 10 body surface sites: 0 , ½ or 1 (**PART 1A**).

PART 1A For each of these 10 body areas please select one choice which best describes your psoriasis today

0	clear or so minor that it does not bother me (0)
±	obvious but still leaving plenty of normal skin (½)
+	widespread and involving much of the affected area (1)

PART 1B is derived by allotting a score between 0 (essentially clear) and 5 (intensely inflamed) to reflect the overall average plaque severity of all the affected areas.

Multiplying the **Extent score** (0-10) by the **Average severity score** (0-5) gives the **Current severity score** (0-50).

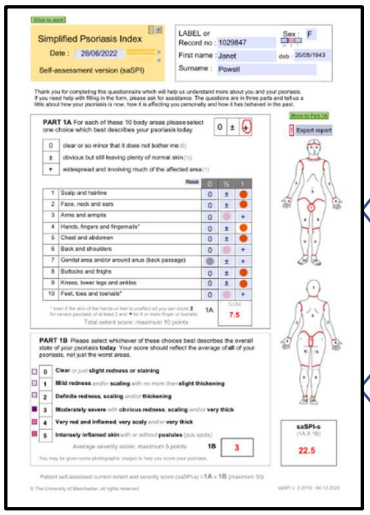
PART 2 provides a simple 11-point global impact score ranging from 0-10 and is selected by the person with psoriasis to indicate how much it is affecting him or her currently (TODAY).

PART 3 is a simple record of how the psoriasis has behaved and been treated in the past together with an optional record of past and current systemic treatments.

Illustration of the Simplified Psoriasis Index (interactive self-assessment version)

PART 1 : CURRENT SEVERITY SCORE

1A: EXTENT



PART 1A For each of these 10 body areas please select one choice which best describes your psoriasis today

0	±	+

0	clear or so minor that it does not bother me (0)
±	obvious but still leaving plenty of normal skin (½)
+	widespread and involving much of the affected area (1)

		Reset	0	½	1
1	Scalp and hairline		0	±	●
2	Face, neck and ears		0	±	●
3	Arms and armpits		0	○	+
4	Hands, fingers and fingernails*		0	○	+

1B: OVERALL AVERAGE SEVERITY OF PSORIASIS

PART 1B Please select whichever of these choices best describes the overall state of your psoriasis **today**. Your score should reflect the average of **all** of your psoriasis, not just the worst areas.

0	**Clear** *or just* **slight redness or staining**
1	**Mild redness** *and/or* **scaling** *with no more than* **slight thickening**
2	**Definite redness, scaling** *and/or* **thickening**
3	**Moderately severe** *with* **obvious redness, scaling** *and/or* **very thick**
4	**Very red and inflamed, very scaly** *and/or* **very thick**
5	**Intensely inflamed skin** *with or without* **pustules** (pus spots)

Average severity score: maximum 5 points **1B** 3

You may be given some photographic images to help you score your psoriasis.

Psoriasis current severity score is 1A x 1B = 22.5

saSPI-s (1A X 1B)
22.5

Selections made by mouse clicks; calculation performed automatically

PART 2 : PSYCHOSOCIAL IMPACT SCORE

PART 2 (SPI-p) Please select a number or mark the line below to show how much your psoriasis is affecting you in your day-to-day life **today**.

0 1 2 3 4 5 6 7 8 9 10

Guide: 0 = my psoriasis is not affecting me at all
5 = my psoriasis is affecting me quite a lot
10 = my psoriasis is affecting me very much (I could not imagine it affecting me more)

The person with psoriasis is asked to judge how much it is affecting him or her personally TODAY by selecting a figure from 0 to 10?

PART 3 : HISTORY AND INTERVENTIONS

This forms a simple record about the person with psoriasis and the treatment he or she is receiving for psoriasis and has a maximum score of 10. In general the responses here will not often need to be amended.

The first three questions give an indication of how long the psoriasis has been present and whether it has been complicated by any of the uncommon, severe forms of psoriasis. The fourth question addresses the question of whether the patient's psoriasis has been complicated by an associated arthritis, which can affect up to about a quarter of people with psoriasis.

About your psoriasis *Please tick each true statement* *maximum 4 points*	
I have had psoriasis for at least 10 years	✔
My psoriasis first developed before I was 10 years old 10 *and/or* has been present for more than 20 years	✔
I have had bright red and very inflamed psoriasis (with or without pus spots) covering all my skin (erythrodermic or generalised pustular psoriasis)	✔
A rheumatologist (arthritis specialist) has confirmed that I have psoriatic arthritis	

Up to six points may then be allotted to record current treatment with either phototherapy (light treatment) or drugs (either pills or injections) given specifically for psoriasis.

About your psoriasis treatment *maximum 6 points*

How many different psoriasis treatments (excluding creams etc.) have you ever had?

Ultraviolet light treatment (UVB *and/or* PUVA)	*maximum 1 point*	✔
Psoriasis tablets or injections (1 point for each different active drug)	*maximum 5 points*	NUMBER 5
Summary of psoriasis tablets or injections received (optional)	Edit lists - +	TOTAL 9

? Please click or tick the box to the left of each treatment you have ever received. If it is not listed, add it. You can get help from a doctor or nurse and/or by selecting Help

Help

Drug name search: +

? ## indicates current treatment

☐ Acitretin	☒ Certolizumab ##	☐ Guselkumab	☐ Risankizumab	☐ :
☒ Adalimumab	☒ Ciclosporin	☐ Infliximab	☒ Secukinumab	☐ :
☐ Apremilast †	☒ Dimethylfumarate	☐ Ixekizumab	☐ Tildrakizumab	☐ :
☐ Brodalumab	☐ Etanercept	☒ Methotrexate	☐ Ustekinumab	☐ :

A simple three part composite severity score can then be recorded either by a health professional or by the person with psoriasis him- or herself.

Proposal for wider adoption of the self-assessment version of the Simplified Psoriasis Index (saSPI) as an appropriate self-monitoring tool for people with psoriasis

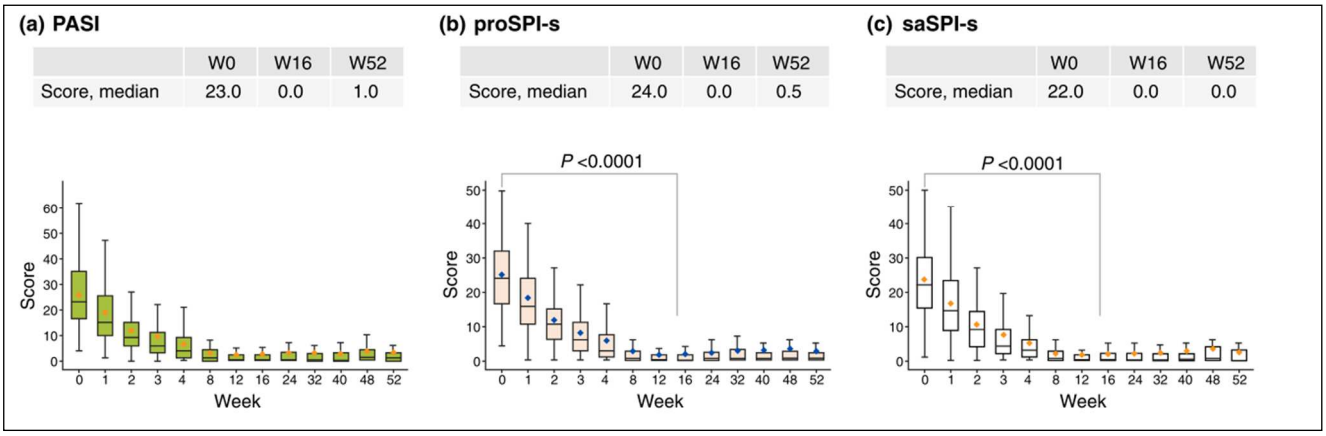
Providing suitable patients with the **saSPI** form would enable them to assess their psoriasis systematically on a regular basis, thus compiling a long-term record of its behaviour. The assessments can currently be exported and printed periodically as a pdf or paper report. This would, importantly, give individuals having to cope with their psoriasis greater ownership of their disease management; at the same time such reports would add value to in-person and, as importantly, virtual consultations. Furthermore, if the patient's psoriasis were to flare, a report could be forwarded to the patient's healthcare professional (dermatologist, nurse or family practitioner) to help decide whether management should be changed.

The prototype **saSPI** form allows patients to score their psoriasis on screen with just a few mouse-clicks. The saSPI file can be dragged into Microsoft's **Edge** internet browser. It can then be filled in and exported as a pdf report. The free PDF Studio Viewer from Qoppa (https://www.qoppa.com/pdfstudioviewer/) is best functionality of the green navigation buttons. Adobe Acrobat Reader should be avoided but Foxit PDF Reader (https://www.foxit.com/pdf-reader/) is a satisfactory alternative.

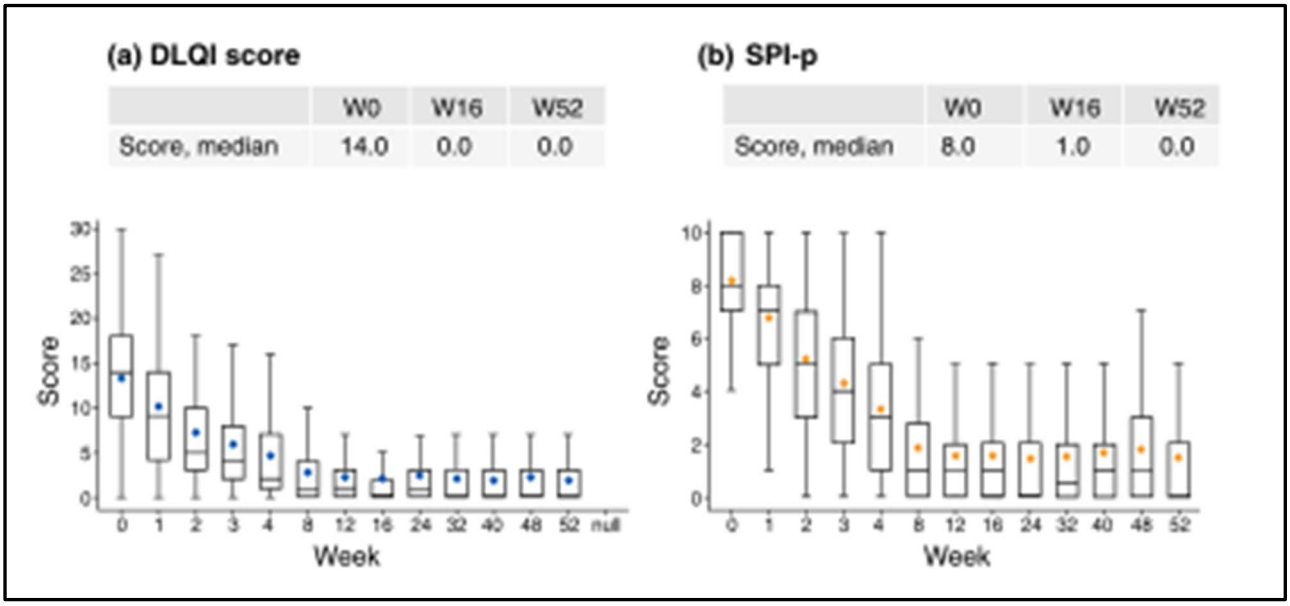
The prototype interactive saSPI and proSPI forms have been developed by me in an attempt to illustrate what I feel is the great potential benefit of enabling patients to keep an ongoing record of their psoriasis and to be able to share this with their doctor or nurse.

The Simplified Psoriasis Index score sheets in English, French, Spanish and Thai are available to download and print as paper proformas from the Global Psoriasis Atlas (https://www.globalpsoriasisatlas.org/en/resources/simplified-psoriasis-index). Validated translations are also available in Brazilian Portuguese, Dutch and Arabic with further translations available in Farsi (Persian), German, Japanese and Russian.

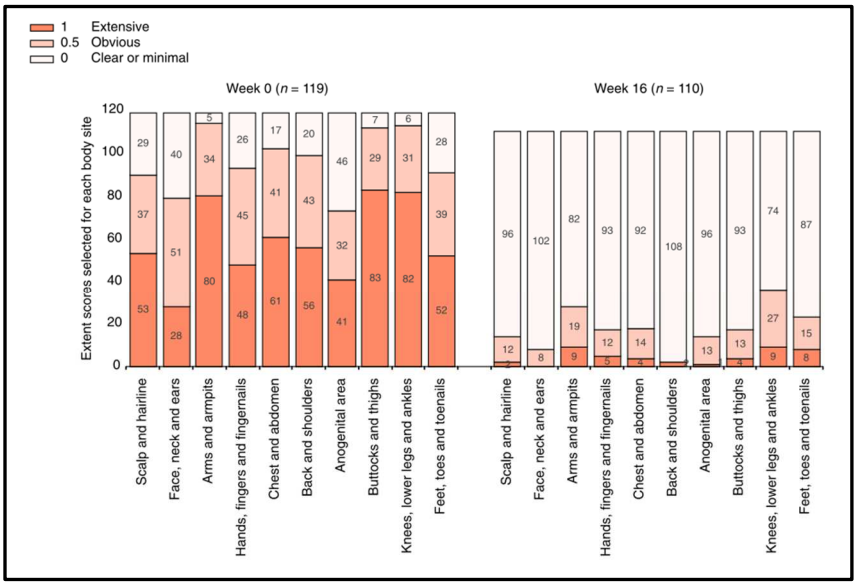
Correlations between PASI, proSPI and saSPI[1]



The French IPSI-PSO study showing progressive fall in scores of PASI, proSPI and saSPI (above) and in DLQI and SPI-p (below) in response to introduction of secukinumab, with this improvement maintained until week 52.



Furthermore, changes in the severity of each individual body site can easily be appreciated. For instance the data shows clearly that the improvement achieved for psoriasis of the **face, neck and ears** was clearly greater than that for **knees, lower legs and ankles**.



Goals and wishes

If the goal of increasing patient participation which I am striving for (see page 2) is to be achieved, professional computer program developers will be needed together with a modest amount of funding. I hope that the participants at the 2023 IDEOM meeting may be willing to support further development of these aims either as a clinical dermatologist with an interest in improving communication between patients and their carers or with an interest in information technology to help achieve the aims I have set out.

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References

Chularojanamontri L, Griffiths CEM, Chalmers RJG.

The Simplified Psoriasis Index (SPI): a practical tool for assessing psoriasis. *J Invest Dermatol* 2013; **133**:1956-62. https://www.jidonline.org/article/S0022-202X(15)36376-4/fulltext

Chularojanamontri L, Griffiths CEM, Chalmers RJG.

Responsiveness to change and interpretability of the Simplified Psoriasis Index. *J Invest Dermatol* 2014; **134**:351-8. https://www.jidonline.org/article/S0022-202X(15)36606-9/fulltext

Chalmers RJ. Assessing psoriasis severity and outcomes for clinical trials and routine clinical practice. *Dermatol Clin* 2015; **33**:57-71.

https://www.sciencedirect.com/science/article/abs/pii/S0733863514001119?via%3Dihub

M.J. van Geel MJ, Otero ME, de Jong EMGJ, van de Kerkhof PCM, Seyger MMB.

Validation of the Simplified Psoriasis Index in Dutch children and adolescents with plaque psoriasis. *Br J Dermatol* 2017; **176**:771-6.
https://onlinelibrary.wiley.com/doi/full/10.1111/bjd.15120

MR de Morais, GA Martins, R Romiti, RE Tonoli1, AVE Carvalho.

Translation and validation of the Simplified Psoriasis Index (SPI) into Brazilian Portuguese* *An Bras Dermatol* 2018; **93**: 813-818. https://pubmed.ncbi.nlm.nih.gov/30484524/

Richard MA, Aractingi S, Joly P, Mahé E, Auquier P, Le Guen S, Acquadro C, Boucher, Chalmers RJG.

Adaptation française d'un nouveau score déstiné à l'évolution globale de la sévérité du psoriasis : l'Indice Simplifié du Psoriasis (Simplified Psoriasis Index, SPI). *Ann Dermatol Venereol* 2019; **146**:783-792.
https://www.sciencedirect.com/science/article/abs/pii/S0151963819302777

Chularojanamontri L, Wongpraparut C, Winayanuwattikun W, Griffiths CEM, Chalmers RJG.

A re-evaluation of the Simplified Psoriasis Index (SPI) using the Thai language version: a study examining the validity, reliability and interpretability of SPI when used in translation. *J Psoriasis Psoriatic arthritis*. 2020; **5**:32-39. doi:10.1177/2475530319892196

https://journals.sagepub.com/doi/pdf/10.1177/2475530319892196

Richard MA, Lacour J-P, Konstantinou M-P, Ruer-Mulard M, Joly P,

Aractingi S, Auquier P, Pelvet B, Augustin ML, Mahé E, Chalmers RJG.

Secukinumab efficacy in reducing the severity and the psychosocial impact of moderate-to-severe psoriasis as assessed by the Simplified Psoriasis Index: results from the IPSI-PSO study. *J Eur Acad Dermatol Venereol* 2021; **35**: 677-684.
https://onlinelibrary.wiley.com/doi/full/10.1111/jdv.16893

DE Barquero-Orias, E Armellini, AJ Anderson, A Armellini, AG Ortega-Loayza, I Helbling, RJG Chalmers.

Traducción al español y ensayos de campo de una nueva escala destinada a la valoración global de la gravedad de la psoriasis: el índice de psoriasis simplificado (SPI) (Translation into Spanish and field-testing of a new score for evaluating psoriasis severity: The Simplified Psoriasis Index (SPI)). *Actas Dermo-Sifiliográficas* 2022; **113**: 363-369.

https://www.actasdermo.org/es-traduccion-al-espanol-ensayos-campo-articulo-S0001731021004336

I Chabchoub, N Litaiem, S Gara, K Jaber, M Dhaoui, F Zeglaoui.

Assessing the validity and interpretability of the Simplified Psoriasis Index in Tunisian patients. Évaluation de la validité et de l'interprétabilité de l'indice simplifié du psoriasis chez les patients tunisiens. *La Tunisie Medicale* 2022; **100**: 49-55.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9002850/?report=reader#!po=53.5714

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