

PSORIASIS WHITE PAPER

A framework for improving the quality of care for people with psoriasis

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Introduction from the European Expert Working Group for Healthcare in Psoriasis

People with moderate to severe psoriasis are undertreated.¹ They are often left on therapies for too long, despite them being ineffective,^{1,2} and there is enormous variation in the experiences and the quality of care that people with psoriasis in Europe receive.^{3,4}

Early access to high-quality care – the right treatment, at the right time – is central to improving the overall treatment experience, and long-term outlook, for a person with psoriasis. It can also help a person to avoid the life course impairment that is commonly associated with psoriasis.

However, there are currently many patients who are not gaining the benefits of early access to high-quality care. This may be due to a number of factors, including a lack of priority by stakeholders (e.g. clinicians, public, payers), a lack of standardised treatment goals, limited long-term data (both in terms of disease evolution and the impact of therapies), a lack of patient empowerment and the absence of national programmes for psoriasis care. In addition, there are inconsistencies in access to quality healthcare for people with psoriasis across Europe.³

In order to address these issues, a European Expert Working Group for Healthcare in Psoriasis (EEWGHP), comprising clinicians and patient advocacy group (PAG) representatives, was convened. The EEWGHP worked between June 2010 and December 2011 to outline the specific issues in psoriasis care, and start developing clear goals and actions that would help to address them.

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The goals and actions set out in this White Paper are based on the opinions of the EEWGHP, formed from extensive experience in their specialist fields and supported by relevant clinical evidence, where possible. They aim to provide a framework for improving early access to high-quality care for people with psoriasis in Europe, through raised awareness and consistent management. Ultimately, it is hoped that this framework will help to raise treatment aspirations in psoriasis (of both healthcare professionals (HCPs) and people with psoriasis), thereby improving clinical outcomes and quality of life (QoL) for people with psoriasis.

The acknowledgements detail the membership of the EEWGHP.

Professor Matthias Augustin, Chair, European Expert Working Group for Healthcare in Psoriasis.

About psoriasis

Psoriasis is more than just skin deep. In fact, it is a chronic autoimmune disease that has a significant impact on the physical and psychological well-being of the people it affects. Approximately 14 million people in Europe⁵ suffer from psoriasis and, although psoriasis is unlikely to be fatal, this highly stigmatised condition can have a negative impact on the life course a person takes, such as decisions about jobs and relationships.⁶

Psoriasis can be classified according to appearance and location. The most common type is plaque psoriasis, which generally presents as scaled plaques (raised, red skin covered by a flaky white build-up of dead skin) and is accompanied by skin tightness, bleeding and burning sensation. It is typically found on the elbows, knees, scalp and lower back. The other types of psoriasis are guttate, inverse, pustular and erythrodermic. The characteristics of these are widely described in the literature.^{6,7} Psoriasis

affects all ages, genders and ethnicities and, although it is not fully understood how psoriasis develops, it is known to be influenced by both genetic and immune-mediated components.^{8,9} The course of the disease is characterised by cycles of remission and exacerbation, where flare-ups can be triggered by infection, trauma, temperature, stress and certain types of medicine, although no obvious trigger exists for many. The cyclical and chronic nature of this disease can also make psoriasis difficult to live with.

Psoriasis is not only a dermatological condition; it involves multiple organ systems (e.g. cardiovascular, liver, respiratory and haematological systems) and people with psoriasis can therefore display a broad spectrum of symptoms and significant co-existing conditions.⁹ In clinical practice, defining psoriasis severity can be a complex task, as there are many clinical variables (such as location of affected body areas, change in disease over time and impact on QoL) and widely used assessment methods; however, the severity of psoriasis can be generally described as being mild, moderate or severe (Box 1).^{10,11}

When choosing the best treatment, dermatologists consider several factors, including: the type, severity and localisation of the psoriasis; the person's age and medical history; and the impact the disease has on QoL. However, in its very basic terms, treatment for generalised psoriasis follows a 1-2-3 approach, starting with topical therapies first, followed by phototherapy and then medications such as oral systemics or infusion therapies (Figure 1).¹⁰

Promoting disease awareness and accurately assessing the true impact of psoriasis

Goals

- Ensure psoriasis is recognised as a serious medical condition in the wider healthcare arena
- Increase public awareness and understanding of psoriasis as a chronic, immune-mediated, non-communicable disease that can greatly affect a person's QoL
- Improve the support and treatment given to patients with psoriasis to help them manage their disease
- Provide cost-effective healthcare to reduce the economic impact of psoriasis on society

Defining the need

Individual impact of psoriasis

Approximately 14 million people in Europe have psoriasis and the disease has a profound effect on QoL.⁵ However, the impact of psoriasis on a person's QoL does not yield the serious consideration it deserves in the wider healthcare arena. For instance, the World Health Organization (WHO), who are responsible for providing leadership on global health matters, do not currently list psoriasis in their action programme for non-communicable diseases.^{12,13} In addition, psoriasis is frequently undertreated: recent

studies in the United States found that as many as 80% of patients had not received treatment in the previous year,¹⁴ and 40% were receiving no treatment, even for the most severe disease.¹⁵ This situation is echoed in Europe, where a recent survey of 17 990 people with psoriasis indicated that over 70% experienced only low-moderate satisfaction with the treatment options made available to them.²

Due to its highly visible nature, people with psoriasis can feel stigmatised by their disease, experiencing open public rejection and being asked to leave public places.⁶ Teasing, taunting and bullying are also experienced by children and adolescents with skin diseases, including those with psoriasis.¹⁶

For many, the impact of psoriasis is similar to other chronic health conditions, including hypertension, diabetes and depression, and is ranked as one of the diseases that has the greatest impact on physical and mental health (Figure 2).¹⁷ In addition to having a direct effect, partners or relatives of people with psoriasis can also be significantly affected (Figure 3).¹⁸

Psoriasis is not merely confined to dermatological symptoms. People with psoriasis commonly suffer from co-existing physical and psychological conditions. In one German study, 57.9% of subjects ($n = 19\ 633$) with psoriasis, versus only 34.5% of control subjects, were diagnosed with at least one comorbidity (Figure 4).¹⁹ These comorbidities can add to the impact that psoriasis has on QoL.

The significant physical, psychological, social and economic burden, and stigmatisation, associated with psoriasis may result in an individual failing to achieve their 'full life potential', especially since the onset of psoriasis can often occur early in childhood.^{4,20,21} From this, the concept 'cumulative life course impairment' (CLCI) has been used to capture the overall effect of psoriasis on a patient's life course.²² CLCI results from the interaction between the burden of stigmatisation and physiological and psychological comorbidities, with coping strategies and external factors. It has been evaluated in chronic skin conditions, including psoriasis, and has been proposed as a concept that may lead to better understanding of the overall impact of psoriasis on a patient (Figure 5). The cumulative impact psoriasis has on a patient's life is such that people with poorly managed psoriasis may follow a different or diminished life course compared with the course they may have taken if they had not had the condition.²²

Economic impact of psoriasis

Not only does psoriasis affect a patient's QoL, it also has an economic impact on society. Studies from several countries show that psoriasis induces considerable costs from the payer's perspective,²³⁻²⁷ with the average annual costs of moderate to severe psoriasis found to range between €3000 and €9000 per patient per year.²⁸ Major cost drivers are drugs and hospital treatment, with costs incurred for the management of comorbidities making up a substantial proportion of this (in moderate to severe psoriasis, the cost of comorbidities is around €2500 per patient per year). In

Box 1: Case studies (National Psoriasis Foundation, images provided by M. Bagot from the Hopital Saint-Louis collection)**A typical case of mild psoriasis**

Affects <3% of the body surface area (BSA) and has some impact on daily activities



Trunk



Elbow

Ms L, 20 years old, has mild psoriasis limited to a few plaques, which are localised to her elbows, knees and trunk. Despite receiving some treatment for psoriasis, her lesions continue to reoccur. As a result, she feels depressed, as she no longer feels she can continue with her hobbies of dancing and swimming.

A typical case of moderate psoriasis

Affects 3–10% of the BSA and has a moderate impact on daily activities



Hands

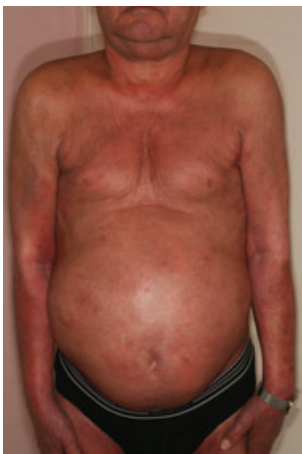


Feet

Mr P, 50 years old, has been suffering from psoriasis for many years. His lesions are mainly localised to his hands and feet, with nail involvement. Despite only a few areas being affected, his lesions impact his QoL greatly. The lesions on his hands are a major cause of discomfort in his public-facing profession and the lesions on his feet are a major cause of discomfort and pain, particularly when walking. He used to enjoy walking with his wife at weekends, but it has become difficult for him to practise this leisure activity.

A typical case of severe psoriasis

Affects >10% of the BSA and has a severe impact on daily activities



Whole body



Legs

Mr B, 35 years old, has been treated for 10 years for disseminated psoriasis. A few weeks ago, his skin lesions worsened significantly with the development of an erythroderma. In addition, his arthritis also worsened and he had major pain and stiffness of his neck and back. He used to work as a bus driver, but is now unable to continue his work. He experiences widespread burning pain. He is also unable to interact normally with his wife and to play with his small children. As a result, his QoL is significantly affected and he feels very depressed and is now taking antidepressants.

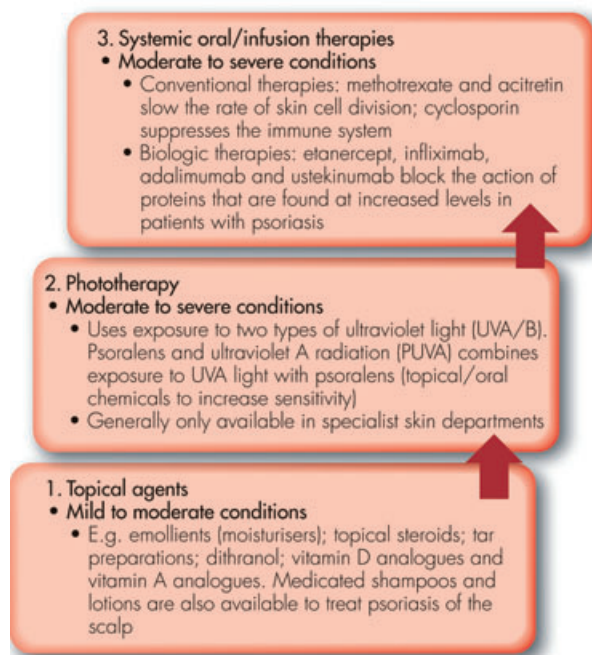


Figure 1 The 1-2-3 approach to psoriasis management.

addition to these direct costs, indirect costs can also arise due to patient incapacitation; patients with psoriasis show greater numbers of days off-work and an increased rate of unemployment.²⁹

Effective treatment of psoriasis can markedly reduce the impairments in QoL and improve work ability and productivity.^{30,31} Cost-effectiveness and cost-utility analyses have shown that both systemic and topical agents can increase the treatment benefit when properly used.^{32–34} Since treatment effectiveness is strongly affected by patient adherence,³⁵ programmes to increase adherence in psoriasis will aid better and more cost-effective care. Accordingly, early treatment of psoriasis and its comorbidities will reduce disease burden and increase long-term benefits.

Overall, psoriasis is a disease that has an economic impact on patients, payers and society. However, early provision of effective treatments and good patient adherence has the potential to improve cost-effectiveness in psoriasis healthcare.

Summary

Psoriasis can have a large, negative impact on a person's life. It is associated with physical and psychological suffering and comorbidities, yet recognition of this in the wider health and public arena is lacking. For many people with psoriasis, broad recognition and understanding of the seriousness of the disease may help alleviate some of their suffering. In addition, psoriasis has a large economic impact on society. Optimal healthcare improves disease outcome, as well as patients' QoL, resulting in efficient use of resources.

In order to achieve the goals stated at the beginning of this assessment, the EEWGHP strongly recommends that the following actions are adopted by relevant stakeholders.

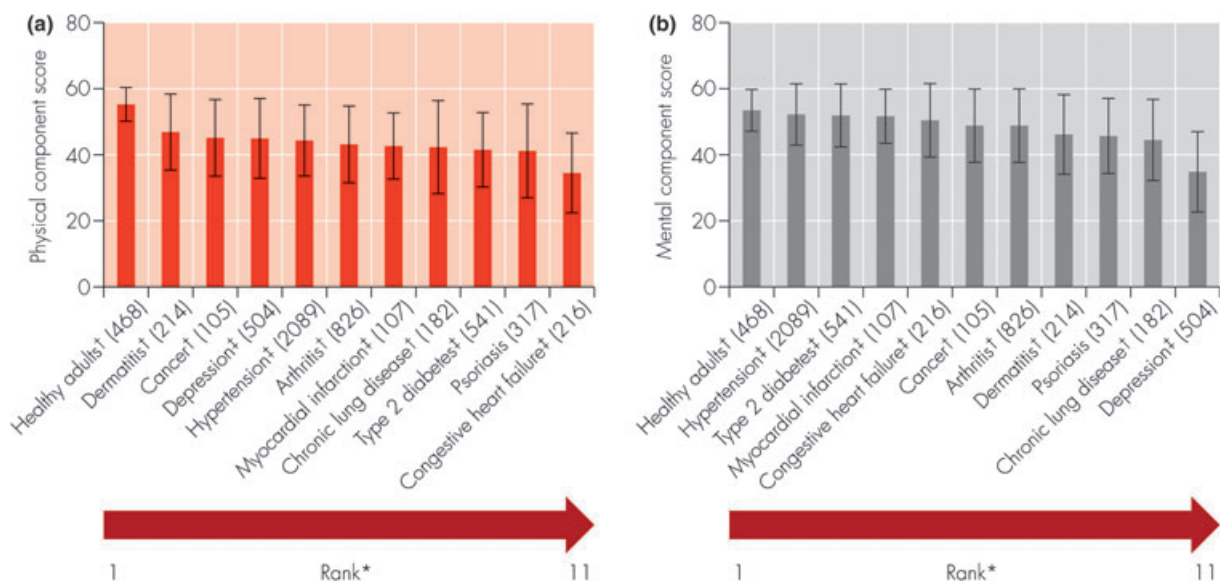


Figure 2 Psoriasis has a negative impact on physical and psychological functioning.¹⁷ Comparison between healthy adults, people with psoriasis and other conditions assessed by SF-36: Physical Component Scores (a) and Mental Component Scores (b). Data in parentheses indicate the number of patients surveyed. *Rank; closer to 1 indicates better functioning. †From National Survey of Functional Health Status. ‡From Medical Outcome Study.

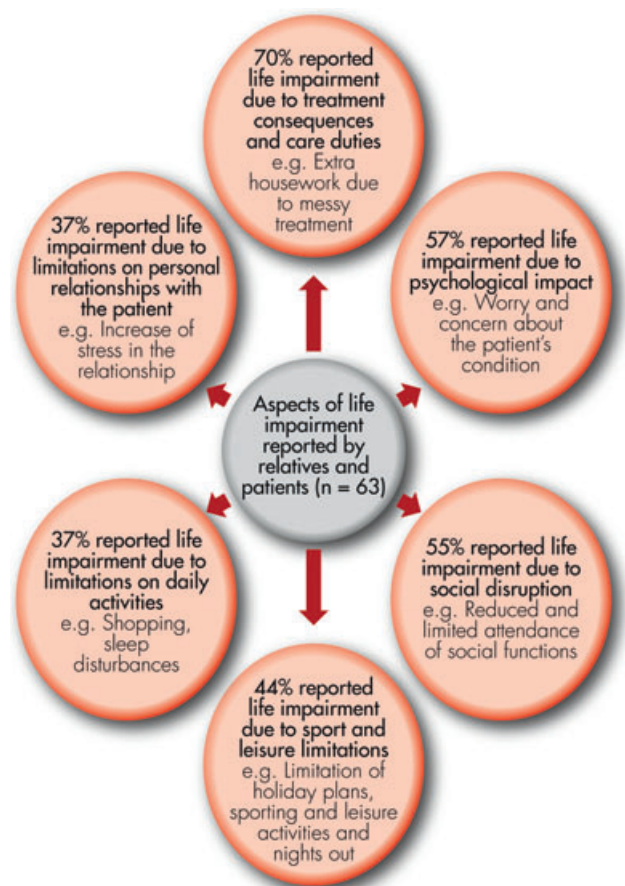


Figure 3 Psoriasis impacts partners, families and carers of people with psoriasis.¹⁸ Data are from a UK study of 63 relatives/partners of patients with psoriasis, obtained through interviews and postal questionnaires.

Actions

- Healthcare organisations, such as the WHO, and governments should recognise psoriasis as a serious medical condition (See Box 2 for current efforts in this regard)
- Government, industry and academia, in partnership with patient groups and HCPs, such as general practitioners (GPs) and dermatologists, should develop educational media campaigns to raise public awareness of psoriasis as a chronic, non-communicable, autoimmune disease that can greatly affect a person’s QoL
- Governments and industry should drive funding for the training and education of HCPs and provision of disease management support programmes (See Box 2 for current efforts in this regard)
- Governments and industry should drive cost-effective use of healthcare resources to improve efficiency

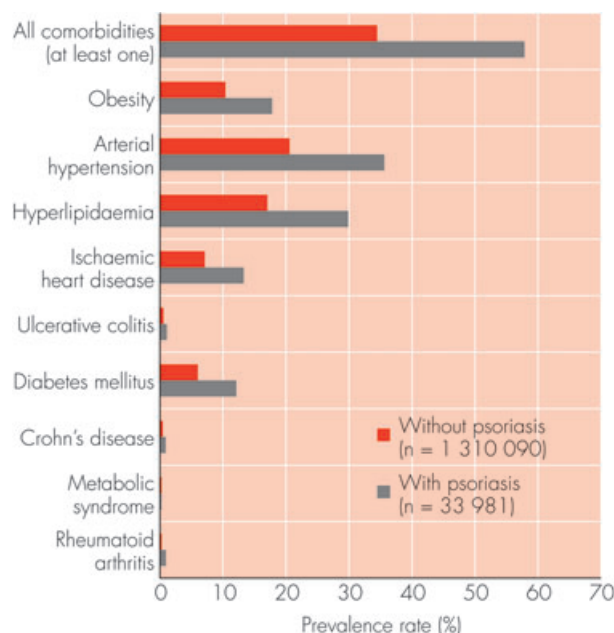


Figure 4 People with psoriasis show markedly increased prevalence of co-existing conditions.¹⁹ Data were retrieved from a database of more than 1.3 million individuals insured by a German nationwide statutory health insurance scheme. All data-sets of patients with World Health Organization (WHO) International Classification of Diseases (ICD)-10 codes marking psoriasis (L40) in the year 2005 were extracted and analysed for diagnoses related to comorbidities of interest. Individuals from the data-set with no diagnosis of psoriasis served as controls.

Improving the development and use of treatment guidelines

Goals

- Drive the development of treatment guidelines (in each European country) that reflect national policies, with European-wide guidelines acting to strengthen and harmonise national guidelines, to fill the gap where there are currently no national guidelines and to provide a framework for the development of new national guidelines
- Ensure that guidelines provide information on key issues such as treatment initiation and switching
- Increase awareness of guidelines amongst relevant HCPs and wider society
- Prioritise the provision of sufficient time during patient consultations to refer to guidelines and follow them appropriately

Defining the need

Guideline development

Evidence-based treatment guidelines can be an important tool for improving the quality of care provided to patients with psoriasis.³⁷

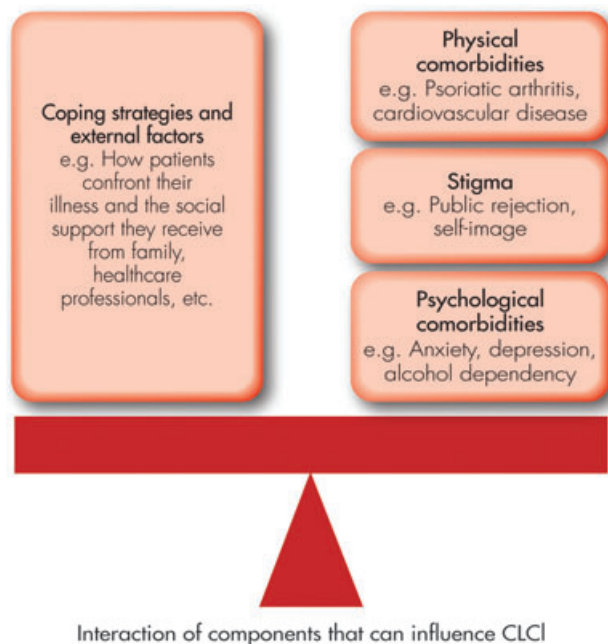


Figure 5 The concept of cumulative life course impairment (CLCI) in psoriasis.²² CLCI results from an interaction between the burden of stigmatisation, physical and psychological co-morbidities; and coping strategies and external factors. Significant impairment may occur in patients with ineffective coping strategies and limited social support, even if they have a small burden. This impairment may be less in patients with effective coping strategies and strong social support networks, even if the burden is large. (Figure adapted from Kimball 2010.)

Box 2: Current efforts to raise awareness of psoriasis and provide disease management support programmes

- The International Federation of Psoriasis Association (IFPA) are campaigning for the WHO to include psoriasis in their Strategy for Prevention and Control of Non-communicable Diseases¹²
- An international disease management programme including 330 patients and consisting of disease education, disease management training and psychological support, together with topical treatments, has been implemented across 10 European treatment centres. Assessment of this programme by self-report demonstrated a high degree of satisfaction with the programme, and a high degree of adherence to topical treatment. Disease severity and QoL were significantly improved. The programme was also well received by the participating professionals³⁶

A study in Germany provides an example of where national guidelines may have helped to improve psoriasis care (Box 3). Despite this, not all countries have their own treatment guidelines; there are no formal guidelines in France (they are currently in develop-

ment) and many Eastern European countries. Although the European S3 guidelines³ in psoriasis can help to fill the gap in these countries, they cannot reflect local policies and practices. For this reason, clinicians often rate national guidelines more highly than European guidelines.

Where countries do have their own guidelines, the general consensus among them can differ. For example, the absolute criteria of when to start patients with moderate to severe psoriasis on systemic therapies, how to measure their success and how to define non-successful therapies varies widely (Table 1). In addition, both European and national guidelines provide little information on the indications for treatment switching and on how to switch, for instance, in the following circumstances:

- When a treatment has not enabled sufficient control of the disease
- When a treatment is contraindicated due to another co-existing disease or condition
- When a treatment is contraindicated due to co-existing medication
- When a patient is intolerant to a treatment

These disparities and omissions can prove problematic for HCPs seeking solid guidance.

Guideline implementation

In addition to guideline development, consideration needs to be given to how guidelines are practically implemented. One barrier to implementation is that many HCPs are unaware of current guidelines due to a lack of promotion and dissemination. Limited time during consultation also makes it difficult to refer to guidelines, with visits of 5–10 min being inadequate for the management of patients with such a complex disease; such short visit times may reflect the lack of priority given to psoriasis as a serious medical condition. Furthermore, limited time during a consultation also means that HCPs may struggle to give appropriate explanations about their proposed treatment approach, or demonstrate empathy towards a patient with psoriasis regarding the challenges of their disease. Both of these factors have been found to determine patient satisfaction and ultimately adherence to medication.⁴²

Summary

A lack of national guidelines in some countries and lack of consensus amongst those that do exist in others is problematic. Specifically, poor and inconsistent advice on initiating and optimising therapeutic interventions is a barrier to improving outcomes. While European guidelines can help to fill the gap in countries without national guidelines, their role should primarily be to strengthen and harmonise existing guidelines, and to provide a framework for the development of new national guidelines. They therefore need to lead the provision of advice that is not given in existing guidelines. Limited awareness of guidelines and increasing pressures on patient consultation can

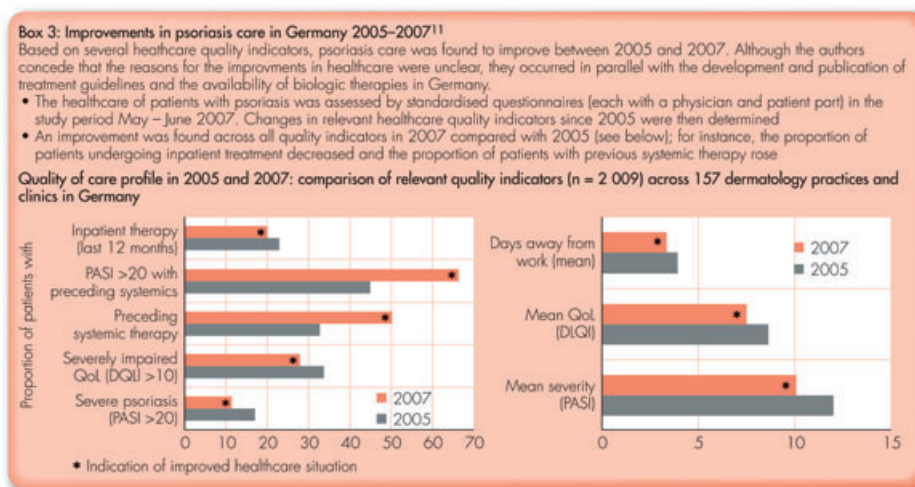


Table 1 National guidelines defining systemic therapy success use different criteria

Country	Systemic therapy initiation	Treatment goals		
		Optimal success	Minimal success	Non-successful therapy
UK ³⁸ 	<i>Non-biologic:</i> 'Rule of 10s' [*]	PASI 75 or PASI 50 and a DLQI improvement ≥5		<i>Non-biologic:</i> Not specified
	<i>Biologic:</i> >10 PASI and >10 DLQI			<i>Biologics:</i> Determined at 10–16 weeks if success criteria are not met
Germany ^{37,39} 	Moderate to severe psoriasis: 'Rule of 10s'	PASI 75 and a DLQI of 0 or 1	PASI 50 and DLQI <5	Determined at 10–16 weeks (depending on specific agent) if minimal success criteria are not met
Spain ⁴⁰ 	>5% BSA 'Rule of 10s' [*]	PASI 90 or PGA 0 or 1 the treatment objective should be one of the following: PASI 75, PASI <5, PGA ≤1, or DLQI <5	PASI 50 or DLQI <5	Response should be assessed continuously; at 3–4 months therapy should be declared non-successful if patients do not meet the minimum success criteria

*'Rule of tens' BSA involved >10% (i.e. 10 hand areas) or PASI score >10 or DLQI score >10⁴¹.

impede the implementation of guidelines and provision of quality care.

In order to achieve the goals stated at the beginning of this assessment, the EEWGHP strongly recommends that the following actions are adopted by relevant stakeholders.

Actions

- Healthcare organisations and professionals in countries that do not have their own national guidelines should strive to develop them
- European bodies supporting the development of European guidelines, such as the European Dermatology Forum (EDF) and the European Academy of Dermatology and Venereology (EADV) should clearly communicate the

role of European guidelines to facilitate the development of national guidelines

- Representatives from across Europe should strive to discuss key issues such as treatment initiation and switching, with the aim of incorporating guidance on this into European guidelines
- European bodies, such as the EDF and the EADV, should work to raise awareness of guidelines across Europe. Representatives from each European country, as well as academia and industry, should be involved in educating HCPs about guidelines at the national level
- Healthcare organisations and professionals should strive to allow enough time during patient consultations to refer to guidelines and provide quality care

Promoting the use of assessment tools and defining treatment goals and management strategies in psoriasis

Goals

- Standardise the use of current psoriasis assessment tools in clinical practice across Europe
- Encourage research into the development of further disease assessment tools, in order to provide appropriately validated evaluation tools for those situations and conditions found to be inadequately addressed by currently available tools
- Define clear and appropriate treatment goals at the European level for standardisation throughout clinical practice across Europe
- Encourage a shared approach to the setting of initial treatment goals and management strategies between patients and physicians
- Encourage inclusion of patient lifestyle factors in treatment plans

Defining the need

Assessment tools

There are a wide range of assessment tools available to measure disease severity and outcomes in psoriasis.⁴³ The current gold standard is the Psoriasis Area and Severity Index (PASI). Other tools include the Physician's Global Assessment (PGA), the Dermatology Life Quality Index (DLQI), the Body Surface Area (BSA) score and the Patient Benefit Index (PBI) (Table 2). There is little consistency in the use and application of assessment tools in clinical practice; for example, the patterns of use of the PASI and DLQI vary widely across Europe and even clinicians who prefer a particular tool do not apply it to all patients systematically (Figure 6). This means that people with psoriasis may not receive consistent diagnosis and management.

This lack of consistency across Europe may be due to the absence of a single 'best' tool that accurately reflects the full complexities of psoriasis and its true impact on the patient. For example, although the PASI considers the severity of, and the area affected by the disease, it has poor sensitivity to change

Table 2 Examples of commonly used tools to measure disease severity and QoL in psoriasis^{44,45}

Acronym	Instrument name	Assessed items	Advantages	Limitations
Measurement of disease severity				
PASI	Psoriasis Area and Severity Index	Degree of erythema, desquamation and duration, and involvement over 4 body sites	Most commonly used in clinical trials 'Objective' measure Relatively high inter- and intra-rater reliability	Only partly validated Very complicated Not sensitive to change when involved areas are small Does not assess symptoms such as itch, irritation and burn May not reflect the true impact of the condition on a patient's life
PGA	Physician's Global Assessment of improvement	Lesion severity on a 6- or 7-point scale from 'severe' to 'clear'	Simple, intuitive Reasonable correlation with PASI (except overall lesion assessment)	Less objective Few validation studies Does not discriminate small changes Does not assess symptoms such as itch, irritation and burn
BSA	Body Surface Area	Degree of body surface area involved	Quick to use	Use of the incorrect assumption that the area of the palm surface alone is equivalent to 1% BSA could lead to a 50% overestimation of BSA involvement
QoL measures				
DLQI	Dermatology Life Quality Index	Assesses QoL using 10 questions covering 6 key categories	Used in most QoL studies in patients with skin diseases Responsive to change Test-retest reliability is high	Does not fully capture emotions and mental health May not be very sensitive to small impairments Scoring of items may be affected by nationality
Combined measures				
PBI	Patient Benefit Index	Combines broad patient needs and treatment benefits	Feasible, reliable and sensitive to change in patients with a broad spectrum of diagnoses Patients can define their personally important treatment goals	Recently developed therefore not yet widely used No transfer to QALYs possible

The advantages and limitations given for each tool are the collective opinion of the EEWGHP, formed from published literature and their own experience.

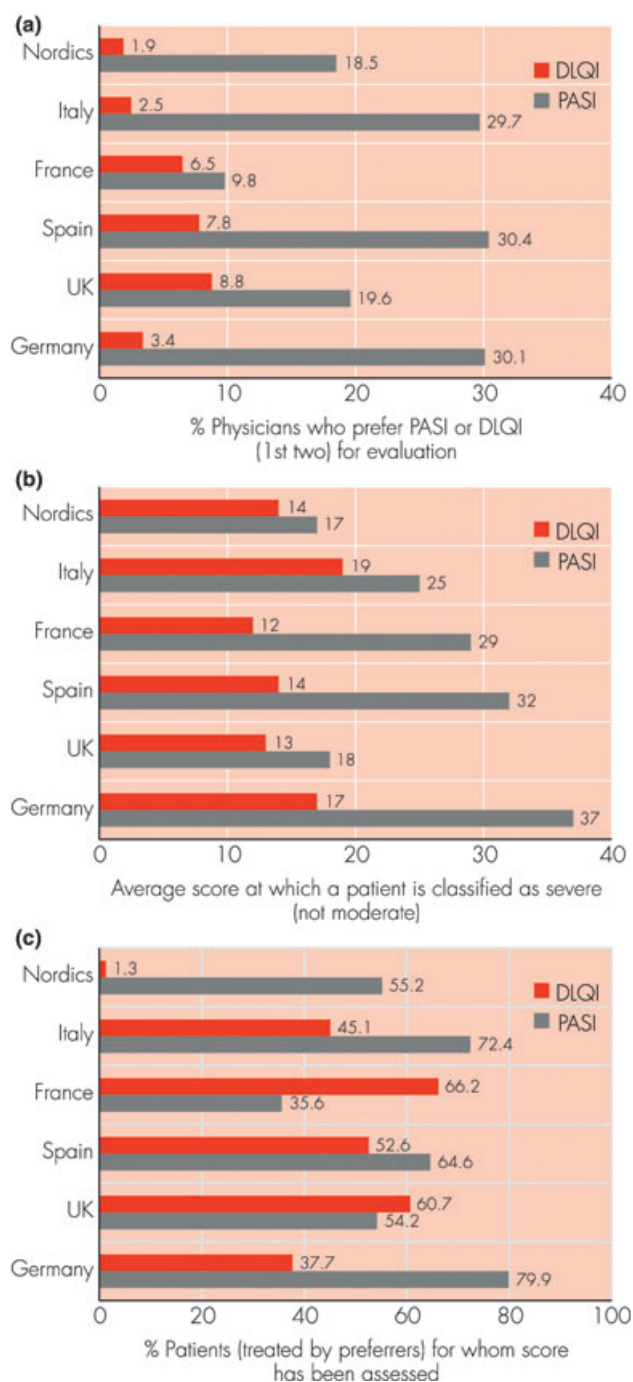


Figure 6 Evaluation tools, criteria and even their application vary widely within and across Europe.⁴⁶ (a) Use of the PASI and DLQI across the EU; (b) Average scores used to determine disease severity using the PASI or DLQI; (c) Application of the PASI and DLQI by clinicians expressing a preference for a particular tool.

for relatively small and sensitive areas of involvement (e.g. hands, feet, genitals). Psoriasis in these areas is likely to affect the lifestyle of the individual significantly more than perhaps larger, less sensitive areas. Moreover, lifestyles are likely to be affected in different ways, with psoriasis on the palms of the hands having a greater impact on the lifestyle of a person who works with their hands for a living (e.g. a carpenter); similarly, psoriasis involving the genitalia would have a significant effect on intimate relationships. Furthermore, the PASI does not account for comorbidities or psychosocial and economic factors. It may be, therefore, that a composite of measures is needed to accurately assess disease severity and outcomes in specific situations and conditions.

Treatment goals and management strategies

The definition of treatment goals in psoriasis is essential for providing high quality care; a judgement as to the success of a therapy is needed to make decisions on a patient's management strategy.^{1,44} In clinical trials, a 'clinically meaningful endpoint' is often defined as PASI 75; i.e. a 75% improvement in the PASI score after a certain point in time. In a real-life situation, defining this is more difficult and, as a result, there is generally no accepted consensus definition regarding treatment success or failure. In addition, as previously discussed, treatment guidelines often vary across Europe in their advice regarding treatment goals and often provide poor and inconsistent advice on initiating and optimising therapeutic interventions, thereby further contributing to the lack of consensus. However, a recent publication from a steering group of 19 European dermatologists reached a consensus on the definition of goals for the treatment of plaque psoriasis with systemic therapy. This definition, and the advice offered regarding related treatment strategies, aims to help dermatologists regularly assess treatment outcomes and improve patient care (Table 3).^{1,44} This definition has the potential to be used as a supplement to existing guidelines.

Strategies currently recommended for the management of psoriasis tend to be highly technical in nature and regard people with the disease as a homogeneous population, with a similar clinical progression and a similar likelihood of treatment success. However, people with psoriasis represent a heterogeneous population with individual disease expressions and personal perceptions about treatment success. For example, PASI 50 may be acceptable to one person, while others may not rate their treatment as successful until they reach PASI 75. Similarly, lifestyle considerations are not routinely incorporated into management strategies. Taken together, purely clinically-driven treatment goals and associated management strategies may not be suitable at an individual level and could lead to people not receiving the right treatment at the right time. Therefore, it is necessary that treatment goals and management strategies address the specific needs of the individual.

Table 3 EU consensus definition on treatment goals and advice regarding associated management decisions in patients with plaque psoriasis receiving systemic therapies¹

Treatment goals are defined as:	Associated management decision
Treatment success (Δ PASI ≥ 75)	Continue treatment
Treatment failure (Δ PASI < 50)	Modify treatment <ul style="list-style-type: none"> • Reduce dose intervals • Add topical agent • Add another systemic therapy • Change the drug
Intermediate response (Δ PASI ≥ 50 < 75)	Modify treatment as above if DLQI > 5 Continue treatment if DLQI ≤ 5

Δ , in comparison to baseline (before treatment initiation)
DLQI, Dermatology Life Quality Index
PASI, Psoriasis Area and Severity Index

Treatment goals are defined as treatment success, treatment failure and intermediate response after induction of and during the maintenance phase of systemic therapy. Treatment should be continued if it is successful. The treatment regimen should be modified if it has failed. In a situation where there is an intermediate response, therapy should be modified according to DLQI score.

Summary

Similar to the lack of consensus that exists around treatment guidelines, the varied approach over the use of assessment tools, and the lack of clear and appropriate treatment goals and strategies, is a challenge to optimal psoriasis treatment.

In order to achieve the goals stated at the beginning of this assessment, the EEWGHP strongly recommends that the following actions are adopted by relevant stakeholders.

Actions

- Educational programmes directed towards HCPs, industry, academia and healthcare organisations should be created to promote awareness of the tools available and their standard use. Programmes can also be directed towards patient groups to increase awareness of these tools in the clinic
- The development of a pan-European questionnaire for HCPs is needed to identify situations and conditions that are not adequately addressed by current assessment tools.

Box 4: Developing a new assessment tool in psoriasis

- For example, a tool to assess comorbidity, or benefit of treatment for the patient
- The tool would need to be easy to use, require little time to complete and would need to be validated in clinical trials and in clinical practice

New assessment tools should be developed where current tools are found to be inadequate (see Box 4 for an example)

- HCPs, industry and healthcare organisations need to be made aware of current guidelines regarding treatment goals and actively engage in conversations with patients regarding definition of treatment goals and associated management strategies
- HCPs should encourage patients to be involved in setting their individual treatment goals and management strategies
- HCPs, industry and healthcare organisations should ensure that treatment goals and management strategies are sufficiently flexible to allow incorporation of lifestyle factors into a patient's treatment plan

Improving access to earlier therapeutic intervention, new therapies, ongoing care and support

Goals

- Provide people with psoriasis in Europe with earlier access to the care and treatments they need, especially those with moderate to severe psoriasis
- Acquire long-term data on the impact of earlier intervention with systemic therapies in psoriasis
- Ensure that PASI of at least 10 is not used as an absolute criterion to initiate biologic therapy, but is used in the context of a patient's historical severity and the impact of the psoriasis on their QoL
- Encourage regular monitoring of treatment effectiveness to allow appropriate disease management and the timely refinement of therapy
- Encourage ongoing access to the local multidisciplinary team (MDT) for patients with psoriasis and ensure that this is part of a standardised referral process

Defining the need

Therapeutic intervention

Despite the availability of a number of options for the treatment of psoriasis, surveys have demonstrated that people with psoriasis do not receive the optimal care that is necessary to clear their skin symptoms, treat their disease and improve their QoL.^{2,4,6,21} In one UK study of 789 300 primary care patient records, 94% were managed on topical agents, with only 0.7% having access to secondary care, even though there were signs (e.g. comorbidities) to suggest that their psoriasis was not optimally controlled and that they should be referred to secondary care.⁴⁷

Although no direct evidence from psoriasis exists to support the earlier intervention with systemic therapies, psoriasis and rheumatoid arthritis (RA) share common pathogenic pathways and, as a result, parallels may be drawn. The benefit of early intervention in RA has been shown in several studies.^{48,49} For example, an Austrian study compared two similarly treated groups of 20 RA

patients, with the only difference being a 9-month average delay in starting therapy in the second group. The patients that received early intervention showed a significantly better response in disease activity and irreversible joint damage after 3 years of follow-up.⁴⁸ It is likely, therefore, that earlier intervention of therapies in diseases like psoriasis, with early and often irreversible cumulative damage, as described by the cumulative life course impairment,²² may help offset this kind of impairment.

Over the years, therapeutic options have improved in many disease areas, including psoriasis, with the development of new, effective systemic treatments. With more investment in the greater use of new treatments, the outcomes for people with psoriasis could improve. There is evidence from Germany that, in regions with more extensive use of systemic drugs, average disease severity (as indicated by PASI score) is lower and QoL (as indicated by DLQI score) is higher.⁵⁰ However, there are currently strict requirements before biologic therapy can be initiated. PASI of at least 10 is often required; however, we have already described that this cannot be taken as an absolute criterion, since this may not accurately reflect the true severity and impact of the disease (particularly because it has poor sensitivity to change in small areas of involvement), and hence, the requirement for biologic therapy.

Therapeutic monitoring

Intervals for monitoring treatment success are driven largely by the specific treatment option. As a result, it is difficult to standardise the appropriate intervals for monitoring treatment effectiveness in people with psoriasis. Clinical trials often use 3-monthly intervals to assess their endpoints and this timeframe is appropriate for the clinical management of people with psoriasis in the majority of cases. Neither guidelines nor publications have gone so far as to recommend such a management strategy and, as such, follow-up times vary across Europe. However, it is clear that timely evaluation is necessary for people with poorly-controlled diseases. Again extrapolating evidence from RA, it has been shown that intense disease management, involving frequent monthly visits and a change of therapy if pre-defined therapeutic targets were not met, led to better rates of remission and improved QoL at no additional cost.⁵¹

Ongoing care

Comprehensive multidisciplinary care is particularly important for patients with psoriasis, as its association with complex comorbidities can pose particular challenges in terms of diagnosis and treatment. For a patient with psoriasis, multidisciplinary care may mean the convergent efforts of their dermatologist (for assessment and treatment of dermatological manifestations of the disease) with other HCPs such as rheumatologists (for assessment and treatment of psoriatic arthritis), psychologists (for assessment and treatment of psychological issues caused or compounded by psoriasis) and nurses (for provision of more holistic care, such as advice and education around preventative measures and advice on

everyday problems). Multidisciplinary care in psoriasis can therefore allow for a more complete appreciation of the overall disease burden, and subsequently lead to a more comprehensive treatment approach.⁵² Associations such as the Scottish Intercollegiate Guidelines Network (SIGN) recommend that the treatment of psoriasis in secondary care requires the skills of an MDT that includes dermatologists, dermatology nurses and allied health professionals (e.g. occupational therapists, psychologists, etc.). In large hospitals and clinics, psoriasis is managed in an MDT setting. However, there is no clearly defined referral pathway for patients and no consensus as to which specialist should be managing which symptoms.

Summary

The case for proactively managing psoriasis, which includes earlier access to new therapies, is strong. However, without supportive, long-term data, it is difficult to build an evidence base that can assess the impact of earlier intervention with systemic therapies. The provision of timely therapeutic monitoring and an integrated approach to ongoing care also have the potential to optimise treatment and the patient experience.

In order to achieve the goals stated at the beginning of this assessment, the EEWGHP strongly recommends that the following actions are adopted by relevant stakeholders.

Actions

- Investment by governments, healthcare organisations, industry and academia to perform research and gather follow-up data on the impact of earlier intervention with systemic therapies. Continued investment in pan-European patient registries (Box 5) and the further development of national patient registries that contribute to European registries (Box 6) can help to generate this follow-up data. Specifically, the EEWGHP propose the establishment of a registry in every European country and the linking of these registries to a European network like Psonet
- Healthcare organisations should ensure there is sufficient resource to provide adequate access to care, especially for patients with moderate to severe psoriasis
- European bodies, healthcare authorities and HCPs should promote the use of PASI of at least 10 as a criterion to initiate biologic therapy in the context of a patient's historical severity and the impact of the psoriasis on their QoL
- Healthcare organisations and HCPs should provide ongoing and timely monitoring of treatment effectiveness. Three-monthly intervals should be appropriate in most cases, although management plans should be sufficiently flexible for patients whose condition is changeable (i.e. for people with a sudden 'flare-up' of symptoms), or for those who are currently transitioning therapy
- Psoriasis should be managed in an MDT setting. Clear referral processes and triggers should be agreed upon between primary and secondary care HCPs. In addition,

Box 5: The Psonet registry: a collaborative network of independent and predominantly European registries of patients with psoriasis and psoriatic arthritis and treated with systemic agents^{53,54}

Psonet's main objective is to establish a network of independent European population registries, in order to perform coordinated post-marketing surveillance studies aimed at monitoring the effectiveness and safety of systemic agents, including biologics, in the treatment of psoriasis.

Its vision is to improve knowledge concerning prognostic factors and clinical outcomes, offering psoriatic patients the best possible treatment.

The network will allow collaboration between the different independent registries to enable easy pooling of data, collaborative analyses and investigations that would not be feasible in a single country registry. In principle, a wide range of analyses would be possible, such as:

- Investigation of the clinical effectiveness of systemic treatments for psoriasis, in a population context
- Identification of prognostic factors that can help in predicting the response to systemic treatments
- Monitoring of adverse effects of systemic treatments, with particular attention to long-term and rare adverse events, such as severe infections and cancers

Since its inception in 2005, many registries have joined the network (see table below) and work so far has focused on standardising the core data set, with further analysis desired for the future. Collectively, the registries participating in Psonet are prospectively collecting data on 12 000 patients on biological therapies, with this number growing steadily year on year.

Independent registries participating in Psonet, at the end of January 2010	
Australia (Australasian Psoriasis Registry)	United Kingdom (BADBIR)
Denmark (DERMBIO)	Spain (BIOBADADERM)
The Netherlands (AMC Psoriasis Registry)	Sweden (PsoReg)
Germany (PSOBEST)	France (PsoBioTeq)
Italy (PSOCARE)	Switzerland*
Israel (Clalit Health Services)	Portugal*

*Registries which are not yet live but are about to commence recruitment

standardised management processes should be used within secondary care

Defining the role of patient advocacy in psoriasis healthcare

Goals

- Create powerful alliances between PAGs and other associated organisations to ensure they communicate coherent and effective messages
- Enable PAGs to engage with guideline makers to ensure that treatment guidelines reflect the needs of the patient and can be understood by them
- Enable PAGs to engage with health technology assessment (HTA) agencies to ensure HTA recommendations address patient needs
- Ensure that guidelines and health policy publications use patient-friendly language

Defining the need

PAGs provide support and education for patients, and participate in lobbying and fundraising activities that raise awareness around a disease and increase research into a disease and its treatment.⁵⁶ However, the high number of PAGs, often with wide geographical distribution, can lead to scattered efforts and disparate messages. Therefore, it is important that these groups create powerful alliances with other advocacy organisations, professional societies and HCPs to create a more centralised approach and increase the coherence and impact of their messages (Figure 7).⁵⁶ For psoriasis,

as a disease that is often under-treated and underestimated in terms of the impact it has on a sufferer's life, a coherent PAG presence is especially important, as it can help to provide much-needed support.

With the increasing demand for patient-centric approaches in modern healthcare, the role of PAGs is expanding. PAGs can now be considered to represent patients' perspectives and, therefore, be important stakeholders in guideline committees and healthcare policy making.⁵⁶ Despite this, the patient perspective is often not fully considered, and there remains scope for PAGs to engage guideline and policy making parties further. For instance, although patient representatives are often involved in the development of guidelines, their recommendations are often not given a high priority in comparison with other forms of evidence upon which guidelines are based (e.g. clinical evidence).⁵⁷ In addition, the HTA is becoming an increasingly prevalent influencer of health policy, yet the role of PAGs within this has not been fully defined.^{57,58}

HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology (e.g. a medicine or device) in order to inform clinical decision making.

Historically, HTAs have been driven by the assessment of quantitative evidence from clinical trials or economic modelling, and the patient perspective has been largely ignored, perhaps because this information is considered to be anecdotal or biased.⁵⁷ It is only in recent years that the HTA process has involved open dialogue with PAGs; however, in many cases, this means giving them a 'seat at the decision-making table' without a clear or

Box 6: The Psocare registry: an example of a national registry set-up within the Psonet network⁵⁵

Overview:

- Developed as a country-wide outcome study within the Italian National Health Service, involving all the 156 centres appointed by the Italian Regional Health Authorities as referral centres for the treatment of moderate to severe psoriasis in Italy
- Approved by the ethics committee of the hospitals hosting the Psocare centres in 2005

Entry criteria:

- Psoriasis patients receiving a new systemic agent
- Surveying conventional systemic treatments and any new agent registered at the European level for the treatment of chronic plaque psoriasis
- Patients are provided with a card (psocard) to be used for systemic drug prescriptions

Follow-up and data collection:

- Collection of data at entry and after 8, 16, 32, 52, 78, 104 and 208 weeks
- 3-year minimum follow-up
- Information is gathered by the treating physicians with the aid of a web-based electronic data collection form (<http://psocare.agenziatfarmaco.it/>)

<p>Data collected at entry:</p> <ol style="list-style-type: none"> 1 Demographic data, weight, height, personal habits (smoking and average alcohol consumption) 2 Comorbidity, selected medications taken by the patient for relevant indications 3 Dermatological history and lifelong history of psoriasis, including age at first appearance and first diagnosis, type/location of lesions, associated symptoms, previous systemic treatments, periods of clinical remission, hospitalisation, presence of arthritis 4 Psoriasis severity, drug dosage, clinical and laboratory examinations performed before prescription 	<p>Data collected at follow-up:</p> <ol style="list-style-type: none"> 1 Update on demographic data and personal habits 2 Update on treatments received and on the progression of psoriasis 3 Any events, new diagnoses, hospitalisation or specialist attendances during follow-up intervals
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Funding source:

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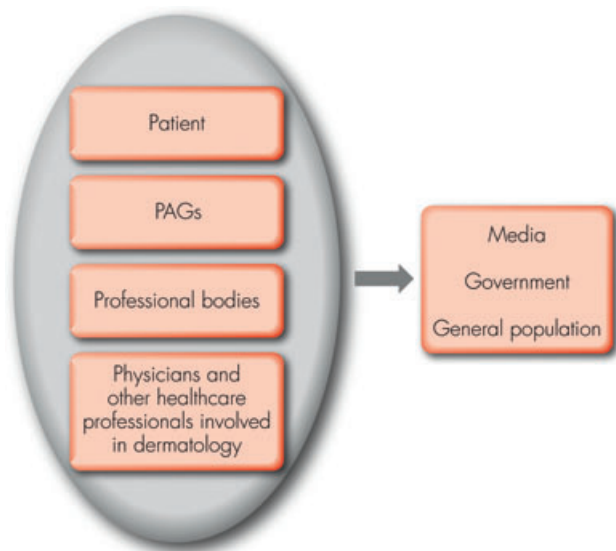


Figure 7 Increasing the coherence and impact of patient advocacy.⁵⁶ A schematic representation of a patient advocacy groups (PAGs) alliance with other PAGs and bodies involved in dermatological healthcare and the focus of this alliance as an information conduit for the media, government and general population. (Adapted by permission from Macmillan Publishers Ltd: *J Inv Dermatol* [Nijsten T:130:1757–1759], copyright 2010.)

defined role. Moreover, many patient groups have little experience of gathering evidence and may not have sufficient resources in terms of both staff and budget to influence outcomes.⁵⁷ This

results in guidelines and HTA appraisals that are largely targeted at HCPs and policy makers and, therefore, use language that is often technical in nature and not suitable for lay audiences.

Patient perspectives should help inform HTA recommendation. Relevant patient evidence can be generated in a systematic manner, for instance, in the form of collective experience gathered by PAGs or evidence from individual experiences of people who would benefit from the technology.⁵⁷ PAGs may help contribute to evidence by encouraging members to take part in research and can also help to shape the research in terms of defining outcomes that matter to people with psoriasis.

Summary

PAGs need to become more engaged with guideline and policy making groups. Without their input, new guidelines and policies will continue to be created without proper and thorough consideration of the target patient audience.

In order to achieve the goals stated at the beginning of this assessment, the EEWGHP strongly recommends that the following actions are adopted by relevant stakeholders.

Actions

- Patients, HCPs, PAGs and others involved in psoriasis should seek to adopt a co-operative approach to achieve their common goals
- Greater collaboration between PAGs and European and national healthcare organisations should be sought to ensure that guidelines sufficiently reflect patient preference

Box 7: Suggested next steps towards increased PAG engagement in the HTA process

- PAGs should clearly define their role in the HTA process
- PAGs should contact relevant healthcare government departments and request inclusion in key meetings and decision-making processes
- If PAGs are unsure of how to proceed, they may find that some of the larger PAGs (cancer, arthritis, etc.) can provide direction
- Universities and/or private providers should provide training to PAG representatives to help them understand the type of evidence considered in an HTA, the impact of pricing and reimbursement, and issues related to quality of healthcare. Currently, an initiative driven by the European Federation of Neurological Associations (EFNA), in collaboration with the London School of Economics, delivers a European HTA training course for PAG representatives. The EFNA has also developed a toolkit that describes how PAGs can contribute to the HTA process⁵⁹

- Greater collaboration between PAGs, HTA agencies, HCPs, academia and industry should be sought to increase engagement, through the provision of HTA training courses for PAG representatives, for example (see Box 7 for suggested next steps)
- PAGs should strive to create patient-friendly versions of relevant guidelines and HTA reports or to be involved as consultants at key review points to ensure patient-friendly language is used and that these documents can be understood by patients

Concluding remarks and action points

Despite significant clinical advances in the field of psoriasis, people living with this condition are still undertreated. Underpinning many of these failings is a lack of priority among the multitude of stakeholders who, collectively, are responsible for raising the bar in the care and management of this chronic condition.

Within this White Paper, the EEWGHP have developed goals and actions in order to provide a framework for improving access to high quality care and, ultimately, improving clinical outcomes and QoL for people with psoriasis. In essence, this White Paper is a call to action for key stakeholders to:

- Raise awareness of psoriasis as a serious medical condition that can greatly impact on a person's QoL and ensure that it is officially recognised as such, so that people with psoriasis receive quality and cost-effective healthcare that reduces the individual and wider economic impact of the disease
- Promote the development, awareness and use of treatment guidelines
- Raise awareness of assessment tools and their standard use, while identifying the potential for new assessment tools that can help to accurately assess disease severity and outcomes in specific situations and conditions
- Define treatment goals and associated management strategies that improve standards for people with psoriasis and encourage patients to be involved in setting their individual treatment goals and management strategies
- Drive data collection on the impact of earlier intervention with systemic therapies through national patient registries that contribute to European registry networks and proactively manage psoriasis through the provision of timely therapeutic monitoring and an MDT approach to ongoing care
- Drive PAG engagement with guideline and policy making parties so that the patient perspective is given appropriate consideration

For comments on the issues discussed in this White Paper, please address the most relevant member of the EEWGHP.

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Actions outlined in the White Paper as required from stakeholders or specific audiences

Actions	Stakeholders/Audiences
Raise awareness of psoriasis and ensure that it is officially recognised as a serious medical condition	PAGs, healthcare organisations, government, industry, academia, HCPs
Promote the development, awareness and use of treatment guidelines	Healthcare organisations, HCPs, PAGs, European bodies
Raise awareness of assessment tools and their standard use, whilst identifying the potential for new assessment tools	HCPs, industry, healthcare organisations, academia
Define treatment goals and associated management strategies and encourage patients to be involved in setting their individual goals and strategies	HCPs, industry, healthcare organisations, patients
Drive data collection on the impact of earlier intervention with systemic therapies and proactively manage psoriasis through provision of timely therapeutic monitoring and an MDT approach to ongoing care	Healthcare organisations, governments, industry, academia, primary and secondary care HCPs (e.g. GPs, nurses, dermatologists, psychologists), European bodies
Drive PAG engagement with guideline- and policy-making parties	Healthcare organisations, governments, industry, HCPs, HTA agencies, patients, PAGs

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