A patient-centred approach to biological treatment decision making for psoriasis: an expert consensus

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Abstract

Background Each individual psoriasis patient has different expectations and goals for biological treatment, which may differ from those of the clinician. As such, a patient-centred approach to treatment goals remains an unmet need in psoriasis.

Objective The aim of this study was to review available data on patients’ and physicians’ decision criteria and expectations of biological treatment for moderate-to-severe psoriasis with the aim of developing a core set of questions for clinicians to ask patients routinely to understand what is important to them and thus better align physicians’ and patients’ expectations of treatment with biologics and its outcomes.

Methods A literature search was conducted to identify key themes and data gaps. Aspects of treatment relevant when choosing a biological agent for an individual patient were identified and compared to an existing validated instrument. A series of questions aimed at helping the physician to identify the particular aspects of treatment that are recognised as important to individual psoriasis patients was developed.

Results Key findings of the literature search were grouped under themes of adherence, decision-making, quality of life, patient/physician goals, communication, patient-reported outcomes, satisfaction and patient benefit index. Several aspects of treatment were identified as being relevant when choosing a biological agent for an individual patient. The questionnaire is devised in two parts. The first part asks questions about patients’ experience of psoriasis and satisfaction with previous treatments. The second part aims to identify the treatment attributes patients consider to be important and may as such affect their preference for a particular biological treatment. The questionnaire results will allow the physician to understand the key factors that can be influenced by biological drug choice that are of importance to the patient. This information can be used be the physician in clinical decision making.

Conclusion The questionnaire has been developed to provide a new tool to better understand and align patients’ and physicians’ preferences and goals for biological treatment of psoriasis.

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Conflicts of interest

Prim. Professor Robert Strohal serves on speaker bureaus for Pfizer, Schülke and Mayer, Lohmann and Rauscher, Meda Pharmaceuticals, Menarini Pharmaceuticals, Stockhausen, and Smith and Nephew. He has consulting agreements with Pfizer, Astellas, Novartis, Lohmann and Rauscher, Urgo, Chemomedica, Schülke and Mayer and Pantea Biotechnologies. He receives research and educational grants from Pfizer, Stockhausen, 3M-Woundcare, Smith and Nephew, Lohmann and Rauscher, Enjo Commercials, Urgo, Chemomedica, and Schülke and Mayer. Professor Prinz has served as a consultant, investigator, speaker or advisory board member for Biogen-Idec (formerly Biogen), Novartis, Wyeth, Pfizer, Merck-Serono (formerly Serono), Essex Pharma, MSD, Galderma, Centocor, Abbott, Janssen-Cilag/Janssen-Ortho. Furthermore he has received an unrestricted research grant from Biogen-Idec and Wyeth in the past. Professor Giampiero Girolomoni has received honoraria for lectures, manuscript preparation or board membership from Abbvie, Amgen, Boehringer Ingelheim, Celgene, Dompé, Galderma, Janssen, Eli Lilly, Hospira, Leo Pharma, Merck-Serono, Mundipharma, Otsuka, MSD, Novartis, Pfizer, Pierre Fabre, Rottapharm and Shiseido. PD Dr. Alexander Nast, has received honoraria for CME speaker activities that received indirect funding from Abbott (now Abbvie) and direct funding from Bayer Health Care, Biogen-Idec (formerly Biogen) and Pfizer.
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**Introduction**
Biological therapies such as TNF inhibitors are used to treat patients with moderate-to-severe psoriasis. They have been shown to improve both disease control and patient satisfaction rates in clinical dermatology practice.\(^1\)\(^-\)\(^3\) The ability of biologics to clear, or almost clear, cutaneous disease has changed the outcomes and expectations of many patients with psoriasis.\(^4\) Moderate-to-severe psoriasis has a negative impact on patient’s quality of life and the chronic nature of the disease means that it is important to get treatment right.\(^4\)\(^,\)\(^5\) Patient-reported satisfaction is highest for biologics compared with topical or systemic treatments, with patients rating treatment effectiveness as the most important factor, followed by treatment safety and doctor–patient communication.\(^6\)

Physicians’ treatment goals based on the psoriasis area severity index (PASI) may not correlate well with measures of patient satisfaction. The recent MAPP study revealed that 22% of patients with a BSA of ≤3 palms rated their disease as severe.\(^5\) In one study, more than half of patients who achieved PASI-50 and 15% of those with PASI-75 were not satisfied with the condition of their skin; conversely, a third of patients who did not attain PASI-50 reported a high level of treatment satisfaction.\(^7\) Patients tend to focus on subjective concerns such as the softness and suppleness of their skin or alleviation of itch, whereas dermatologists focus on objective measures such as clearance of lesions.\(^8\) Anecdotally, clearance of scales, or clearance of psoriasis from visible parts of the body alone, may be sufficient.

The patient benefit index (PBI) is a validated instrument for assessing patient-relevant benefit in skin diseases. It comprises 25 items grouped into five subscales: (i) reducing social impairment; (ii) reducing psychological impairment; (iii) reducing impairment due to therapy; (iv) reducing physical impairment and (v) having confidence in healing. The validity, feasibility and reliability of the PBI in patients with psoriasis have been tested using data from a cross-sectional study and a longitudinal study; it was developed in collaboration with patient groups and was shown to be a suitable instrument for the assessment of patient-reported benefit in the treatment of psoriasis.\(^9\)

A working group was set up based on the concept that each individual patient has different goals for biological treatment. These treatment goals may differ from those of the clinician. While PASI and patient-reported outcomes (PROs) are related, they are based on different concepts. As such, a patient-centred approach to treatment goals remains an unmet need in psoriasis. The working hypothesis for the project reported here was: ‘Understanding the needs and expectations of patients from treatment should constitute a fundamental part of treatment with biologics. At this point this goal has not been fully realised. New tools are needed to incorporate these aspects within therapeutic goals’.

The aim of the working group was to develop a core set of questions for clinicians to ask patients routinely to understand what is important to them and thus better align physicians’ and patients’ expectations and goals of treatment and its outcomes. A literature search was conducted to review existing literature on expectations and goals of both patients and physicians and the decision criteria or existing tools used by physicians to decide on the choice of biological treatment for moderate-to-severe psoriasis. Key themes and data gaps were identified and based on this

| Box 1 | Terms used in literature search |
|---|---|
| **Primary search terms** | **Psoriasis** + **Biologics** |
| **Secondary search terms** | **Adherence** |
| | **Patient global assessment (PtGA)** |
| | **Attitude** |
| | **Patient goals** |
| | **Beliefs** |
| | **Patient-reported outcomes** |
| | **Communication** |
| | **PBI** |
| | **Decisions** |
| | **Perception** |
| | **Dermatology life questionnaire index (DLQI)** |
| | **Physician global assessment (PGA)** |
| | **EQ-SD** |
| | **Physician goals** |
| | **Expectation** |
| | **Preference** |
| | **Experience** |
| | **Pregnancy** |
| | **Health assessment questionnaire-disability index (HAQ-DI)** |
| | **Quality of life** |
| | **Health-related quality of life (HRQoL)** |
| | **Questionnaire** |
| | **Infection** |
| | **Satisfaction** |
| | **Intervention** |
| | **SF-36** |
| | **Life events** |
| | **Surgery** |
| | **Patient expectations** |
| | **Trust** |
| | **Vaccination** |
| | **Visual analogue scale (VAS)** |

Search completed 30.10.2013.
information a series of questions was devised by the working group to aid the practising dermatologist identify aspects of treatment that are recognised as being important to the individual psoriasis patient.

Materials and methods

Literature search
A literature search was designed to answer the following questions:
1. What are the important decision criteria for clinicians when choosing a biological for the treatment of moderate-to-severe psoriasis?
2. What are patient’s expectations from biological treatment?
3. Do patients’ expectations from treatment differ from those of the physician?
4. How can we balance these expectations?
5. What measures can be taken to accommodate life events?
6. How can dermatology consultation styles be adapted to better align with individual psoriasis patients preferences?
7. How can we increase patient involvement in disease management and improve interactions with dermatologists?
8. Which patient-reported outcome questionnaires align best with patients’ expectations?

A search of PubMed was conducted to find articles published in English between January 1980 and December 2013. Box 1 shows the search terms used. The search was restricted to adult psoriasis patients. Screening was performed by an initial assessor and refined subsequently by an additional assessor. Relevance to the topic was determined by scanning the title and, where available, the abstract of the retrieved articles. To be deemed relevant, articles were required to be related to at least one of the key questions. Related citations to relevant topics were also searched and were required to meet the same criteria for inclusion.

Table 1 Key literature search findings, grouped by theme

| Theme                  | Key findings                                                                                                                                                                                                 |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Adherence              | Different biologics have different levels of adherence\(^9\)                                                                                                                                                 |
|                        | Better adherence is observed when the dermatologist clarifies the treatment schedule\(^10\)                                                                                                                  |
|                        | Better adherence is observed when the dermatologist keeps the patient informed and meets the patient’s requests\(^10\)                                                                                  |
| Decision making        | No biological can be considered best for all patients\(^11\)                                                                                                                                              |
|                        | Patient preference should be a major deciding factor in biological choice\(^11\)                                                                                                                           |
|                        | The dermatologist is the most important source for patient understanding of biologics, followed by research on the internet\(^12\)                                                                      |
|                        | The life course of patients has an impact on treatment strategies\(^13,14\)                                                                                                                              |
|                        | Fear of adverse effects is an important factor in patient preference\(^11,15\)                                                                                                                           |
| Quality of life        | Treatment strategy has an impact on DLQI\(^16\)                                                                                                                                                           |
|                        | Patients on topical and traditional systemic therapies have higher DLQI scores\(^16,17\)                                                                                                                   |
|                        | Patients with high DLQI and PASI scores benefit most from biologics\(^18\)                                                                                                                                |
|                        | Skindex-29, a QoL scoring system, does not correlate with improvements in PASI\(^19\)                                                                                                                      |
|                        | DLQI is an independent predictor of work productivity\(^20\)                                                                                                                                                |
| Patient/physician goals| Achieving PASI-75 leads to improvement of the HRQoL index (lack of direct correlation of PASI with DLQI)\(^21,22\)                                                                                  |
|                        | The Patient Benefit Index can be used as goal attainment scaling tool\(^23\)                                                                                                                                  |
| Questionnaires         | When addressing the patient, the physician should use simple language and improve the patient’s psychological skills\(^24\)                                                                            |
|                        | (i) That the physician understands the disease                                                                                                                                                            |
|                        | (ii) That there is hope of cure                                                                                                                                                                           |
|                        | (iii) The perception of control                                                                                                                                                                           |
| Patient-reported outcomes| A clear definition of patient-reported outcomes is needed                                                                                                                                                |
|                        | Biologics also have a benefit on non-PASI outcomes\(^9\)                                                                                                                                                 |
| Satisfaction           | Patients with high disease severity need a patient-centred approach, as they are often dissatisfied with therapy\(^25\)                                                                                |
|                        | A study of 1293 patients revealed that topical therapy was significantly associated with least satisfaction; highest satisfaction was seen with biologics\(^5\) |
|                        | For satisfaction, patients rated treatment effectiveness as most important, followed by treatment safety and doctor/patient communication\(^5\)                                                          |
| Patient benefit index  | PB1 is a suitable instrument for the assessment of the patient-reported benefit\(^6\)                                                                                                                                 |
|                        | More tools for understanding parameters of patient benefit and satisfaction are needed\(^26\)                                                                                                                 |

DLQI, dermatology quality of life index; HRQoL, health-related quality of life; PASI, psoriasis area severity index.
Questionnaire development

Using their expertise and the findings from the literature search, the core group identified key aspects of treatment relevant to clinicians when making decisions regarding the choice of biological agent for an individual patient. These aspects were checked for consistency with aspects that had previously been identified as important to patients; the validated PBI items. The core group then devised a series of questions to help physicians to better identify and understand the aspects of treatment important to psoriasis patients and to support informed decision making on treatment choice. Inviting a patient organisation for comment was an important step in the project plan. Currently, no pan-European patient organisation is in place. The Italian Association of Psoriatic Patients (ADIPSO), Rome, Italy was invited to review the questionnaire in December 2014. The president of ADIPSO was also the patient representative in the European S3 Psoriasis Guidelines. Following comments from this organisation, the questionnaire underwent revision.

A Likert scale, which assumes that all items are considered parallel instruments, was selected as the most suitable way through which patients should specify their level of agreement or disagreement with each statement, thereby expressing the intensity of their feelings for a given item and determining their preference. Scores from each question are given equal importance to allow patients to specify their individual perspectives on the importance of each factor. Linking summative responses from the scale to individual biologics should support treatment decisions according to the suitability of each different biological to meet a patient’s preferences.

Table 2 Correlation of PBI with biological treatment-relevant attributes, as defined in Box 2

| Corresponding items                                      | 3 | 4 |
|--------------------------------------------------------|---|---|
| To be free of pain                                      | 3 | 4 |
| To be free of itching                                   | 3 | 4 |
| To no longer have burning sensations on your skin        | 3 | 4 |
| To be healed of all skin defects                         | 3 | 4 |
| To be able to sleep better                              | 3 | 4 |
| To feel less depressed                                  | 3 | 4 |
| To experience a greater enjoyment of life                | 3 | 4 |
| To have no fear that the disease will become worse      | 3 | 4 |
| To be able to lead a normal everyday life               | 3 | 4 |
| To be more productive in everyday life                  | 3 | 4 |
| To be less of a burden to relatives and friends         | 3 | 4 |
| To be able to engage in normal leisure activities        | 3 | 4 |
| To be able to lead a normal working life                | 3 | 4 |
| To be able to have more contact with other people       | 3 | 4 |
| To be comfortable showing yourself more in public       | 3 | 4 |
| To be less burdened in my partnership                    | 3 | 4 |
| To be able to have a normal sex life                     | 3 | 4 |
| To be less dependent on doctor and clinical visits      | 3 | 4 |
| To need less time for daily treatment                   | 3 | 4 |
| To have fewer out-of-pocket treatment expenses           | 3 | 4 |
| To have fewer side-effects                              | 3 | 4 |
| To find a clear diagnosis and therapy                    | 3 | 4 |
| To have confidence in the therapy                       | 3 | 4 |

Items within the PBI were correlated with the biological treatment-relevant attributes (numbered 1–13; Box 2) defined based on expert consensus.

Results

The literature search returned a total of 398 articles, of which 61 were deemed relevant based on the pre-specified criteria. A further 22 relevant associated articles were found. Excluding duplications, a total of 52 relevant articles were identified.

Table 1 summarises the agreed key findings of the literature search, grouped under themes of adherence, decision-making, quality of life, patient/physician goals, questionnaire, patient-reported outcomes, satisfaction, and PBI. A number of search terms returned no relevant articles (for example, attitude, belief, infection, life events, patient expectations, perception, pregnancy, vaccination), suggesting gaps in the data in these areas.

Based on the literature search and their expertise, the core group identified the following attributes as being relevant when choosing a biological agent for an individual patient:

The above list was compared with the validated PBI and through this process, condensed into 9 key questions (Table 2). In this process, each item of the PBI could be assigned to at least two proposed biological treatment-related attributes, as defined in Box 2, this suggested that the physician’s questions – the responses to which will ultimately inform the treatment option chosen – closely align to aspects...
of treatment of recognised importance to the patient. The assignment also showed that the specific attributes of ‘likelihood of response’ (3) and ‘overall efficacy’ (4) are related to each of the 23 items of the PBI. Conversely, the PBI aspects, ‘ability to lead a normal life’, ‘burden in partnership’, ‘frequency of doctor visits’, ‘out of pocket treatment expenses’ and ‘confidence in the therapy’ were related to greater numbers of biologics attributes and therefore seem to be particularly relevant in differentiating between biologics.

Following receipt of feedback from ADIPSO, the group reviewed and analysed the comments received. The patient organisation agreed that tailored medicine or the individualisation of treatment for psoriasis is of fundamental importance. The changes recommended and subsequently made included offering patients an opportunity to specify their reasons for rating aspects of the questionnaire in a certain manner, and providing patients with options to select from when asking for main symptoms of their disease or treatment history. These changes support the clarification of views or patient preferences that previously may have been unclear to the physician.

The questionnaire is designed for dermatologists to use while with psoriasis patients for whom biological treatment is recommended. Use during consultation will highlight to the patient the physician’s awareness of their individual needs.

According to purpose and proposed usage, the questionnaire devised by the working group was split in two parts. The first part aims to establish a patient profile (Fig. 1) and determine the patient’s experience of psoriasis, as well as patient expectations and satisfaction with previous treatments. The second section aims to identify aspects of biological treatment that are important to the individual patient and the relative importance of these aspects (Fig. 2). Patients are asked to score psoriasis biological treatment-related considerations from 1 (very important) to 5 (not important). Following this, patients provide more information on their preferences and values with regards to treatment by ranking the three most important treatment

| Date of birth | Sex
| Profession | Marriage status |
| Children | Disease duration |
| What are the main symptoms of your psoriasis (tick all that apply)? |
| Itch | Stinging |
| Flaking | Inflammation |
| Joint pain | Redness |
| Pain | Scaling |
| Burning | Cracking of skin |

Other (please specify)

Q1. What would you do if your psoriasis was healed?

Q2a. Is there a certain place where your psoriasis is most troublesome?

Q2b. Why is this?

Q3. Which previous treatments have you received (tick all that apply)?

| Systemics | Phototherapy | Biologics |
| Soriatane (acitretin) | Ultraviolet light B (UVB) | Enbrel (etanercept) |
| Cyclosporine | Sunlight | Humira (adalimumab) |
| Methotrexate | Psoralen + UVA (PUVA) | Remsima (infliximab) |
| Hydrea (hydroxyurea) | Laser treatments | Simponi (golimumab) |
| Isotretinoin | Tanning beds | Stelara (ustekinumab) |

Other (specify)

| Completely satisfied | Completely dissatisfied |
| Q4a. How satisfied are you with your current treatment? | 1 | 2 | 3 | 4 | 5 |

Q4b. What do you like/dislike about your current treatment?

Q5. What does your psoriasis stop you doing?

Figure 1 Part 1 of the patient-centred questionnaire.
aspects from their perspective. Clinical experience may then be used to assign these three most important aspects to different biologics. If several biologics would be covered by these aspects, the other less important aspects may then provide additional help to refine the treatment choice/decision further to best suit the patient’s preference and needs.

The questionnaire results will allow the physician to understand the key factors that are of importance to the patient with regards biological treatment. The final question, which asks patients to rank the top three most important factors, allows for a more in depth understanding of the patient’s priorities with respect to experience with and outcomes from biological treatment.

Discussion

The new questionnaire described has been developed to provide a tool to better understand and align patients’ needs and goals for biological treatment of psoriasis with the goals of their physicians.

Surveys have found that psoriasis is often perceived by patients as being incomprehensible, incurable and uncontrollable; dermatologists need to convey to patients that the disease can generally be controlled, and provide hope that effective therapies are available. Good patient–physician communication is of great importance in ensuring acceptance of, adherence to and satisfaction with therapy. In one Italian study, treatment adherence was significantly associated with the degree of patient satisfaction with his/her relationship with the dermatologist.

A Spanish group has published consensus criteria for the selection of biological therapy in moderate-to-severe psoriasis in which they conclude that choice of biological agent could not be based solely on clinical trial response rates and should consider patient-related factors such as co-morbidities, disease activity and stability and patient preferences. Psoriasis treatment guidelines also recognise the importance of tailoring treatment to the needs of the individual patient.

The concept of patient-centred care, with its emphasis on effective two-way communication, is particularly important in long-term conditions such as psoriasis that require patient involvement for optimal management. Patient preference will

### Q1. Please score the following aspects of treatment based on their importance to you

|                                | Very important | Not important |
|--------------------------------|----------------|--------------|
| High treatment effectiveness   | 1              | 2            |
| Effectiveness on joint pain and stiffness | 1              | 2            |
| Few doctor visits needed for monitoring | 1              | 2            |
| Possibility to self-inject     | 1              | 2            |
| Infrequent injections          | 1              | 2            |
| Rapid onset of action          | 1              | 2            |
| Long duration of efficacy      | 1              | 2            |
| Possibility to stop and restart treatment | 1              | 2            |
| Safety                         | 1              | 2            |

### Q2a. Which of the above attributes are most important to you?

Rank the three most important aspects of treatment from the above list where:
1 = most important, 2 = second-most important and, 3 = third-most important

|                                | 1 | 2 | 3 | 4 | 5 |
|--------------------------------|---|---|---|---|---|
| High treatment effectiveness   |   |   |   |   |   |
| Effectiveness on joint pain and stiffness |   |   |   |   |   |
| Few doctor visits needed for monitoring |   |   |   |   |   |
| Possibility to self-inject     |   |   |   |   |   |
| Infrequent injections          |   |   |   |   |   |
| Rapid onset of action          |   |   |   |   |   |
| Long duration of efficacy      |   |   |   |   |   |
| Possibility to stop and restart treatment |   |   |   |   |   |
| Safety                         |   |   |   |   |   |

### Q2b. Why are these aspects of most importance to you?

Figure 2 Part 2 of the patient-centred questionnaire.
depend on a range of factors including age and gender; matching patient preferences for care with the treatment provided is considered to be one of the key attributes of patient-centred care.\textsuperscript{52,53} Positive treatment outcomes such as increased patient satisfaction and health-related quality of life have been demonstrated when patients’ preferences were incorporated into decision making about treatment.\textsuperscript{57,58} In turn, satisfaction with treatment may increase patient adherence, which is important for achieving optimal treatment outcomes.\textsuperscript{52} Shared decision making, involving negotiation of a treatment regimen that accommodates patients’ goals and preferences, has also been shown to improve adherence and clinical outcomes in other chronic diseases such as asthma.\textsuperscript{59}

This new questionnaire – issued to the patient during consultation with their dermatologist – provides a forum for the patient to clearly and quickly convey their preferences for care. Importantly, its use will also ensure that the physician considers these factors and their importance to the patient when making treatment decisions. Consultation duration in Europe ranges from 10 to 15min\textsuperscript{60,61} and it is hoped that this questionnaire will support improved and efficient patient–physician communication while taking into consideration the time challenges of clinical practice.

A full validation process by psoriasis patient organisations to review the final questionnaire and testing under clinical conditions should be undertaken as a second step. While this questionnaire focuses predominantly on the dermatological manifestations of psoriatic disease, a future questionnaire could be developed to include psoriatic arthritis, taking into consideration the potential impact that multidisciplinary care may have on patient–physician communication.

It is hoped that this psoriasis questionnaire will help physicians to take a more structured approach when choosing a biological therapy that incorporates patients’ treatment preferences. The way patients answer the questions will depend on their beliefs, and their views may change after discussion with the dermatologist. The value of this questionnaire is in helping the dermatologist to understand existing patient preferences so that patient-centred care can be provided. Future steps could include linking summated scores to recommended biologics for individual patients; however, in doing so, care would need to be taken to avoid introducing physicians’ bias and losing the important focus on a patient-centred approach.

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