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Value in psoriasis (IRIS) trial: implementing value-based healthcare in psoriasis management – a 1-year prospective clinical study to evaluate feasibility and value creation

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ABSTRACT

Introduction Currently, the healthcare sector is under tremendous financial pressure, and many acknowledge that a dramatic shift is required as the current system is not sustainable. Furthermore, the quality of care that is delivered varies strongly. Several solutions have been proposed of which the conceptual framework known as value-based healthcare (VBHC) is further explored in this study for psoriasis. Psoriasis is a chronic inflammatory skin disease, which is associated with a high disease burden and high treatment costs. The objective of this study is to investigate the feasibility of using the VBHC framework for the management of psoriasis.

Methods and analysis This is a prospective clinical study in which new patients attending the psoriasis clinic (PsoPlus) of the Ghent University Hospital will be followed up during a period of 1 year. The main outcome is to determine the value created for psoriasis patients. The created value will be considered as a reflection of the evolution of the value score (ie, the weighted outputs (outcomes) divided by weighted inputs (costs)) obtained using data envelopment analysis. Secondary outcomes are related to comorbidity control, outcome evolution and treatment costs. In addition, a bundled payment scheme will be determined as well as potential improvements in the treatment process. A total of 350 patients will be included in this trial and the study initiation is foreseen on 1 March 2023.

Ethics and dissemination This study has been approved by the Ethics Committee of the Ghent University Hospital. The findings of this study will be disseminated by various means: (1) publication in one or more peer-reviewed dermatology and/or management journals, (2) (inter)national congresses, (3) via the psoriasis patient community and (4) through the research team's social media channels.

Trial registration number NCT05480917.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This trial addresses several of the core items of the value-based healthcare agenda.
⇒ In this study, we will measure value in a novel way for each individual patient by using a data envelopment analysis.
⇒ By accurately measuring costs using time-driven activity-based costing, we will gain insight into the actual costs linked to managing psoriasis, identify relevant drivers of costs and suggest bundled payment methods for psoriasis in the Belgian healthcare setting.
⇒ Seeing that this is a monocentric trial we cannot compare the value we create against other centres, and as such a multicentric trial is needed in a second stage to allow for benchmarking.

INTRODUCTION

The healthcare sector is under tremendous financial pressure but an increase in healthcare spendings does not seem to equate to better health outcomes or quality of care.[1–3] Therefore, a dramatic shift is required as the current system is not sustainable.

Psoriasis is a chronic inflammatory skin disease with a high prevalence of 0.1%–11%.[4] Patients can have varying symptoms, such as, itch and pain, and skin lesions can also be disfiguring.[4 5] As such, psoriasis can significantly impact patients' quality of life (QoL).[6] Nowadays, psoriasis is considered a systemic disease as it is associated with numerous comorbidities such as psoriatic arthritis (PsA), obesity and diabetes—underlining the need for a multidisciplinary approach.[7] The cost associated with managing psoriasis and its comorbidities present a substantial economic burden.[8–10] Therefore, there is a clear need for an economically sustainable system.

Value-based healthcare (VBHC) is a widely known conceptual framework, proposed by Porter and Teisberg, aimed at tackling the ever-rising healthcare costs and variation in quality of delivered care.[11] The framework

is formulated on the premise that the healthcare sector should strive to achieve greater value for its patients. Value is defined through an equation in which the achieved patient-relevant outcomes are divided by the costs needed to achieve these outcomes. The agenda to transform current healthcare systems into high-value healthcare delivery systems encompasses six components: (1) organise into integrated practice units (IPUs) around a medical condition; (2) measure outcomes and cost for every patient; (3) reform payment systems (fee-for-value instead of fee-for-service); (4) integrate care delivery systems across separate facilities; (5) expand geographic reach and (6) build an information technology platform.[11]

Measuring outcomes is an essential part of VBHC as it allows us to evaluate the results we obtain, thereby also allowing resources to be allocated in a sustainable and transparent way.[12] Not measuring and openly reporting outcomes has slowed innovation and has led to ill-advised cost containment.[13] The outcomes collected in VBHC should be relevant to patients and look at the full cycle of care. Previously, for psoriasis, little was known about the outcomes achieved in clinical practice as it was unknown which outcomes actually mattered to patients. Therefore, there was also no set of outcomes available that grasped the overall value healthcare professionals created in daily clinical practice. In previous work, we have defined which outcomes matter to psoriasis patients and proposed a value-based outcome set (VOS), which can be used to direct psoriasis care in a value-based manner.[14 15]

Furthermore, costs should represent all medical interventions, including the costs of referrals to other departments. Time-driven activity-based costing (TD-ABC) is the proposed costing method to accurately measure costs within the VBHC framework.[16] Since its inception in 2004, it has become a highly popular technique for measuring costs, particularly in healthcare.[17–19] It has been demonstrated in literature that TD-ABC can assist with creating greater cost transparency, allowing one to identify relevant cost drivers across different disease domains and finally through better cost understanding can lead to better care coordination.[20–22] Furthermore, in keeping with the VBHC framework, having greater understanding and transparency of costs may help with moving the sector away from the current fee-for-service structure towards VBHC payment initiatives such as bundled payments. Bundled payments represent a lump sum payment to hospitals for the reimbursement of an entire episode of care for a patient. The payment is allocated to all services and providers across the various care activities (inpatient, postacute care, etc). Bundled payments were introduced to incentivise quality improvements and encourage cost reduction through increased accountability by providers and ensure better care coordination.[23]

Lastly, in VBHC, value is created by using IPUs, which represent a fundamental part of the implementation of VBHC. An IPU is an organisational entity that connects multiple specialisms and functions around a medical condition, with a distinct organisational structure, and with a coherent set of agreements/contracts.[24] We have set up such an IPU for psoriasis called PsoPlus at the Ghent University Hospital, Belgium.[25]

In this project, we want to assess the feasibility of using the VBHC framework when managing psoriasis. The value In psoRasIS (IRIS) trial will be set up to assess both the outcomes achieved and costs using our PsoPlus format. Subsequently, we will connect the two by conducting a data envelopment analysis (DEA) which, to the best of our knowledge, has never been done before in this setting. This is a highly innovative project in which several of the core items of the VBHC agenda are applied to the management of psoriasis.

METHODS AND ANALYSIS

We aim to investigate the feasibility of using a VBHC approach when managing psoriasis and the cost associated with this way of working.

Primary objective

To determine the value created over a 1-year period while managing psoriasis patients within PsoPlus. The created value will be considered as a reflection of the evolution of the value score (ie, the weighted outputs (outcomes in VOS) divided by weighted inputs (costs)) obtained using DEA.

Secondary objectives

- Determine change from baseline in VOS (all outcomes) at 6 and 12 months.
- Determine the relationship between individual outcomes.
- Determine variables (eg, age, disease severity, treatment) that contribute to outcome variability.
- Determine total costs at 6 and 12 months.
- Determine variables (eg, age, disease severity, treatment) that contribute to cost variability.
- Create patient profiles that reflect efficient (experience more value) and inefficient (experience less value) patients, using DEA.
- Assess the comorbidity evolution at 6 and 12 months (eg, improvement (significant decrease) of cholesterol serum level).
- Determine number of comorbidities controlled (treated and below cut-offs) at 6 and 12 months.
- Determine number of referrals to other specialists regarding comorbidities.
- Determine a potential bundled payment scheme for treating different subsets of psoriasis patients over a particular time horizon.
- Improve the current IPU from an operational perspective by analysing the value scores.

Study design

The IRIS trial will be a prospective clinical trial in which patients attending the PsoPlus for the first time will be followed during a period of 1 year. The PsoPlus IPU has

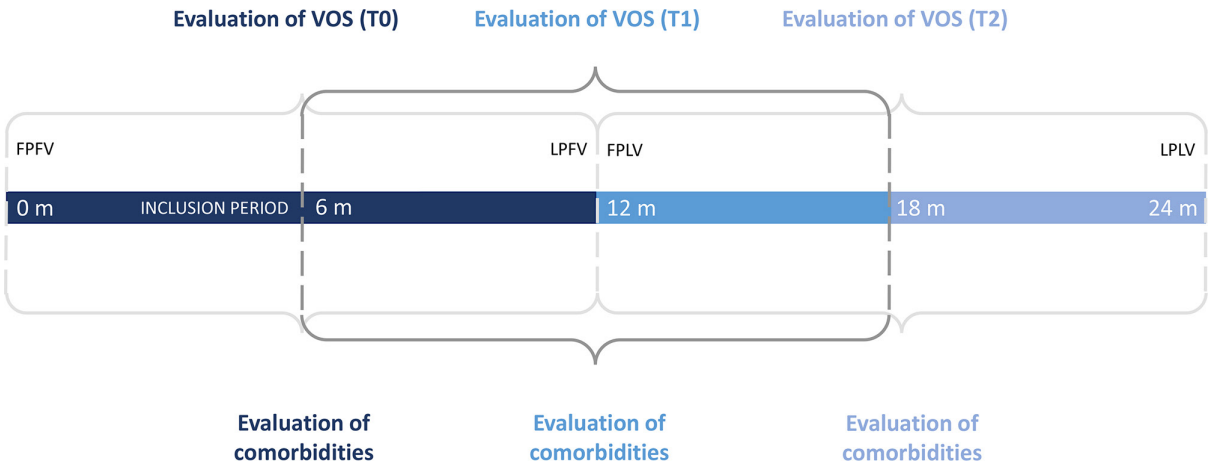

Figure 1 Design of the IRIS trial. The trial will run for 24 months, of which 12 months will serve as an inclusion period. The VOS and comorbidities will be evaluated at months 0, 6 and 12. FPFV, LPFV, FPLV and LPLV are also indicated. FPFV, first patient first visit; FPLV, first patient last visit; IRIS, In psoRiasIS; LPFV, last patient first visit; LPLV, last patient last visit; VOS, value-based outcome set.

been described in detail previously.[25] The focus will lie on patients with no prior experience with PsoPlus. The study will run for 24 months, of which 12 months will serve as an inclusion period. If the sample size is not met, the inclusion period will be prolonged. Both outcomes (VOS) and costs will be collected. The VOS is normally measured on a biannual basis. For this trial, these time points are called T0, T1 and T2, which is also depicted in figure 1. Additionally, screening for comorbidities is performed to account for the integrated way of working. Patient as well as disease characteristics are also captured in a standardized way. This is all considered to be standard of care within PsoPlus. Cost data is collected using TD-ABC over the full cycle of care.

Patient and public involvement

No patients were directly involved in the design of the IRIS trial, however, they played a major role in the development of the VOS.

Recruitment and eligibility

A study nurse will screen all new patients attending the PsoPlus against the eligibility criteria (table 1). They will review together with them the informed consent (IC) and consent will be obtained verbally as well as in writing. Consent procedure will be performed in duplicate, a copy will be stored in our department and the other one will be given to the patient. A screening log and subject identification log will also be kept. The study initiation is foreseen on 1 March 2023. The last patient visit is foreseen on 1 March 2025.

Withdrawal and replacement of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons. Subjects that neglect our referrals or miss a follow-up visit will be excluded from the ongoing study. No specific evaluations will be performed for subjects who terminated the study early.

Outcome collection

The main outcome is to determine the value created over 1 year, where value is defined as outcomes over cost. Data on clinical outcomes, such as skin clearance, in the VOS will be collected during follow-up visits at our clinic. Outcomes which are assessed via a questionnaire will be collected using a specialised patient platform (PsoQuest)

Table 1 Eligibility criteria

Inclusion criteria	Exclusion criteria
► Dermatologist reported diagnosis of psoriasis vulgaris ► ≥18 years but ≤75 years ► New patients that have never visited our specialised psoriasis consultation PsoPlus	► Children, adolescents (<18 years) ► Patients unable to provide consent ► Patients who previously visited our specialised psoriasis consultation PsoPlus within the last 5 years ► Patients who previously visited our psoriasis expert within the last 5 years ► Patients with an uncertain diagnosis of psoriasis vulgaris ► Patients with all other subtypes of psoriasis ► Patients who are unable to understand the tasks and questionnaires

Table 2 Study parameters assessed at each time point

Assessment	Individual items
VOS (during consultation)	► PASI ► BSA ► Adverse events (according to CTCAE) ► Time to clearance (Y/N) ► Treatment sustainability (Y/N)
VOS (via PsoQuest)	► TSQM ► PBI ► PSI ► SDM-Q9 ► DLQI ► WPAI-PSO ► T2T (regarding difficult location and tolerability) ► Costs (Y/N)
Comorbidities	► HADS ► CAGE ► PEST ► Technical measurements (eg, laboratory findings*, full skin examinations, etc) ► Additional questions regarding comorbidities (either during consultation or via PsoQuest)
Additional questionnaires	► EQ-5D-5L*

Note that these are all considered standard of care with exception of the additional questionnaire.
*Will only be assessed at month 0 (T0) and 12 (T2).
BSA, body surface area; CTCAE, Common Terminology Criteria for Adverse Events; DLQI, Dermatology Life Quality Index; EQ-5D-5L, EuroQol 5 Dimensions 5 Level; HADS, Hospital Anxiety and Depression Scale; PASI, Psoriasis Area Severity Index; PBI, Patient Benefit Index; PEST, Psoriasis Epidemiology Screening Tool; PSI, Psoriasis Symptom Inventory; SDM-Q9, 9-item Shared Decision-Making Questionnaire; TSQM, Treatment Satisfaction Questionnaire for Medication; T2T, treat to target; VOS, Value-based Outcome Set; WPAI-PSO, Work Productivity and Activity Impairment-Psoriasis; Y/N, yes/no question.

in which patients have to fill in the questionnaires 3 weeks prior to the consultation.[25] In addition, for this study, the EuroQol 5 Dimensions 5 Level questionnaire will need to be filled in. Screening for comorbidities will also be performed. An overview of all data collected can be found in table 2. When consultations do not coincide with the time points of the trial, data will be collected by a study nurse on a study visit (at our department or the patient's home). A 1-month period will be in place around the time point, meaning that the data can be collected 2 weeks beforehand or afterwards.

Cost collection

We will follow the approach set out by Kaplan and Porter for calculating patient costs under the TD-ABC approach.[16] Patient costs are calculated by multiplying the time spent for each step in the care process with the costs per time unit of that resource. The starting point for the measurement of costs is the development of process maps throughout the whole IPU.[25] The process maps are an aerial representation of all the key activities, which are performed and their location for the patients requiring treatment. The process maps are developed by following the patients through their care pathway. Once we have identified the activities, we can then assign the necessary medical personnel, equipment and machines, as well as the direct and indirect medical costs to each of the necessary activities. The process maps will be validated by the appropriate medical staff through face-to-face interviews. In addition, the process maps regarding the comorbidities will be validated by patients as well.

Time

The amount of time the patient spends within each of the activities in their treatment pathway will be measured via PsoSmart (our detailed information technology platform) and manually by a study nurse for the referral departments.[25] The exact time measurement will only be calculated in the PsoPlus. Regarding the referral departments, the same steps will be applied, however, average time stamps for each activity will be used. This will be done by following five patients, for each comorbidity, visiting the various referral departments and noting the times for those consultations.

Costs

The annual costs for personnel, medical equipment and hospital facilities will be retrieved from the financial database of the hospital. Given the sensitive nature of remuneration data, we will use salary scales instead of actual salaries. For all medical machines the annual cost will be made up of the maintenance and depreciation costs for a year. Facilities costs are usually incorporated into the indirect costs for departments. The indirect costs cover depreciation and maintenance costs, financial and general costs, heating, administrations, etc. For the annual practical capacity, we will take into consideration the available working hours, excluding holidays and training days. This information will allow us to calculate the per unit cost of supplying the resources to help calculate the cost for each activity.

Sample size calculation

No formal sample size calculation could be done due to the exploratory design, however, to conduct a trustworthy DEA, the number of observations should exceed the max{#inputs×#ouputs, 3× (#inputs+#outputs)}.[26] As inputs we look at all the costs made during a patient's consultation (eg, doctor, nurse). As there will be 15 outcome measurements (each questionnaire/question in the VOS is seen as an outcome), at least 75 observations are necessary. However, since we would also like to examine the value within certain subgroups, we need 75 observations for every different category (eg, disease severity, sex, comorbidities).

Based on a retrospective dataset of our department, we were able to draw some conclusions about the proportion of certain psoriasis patient subgroups. We looked at the subgroups that we would like to study but that showed to be in the minority. These were patients with severe psoriasis (PASI≥10), patients with (undefined) joint complaints and patients suffering from PsA. As they represented respectively about 27%, 24% and 14% of the patients in the dataset, we would need approximately 310 observations to be able to examine the first two subgroups separately. The number of PsA patients consulting PsoPlus appears to be low, and therefore, we would need a large sample size (n=535). As such, we will only consider PsA patients during their overall treatment and not per specific consultation. This means we will need a total of around 38 PsA patients during the inclusion period and thus a target sample size of approximately 270 patients. Since we will look at the increments and decrements of outcome measurements between consecutive consultations, this will result in 76 different PsA observations after three consultations.

Consequently, we take 310 observations as an estimate to provide us with the necessary data and flexibility to examine several subsets without losing quality in the analysis. Regarding the other subgroups, 310 observations are more than sufficient as there the proportion is more equally distributed. Accounting for a drop-out rate of 10%, a sample size of around 350 patients would be sufficient to conduct a trustworthy DEA.

Statistical analysis

Data analysis will be executed with Stata V.17 (StataCorp).

Clinical parameters

We will initially start by providing an overview of descriptive statistics such as means, medians, SD and percentiles pertaining to both disease specific and patient specific variables collected during the trial. To determine the relationships between the evolution of individual outcomes correlations will be sought (both positive and negative). To assess these correlations, a Pearson correlation coefficient will be calculated. To further assess the variables contributing to outcome variability, multiple linear regression models will be used. Regarding the evolution of the comorbidities and number of referrals, absolute numbers as well as percentages will be used.

Costs

A similar overview regarding the total treatment costs will be provided. Using basic statistical methods, we will be able to calculate the average treatment costs for each patient in the trial over the full year. Regarding the costing data, we will provide distributions of the total costs for the nurse consultations, doctor consultations, direct medications, cost of referral departments as well as the full treatment costs pertaining to the treatment of a patient, collected within the scope of the trial. To further assess the variables contributing to cost variability, multiple linear regression models will be employed to identify variables contributing to variations in the treatment costs for patients. Thereafter, with these insights, we will be able to make suggestions regarding process improvement initiatives and potentially provide ways in which bundled payments could be designed for this medical setting.

Value

To obtain a value score, we will use a methodological technique called DEA, first developed by Charnes *et al*.[27] This analysis makes it possible to link outcomes and costs. It is a flexible technique, and therefore, an appropriate method as it allows to consider multiple inputs and multiple outputs at the same time without having to make assumptions about their relation beforehand. This data-oriented method evaluates the relative performance and efficiency of different decision-making units (DMUs) based on a linear programming model. In our case, the individual patients will be modelled as the DMUs, meaning that the patients will be benchmarked with each other based on the value score that is calculated for each. This score is the result of dividing the weighted outputs (outcomes) by the weighted inputs (costs), as determined by the linear programming model, and can be considered as a reflection of the relative value created for the patient. By studying the efficient and almost efficient patients, targets for improvements can be provided.

As the primary objective is to determine the value created over a 1-year period, the outputs will be the increments or decrements of the outcome measures between different consultations. For consultation X and Y this would mean the value score is calculated as follows: weighted (outputs Y–outputs X)/weighted inputs X. The DEA results in a value score between 0 and 1 for each patient individually whereby a score closer to 1 indicates more efficiency, and thus more value created for the patient relative to the other patients and given the input levels. A score closer to 0 indicates inefficiencies and thus room for improvement. X and Y can be consecutive consultations, but they can also be the last and first consultation of the year in order to determine the overall value created during their treatment that year. We also want to examine if the efficient and inefficient patients show similar characteristics and if they can thus be clustered. By doing this, certain patient profiles can be identified, which gives a better understanding of what the focus should be on to create more value for the inefficient patients (including how to improve the IPU). To be able to make patient profiles, a multiple linear regression analysis will be conducted to identify the variables that can explain part of the variance in patients' value scores. Those variables can be both patient and disease characteristics. Furthermore, a multiple linear regression can also show whether the position in the treatment has an influence on the patients' value scores. By doing so, we can examine whether the marginal value of a consultation is constant over time or if it changes depending on whether one is further in the treatment.

ETHICS AND DISSEMINATION

This study has been approved by the Ethics Committee of the Ghent University Hospital (B6702022000344) and has been registered on ClinicalTrials.gov (NCT05480917). The trial will be conducted according to the Declaration of Helsinki and in accordance with the Medical Research Involving Human Subjects Act (WMO).

Handling and storage of data and documents

All data from the electronic health record as well as the time measurements will be transferred and stored in REDCap. Data collected via PsoQuest will remain there. Good clinical practice/general data protection regulation (GDPR) regulations will be applied and a detailed GDPR data register will be kept up to date.

Amendments

Amendments will be submitted to the accredited Medical research Ethics Committee (METC) for approval.

Annual progress report

A summary of the progress of the trial will be submitted to the accredited METC once a year.

Temporary halt and (prematurely) end of study report

The accredited METC will be notified of the end of the study and of any temporary halt. Within 1 year after the end of the study a report, with the results of the study, will be submitted to the accredited METC.

Dissemination of project findings

The findings of this study will be disseminated by various means, determined by the target audience. The results of this clinical trial will lead to a publication in one or more peer-reviewed dermatology and/or management journals. In addition, findings will be presented at (inter) national congresses with a focus on dermatology and psoriasis. Coauthorship will be determined based on the International Committee of Medical Journal Editors guidelines.[28] The psoriasis patient community will receive info on the results through different (patient) organisations (eg, the National Psoriasis Foundation or the Flemish Psoriasis League), including a laymen summary of the findings. Lastly, we will reach the general public by communicating the main results through the research team's social media channels.

DISCUSSION

The concept of VBHC is intensively discussed nowadays as a paradigm to improve how we organise our care and allocate our resources. However, well-designed studies assessing the results of working in a value-based manner are currently scarce. Here, we have designed a trial addressing several of the core items of the VBHC agenda (measuring value, delivering care throughout an IPU, and trying to define bundled payment schemes). Furthermore, this will be the first VBHC study to be conducted in a dermatological setting. The findings of this trial could be translated to direct care for other chronic dermatosis, such as atopic dermatitis and vitiligo, in a value-based manner. These diseases are both also chronic inflammatory skin diseases which can also have a high impact on QoL.[29 30] Care for other chronic diseases in general could also benefit from the results of our study as management of chronic diseases share similarities. As such, we believe that the results of this trial will extend beyond the field of dermatology.

Multicriteria decision analysis is an umbrella method, which has previously been used to determine value, based on the input of different stakeholders, for integrated care programmes.[31] In this study, we will try to define value in a novel way by using DEA. This analysis allows us to link the multiple heterogenic outputs, for example, patient-reported outcomes (PROs) and clinician-reported outcomes, with the heterogenic inputs, that is, the costs, into a single score. Expressing the created value in a single score makes it a very tangible and understandable concept which could aid with the current struggles to use outcomes for value-based quality improvements. For instance, based on this score and the evolution of this score conclusions can be made about the characteristics of patients that appear to experience more value compared with the other patients and the evolution of this created value over time. Using this type of analysis also has its limitations as the maximum achievable value is determined by the most efficient patient in our study population. Theoretically, more efficient patients, showing higher value care, might exist though are not considered in the analysis as these are not represented in our sample. Nonetheless, this technique will generate insights into the drivers behind value creation and will allow us to strive towards maximum value for patients.

Alternative payment models for dermatology are being developed and used across the USA, but there is currently no established bundled payment scheme for psoriasis care.[32] Bundled payment initiatives in other fields, such as orthopaedics, have already shown to be successful in reducing cost of care while providing the same quality of care.[33 34] However, little is known about the costs of managing psoriasis and potential cost drivers or factors contributing to cost variability. The IRIS trial will provide us with insight into such matters and, subsequently, we will be able to suggest bundled payment methods for a psoriasis outpatient setting in the Belgian healthcare setting. With a deeper understanding of the outcomes achieved in daily clinical practice for psoriasis, we will be better equipped to align outcomes with bundled payments. In addition, a better understanding of psoriasis cost drivers will allow us to make more informed risk adjustments for bundled payments.

Furthermore, the IRIS trial will also provide additional insights concerning further optimisation of the IPU as some concerns remain, for example, regarding the current comorbidity screening programme's effectiveness and feasibility of routinely collecting PROs.[25] The IRIS trial will also help to define different psoriasis IPUs

in the future, as not every psoriasis patient will require the same level of care. In addition, based on this optimised IPU, IPUs for another chronic dermatosis can be more easily set up.

Future research is warranted to address the benchmarking aspect across different centres of VBHC. As such, a multicentric trial is needed to assess the value created across centres. However, the results of the IRIS trial are essential for the further development of such a trial as most of the methods used here remain completely novel. The IRIS trial will have to show if these methods are viable or if alternatives need to be sought.

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Correction: *Value in psoriasis (IRIS) trial: implementing value-based healthcare in psoriasis management – a 1-year prospective clinical study to evaluate feasibility and value creation*

Hilhorst N, Roman E, Borzée J, *et al*. Value in psoriasis (IRIS) trial: implementing value-based healthcare in psoriasis management – a 1-year prospective clinical study to evaluate feasibility and value creation. *BMJ Open* 2023;13:e067504. doi: 10.1136/bmjopen-2022-067504

This article was previously published with an error.
There was an error in the sample size calculation. As this is an exploratory trial no hypotheses were formulated. As such, no formal sample size calculation can be done and no statement can be made about any p-values (as there are no hypotheses). To make this more clear, the first part of the sample size paragraph has been rewritten.

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