

Prioritising treatment outcomes: how people with acne vulgaris decide if their treatment is working.

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Running title: Self-assessed acne treatment outcomes

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Abstract

Aim: To collect information about how people with acne make day-to-day decisions concerning the effectiveness of their treatment.

Methods: Between May and August 2013, an optional question was embedded in the James Lind Alliance Acne Priority Setting Partnership's online survey to collect treatment uncertainties. The question asked people with acne to 'Tell us in your own words how you decide if your treatment has been effective'.

Results: A total of 742 respondents specified at least one outcome or means of assessing change (outcome measure). Fewer spots was the most commonly cited outcome, identified by 272 respondents (36.7%). Other frequently mentioned outcomes were, in descending order: less redness (19.4%), reduction in spot size (12.1%) and less pain/discomfort (11.4%). Signs were much more commonly used than symptoms and surrogate outcomes such as changes in aspects of life quality were infrequently mentioned. Visual inspection of the skin was the most widely adopted outcome measure (16.3%).

Conclusions: Although the most frequently used methods map well onto the outcome measures adopted in the majority of acne trials, namely physician-assessed changes in lesion counts and global acne severity, people with acne often take into account several factors that cannot be assessed by a third party at a single point in time. The minimal use of changes in psychosocial wellbeing and mood may reflect that these are regarded as secondary consequences of improvements in appearance. The robustness of these findings now requires independent evaluation. If confirmed, they could form the basis of a new patient-reported outcome measure.

Key words: acne vulgaris, decision-making, self-assessment, treatment outcome

Introduction

The most widely used methods for measuring treatment-related change in acne clinical trials are lesion counting and physician-assessed global acne severity (1, 2). The latter is typically measured using interval scales of low sensitivity such as the widely used five-point scale recommended by the US Center for Drug Evaluation and Research (3). Many different scales were developed before patient input into the reporting of outcomes and construction of outcome measures became widely recognised as fundamental aspects of best practice. Recent trials of acne therapies are more likely to include assessment of changes in health-related quality-of-life (QoL) but there is no consensus about which instrument should be employed; subsequently generic, dermatology-specific and acne-specific measures have been used by different investigators in different settings (4-6). Although the developers of acne- and dermatology-specific QoL instruments and a new patient-reported outcome measure (PROM) for acne have consulted patients (7-11), in the main, the final instruments were based on the most commonly mentioned clinical features of acne and/or impacts on everyday life. None sought to establish which of the clinical features and impacts identified are commonly employed by acne patients to make day-to-day decisions about treatment effectiveness.

In contrast, this study set out with the sole aim of addressing the paucity of available information about ways people with acne (PwA) instinctively monitor how well their treatment is working. We use PwA throughout in preference to acne patients as many acne sufferers self-manage their condition and do not consult doctors (12,13). Within the UK, James Lind Alliance Priority Setting Partnerships (PSPs, <http://www.jla.nihr.ac.uk/about-the-james-lind-alliance/>) represent a well-established

National Institute of Health Research process that involves a data gathering exercise from both patients and professionals with the aim of identifying and subsequently prioritising through consensus unanswered questions about treatments for a particular condition. A total of 1,456 PwA took part in the Acne PSP together with 652 healthcare and related professionals (14). The opportunity was taken to embed an additional research question within the PSP's questionnaire to harvest treatment uncertainties with the implicit aim of identifying the most commonly used ways PwA decide if their treatment is working.

Methods

A single question designed to identify how PwA decide whether their treatment is working was identified in consultation with the COMET (Core Outcome Measures in Effectiveness Trials) Initiative and the editor of the UK Database of Uncertainties about the Effects of Treatment. Small groups of acne patients (n = 11) and clinical staff (n = 9) from two dermatology units in the UK were asked to review different wordings of the question. The most popular (12/20, 60%) was "Please tell us in your own words how you decide if your treatment has been effective". The question was included in the online patient survey to harvest treatment uncertainties which was hosted on the Acne PSP website and promoted to PwA within and beyond the UK.

Once the survey closed, responses were downloaded into Excel™. A simplified thematic analysis of the extracted data was performed by one investigator (AE) to ensure consistency in interpretation based on the method of Braun and Clarke (15) whereby data are manually organised into meaningful groups. This approach enabled identification of all ways used by PWA to decide if their treatment was

working. Codes were then used to group responses into candidate themes and sub-themes by one author (AE) and checked by two independent authors (HW and KW). Once all sub-themes had been identified and verified, responses relating to each were enumerated. For analysis, the number of respondents who described a symptom, sign or impact or a change in the same parameter were combined (e.g. intensity of redness, skin less red).

Ethical approval to embed a research question within the PSP harvesting survey was obtained from West of Scotland REC4 (reference number 13/WS/0015). NHS governance approval was obtained from Harrogate and District NHS Foundation Trust.

Results

Demographics

A total of 897 people responded to the outcomes question, representing 61.6% of PwA who took part in the harvesting survey. Of these, 742 PwA (84.2% female) identified at least one outcome or outcome measure and their responses were included in the analysis. The remaining responses were excluded as they did not contain any usable outcomes related information. Almost half of all respondents (46.8%) were aged 16 to 24 and the age distribution mirrored what would be expected for acne. A quarter (27.4%) lived outside the UK and one in five (20.5%) were non-white (Figure 1). Within the UK, responses were obtained from 102 of 121 postcode areas. Demographic data for the excluded subjects were broadly similar and there were no significant demographic differences between the included and excluded populations.

Themes

Three distinct themes were identified: signs and symptoms, impacts and ways of assessing change. Quotations illustrating these themes are shown in Table 1. They were not mutually exclusive. Among the 742 respondents, only 38 mentioned impacts (5.1%) whereas 507 (68.3%) mentioned at least one symptom or sign which they expected treatment to ameliorate. Eighty-six respondents (11.6%) mentioned no specific signs, symptoms or impacts e.g. using phrases such as general clarity of skin, skin condition, feel better about my appearance, etc. The majority of PwA (521, 70.2%) used one or two criteria to assess treatment effectiveness. Ninety-six people mentioned three, 35 mentioned four and 14 mentioned five or more criteria.

Sub-theme: signs and symptoms

A summary of signs and symptoms mentioned by at least 2% of respondents is shown in Figure 2. Less commonly mentioned signs and symptoms are shown in Supplementary Table 1. Reduction in the number of spots, the most frequently mentioned outcome, was unambiguously reported by 272 responders (36.7%). A further 40 (5.4%) said they expected treatment to reduce the numbers of a specific type of spot. In addition, 61 people (8.2%) stated that they would want treatment to reduce the number of new spots or prevent new spots forming and 39 (5.2%) identified fewer breakouts or acne flares. Both breakout and flare suggest a crop of new spots occurring simultaneously although, from the context, some respondents also used these terms to mean a single lesion.

The second most commonly mentioned sign was redness or inflammation, reported by 144 people (19.4%). The only other sign mentioned by >10% of respondents was spot size (90, 12.1%). Aspects of scarring were identified as important by 41 respondents (5.5%) and oiliness of skin by 37 (5.0%). Skin texture was identified by 49 people (6.6%) and overall appearance by 41 (5.5%). The most commonly mentioned symptom was pain, soreness or discomfort (85, 11.4%).

Sub-theme: impacts

The impact most frequently identified was level of confidence (22 people, 3.0%). Whilst most people wrote about confidence in general, some women (7, 0.94%) said they felt more comfortable, happier or more confident without make-up if treatment had been effective. Nine people (1.2%) mentioned effective treatment would alter how they feel about their skin or about themselves and seven (0.94%) said they were happier or felt better when their treatment worked.

A negative treatment impact (as opposed to an acne impact modulated by treatment) was the trade-off between efficacy and side effects. Sixteen people mentioned they would not consider a treatment to be effective if it deleteriously affected the condition of their skin. For example, one respondent commented “It's not really a great success if you eliminate spots, which can be concealed by make-up to a certain extent, but replace them with dry, red flaking skin that cannot be hidden.”

Outcome measures

The most frequently used ways of assessing change are shown in Figure 3. The most common way of detecting treatment effects was by looking at the skin and

noticing a difference in 'spottiness', clarity or general condition (121, 16.3%). Many respondents described using a mirror (45, 6.1%) or taking photographs (68, 9.2%) to monitor changes; one kept a video diary. Although the number of spots was the sign most people wanted treatment to address, only 46 (6.2%) clearly stated that they counted spots. Interestingly, 24 people (3.2%) said they didn't count or didn't think it was useful to do so. For example, one respondent commented "It's not the math of how many, but, how wonderful or how awful it [the skin] looks - qualitative, not quantitative". Five people said they used a scale to assess improvement, one specifically to assess redness. Although 48 people (6.5%) used one or more aspects of how their skin felt as a means of measuring treatment efficacy, only 22 (3%) described in detail how they did this e.g. "It works if I can feel the bumps going down and the texture of my skin improve".

Frequency of assessment and time to achieve change was an important aspect. Some people checked their skin daily (36, 4.9%), others weekly or monthly (17, 2.3%). Some (35, 4.7%) specified a deadline by which they expected to detect an improvement. This varied from 1-2 weeks to 3-5 months.

Expectations of the degree of treatment effectiveness also varied amongst the respondents (Table 2). A good example was clear versus clearer skin; whilst 70 people (9.4%) wanted clearer skin or an improvement in skin clarity, 51 (6.9%) expected their skin to be totally clear of spots in order to regard treatment as effective. The way responses were expressed suggested that most people had realistic expectations, using words like fewer, less or reduced in recognition that complete cure was unlikely.

Word usage: signs and symptoms

Acne lesions were most often referred to as spots (414 people, 55.8%), occasionally as pimples (26, 3.5%) or bumps (21, 2.8%) and uncommonly as blemishes (5, 0.7%), lesions (5, 0.7%), lumps (5, 0.7%) or zits (2, 0.3%). Specific lesion types were mentioned infrequently: cysts by 26 (3.5%), blackheads by 18 (2.4%), pus/pustules by 15 (2.0%) and whiteheads by nine people (1.2%). Various qualifying words were used to describe acneic skin more generally, the commonest being red (100 people, 13.5%), painful (46 people, 6.2%), inflamed (44 people, 5.9%) and bad (27 people, 3.6%). Sebum was most commonly referred to as oil (25 people, 3.4%) and less frequently as grease (11 people, 1.5%). Scar or scarring (42 people, 5.7%) was used more commonly than mark (8 people, 1.1%) or splotch (2 people, 0.3%) and it was sometimes difficult to tell if people were describing scars or macules (e.g. “red mark”).

Word usage: outcome measures

A variety of words and phrases were used to describe change or how change was assessed. The most common way of describing change was as less or lessening (123 people, 16.6%), followed by clearer or clearing (103 people, 13.9%). The word “how” was used by 153 respondents (20.6%) as a quantitative (e.g. how red, how many pimples) or qualitative measure (e.g. how I felt). The most frequently used verbs to describe how change was assessed were look/looking (192 people, 25.9%) and see/seeing (159 people, 21.4%).

Discussion

A recent systematic review, across all disease categories, of studies that sought to determine which outcomes to measure in future clinical trials found no published evidence that PwA have been consulted on this important topic (16). In contrast to the numerous studies which have sought to determine what bothers people about having acne, we are not aware that any have previously asked patients about the changes they would expect to see as a result of treatment or how they would assess these.

The Acne PSP provided a legitimate platform to ascertain how a large number of PwA decide if their treatment is working. The number of spots or, perhaps more correctly, extent of spottiness was by far the most frequently mentioned outcome PwA wanted treatment to address. In general, they assessed how their skin looked in the mirror, in a photograph or to others rather than by counting spots to monitor treatment effects; methods that can be likened to global severity grading. However, respondents used a much broader range of criteria to assess treatment efficacy than are captured by lesion counts and acne severity grades which together represent the most commonly used measurements in current clinical trials. Their responses show that PwA recognise the insidious nature of acne and incorporate this into their assessments of treatment effect. For example, they notice that the number of new spots decreases, gaps between breakouts lengthen, the areas of affected skin become smaller, the size, depth, prominence or type of spot changes and spots heal more quickly when treatment is effective. These changes cannot be easily captured by existing physician administered grading scales or by assessments made at fixed points in time, as in a clinical trial. Whilst standardised digital imaging techniques now

under development (17) may provide a potential novel and improved method to capture more subtle treatment effects, the findings suggest that patient-reported symptoms and signs should be considered within future clinical trials.

The second most common feature of acne which respondents used as a measure of treatment effectiveness was reduction in the degree of inflammation, typically described as redness. Many acne severity scales ignore the persistent inflammation associated with healing lesions (macules) and scars. Lack of response to oral and topical acne medications has been used to justify the exclusion of macules and scars (which can be numerous) from lesion counts and severity grades. However, it is now recognised that several acne therapies including physical ones have a positive impact on both scarring and macules (18, 19), and it may be timely to devise new grading methods to reflect this.

Skin feeling better (less pain, soreness or discomfort) was the third most frequently mentioned outcome and uncomfortable skin was the most commonly mentioned symptom. Treatment effects on how the skin feels from within are not captured by counting spots or acne severity grading scales and are invariably not assessed in acne trials. Respondents often used one or more aspects of their complexion such as the overall appearance or condition/texture/tone of their skin as a measure of treatment effectiveness. There was considerable variation in how people did this ranging from a quick glance in the mirror to a standardised daily assessment regimen that included both looking and feeling. We are not aware of any validated scales which would enable subjects to rate the quality of their complexion or how their skin feels within a clinical trial.

Whilst frequency of reporting is not necessarily a reliable indicator of importance, we applied an arbitrary cut-off of 2% of respondents to identify outcomes which might be important for those developing novel outcome measures. Using this cut-off, reduction in skin oiliness also ranked among the criteria which future trial investigators should perhaps include, especially since more acne treatments are now able to address this.

Because the Acne PSP was based in England, most participants were white and lived in the UK. We recognize that linguistic issues may have meant that respondents for whom English was a second language may have interpreted the research question somewhat differently. Unexpectedly, there was significant gender bias amongst the respondents with females outnumbering males by more than four to one. Some of the ways in which outcomes were assessed such as need for make-up to cover spots were mainly applicable to women. Apart from these, there was no evidence that males and females use different ways of assessing treatment effectiveness.

We examined word usage to find out which words or phrases were most commonly used to describe symptoms and signs or change as this information could be useful when devising new PROMs. We found that many more respondents used the word spot than any other term for an acne lesion, possibly reflecting our own usage of this term in the harvesting survey into which the outcomes question was embedded. In contrast, a recent study in 48 patients aged 12 to 50 years from five US cities found that the most commonly used words to describe lesions were acne, pimples and zits (11). However, another US study conducted 10 years earlier, which also looked at word usage by patients when devising an acne specific QoL instrument, utilized

bump in the final questionnaire (9). When responses to the outcomes question from the USA and Canada were analyzed separately (n = 111), it was found that fewer respondents used the term spot (33.3%) than in the rest of the sample (66.6%). Further study of word usage by PwA is needed to inform the language used in PROMs. It may be that national differences and trends in word usage over time preclude the use of a universal terminology.

The information obtained from this international study provides a valuable insight into the ways PwA monitor treatment effectiveness. It has shown that widely used outcome measures including lesion counting and global severity assessments capture some of the signs of acne which PwA want their treatment to address. However, PwA employ a much wider range of criteria, including clinical features which are not included within the commonly used acne-specific and dermatology-specific health-related QoL questionnaires or a new PROM (Table 3). Many of the aspects identified in this study could not be measured by a third party, but could form the basis of one or more novel PROMs. Psychosocial impacts were rarely used by PwA to assess treatment efficacy suggesting that inclusion of instruments to measure these in acne trials may not always be of value.

These preliminary findings, if confirmed by others especially in predominantly non-white populations and in males, might be useful to the Acne Core Outcomes Research Network, which is seeking to develop a minimum set of consensus-derived outcome measures for global adoption in future acne trials (see <http://sites.psu.edu/acnecoreoutcomes/>). They suggest that greater emphasis should

be placed on participant as opposed to physician-rated assessment of symptoms and signs.

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Table 1. Quotations from patients relating to major themes

Signs	Symptoms	Impacts	Ways of assessing change
“Size and area of face covered with spots.”	“When I no longer have sore spots on my face I feel it is improving.”	“If I feel confident to go out without a full face of make up on.”	“Eyeball my skin condition.”
“Dramatic reduction in number of spots and size and colour of spots.”	“How uncomfortable it feels when I touch it.”	“...allow me to do sports without worrying about showing off my skin to others.”	“Nothing too accurate, just by looking and feeling every day.”
“If I get less breakouts, and my spots decrease in size and don't leave me with hyper-pigmentation.”	“If I can eat and smile without pain.”	“How happy or otherwise I feel when I look at my face in the mirror.”	“Whether my spots heal more quickly than normal.”
“If the scars start to fade & I get my natural complexion back.”	“Feeling less discomfort from deep spots.”	“I rate it more by the psychological impact i.e. how much it bothers me mentally.”	“Just generally looking at the affected areas to see how pimply and angry they look.”
“If my skin is less oily and I'm not having as many spots.”	“If my face doesn't hurt it's always better.”	“When I could go out without thinking people could only see the spots, not me.”	“I .. use my clean hands to feel the surface of my face to see if the bumps have gone down.”

Table 2. Different expectations of treatment outcomes

Nothing less than clear skin	Better than it was before
"When the pimples are gone."	"Quite simply less spots and less large."
"Spotless."	"I can usually just tell by areas clearing up or not."
"...cleared the spots completely and worked quickly."	"When the spots start to clear."
"If they disappear and don't come back."	"If there are fewer, less obvious spots".
'Clear and comfortable skin or not. Simple.'	"If the spots have lightened considerably."
"If my acne is gone it's effective, if I still get pimples it's not."	"When I feel less bumps on my skin."
"I'll consider my acne treated once my skin is completely clear."	"By an improvement in my skin I could see."
"I would expect my acne to be cured."	"If there are no real bad sore angry looking spots I'm happy. I can cope with that."
"It's quite easy to see if a treatment works or not. If I still have spots, that means it doesn't!"	"I just look to see if there's a change in the density and amount of my impurities and uneven tones on my skin."

Table 3. Signs and symptoms included in the most widely used acne and dermatology specific health related quality of life questionnaires and a new patient-reported outcome measure for acne

Acne signs and/or symptoms included in					
Acne-specific quality of life questionnaire: Acne-QOL (7)¹	Cardiff Acne Disability Index: CADI (20)	Skindex-16 (21)	Skindex-29 (21)¹	Dermatology Life Quality Index: DLQI (22)/ Childrens' DLQI (23)²	Acne Symptom and Impact Scale: ASIS (11)
Bumps	No signs or symptoms included	Skin hurting		How itchy, sore, painful or stinging (itchy, scratchy, sore or painful in childrens' version)	Pimples
Bumps full of pus		Skin burns or stings			Blackheads
Scabbing		Skin itching			Whiteheads
Oily skin		Skin being irritated	Skin sensitive Skin bleeds		Scars Dark marks Scabs Oily skin Redness

¹These questionnaires also contain an item “worry about getting scars” which we considered to be an impact not a sign.

²These four symptoms are included within a single item.

Figure Legends

Figure 1: Participant demographics.
(a) Age distribution, (b) Ethnicity, (c) Location.

Figure 2. Sign, symptom and impact-related sub-themes identified by at least 2% of respondents.

Figure 3. Ways of assessing change identified by at least 2% of respondents.
Make-up was used as a measure of treatment success in several ways: amount used (14), no longer needing to use it (9), confident without it (7), visibility of spots through it (4), time taken to apply it (2). Responses describing use of a mirror or taking photos were not included in the looking and seeing category. Comments from others included both solicited and spontaneous ones.