

AN EXPERT PANEL QUESTIONNAIRE (EPQ) FOR ASSESSING PATIENT-REPORTED AND CLINICIAN-REPORTED OUTCOMES IN ACTINIC KERATOSIS

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BACKGROUND

- Timely, effective treatment of actinic keratoses (AKs) is important because there is no reliable way to predict which of these hyperkeratotic lesions on chronically sun-exposed skin will become cancerous.^{1,2}
- Some topical treatments for AKs such as 5-fluorouracil and imiquimod are associated with uncomfortable and visible local skin reactions (LSRs), which have been linked to poor treatment tolerability and low treatment satisfaction.^{3,4}
- Clinical trials of AK have not typically included patient-reported outcomes (PROs).
- AK treatment-related factors such as skin reactions are known to impact QOL and treatment adherence.⁵
- Current assessments on topical treatment attributes in AK do not evaluate safety, effectiveness, and satisfaction from both clinician and patient perspectives, creating an unmet need for more comprehensive AK-specific measures that fully capture the patient experience.^{3,6,7}
- An AK-specific PRO instrument may help highlight patient-centric issues and outcomes in clinical studies and real-world clinical practices.
- Comparing current and previous AK treatments would be useful in gauging the relative impact of different treatments. Further, simultaneously assessing PROs and clinician-reported outcomes (ClinROs) on treatment attributes may enhance clinician-patient communication, providing great utility among clinical practitioners.⁷

OBJECTIVE

- To create an expert panel questionnaire (EPQ) comprising of AK-specific PROs and ClinROs for use in research studies and clinical practices.

METHODS

- A 9-person consensus panel of dermatologists with expertise in the treatment of AKs was virtually convened using a two-step modified Delphi method to establish consensus on EPQ items.
- Input from AK patient interviews and targeted literature reviews was used to identify 11 EPQ items.
- In first round, EPQ items were distributed to the panel for discussion of each item and solicit comments individually and collectively.
- In the second round, the panel refined EPQ items which were distributed for feedback and approval.

RESULTS

- The panel discussed nine PROs encompassing cosmetic outcomes ('overall appearance of the skin', 'ability to improve how skin looks', 'ability to improve skin texture'), effects of Local Skin Reactions ('compared to previous topical treatment experience', 'relative rating of 'duration of skin reactions', 'severity of skin reactions', 'impact on your daily activities'), relative convenience/ease of use of new treatment, overall satisfaction with new treatment, and likelihood of future use.
- Two ClinROs encompassing Physician Global Assessment (PGA) of AK and severity of skin photodamage were also reviewed.
- The panel suggested wording changes to PROs and ClinROs as outlined in Table 1.
- For Subjects re-treated with another topical treatment at Week-24, questions 3-8 are reworded to enable the assessment of relative satisfaction associated with tirbanibulin in comparison to the 'most recent topical treatment for AK'.
 - The clinician version of the questions 1-9 were worded to refer to clinician experience / observation of tirbanibulin effects among their patients.
- Following refinement of EPQs, panelists unanimously (100%) achieved consensus in approving each of the 11 EPQ items.
- Panelists also suggested using the nine PROs as ClinROs to gather patient-experience from both patient and clinician perspective on identified domains.

REFERENCES

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RESULTS

Table 1. Expect Panel Deliberations on EPQ

DOMAIN	QUESTION	EDITS FROM ROUND 1	FINALIZED EPQ
Cosmetic Outcomes	1	Changed from "treated area" to "original AK treated area" and added definition of "original AK treated area". Same change was made to all relevant EPQ items.	Compared to X weeks ago, how has the overall appearance of your skin in the original AK treated area changed? (Scale: 1-5; much worsened - much improved) <i>Note: The "original treated area" is the skin area with AK that was treated with Treatment Y at beginning of this study.</i>
	2	Updated scale from "0-4; not satisfied – completely satisfied" to 1-7; extremely dissatisfied – extremely satisfied)	How satisfied are you with this treatment's ability to improve how your skin looks (example: reduced redness, discoloration, crusting, scaling) in the original AK treated area? (Scale: 1-7; extremely dissatisfied – extremely satisfied)
	3	Added description for skin texture. Changed scale from "(0-4; not satisfied – completely satisfied)" to (1-7; extremely dissatisfied – extremely satisfied)	How satisfied are you with this treatment's ability to improve your skin texture (ie, how your skin feels in terms of roughness, bumpiness, scaliness) as a result of the treatment in the original AK treated area? (Scale: 1-7; extremely dissatisfied – extremely satisfied)
Future Preferences	4	No change to the question. Updated scale from "0-4; very unlikely – very likely" to "1-5; very unlikely – very likely."	In case you need to be retreated for AK, how likely are to you consider Treatment Y again? (Scale: 1-5; very unlikely – very likely)
	5	Added "considering the factors such as convenience / ease of use, duration and severity of skin reactions, impact on daily life, etc." describing satisfaction. Changed scale from "(0-4; much worse – much better)" to (1-5; much worse – much better)	<u>If patient has used a topical treatment in the past:</u> Compared to your previous experience with topical treatment X for AK, how would you rate your overall satisfaction (considering the factors such as convenience / ease of use, duration and severity of skin reactions, impact on daily life, etc.) with Treatment Y? (Scale: 1-5; much worse – much better)
Effect of LSRs	6	Added description for duration of skin reactions.	<u>If patient has used a topical treatment in the past:</u> Compared to your previous experience with topical treatment X for AK, how would you rate the duration of skin reactions (i.e., how long the skin reactions lasted) associated with Treatment Y in the original AK treated area: (Scale: 1-5; much longer – much shorter) much shorter - much longer with tirbanibulin
	7	New question added.	<u>If patient has used a topical treatment in the past:</u> Compared to your previous experience with topical treatment X for AK, how would you rate the severity of skin reactions (i.e., how bad the skin reactions were) associated with Treatment Y in the original AK treated area (Scale: 1-5; much worse – much better)
	8	Updated description of daily activities from "(such as shopping, bathing, social engagements, activities, etc)" to (i.e., ability to carry out shopping, bathing, social engagements, scheduling vacations, outdoor activities, activities at work, attendance at work, etc.)	<u>If patient has used a topical treatment in the past:</u> Compared to your previous experience with treatment X, how would you rate the impact on your daily activities (i.e., ability to carry out shopping, bathing, social engagements, scheduling vacations, outdoor activities, activities at work, attendance at work, etc.) <u>due to skin reactions</u> associated with Treatment Y use in the original AK treated area? (Scale: 1-5; much worse – much better)
	9	New question added.	<u>If patient has used a topical treatment in the past:</u> Compared to your previous experience with topical treatment X for AK, how would you rate the convenience/ease of use (such as frequency of use, easy to follow instructions, comfortable at apply, etc.) associated with Treatment Y? (Scale: 1-5; much worse – much better)
PGA (AK)	10*	AK lesion clearance levels were added to the response scale.	Overall, how is your patient's AK in the original treated area right now? (Scale: 0-4; not cleared, minimally cleared [≥5%-49%], partially cleared [≥50%-74%], almost cleared [≥75%-99%], cleared [100%])
Photodamage Severity Assessment	11*	Changed from "rate the severity" to "rate the current severity". Added description on photodamage.	How do you rate the current severity of skin photodamage in the original AK treated area? <i>Note: Photodamage can be described as alterations in the structure, function, and appearance of the skin as a result of prolonged or repeated exposure to ultraviolet (UV) radiation from the sun or other UV sources.</i> (Scale: 0-3; absent – severe) 0: Absent - Smooth evenly pigmented skin 1: Mild - Freckling and/or other dyspigmentation 2: Moderate - Above plus mildly rough "dry" skin, fine wrinkling and/or telangiectasias or blotchy erythema 3: Severe - Above plus pronounced "dryness" and/or dyspigmentation and/or telangiectasia or erythema, and/or wrinkling, with or without areas of actinic purpura

*ClinROs, answered only by clinicians; LSRs (Local Skin Reactions), PGA (Physician Global Assessment)

CONCLUSIONS

The newly developed EPQ may address important gaps in the existing PRO measures and help elicit patient-centric, AK-specific outcomes from patients and their clinicians and help optimize AK management and enhance patient outcomes.

