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A Global eDelphi Exercise to Identify Core Domains and Domain Items for the Development of a Global Registry of Alopecia Areata Disease Severity and Treatment Safety (GRASS)

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IMPORTANCE A recent expert consensus exercise emphasized the importance of developing a global network of patient registries for alopecia areata to redress the paucity of comparable, real-world data regarding the effectiveness and safety of existing and emerging therapies for alopecia areata.

OBJECTIVE To generate core domains and domain items for a global network of alopecia areata patient registries.

EVIDENCE REVIEW Sixty-six participants, representing physicians, patient organizations, scientists, the pharmaceutical industry, and pharmacoeconomic experts, participated in a 3-round eDelphi process, culminating in a face-to-face meeting at the World Congress of Dermatology, Milan, Italy, June 14, 2019.

FINDINGS Ninety-two core data items, across 25 domains, achieved consensus agreement. Twenty further noncore items were retained to facilitate data harmonization in centers that wish to record them. Broad representation across multiple stakeholder groups was sought; however, the opinion of physicians was overrepresented.

CONCLUSIONS AND RELEVANCE This study identifies the domains and domain items required to develop a global network of alopecia areata registries. These domains will facilitate a standardized approach that will enable the recording of a comprehensive, comparable data set required to oversee the introduction of new therapies and harness real-world evidence from existing therapies at a time when the alopecia areata treatment paradigm is being radically and positively disrupted. Reuse of similar, existing frameworks in atopic dermatitis, produced by the Treatment of Atopic Eczema (TREAT) Registry Taskforce, increases the potential to reuse existing resources, creates opportunities for comparison of data across dermatology subspecialty disease areas, and supports the concept of data harmonization.

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A recent systematic review highlighted the paucity of evidence to guide treatment of alopecia areata.¹ Although recent national treatment guidelines²⁻⁴ provide regional expert consensus in the absence of high-quality evidence, the need to engage a wider network to challenge a possible groupthink and confirmation bias was recognized.^{5,6} To this end, at a time when new drugs are revolutionizing treatment of alopecia areata, the global Alopecia Areata Consensus of Experts (ACE) eDelphi exercise was conducted^{7,8} to facilitate greater international harmony in the guidance of existing and emerging alopecia areata therapies. A secondary benefit, endorsed during the exercise, was the establishment of a group capable of developing a global network of patient registries to produce long-term, comparable, real-world data to better inform clinical practice, monitor safety of current and emerging therapies, drive research, improve communication, and promote patient inclusion.

The establishment of internationally agreed core variables has been identified as a critical component in the development of high-quality, cross-border patient registries.^{9,10} Mirroring work conducted by the Treatment of Atopic Eczema (TREAT) Registry Taskforce to establish consensus regarding core domains and domain items for research registries for atopic dermatitis, an eDelphi exercise to develop similar outcomes for alopecia areata was developed.^{9,11-13} To increase comparable data across dermatology subspecialties, the outcomes of the TREAT Registry Taskforce served as a blueprint around which proposed core domains and data items for this eDelphi process were modeled. To broaden representation, the ACE group was expanded, to include scientists involved in alopecia areata research, patient organizations, the pharmaceutical industry, and pharmacoeconomics representatives.

The primary objective of this eDelphi study is to reach international consensus regarding the core domains and data items (ie, what to measure) required to build a network of patient registries to monitor real-world demographics and outcomes of alopecia areata.⁹ A secondary objective is further alignment of the international alopecia areata community to maximize limited resources and use technology to better harness higher-quality data to promote deeper understanding of a complex, quality-of-life-altering condition.

Methods

This study was reported with reference to a checklist developed for the reporting of Delphi studies and followed the Standards for Quality Improvement Reporting Excellence (SQUIRE) 2.0 guidelines.^{14,15} Consent to participate was assumed through self-registration and round completion. Consent to be acknowledged in this publication was specifically sought. Consistent with previous similar studies, the Medical Research Involving Human Subjects Act was not considered to be applicable to this study.⁹

Delphi Process

The Delphi method was selected because it enables participants to reach consensus by iteratively answering a questionnaire relating to a specific topic. Over successive rounds, participants review their answers in light of the anonymized replies of other participants to minimize bias.¹⁶⁻¹⁹ In the eDelphi format, questionnaires are distributed electronically for the initial rounds, followed by a final round

Key Points

Question What data that should be captured by a global network of alopecia areata patient registries to describe the safety and effectiveness of existing and emerging therapies?

Findings This review included 66 expert physicians, patient organizations, scientists, representatives of the pharmaceutical industry, and pharmacoeconomic experts, who identified 92 core and 20 noncore data items in a 3-round eDelphi process.

Meaning The identified data items provide a blueprint for the development of a global network of alopecia areata patient registries capable of addressing a real-world evidence gap regarding alopecia areata therapeutics and outcomes.

face-to-face meeting to address contentious issues and achieve consensus where possible.

Stakeholder Groups

Four stakeholder groups were identified as crucial for alopecia areata registry development: patients, through their support groups; dermatologists; scientists; and pharmaceutical industry/pharmacoeconomic representatives. In total, 88 participants from 6 continents were invited to participate.

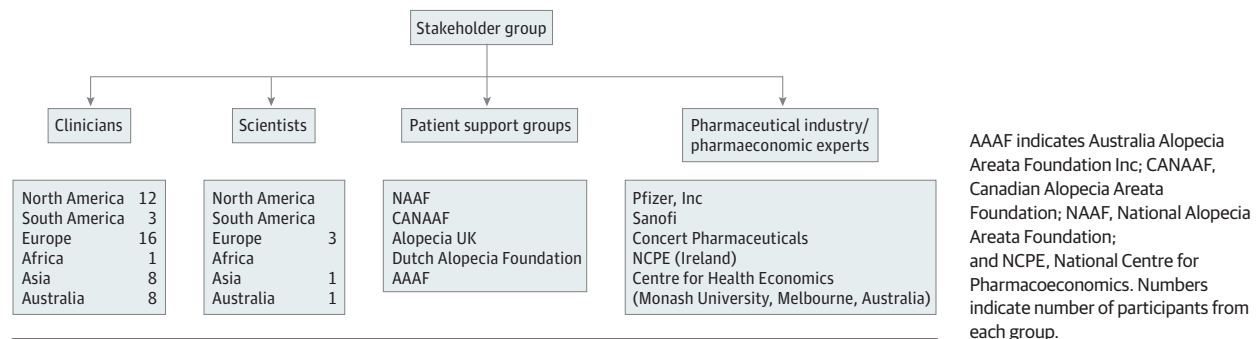
Questionnaire Design

A core panel of dermatologists, a health informatician, and a scientist (D.W., N.M., K.Y., B.B., L.B., and R.S.) developed the primary questionnaire. A systematic literature review, analysis of existing registries, and multiple round table discussions were undertaken to identify and incorporate core domains (categories) and domain items (specific measures) for an alopecia areata registry. Two patient pathways were considered: new enrolment and already enrolled. Domains and domain items pertained to each stream; patient-reported outcome measures (PROMs) were considered separately. In total, 25 domains containing 97 domain items were identified for round 1.

eDelphi Survey

The eDelphi questionnaire was distributed using DelphiManager, an online eDelphi management tool, maintained by the COMET (Core Outcome Measures for Effectiveness Trials) Initiative and used in similar exercises.^{9,20} A comprehensive summary outlining study aims, the eDelphi process, scoring instructions, expected timeline, and a link to participate were emailed to participants. Each domain item was scored on a scale from 1 (absolutely not important) to 9 (absolutely critical) or unable to score. Where indicated, a help text option for each domain item provided additional context, clarification, and explanation of abbreviations. Comments and further items for inclusion in future rounds were invited for each item. Scores of 1 to 3 represented domain item rejection; 7 to 9, acceptance; and 4 to 6, equivocal. Consensus threshold was defined as at least 66.7% agreement or disagreement with each statement. Consensus agreement domains were identified as core items, whereas consensus disagreement domains were identified as noncore (optional) items. These were retained in the final data set to ensure data comparability across sites choosing to capture them. Timelines were reinforced by reminder emails to increase response rate. An independent

Figure 1. Stakeholder Group Participation



observer monitored the final face-to-face meeting on June 14, 2019, in Milan, Italy. We used R, version 3.5.3 (R Foundation for Statistical Computing) statistical software package for data analysis.²¹

Results

Participants

Figure 1 represents a summary of stakeholder group participation. Of 88 invited participants, 66 (75%) completed round 1; 63 (72%), round 2; and 18 (20%), round 3. Round 1 was completed by 49 clinicians (73%), 5 patient representatives (8%), 6 pharmaceutical industry representatives (9%), 2 pharmacoeconomics experts (3%), and 5 scientists (8%). Round 2 was completed by 46 clinicians (73%), 5 patient representatives (8%), 5 pharmaceutical industry representatives (8%), 2 pharmacoeconomics experts (3%), and 5 scientists (8%). Representation at the face-to-face final stage was by 17 clinicians (94%) and 1 pharmaceutical industry representative (6%).

Delphi Rounds

Rounds 1 and 2

Figure 2 summarizes all rounds of the Delphi process. Following round 1, consensus was achieved for 63 of initial 97 domain items (65%). Nine additional domain items proposed by participants were accepted and submitted for round 2. These included gluten sensitivity, but not diagnosed celiac disease/nonceliac gluten sensitivity; other potential triggers; hair color; effect on family members; bodily symptoms not classified with an official diagnosis; alexithymia assessment questionnaire; questionnaire specifically assessing ability to cope with or process stressors/stress; hair pigmentation anomaly (either during hair loss or hair regrowth); and hair regrowth of at least 50%. Round 2 achieved consensus for 14 of 39 domain items (36%). The remaining 25 domain items were discussed at the face-to-face consensus meeting.

Consensus Meeting (Round 3)

The final round, the face-to-face meeting, took place at the 2019 World Congress of Dermatology in Milan. Representation was from 17 clinicians and 1 pharmaceutical industry representative. An additional data item fulfilled the criteria for discussion; thus 26 domain items were debated for consensus. A summary of prior rounds was presented to participants.

New Enrollment/Baseline Visit

On completion of the first 2 rounds, consensus was achieved for baseline domains and domain items: consent, concomitant medication, current alopecia areata treatment, past alopecia areata treatment, adverse effects, treatment response, management intended at first review, and prognostic indicators (Table).²⁴⁻³⁴ A number of domain items from other baseline categories also reached consensus threshold for inclusion in the alopecia areata registry. Baseline domain items addressed at the face-to-face meeting with proposed recommendations are as follows.

Demographic Data

Educational status and current occupation or education were determined as noncore domain items. Recommendations were made to identify appropriate income brackets and international classification systems to capture socioeconomic data for those who wish to record these data.

Etiopathogenesis

Gluten sensitivity but not diagnosed celiac disease/nonceliac gluten sensitivity (NCGS) was deemed a noncore item. A recommendation was made to identify a pragmatic and reliable means of capturing NCGS before recording it in a global alopecia areata registry for voluntary recording. This correlates with existing literature relating to NCGS, in which an absence of diagnostic biomarkers and uncertainty regarding its place as a clinical entity has made it a diagnosis of exclusion.^{32,35-37}

Disease Triggers

Other potential triggers were determined to be a core domain item. Development of a standardized list of alopecia areata triggers was recommended.

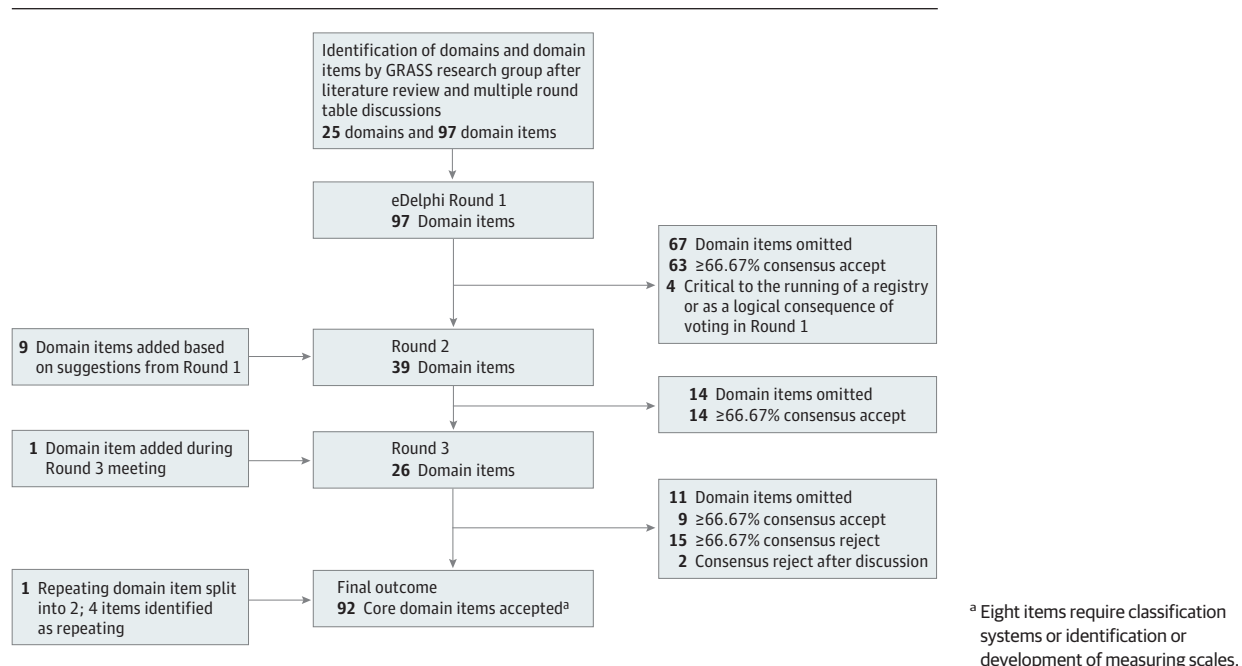
Baseline History

Days lost from usual activities was determined to be a core domain item. However, a reliable definition of the term is required before it can be recorded in a registry.

Baseline Clinical History

Fitzpatrick skin phototype, ethnicity, and original hair color were deemed core domain items. Identification of a validated list of ethnicities and definition of hair color was recommended.

Figure 2. The Global Registry of Alopecia Areata Disease Severity and Treatment Safety (GRASS) eDelphi Exercise



Baseline Investigations

Routine blood tests (including complete blood cell count [FBC], measurement of urea and electrolyte levels [U&E], and liver function tests [LFTs]) and recording of baseline scalp biopsy findings were confirmed noncore optional domain items. Additional blood tests for autoimmune disease were confirmed pertinent for an alopecia areata registry. Although a registry should ideally incorporate these data, preferably through importing data from existing electronic health records/data repositories, manual entry would be prohibitive. Recommendations were made to develop facilities to enable this.

Already Enrolled Patients With Alopecia Areata/Follow-up Visit

Voting regarding domains pertaining to follow-up visits reflected voting regarding baseline data, with all items accepted as core, except in the domain follow-up investigations, where routine blood tests (no consensus) and other investigations (consensus disagreement) were considered to be noncore items (Table). Follow-up specific data items were also considered core, including hair pigmentation anomaly (either during hair loss or hair regrowth), response, and hair regrowth of at least 50%.

Support Group Membership and PROMS

Alopecia areata association membership was identified as a core domain item at baseline but not follow-up. PROMs, including Skindex-29,^{28,33} Hairdex,³⁴ the 36-Item Short Form Health Survey,²⁵ and the Alexithymia Assessment Questionnaire, did not achieve consensus for core item inclusion. Submitted participant suggestions included a questionnaire to specifically assess ability to cope with or process stressors/stress, bodily symptoms not classified with an official diagnosis, and effect on family members if applicable. The

first 2 items failed to achieve consensus for core item entry; however, the latter succeeded.

It was recognized that ideally a registry should be capable of capturing any potential PROM; however, resource limitations may hinder this. Recommendations were to focus on capture of Alopecia Areata Quality of Life Index (AA-QLI/AAQ),²⁶ Alopecia Areata Symptom Impact Scale (AASIS),^{27,29} and Dermatology Life Quality Index (DLQI)^{30,31}/Dermatology Quality of Life Scales (DQOLS),²² along with defining an appropriate measure of the effects of alopecia areata on family members, given the additional effect on patients' families. There was consensus rejection of Skindex-29, Hairdex, and 36-Item Short Form Health Survey as core items to record at follow-up visits.

Summary of Results

This eDelphi process identified 92 core and 20 noncore items. Eight of the former and 9 of the latter require further work to enable recording within a patient registry, for example, identification or development of appropriated classification systems and measurement scales.

Discussion

This study will enable the development of the first alopecia areata patient registry developed by an international, multiple-stakeholder group. The endorsement of this core set by the group has the capacity to improve data quality through harmonization of data and, more importantly, of core stakeholders involved in implementing alopecia areata patient registries across the globe.

Further work is currently addressing the domain items at a more granular level to facilitate their accurate and consistent measurement. Although some data are self-evident (eg, date of birth), other

Table. Domains and Domain Items for a Global Alopecia Areata Patient Registry^a

Domain	Domain items	Core	Comments
New enrollment/baseline visit			
1. Demographics	Date of birth	Core	None
	Date of enrolment into registry	Core	None
	Gender	Core	None
	Ethnicity	Core ^b	Requires identification of appropriate classification system
	Educational status	Noncore ^b	Requires identification of appropriate classification system
	Current occupation or education	Noncore ^b	Requires identification of appropriate classification system
	Location and name of treatment center	Core	None
2. Etiopathogenesis	History of autoimmune disease	Core	None
	History of allergic comorbidities	Core	None
	Patient comorbidities	Core	None
	Family history of alopecia areata, atopy, or autoimmune disease	Core	Record specific diseases
	Gluten-sensitivity but not diagnosed celiac disease	Noncore ^b	Requires availability of diagnostic biomarkers and criteria
3. Disease triggers	Stressful life event preceding current episode	Core	None
	Environmental history (infection/vaccination history)	Core	None
	Other potential triggers	Core ^b	Requires standardization of expandable list of triggers
4. Baseline history	Days lost from usual activities	Core ^b	Requires further work to define usual activities to facilitate objective measurement
	Adherence to therapy	Core ^b	Requires identification of appropriate scale
5. Baseline clinical features	Fitzpatrick skin phototype	Core	None
	Hair color	Core ^b	Requires development of appropriate classification system
	Nail changes	Core	Including nail pitting, longitudinal ridging, and trachyonychia
	Shedding scale and score	Core	None
	SALT ^{22,23}	Core	None
	SSA ²²	Core	None
	ALODEX ²⁴	Core	None
	Trichoscopic signs of activity	Core	Including yellow dots, black dots, exclamation mark hairs, broken hairs, other
	Hair pull	Core	None
	Alopecia areata phenotype	Core	Patch, ophiasis, sisaipho, alopecia totalis, alopecia universalis, diffuse
	Body hair involvement	Core	None
6. Investigations	Routine blood tests	Noncore	Including FBC, U&E, and LFTs
	Additional blood tests for autoimmune disease	Core	None
	Scalp biopsy	Noncore	Including anatomical site, number of biopsies, biopsy type, sections, and report
7. Consent	Consent to biomaterial	Core	None
	Consent to images	Core	None
8. Concomitant medication	Concomitant medication	Core	Other than specific alopecia areata medication
9. Current alopecia areata treatment	Topical therapy	Core	None
	Intralesional therapy	Core	None
	Phototherapy	Core	None
	Systemic therapy	Core	None

(continued)

Table. Domains and Domain Items for a Global Alopecia Areata Patient Registry^a (continued)

Domain	Domain items	Core	Comments
10. Past alopecia areata treatment	Topical therapy	Core	None
	Intralesional therapy	Core	None
	Phototherapy	Core	None
	Systemic therapy	Core	None
11. Adverse effects	Current treatment	Core	None
	Previous treatment	Core	None
12. Treatment response	Treatment response	Core	Marked improvement, some improvement, no change, some deterioration, marked deterioration
13. Management intended at first review	Topical therapy	Core	None
	Intralesional therapy	Core	None
	Phototherapy	Core	None
	Systemic therapy	Core	None
	Current treatment discontinued	Core	None
	Reason for discontinuation	Core	None
14. Prognostic indicators	No. of relapses in 12 mo	Core	None
	Age of onset of alopecia areata	Core	None
	Duration of longest disease episode	Core	<6, 6-12, and >12 mo (if possible to specify)
	Phenotype of longest disease episode	Core	Current disease duration and phenotype will be captured by current history
	Predominant alopecia areata phenotype	Core	Patch, ophiasis, sisaipho, alopecia totalis, alopecia universalis, diffuse
	Previous history of alopecia totalis/alopecia universalis	Core	None
15. PROMs/quality of life measures	Patient-reported symptoms	Core	None
	Patient global assessment	Core	Marked improvement, some improvement, no change, some deterioration, marked deterioration
	AA-QLI/AAQ ²⁵	Core	None
	AASIS ^{26,27}	Core	None
	Hairdex ²⁸	Noncore	None
	DLQI ^{29,30} /DQOLS ³¹	Core	None
	Skindex-29 ^{32,33}	Noncore	None
	SF-36 ³⁴	Noncore	None
	Effect on family members, if applicable	Core ^b	Requires further work to define appropriate means of measuring personal and socioeconomic impact
	Bodily symptoms not classified with an official diagnosis	Noncore ^b	Requires appropriate classification system
Alexithymia assessment questionnaire	Noncore ^b	Requires appropriate classification system	
Questionnaire specifically assessing ability to cope with or process stressors/stress	Noncore ^b	Requires appropriate classification system	
16. Alopecia areata organization membership	Membership of alopecia areata associations	Core	Capturing specific group membership
Already enrolled/follow-up visit			
17. Follow-up history	Days lost from usual activities	Core ^b	Requires further work to define usual activities to facilitate objective measurement
	Adherence to therapy	Core	None
18. Follow-up examination general	Nail changes	Core	Including nail pitting, longitudinal ridging, and trachyonychia

(continued)

data, such as defining hair color, require further work. The creation of a network ideally placed to solve such a problem is a benefit of undertaking patient registry development exercises worth highlighting.

Although the list of core domain items may seem burdensome, it is worth noting that a considerable number of items are accounted for by the need to capture the same data at multiple time points. For example, the Severity of Alopecia Tool (SALT)^{23,38} and

score are expected to be captured at baseline and follow-up visits, whereas systemic therapy is captured on multiple occasions, reflecting past, current, intended, and future management. The Table is formatted to reflect the sequential manner in which registry data are typically generated in alopecia areata clinical encounters and, as such, is intended to be a useful tool to facilitate development of more user-friendly registry software.

Table. Domains and Domain Items for a Global Alopecia Areata Patient Registry^a (continued)

Domain	Domain items	Core	Comments
19. Follow up examination hair	Shedding scale and score	Core	None
	SALT ^{22,23}	Core	None
	SSA ²²	Core	None
	ALODEX ²⁴	Core	None
	Trichoscopic signs of activity	Core	Including yellow dots, black dots, exclamation mark hairs, broken hairs, other
	Hair pull	Core	None
	Hair pigmentation anomaly either during hair loss or hair regrowth	Core	Spontaneous or treatment associated
	Alopecia areata phenotype	Core	Patch, ophiasis, ssaipho, alopecia totalis, alopecia universalis, diffuse
	Body hair involvement	Core	None
	Eyebrow	Core	None
20. Follow-up treatment response	Response	Core	Marked improvement, some improvement, no change, some deterioration, marked deterioration
	Hair regrowth of ≥50%	Core	Requires further work to identify meaningful response for patients
21. Follow-up adverse effects	Serious adverse events attributed to current treatment	Core	None
22. Follow-up investigations	Routine blood tests	Noncore	FBC, U&E, and LFTs
	Other investigations	Noncore	Other blood investigations or biopsies
23. Follow-up management	Topical therapy	Core	None
	Intralesional therapy	Core	None
	Phototherapy	Core	None
	Systemic therapy	Core	None
	Current treatment discontinued	Core	None
24. Follow-up PROMs/quality-of-life measures	Reason for discontinuation	Core	None
	Patient-reported symptoms	Core	None
	Patient global assessment	Core	Marked improvement, some improvement, no change, some deterioration, marked deterioration
	AA-QLI/AAQ ²⁵	Core	None
	AASIS ^{26,27}	Core	None
	Hairdex ²⁸	Noncore	None
	DLQI ^{29,30} /DQOLS ³¹	Core	None
	Skindex-29 ^{32,33}	Noncore	None
	SF-36 ³⁴	Noncore	None
	Effect on family members, if applicable	Core ^b	Requires further work to define appropriate means of measuring personal and socioeconomic effects
Bodily symptoms not classified with an official diagnosis	Noncore ^b	Requires appropriate classification system	
Alexithymia assessment questionnaire	Noncore ^b	Requires appropriate classification system	
Questionnaire specifically assessing ability to cope with or process stressors/stress	Noncore ^b	Requires appropriate classification system	
25. Follow-up alopecia areata organization membership	Membership of alopecia areata associations	Noncore	Capturing specific group membership

Abbreviations: AA-QLI/AAQ, Alopecia Areata Quality of Life Index; AASIS, Alopecia Areata Symptom Impact Scale; ALODEX, Alopecia Density and Extent Score; DLQI, Dermatology Life Quality Index; DQOLS, Dermatology Quality of Life Scale; FBC, full (complete) blood cell count; LFTs, liver function tests; PROM, patient-reported outcome measures; SALT, Severity of Alopecia Tool Score; SSA, Scalp Surface Area; SF-36, 36-Item Short Form Health Survey; U&E, measurement of urea and electrolyte levels (renal profile).

^a Organized to reflect the sequential manner in which data are generated during typical alopecia areata clinical encounters to facilitate development of a patient registry that can be incorporated within a clinic or be used to retrospectively harvest data from patient notes more easily.

^b Denotes a requirement for further work by the group to enable accurate measurement of the domain item.

It is envisaged that the core data set and its nomenclature will evolve with implementation of a network of patient registries, and the feasibility of their data collection will reveal more minimal, practical core data sets. Such iterative changes stress the requirement to conduct network building exercises, to ensure diverse needs are met in data item specification and nurture communication and collaboration among a group of representative stakeholders capable

of promoting cohesive development of registries throughout the alopecia areata community.

In view of the potential financial effects of divergent attempts to develop costly patient registries in an area where resources are limited and at a time when privacy and security requirements are becoming more costly, parallel work is under way to develop a prototype registry. It is proposed that this prototype can then be

reused by members of the network to create the Global Registry of Alopecia Areata Disease Severity and Treatment Safety (GRASS). In a further cost-saving effort, this group will reuse technology developed to capture an implementation of the TREAT Registry Taskforce. In addition to direct cost-savings, a central registry design philosophy has the capacity to promote data harmonization in a longitudinal manner because future design iterations can be made centrally and extended to all centers using the software.

By reusing the domains and domain item framework developed by the TREAT Registry Taskforce, facilitating cross-disease harmonization of data collection, developing and strengthening collaboration with other networks to share knowledge and resources, and highlighting the value of standardization of data collection are possible. It is envisaged that this approach has a capacity to enable clinical need to direct information technology and patient registry development, rather than the often-infuriating experience of technology dictating clinical activity.

Limitations

Although considerable efforts were made to recruit significant numbers of participants from each representative group, physicians were overrepresented. In particular, greater participation from patients and their support groups is required. Of the 66 round 1 participants, 18 (27%) were present for the face-to-face round 3, reflecting the difficulty in facilitating global eDelphi projects. Consensus had been achieved for 77 of 106 domain items (73%) by this stage, however. Although alopecia areata patient registries will first be developed within clinical centers, their true value will only ever be fully

realized when emerging technology is harnessed to increase patient inclusion and enable integration of high-quality, patient-generated data. The current data set will be adapted based on real-world use in pilot registries that are in development. It is proposed that these projects will also present opportunities to identify and incorporate patient-identified data and extend the registries beyond the clinical setting to capture data regarding those with alopecia areata who do not present to a clinic, thereby generating data that more accurately reflects the true incidence, prevalence, and impact of alopecia areata in the population.

Conclusions

Through a 3-round global eDelphi process, reusing a framework published by the TREAT Registry Taskforce, and building on a multiple-stakeholder group developed by the ACE project, this study validated a data set capable of developing an alopecia areata patient registry.^{7-9,12,13} Pilot work is under way that reuses a platform that was implemented in a cross-border implementation by TREAT members with a view to creating a network of registries that will become the GRASS registry. The aim will be to increase intersubspecialty data harmonization and collaborative potential in addition to maximizing resources. Although further stakeholder, particularly patient, involvement will be necessary, we hope the capacity of this network to capture epidemiological in addition to safety and effectiveness data will be unprecedented and exceptionally valuable at a time when the treatment of alopecia areata is fundamentally changing.

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