Minutes

Introduction

The HOME VI meeting was held on Wednesday 11th April 2018, 09:00-12:00, at the Matthias Descartes Centre, Utrecht, The Netherlands. The meeting was held as a satellite to the 10th Georg Rajka International Symposium on Atopic Dermatitis.

Pre-meeting

A pre-meeting was attended by 17 from 5.30-6.30pm on Tuesday 10th April and was open to all participants, but was particularly designed to support patients attending the HOME IV meeting. Eric Simpson provided an overview of what to expect at the main meeting, and the reasoning behind the need for a clinical practice set. There was opportunity for questions and general discussion.

Main HOME VI meeting

The HOME VI meeting was chaired by Phyllis Spuls (Amsterdam, The Netherlands) and led by Eric Simpson (Portland, USA).

The aims of the meeting were to agree which instruments should be recommended for inclusion in the clinical practice set for the domain of symptoms and (if time) patient global assessment (PGA).

A total of 72 voting participants attended the meeting, including 11 patients (

Table 1). Participants were sent a copy of all the instruments that would be discussed, along with a summary of their measurement properties prior to the meeting.

	Responses	
	Percent	**Number**
Patient / parent / patient group representative	15.28%	11
Clinician	55.56%	40
Methodologist	12.50%	9
Pharmaceutical industry	16.67%	12
	100%	**72**

Table 1: Breakdown of attendees by stakeholder group

One of the founders of the HOME initiative, Hywel Williams (Nottingham, UK), opened the meeting, followed by an introduction to the concept of the clinical practice set for eczema from Eric Simpson. Yael Leshem presented the results of the pre-meeting prioritisation exercise. This contained a survey conducted within HOME in which respondents were asked to state what they considered to be their top 5 domains for the clinical practice set. The results indicated the most important domain to address was symptoms, with long-term control and patient global assessment second and third respectively (Figure 1Figure 1: Results of HOME prioritization exercise - % rating the domain in their

"top 5"). The results guided the focus of the work conducted by the clinical practice set working group prior to the HOME VI meeting and the content of the HOME VI meeting.

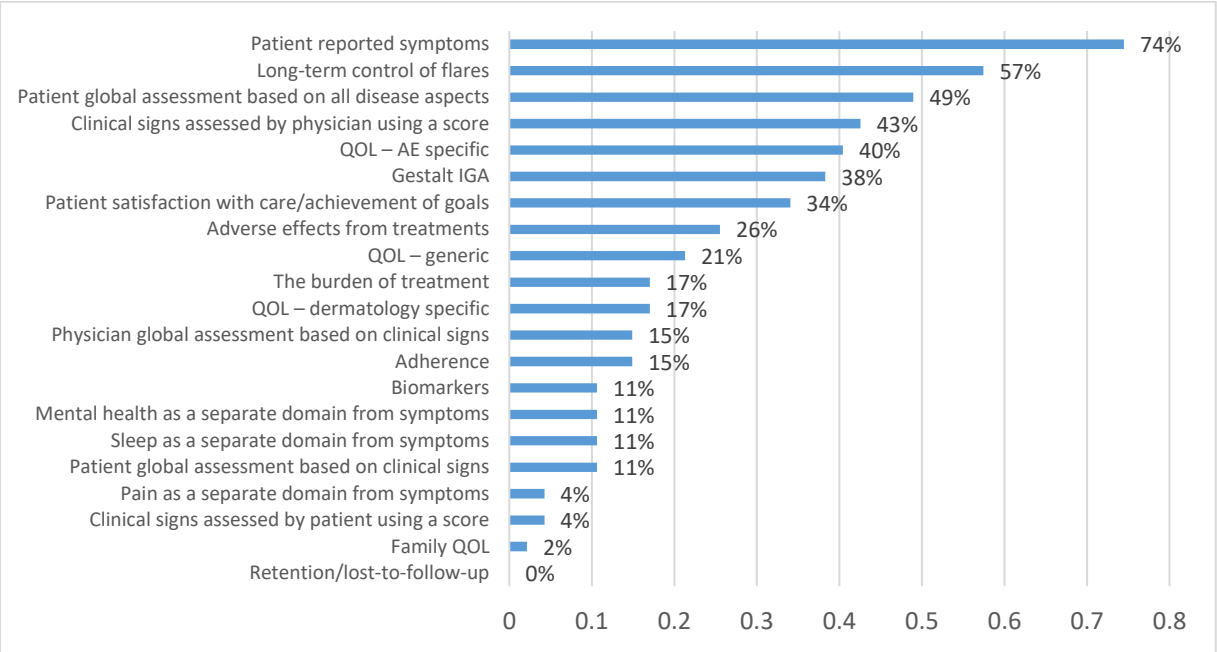

Figure 1: Results of HOME prioritization exercise - % rating the domain in their "top 5"

Yael Lesham reminded the group of the difference between the core outcome set (COS) for trials in which all of the four agreed essential core domains should all be measured using the recommended instruments, compared with the clinical practice set where *any* domains can be included. The concept of the clinical practice set is to provide a "pick and choose" list of instruments for each domain.

Symptoms domain

Louise Gerbens presented the measurement properties and the feasibility for each of the symptom outcome measurement instruments for eczema (Table 2 and Table 3) based on the previously published systematic review (1), which was updated for this meeting. In the update a further six validation studies (POEM, PO-SCORAD and PED-ISS) were included. All participants were provided with a copy of Table 3.

Rating	Criteria	Instruments
A	Meets **all required quality items** and is recommended for use	None
B	Meets **two or more required quality items** and has the potential to be recommended in the future depending on the results of further validation studies	Paediatric ISS, POEM, PO-SCORAD, SA-EASI, adapted SA-EASI
C	Has **low quality in at least one required quality criteria** and therefore is not recommended to be used any more	ADAM, EIQ, adult ISS, LIS, SDQ, ZRADSQ
D	**Has (almost) not been validated**. Its performance in all or most relevant quality items is unclear, so that it is not recommended to be used until further validation studies clarify its quality	ADQ, CoIQ, Method 4, NESS, subjective SCORAD, VAS pruritus, VRS pruritus

Table 2: Rating of symptoms instruments based on assessment of measurement properties

	Measurement properties - rating				Symptoms assessed			Time to complete (min)	Cost	Languages	App
	+	±	?	Not inv.	Itch	Sleep	Other				
Paediatric ISS	5		1	2	x			?	?	4	No
POEM	2	2	2	2	x	x	N=5	1-2	Free	11	Yes
PO-SCORAD	2	1		5	x	x	N=6	<5-10	Free	22	Yes
SA-EASI	2		1	5	x		N=4	?	?	2	No
Adapted SA-EASI	2			6	x		N=4	?	?	1	No
ADQ	1		1	6	x		N=5	<5	?	1	No
ColQ	1		2	5	x			15-20	?	1	No
Method 4			1	7	x	x		?	?	2	No
NESS			5	3	x			1	?	2	No
Subj SCORAD	1	1	3	3	x	x		10 (total score)	Free	9	No
VAS itch			1	5*	x			? (<1)	Free	1	No
VRS itch			1	5*	x			? (<1)	Free	1	Yes

Table 3: Summary of measurement properties and feasibility data for each instrument for patient-reported symptoms

Louise reminded the group that the definition of symptoms used by HOME (and agreed at HOME III) is "*a departure from normal function, appearance or feeling which is **noticed by a patient**, indicating the presence of disease or abnormality*" so this definition includes patient-reported clinical signs.

A discussion was held to discuss the instruments and the clinical practice set in general:

- Need to consider that this clinical practice set is also likely to be used in primary care as well as a dermatology specialist setting.
- The proposed instruments could be a mixture of symptoms and patient-reported signs.
- Some are better quality than others, and some are far easier to use than others.
- When considering feasibility, it should be remembered that it may be possible for patients to complete the instrument at home or in the waiting area prior to the clinical consultation.
- The overall burden on patients should be considered, particularly when the eczema is relatively controlled. Could use a simple "global" question when the eczema is controlled and more detailed instruments when the eczema is flaring. People may be more willing to complete questionnaires if the results over time are shared back with them.
- For the clinical practice set, some measurement properties such as inter-rater reliability are not as important as for clinical trials.
- Some instruments including PO-SCORAD and SA-EASI require an electronic version because the score calculation is complicated and otherwise not feasible to do in a clinic setting.

Yael Leshem presented the results of the pre-meeting task in which those registered for the HOME VI meeting were asked to categorise all instruments into i) definitely include, ii) possibly include and iii) definitely exclude from the clinical practice set. A total of 46 out of 73 registered for the meeting (63%) completed the task (Figure 2). The order in which the instruments were considered mirrored the results of the voting.

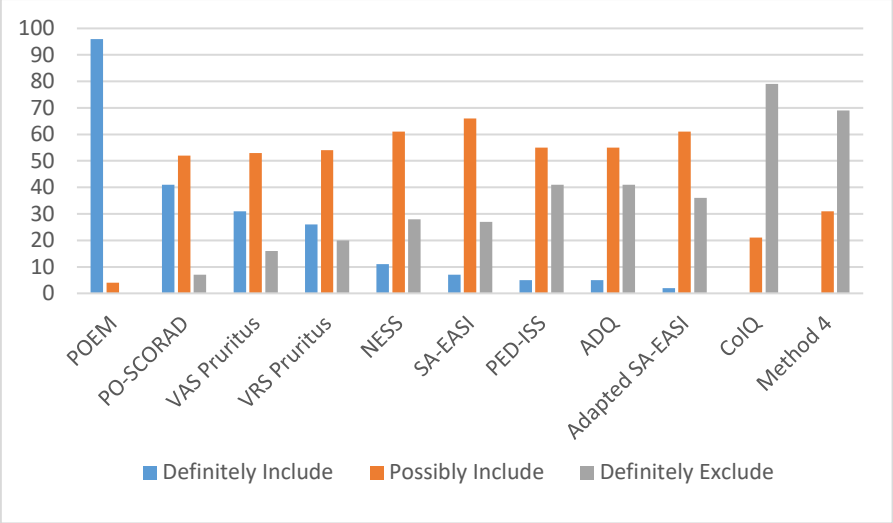

Figure 2: Results of pre-meeting task

The meeting was then opened for questions and discussion:

- Although numerical rating scale (NRS) for pruritus is generally liked and easy to use, in practice, the validation studies have been conducted in other skin conditions such as psoriasis.
- Only peer-reviewed papers are included in the systematic review of measurement properties, not abstracts or posters.
- Clarified that anyone with a strong conflict of interest for a particular scale e.g. developed or owned copyright should make this known prior to voting and refrain from voting.

Before considering instruments individually, a vote was held which confirmed that instruments rated as category C (i.e. low quality in at least one required quality criteria) - ADAM, EIQ, adult ISS, LIS, SDQ, ZRADSQ - should be excluded and were not considered further during the meeting (Table 4).

	Responses	
	Percent	**Number**
Yes	80.56%	58
No	11.11%	8
Unsure	8.33%	6
	100%	**72**

Table 4: Voting results on whether category C instruments should be excluded

Using a version of the "whisper technique" the group then discussed the remaining instruments (those in category B and D, Table 2) in groups of 3-4 people. Patient participants were encouraged to join different groups, so that nearly all groups included patient representation). Following this, each instrument was discussed in turn by the whole group and participants were invited to highlight any issues raised during the small group discussions.

Following the whole group discussion, a vote was held per instrument to determine whether it should be recommended for the clinical practice set. Prior to each discussion and vote, Eric Simpson reminded the group of the content of the instrument, its measurement properties, feasibility aspects including time to complete, cost, access, languages, whether an app version was available, and the results of the pre-meeting voting. The wording for the voting question for each instrument was: "*Do*

you agree to include the [instrument name] in the HOME Clinical Practice Set for assessing symptoms?" The only exception was for the NRS which was worded as "*Do you agree to include a provisional Numerical Rating Scale (NRS) Pruritus (to be defined) in the HOME Clinical Practice Set for assessing symptoms*?"

The results of the voting and the main discussion points raised for each instruments are summarised in table 5.

Instrument	Yes		No		Unsure		Did not vote [1]	Summary of discussion
	n	%	n	%	n	%	n	
POEM	70	98.59	0	0	1	1.41	2	• Delegates were in favour during the pre-meeting task and in the small group discussions.
PO-SCORAD	59	85.51	5	7.25	5	7.25	3	• Need more data on interpretation of the scores • Debate about the length of time it takes to complete. General agreement that it takes new patients longer (up to 15 minutes) • The guidance photos need to be printed in colour if paper version used. • Some concern that this is patients assessing signs, rather than a true symptoms instrument (although as defined by HOME, if reported by a patient, they are considered as part of a symptoms domain).
NRS (pruritus) [2]	65	92.86	3	4.29	2	2.86	0	• *Discussed as one group:* • Support for including a simple measure of itch. • One NRS on the table because it has some validation studies. • Feasibility issues with VAS; i) reproducibility a problem if printed out e.g. the scale length could be changed due to paper size, ii) takes time to measure where the mark is. NRS and VRS in contrast are very quick to do in clinic. • General support for VRS rather than VAS. • Recall period and peak versus average intensity need to be determined. • NRS was not originally included as an option due to lack of validation, but was added in as an extra vote due to overwhelming support in the meeting on the basis of extensive validation across a range of itchy skin conditions despite lack of specific validation for just eczema.
VAS (pruritus)	17	23.94	45	63.38	9	12.68	0	
VRS (pruritus)	12	17.14	55	78.57	3	4.29	0	
Subjective SCORAD (VAS)	13	17.81	52	71.23	8	10.96	1	
NESS	1	1.47	62	91.18	5	7.35	1	• This instrument was not designed for routine care or clinical trials, but as a screening tool or for use in epidemiological studies.
SA-EASI	4	5.71	62	88.57	4	5.71	0	• *Discussed as one group:* • Not accessible so not feasible for practice set. • The EASI group did not develop the SA-EASI. The patient assesses signs, and it is different to EASI
Adapted SA-EASI	2	2.86	65	92.86	3	4.29	0	
PED-ISS	6	8.33	62	86.11	4	5.56	0	• Only relevant for children. • Could add value as it asks detailed questions e.g. about itch pattern but this sort of information may be better elicited through discussion with the patient/parent as appropriate rather than requiring a formal instrument. • Although a proxy score it is worded as a self-completed questionnaire.

								• Asks about itch rather than scratching – may not be suitable for very young children.
ADQ	3	4.29	63	90.00	4	5.71	0	• Questions and response options were considered to be oddly worded. • The total score means little – difficult to interpret. • Only available as a proxy score. • Includes lots about itch and liked by patients
ColQ	1	1.39	67	93.06	4	5.56	0	• Extremely detailed and some of the questions considered to be not particularly relevant.
Method 4	1	1.43	64	91.43	5	7.14	0	• Unclear from validation studies exactly what should be included in the instrument.

[1] strong conflict of interest for a particular scale e.g. developed or owned copyright

[2] Provisional vote pending identification of a suitable instrument

Table 5: results of voting on category B and D instruments and main discussion points

General discussion points following voting:

- The group were in agreement that it is important for clinicians and patients to get a picture of the eczema severity *in between* clinic visits as well as reflecting the status at the time of the clinic visit. The clinical practice set is a set of pick and choose tools that could help with assessing the condition in between visits.
- These instruments are often a snapshot of the severity and shouldn't replace a thorough history taking.
- The list of recommended instruments needs to be inclusive enough to give options for clinicians (i.e. a "pick and choose" list) but not so long that it becomes unhelpful. The point of the clinical practice set is to provide guidance on how to measure the domains chosen to be important by the individual patient and/or clinician.
- Recall period is a difficult issue to address – suggestion from some patients that assessing severity of itch over the last week is impossible.
- The term "average itch" can be interpreted differently – average over time or average over the body?
- Peak itch is used most frequently. May be less important once the disease has been at least partly controlled by treatment.

Summary of recommendations for symptoms:

- The POEM and PO-SCORAD are included in the clinical practice set (fewer than 30% disagreed).
- NRS was provisionally recommended for inclusion but evidence on measurement properties and availability of potential instruments needs to be examined and will be presented at a future HOME meeting to inform discussions and voting to determine the exact content of the instrument. Instrument options will be presented as interim suggestions including those with validation studies from other chronic skin conditions (2) and those included in the TREAT registry (3).

Patient global assessment domain

There was insufficient time available to discuss the domain of patient global assessment. Confirmation of the preferred instrument(s) for assessing patient global assessment t will be carried forward to a future HOME meeting.

References

1. Gerbens LA, Prinsen CA, Chalmers JR, Drucker AM, von Kobyletzki LB, Limpens J, et al. Evaluation of the measurement properties of symptom measurement instruments for atopic eczema: a systematic review. Allergy. 2017;72(1):146-63.
2. Schoch D, Sommer R, Augustin M, Ständer S, Blome C. Patient-Reported Outcome Measures in Pruritus: A Systematic Review of Measurement Properties. Journal of Investigative Dermatology. 2017;137(10):2069-77.
3. Spuls PI, Gerbens LAA, Apfelbacher CJ, Wall D, Arents BWM, Barbarot S, et al. The International TREatment of ATopic Eczema (TREAT) Registry Taskforce: An Initiative to Harmonize Data Collection across National Atopic Eczema Photo- and Systemic Therapy Registries. Journal of Investigative Dermatology. 2017;137(9):2014-6.