PCN265 INITIATIVE TO OBTAIN ADVANCED THERAPEUTIC OUTCOMES IN MULTIPLE MYELOMA

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Background

- During the last years, efforts have been made to quantify multiple myeloma (MM) outcomes accurately using validated instruments[1]. This has led to a wide variability across instruments and variables, hindering outcome comparisons between physicians, institutions and regions. This concern has been addressed by the International Consortium for Health Outcomes Measurement (ICHOM) for various diseases[2], among which MM is not included.
- Therefore, there is an existing need of defining a set of global standards for collecting outcomes that matter most to patients with MM.

Aim

- **To define a Standard Set of outcomes and the most appropriate instruments to measure them for managing MM patients.**

Methods

A Scientific Committee led and coordinated the project. It consisted of 5 highly qualified experts in MM: **2 haematologists, 2 hospital pharmacists and 1 patient representative**

1 Literature Review

To identify MM clinical outcomes, Patient Reported Outcomes (PROs) and the instruments to measure them. The information obtained in the literature review was used to steer five discussion groups.

- The search included original articles, systematic reviews and clinical practice guidelines published in English or Spanish between January 2010 and October 2015.

2 Discussion groups

To share experiences and opinions about outcome variables, definitions, measures of relevance, and to establish the target population, in order to designate the consensual outcomes.

- 5 discussion groups composed by 4 haematologists, 4 hospital pharmacists and 7 patients facilitated the design of Delphi questionnaire.

3 2-Round Delphi consultation

To establish consensus regarding the most important outcome variables, their proper measurements and timeline of data collection for managing MM.

- Affirmative statements assessed the participants' perception related to outcome suitability and feasibility for use in routine clinical practice on a 7-point Likert scale.
- Consensus was reached for each statement when at least 75% of the respondents concurred or disagreed (entirely, mostly or somewhat).
- The 51 participants (20 haematologists, 24 hospital pharmacists and 7 patients) were identified by the Scientific Committee, the Spanish Program of Haematology Treatments Foundation (PETHEMA), the Spanish Society of Hospital Pharmacies (SEFH) and the Spanish Community of MM Patients (CEMMP).

Conclusions

- **A consensual Standard Set of outcomes for managing newly diagnosed MM patients has been defined. The feasibility of its implementation in routine practice will be assesses in a future pilot study.**

References: 1. Howlade N, Noone A, Krapcho M. SEER Cancer Statistics Review, 1975-2009 Vintage 2009 Populations. 2012 **2.** ICHOM 2016. http://www.ichom.org/ [22/06/2017]

Results

Scope

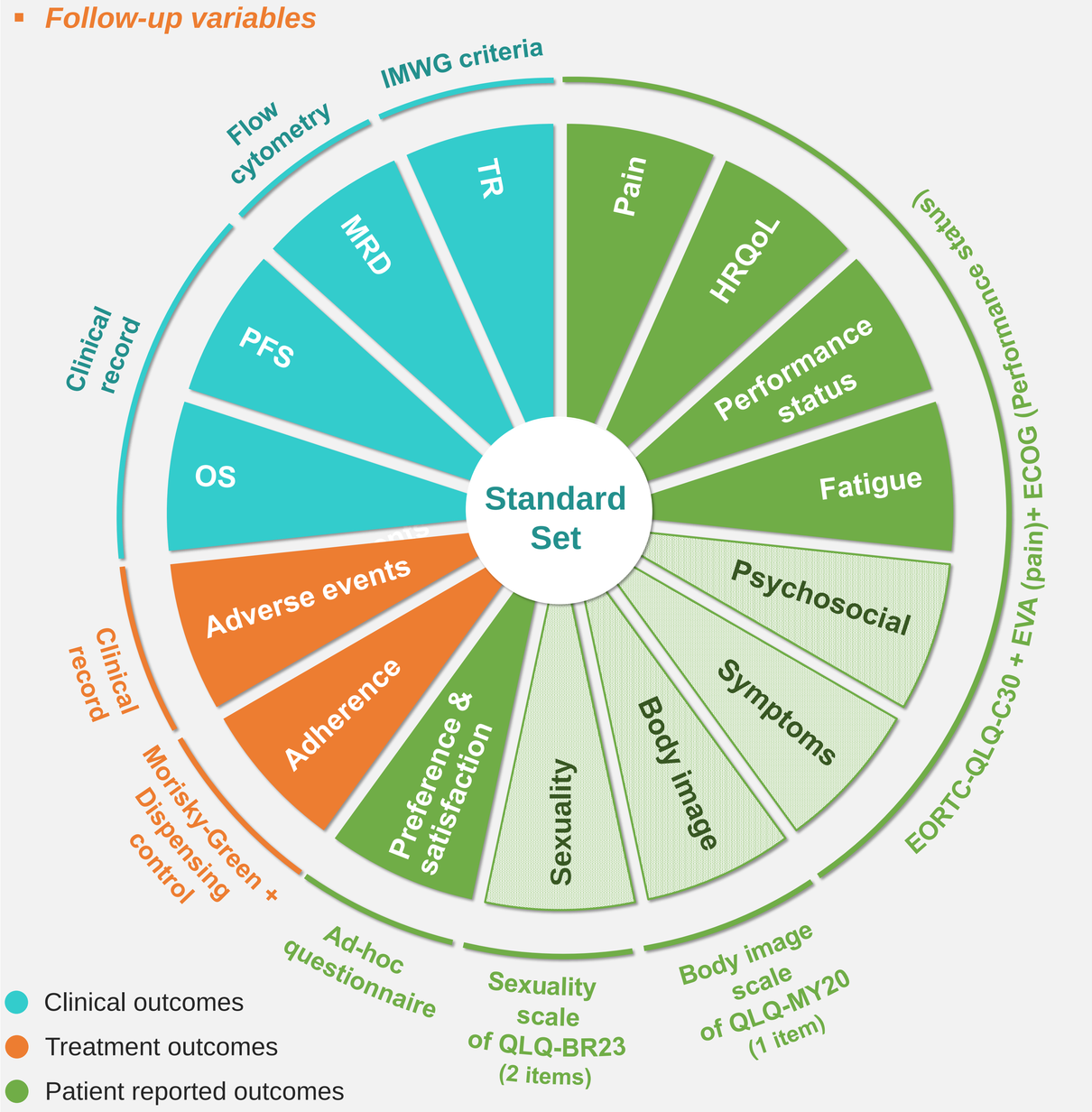
- Health professionals, participants in the discussion groups, agreed that the patients with **newly diagnosed MM** would be the target population for the MM Standard Set.

Standard Set

- ***Basal variables***

  Basal characteristics to be collected included age, gender, ethnicity, family history, international staging system, MM complications, comorbidities and treatment initiated.

- ***Follow-up variables***



Timeline for collecting variables

Variable	Basal	Treatment*			Follow-up / maintenance	Milestone
		Before	During	After		
Pain	X	X	Monthly**	X	-	-
HRQoL	X	X	-	X	Every 6 mth	-
Performance status	X	X	Monthly**	X	Every 6 mth	-
Fatigue	X	X	-	X	Every 6 mth	-
Psychosocial	X	X	-	X	Every 6 mth	-
Symptoms	X	X	-	X	Every 6 mth	-
Body image	X	X	-	X	-	-
Sexuality	X	X	-	X	-	-
Preferences & satisfaction	Preferences	-	-	Satisfaction	-	-
Adherence	-	At each dispensation				-
Adverse events	-	Monthly			Every 2-3 mth	-
OS	X	-	-	-	-	Decease
PFS		X	-	-	-	Progression
MRD	-	-	-	-	-	CR
TR	-	-	Monthly	-	Every 2-3 mth	-

HRQoL, Health Related Quality of Life. **OS**, Overall Survival. **PFS**, Progression Free Survival. **MRD**, Minimal Residual Disease. **TR**, treatment response. **CR**, Complete Remission. **Mth**, month.
* PROs: In continuous and long-term treatments (>6 months), every 2-3 months
** Only with EVA (pain) and ECOG (performance status).

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