

MERACT 2014

Budapest, Hungary | Hilton Budapest

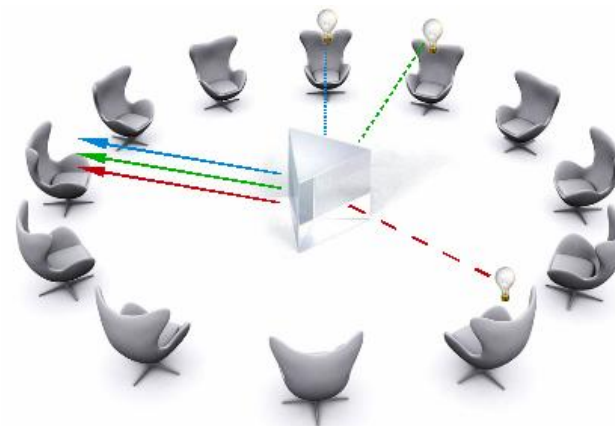
May 7 – 10, 2014





Pre-OMERACT May 2014 meeting:
Partnerships for Consensus
on
Patient-Important Outcomes
In
Cochrane Summary of Findings (SoF) Tables
using
PAIN as exemplar

Meeting Objective



- Develop a deliberative dialogue between, Cochrane ,OMERACT and other groups interested in achieving consensus on patient-important outcomes in **Musculoskeletal Pain and Function** in order to provide easy-to-understand optimal evidence for patient-important benefits and harms in systematic reviews of interventions.

Participating organizations

42 individuals

- OMERACT, including Patient Partners
- Cochrane Back Group
- Cochrane Musculoskeletal Group
- Cochrane Pain, Palliative and Supportive Care Group
- Cochrane Applicability and Recommendations Methods Group
- Cochrane Patient Reported Outcomes Methods Group
- Cochrane Editorial Unit
- COMET (Core Outcome Measures in Effectiveness Trials)
- COSMIN (COnsensus-based Standards for the selection of health Measurement Instruments)
- GRADE
- IMPACT/ACTION (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials/Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks)
- VAPAIN (Validation and Application of a core set of patient-relevant outcome domains to assess the effectiveness of multimodal pain therapy)

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The OMERACT Handbook

Maarten Boers, John Richard Kirwan, Peter Tugwell, Dorcas Beaton,
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who provided comments on earlier versions of the chapters of this Handbook.

Boers M, Kirwan JR, Tugwell P, et al. The OMERACT Handbook

Published by OMERACT, July 2014


Incorporating
The OMERACT Glossary

Compiled by Maarten de Wit and Pamela Richards

OMERACT 'FILTER'

TDF: Truth, Discrimination, Feasibility

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Developing Core Outcome Measurement Sets for Clinical Trials: OMERACT Filter 2.0

[Maarten Boers](#) , [John R. Kirwan](#), [George Wells](#), [Dorcas Beaton](#), [Laure Gossec](#), [Maria-Antonietta d'Agostino](#), [Philip G. Conaghan](#), [Clifton O. Bingham III](#), [Peter Brooks](#), [Robert Landewé](#), [Lyn March](#), [Lee S. Simon](#), [Jasvinder A. Singh](#), [Vibeke Strand](#), [Peter Tugwell](#)

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Concepts, Core Areas, & Domains

for Outcome Measurement in Health Intervention Studies

Concepts

Impact
of Health Conditions

Pathophysiological
Manifestations

Core Areas

Death

Life
Impact

Resource Use/
Economic Impact

Pathophysiological
Manifestations

Domains

- disease
- intervention

- ICF domains: activity and participation
- quality of life
- **Pain**
- patient perception of health
- loss of ability to work
- psychosocial impact
- 2^{ary} impact on family, caregivers
- utility

- societal
- individual
- health care
- direct/indirect (productivity)
- intangible costs

- ICF: body function and structure
- organ function (eg lung function)
- reversible manifestations
- irreversible manifestations
- biomarkers
- surrogate outcomes

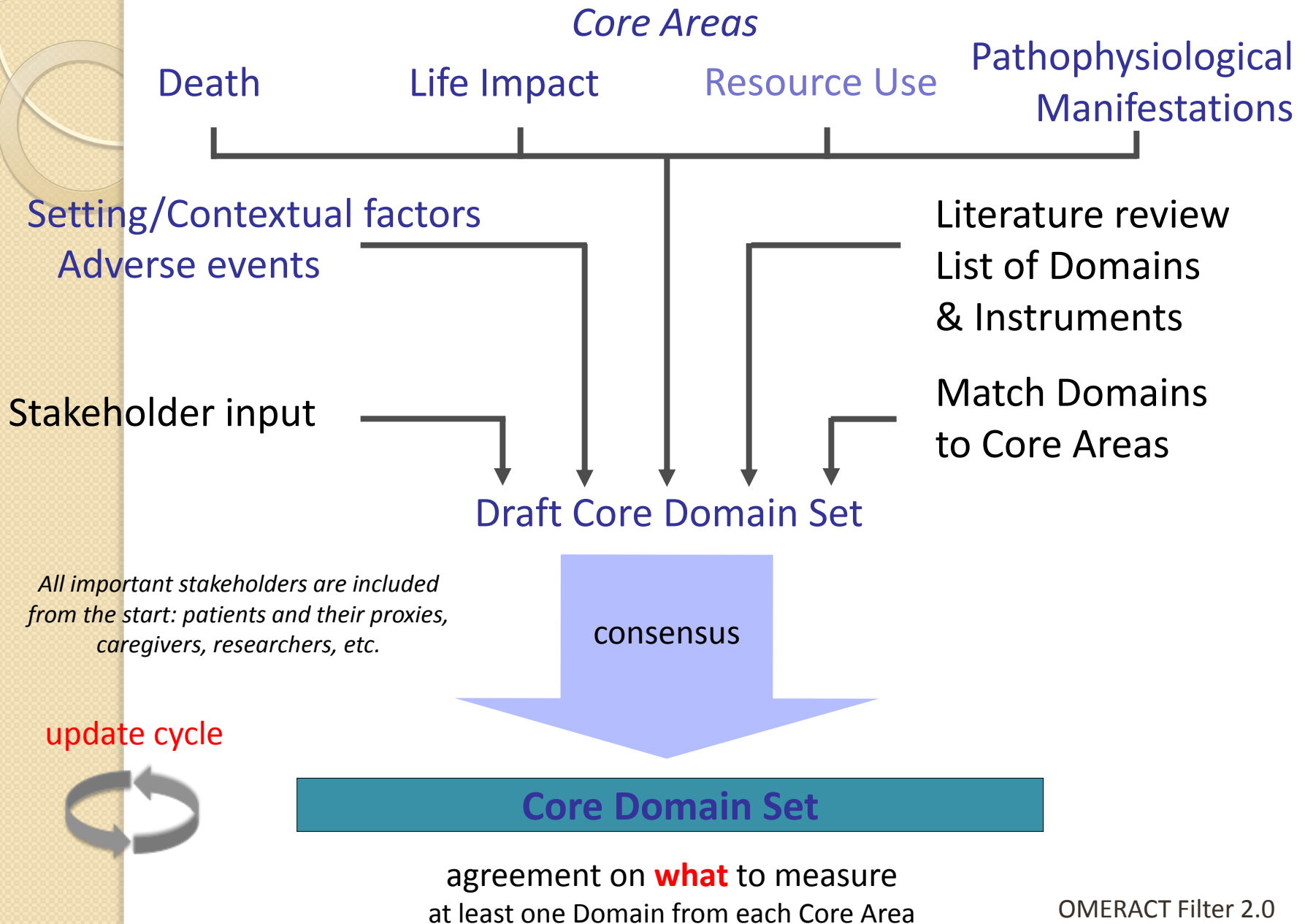
Examples of specific Domains within Areas

Adverse Events

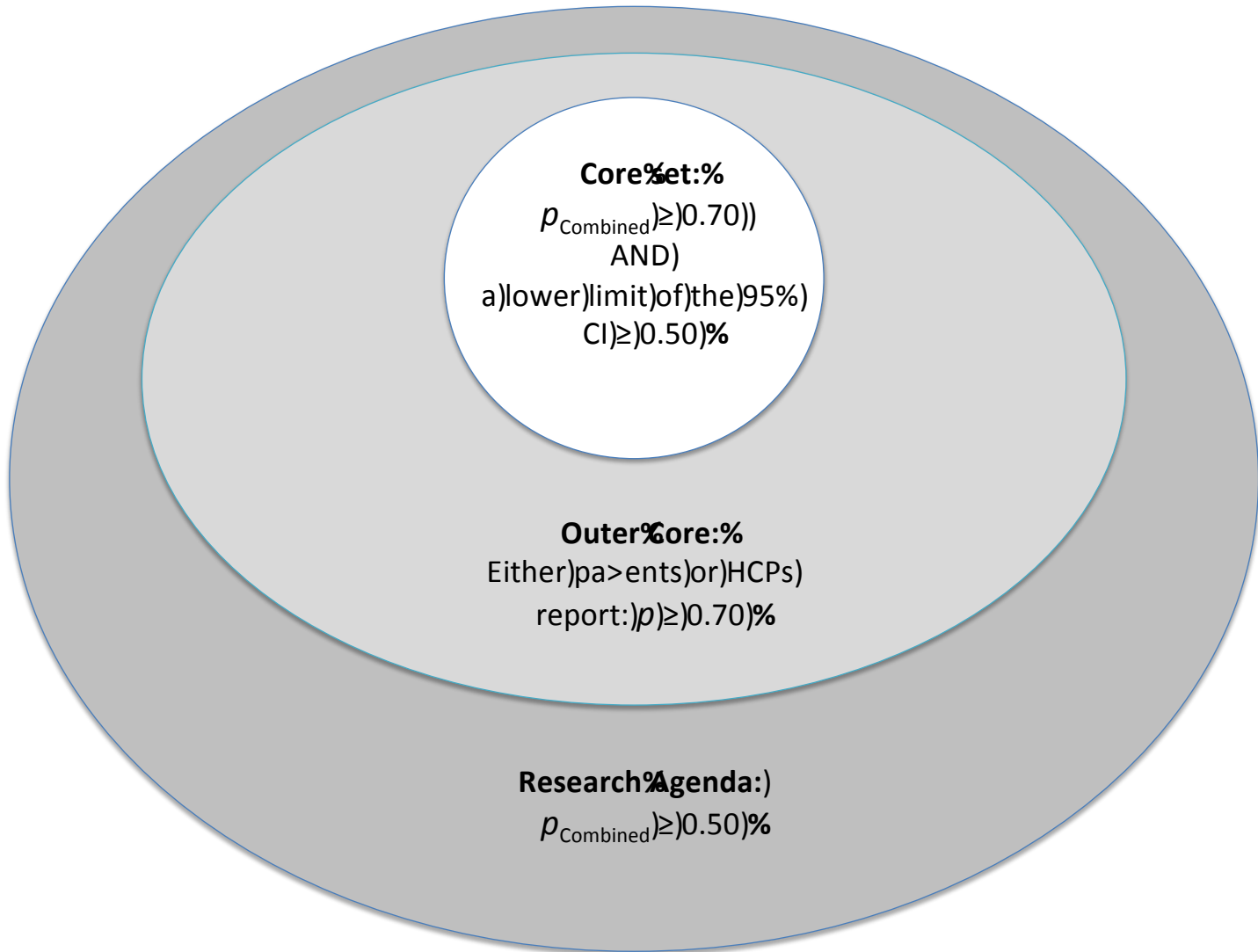
are measured within the core areas, but are labeled separately to allow assessment of benefit and harm.

Choices Influenced by Context

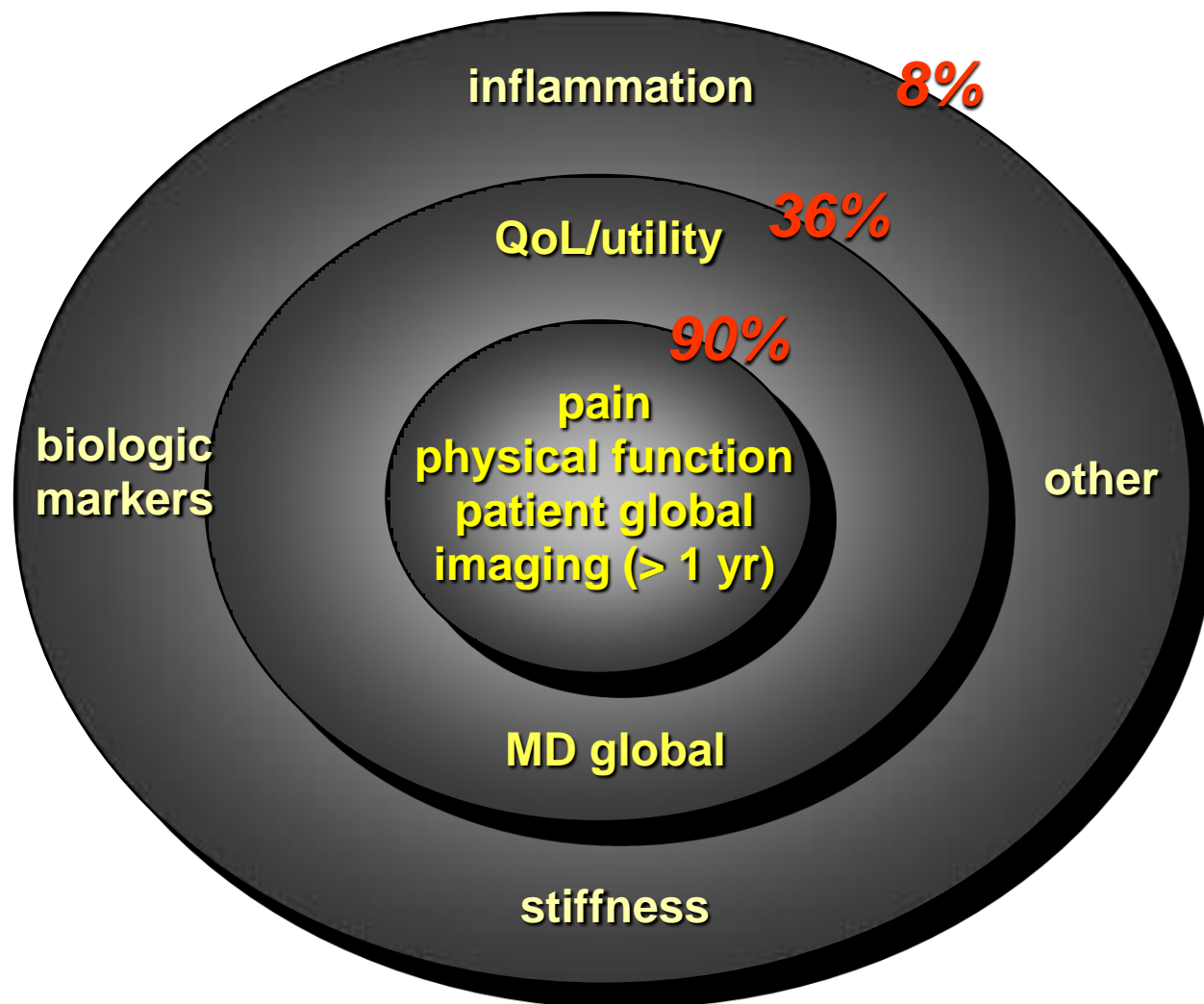
Developing a Core Domain Set



“OMERACT Onion model”



Example: Core Domain set Osteoarthritis



Background work

Lara Maxwell



1. Assessment of **Pain Outcomes** in all Cochrane Reviews covering musculoskeletal conditions from the Back, Musculoskeletal, and Pain, Palliative, and Supportive Care Cochrane Review Groups
2. Survey and interviews with key stakeholders: how to best present **Pain Outcomes** in Cochrane Summary of Findings tables in systematic reviews of interventions for chronic pain conditions?



Background work

Lara Maxwell



1. MSK Reviews reported over 40 different Pain Domains, Instruments and thresholds.
2. Variability = substantial problems for both the science of evidence synthesis, and the interpretability
3. Survey and interviews identified 4 themes for a future research agenda; develop partnerships to build consensus

4 Workshop Themes



I. Pain Domains

A] Is Pain a 'Disease/Condition/Symptom

B] In Cochrane Summary of Findings which 1-2 Pain Domains should be 'core'

Pain Intensity vs Pain Interference with Function
Change and/ or State

Workshop Themes



2. Instrument Clinimetric considerations

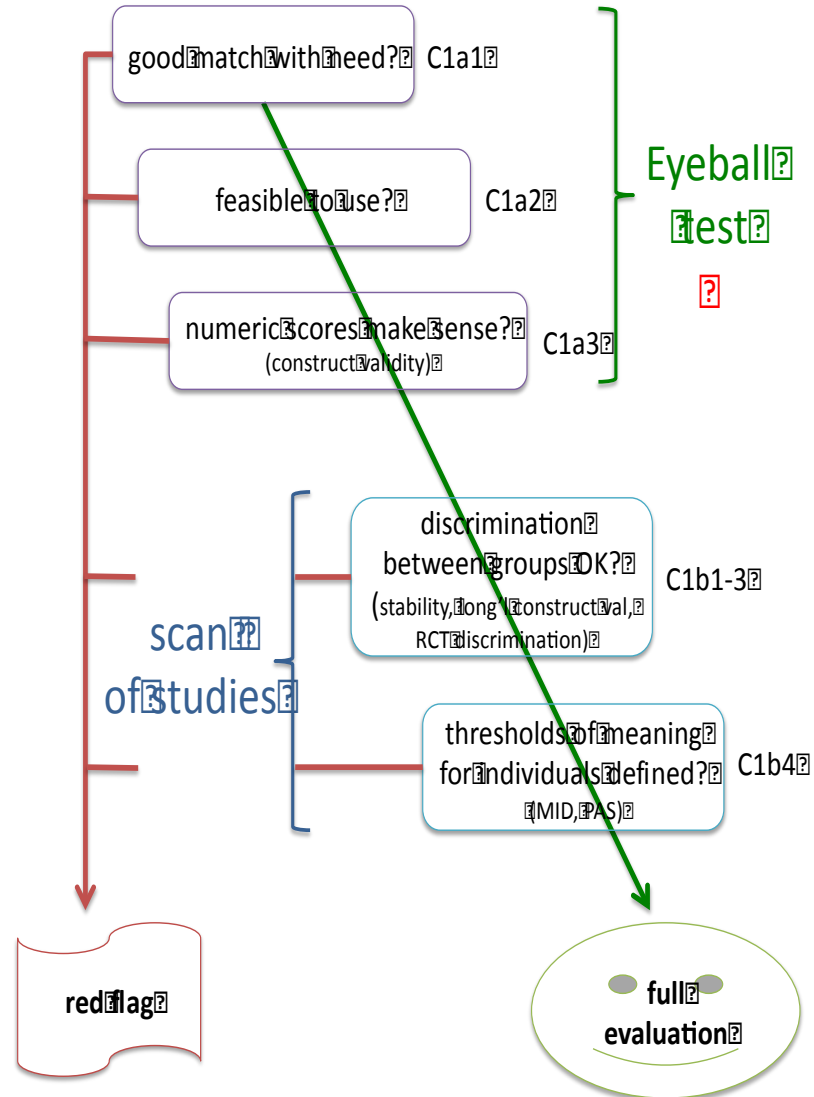
- Deciding on measurement property criteria to ensure instruments measuring pain meet requirements
- OMERACT Filter 2.0 flowchart; stepwise approach to evaluating measurement properties







OMERACT Filter 2.0 Instrument Selection Algorithm
















domain


instrument





TRAFFIC LIGHT OMERACT APPROVAL SYSTEM (each element is graded on the level of evidence):

-  = +++ = two or more studies with evidence supporting this property in A/MSK
-  = ++ = one study with evidence supporting this property in A/MSK
-  = (+) = there is evidence of this property, but not in A/MSK
-  = - = insufficient evidence of achievement of this property found.

Instrument	Eyeball test: (Truth & Feasibility)			Scan of studies (Discrimination)	
	good match with need?	feasible to use?	numeric scores make sense? <small>Construct validity</small>	discrimination between groups OK? <small>stability, long^l construct val, RCT discrimination</small>	thresholds of meaning for individuals defined? <small>(MID, PAS)</small>
	1C1a	1c1b	1C1c	1C2a-c	1C2d
Gout: SF-36-PF10					
NRS Pain					
WP: WALS					

 **Green** – good to go on this criterion

 **Yellow** – caution; pay attention to this aspect

 **Red flag** -- insufficient supporting evidence

A. OMERACT Checklist for developing Core Outcome Measurement Sets

OMERACT Checklist for developing Core Outcome Measurement Sets				
Chapter/ Section/ Paragraph	Item	Not	Answer	Green
2.B.1.1	Working group in place and agreed by OMERACT Exec			
2.B.2.1	Stakeholder groups and their contacts identified			
2.B.3.1	Protocol for literature review of domains (and instruments)			
2.B.4.2	Protocol for consensus procedures			
2.B.4.3	Consideration of specific adverse events			
2.C.1.1	Definition of context: scope and setting			
2.C.2.1	Decision on inclusion of Resource Use			
2.C.3.1	Literature review of domains undertaken			
2.C.4.1	Identification of other domains			
2.C.4.2	Conduct of consensus procedures for domains			
2.C.5.1	Development of draft Core Domain Set			
2.C.6.1	Core contextual factors			
2.C.7.1	Core adverse effects agreed			
2.C.8.1	OMERACT consensus on Core Domain Set and timeline for update cycle			
2.D.0.1	Protocol for literature review of instruments			
2.D.0.6	Apply the OMERACT OFISA review:			
2.D.1.1	Eyeball test:			
2.D.2.1	Good match with need			
2.D.3.1	Feasible to use			
2.D.4.1	Numeric scores make sense			
	Scan of studies:			
	Discrimination between groups OK?			
2.D.5.1-4	Stability in situations of no change (test-retest reliability)			
2.D.6.1-4	Detecting change in situations of change (longitudinal construct validity)			
2.D.7.1-10	Sensitivity to change in the context of an RCT			
2.D.8.1-8	Thresholds of meaning for individuals defined			
	Apply full evaluation:			
9.A To be developed	Domains well defined			
	All Domains well characterized			
9.B To be developed	Document 'truth' of each instrument			
	Face validity			
	Content validity			
	Construct validity			
	Document 'discrimination' of each instrument			
	Test-retest reliability			
	Longitudinal construct validity			
	RCT discrimination			
	Thresholds of meaning			
	Document 'feasibility' of each instrument			
	Respondent burden			
	Monetary and other costs			
	Interpretability of results			
	Fit for recommended application			
	Identify the need for any instrument development			
	Develop or invent any instruments required			
	Preliminary Core Outcome Measurement Set and timeline for completion			
	Core Outcome Measurement Set and timeline for update cycle			

Workshop Themes



3. Thresholds for presenting results/Expressing change

A] Minimal/Major Important Differences

- % improvement from baseline pain
 - Minimal ?20% relative , ?10% Absolute
 - Major ? 50% relative ? Absolute

B] PAS:Patient Acceptable State

Achievement of a pain state (e.g. no worse mild pain)

do you feel
good?

Workshop Themes



4. Hierarchy of pain outcome instruments

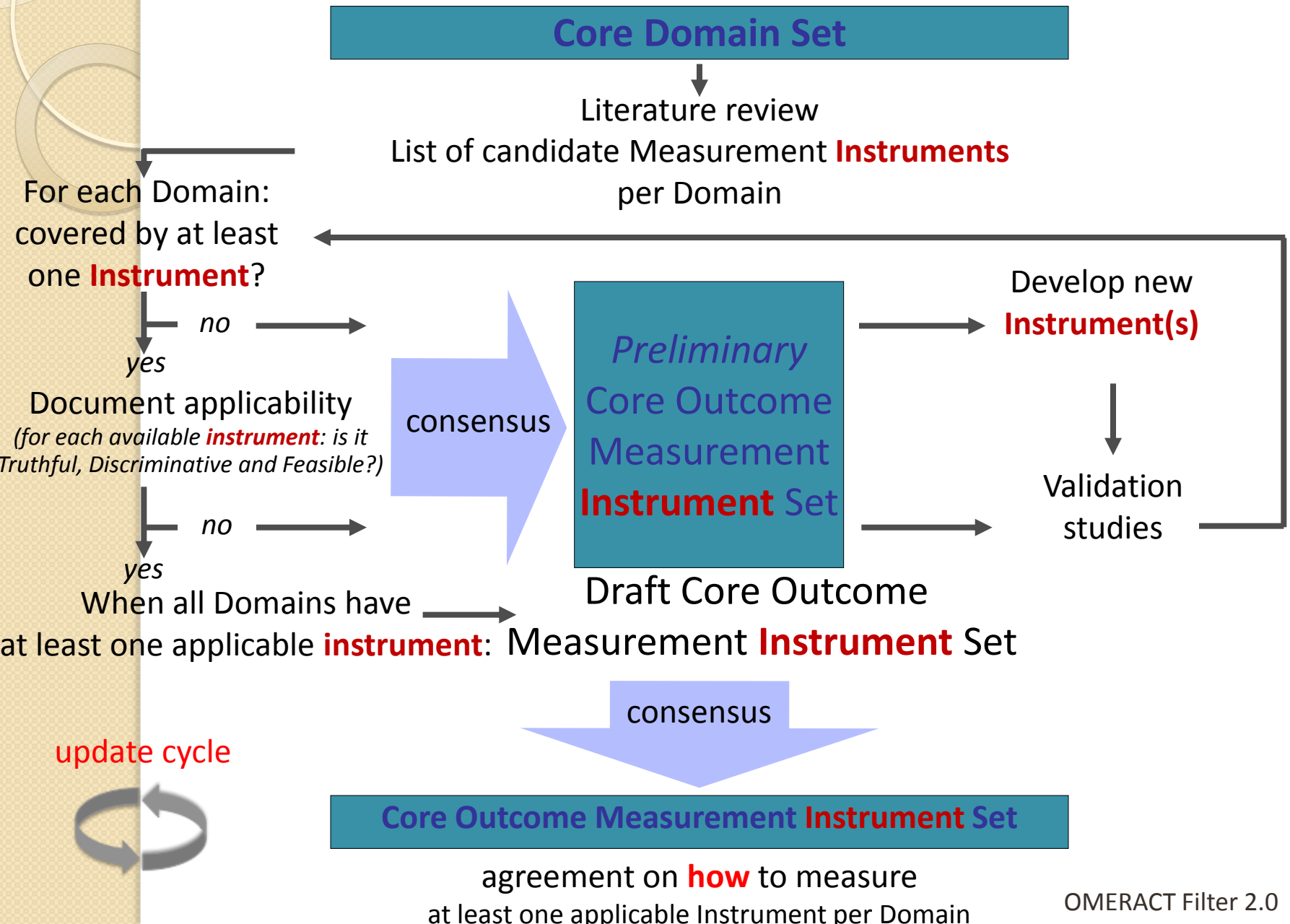
- Avoid selective outcome reporting bias
- Need to develop methodology to guide generating hierarchial lists



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	Core Outcome Measurement Set and timeline for update cycle			

Developing a Core Outcome Measurement Instruments



Upcoming JRheum manuscripts

1. A deliberative dialogue on partnering across networks to develop consensus on measurement and presentation of patient important outcomes in systematic reviews: a pre-conference meeting at OMERACT 12. P.Tugwell, L.Maxwell, D.Beaton, et al
2. Current state of reporting of pain outcomes in Cochrane reviews on chronic musculoskeletal pain conditions and considerations for an OMERACT research agenda. L Maxwell, P Tugwell, GA Wells, et al.
3. OMERACT 2014: debating the issue 'is chronic pain a disease in its own right?'" A. Taylor, J.O Taylor, K. Phillips, et al.
4. Harmonizing pain outcome measures: Results of a nominal group technique on pain domains at the Pre-OMERACT meeting on Partnerships for Consensus on Patient-important Outcomes domains between the Cochrane Musculoskeletal Group (CMSG) and OMERACT. K Phillips, A Taylor, P. Mease, et al
5. Optimal Strategies for Reporting Pain in Clinical Trials and Systematic Reviews. J.W. Busse, G.A. Wells, S. Bartlett, et al.
6. Raising the bar: a call for evidence-based decisions when selecting outcome measurement instruments in clinical research, systematic reviews and meta-analyses. D. Beaton, C. Terwee, et al
7. Consensus on the Need for a Hierarchical List of Patient-Reported Pain Outcomes for Meta-Analyses of Knee Osteoarthritis Trials. R. Christensen, L. Maxwell, P. Juni, et al.

Next steps

- Move forward with research agendas identified in Budapest
- Exploratory discussions on developing of a new '**Cochrane Alliances**' eg a 'Pain Alliance' Sept 2015 Vienna
- Next OMERACT May 2016 Whistler Canada

OMERACT 2016

SAVE THE DATE

Whistler, Canada | Westin Whistler | May 10-15 2016





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Thank you!