Harmonizing COS-
The next generation of challenges

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Conflict of Interest

I believe in COMET

Introduction

COS definition

Core Outcome Sets (COSs) are a minimum set of domains and measurement instruments recommended to be applied in any clinical trial to ensure comparable outcome assessment (both domains and instruments).

COSs are not exclusively recommended for clinical trials, but also for daily record keeping in routine care (HOME roadmap, Schmitt et al. 2014).

COS update

COS Aim

Harmonizing outcome Measurement to enhance evidence based medicine

COS Resources

COMET

COMET data source for coordinating the research effort and save resources

COS for chronic low back pain
-the situation-

Methods

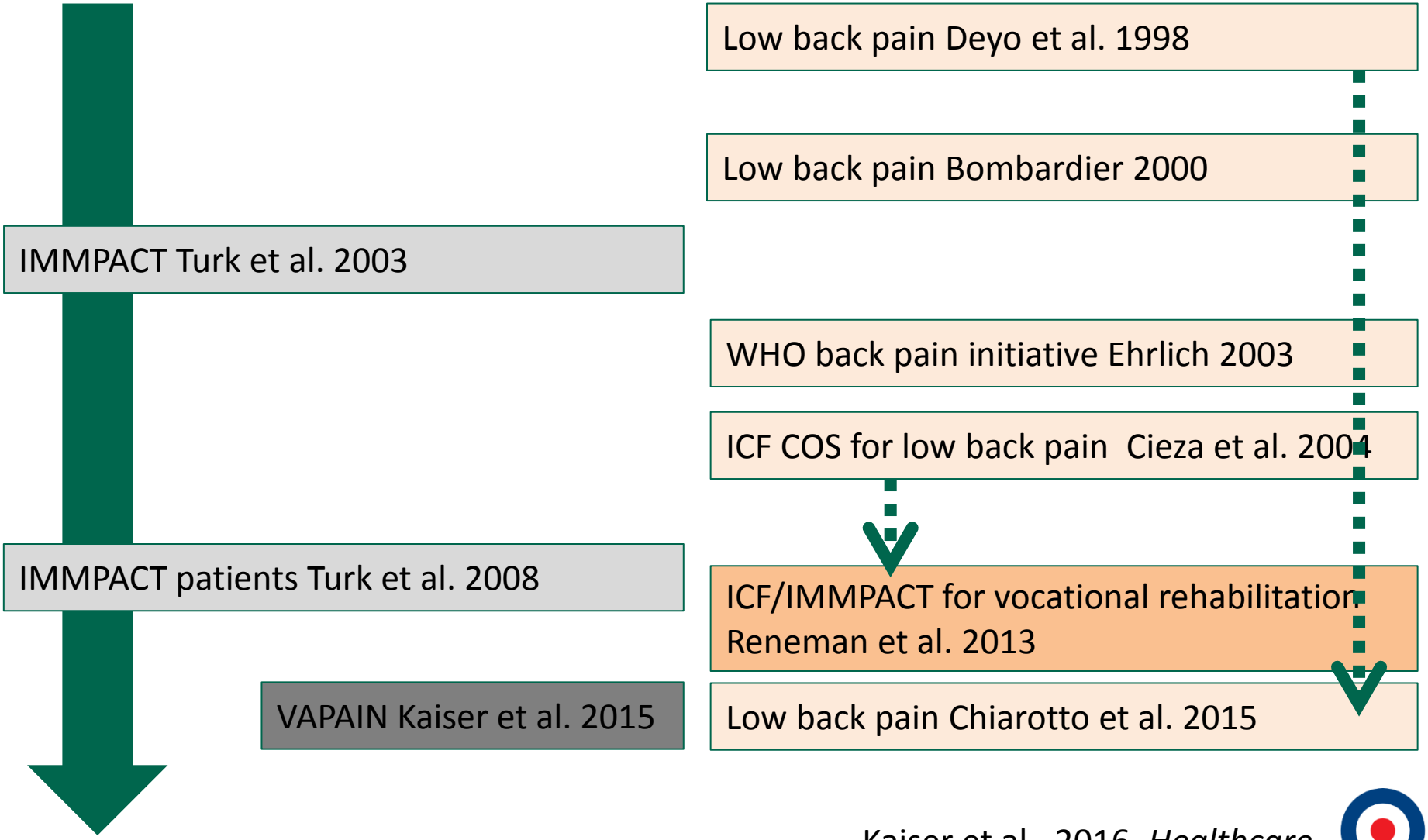
A simple search strategy (by March 2016) with focus on *chronic pain* and *low back pain* in Medline and COMET databank for either clinical trials or routine care was conducted.

Kaiser et al., 2016, *Healthcare*

Results

Setting		condition	OD	MI	other
	N		n	n	
CT	9	Chronic pain in general	3	1	Different focus on therapy aims
		Chronic low back pain	6	4(+2)	Different focus on settings (not specific, therapy specific)
Routine care	5	Chronic pain in general	5	5	Only national

COS for chronic low back pain
-the situation-



Kaiser et al., 2016, *Healthcare*

COS for chronic low back pain
-the situation-

Name of initiative/ Author	Condition	Intervention	Scope of application	Location		Recommendations	
				nat	intern	OD	MI
IMMPACT Turk et al. 2003 Dworkin et al. 2005	Chronic pain	Unspecified	CT		X	6	unclear
IMMPACT Survey with patient representatives Turk et al. 2008	Chronic pain	unspecified	CT		X	19	
WHO back pain initiative Ehrlich 2003	Low back pain	unspecified	All studies		X		6
ICF Core sets for low back pain Cieza et al. 2004	Low back pain	Not reported	Not reported		X	4	ICF
ICF/IMMPACT for vocational rehabilitation Reneman et al. 2013	Musculoskeletal pain (subacut and chronic)	Vocational rehabilitation	Clinical research and clinical practice	X		18	12
Low back pain Deyo et al. 1998	Low back pain	unspecified	Clinical trials and other kinds of research (also routine care)		X	6	6
Low back pain Bombardier 2000	Low back pain	unspecified	Clinical and health policy setting		X	5	5
Low back pain Chiarotto et al. 2015	Non-specific low back pain	unspecified	CT		X	4	(X)
VAPAIN Kaiser et al. 2015	Chronic pain	Interdisciplinary multimodal pain therapy	Effectiveness studies and daily record keeping		X	7(+1)	(X)

COS for chronic low back pain
-the situation for OD-

Name of initiative/ Author	Stakeholders	Patient involved	Transparency of consensus	Dimensions of OD			
				bio	psycho	social	
IMMPACT Turk et al. 2003 Dworkin et al. 2005	Multiple professions			Pain Physical function Adverse events	Emotional functioning		Patient global Participant's disposition
IMMPACT Survey with patient representatives Turk et al. 2008	Patients	**X**		X	X	(X)	
WHO back pain initiative Ehrlich 2003	Not reported						
ICF Core sets for low back pain Cieza et al. 2004	Multiple professions			body functions body structures		activities and participation environmental factors	
ICF/IMMPACT for vocational rehabilitation Reneman et al. 2013	Multiple professions			Physical functioning Pain intensity	Emotional functioning		Quality of life
Low back pain Deyo et al. 1998	Multiple professions			Pain symptoms (Physical) function Disability	(Well being)	Disability (social role)	
Low back pain Bombardier 2000	Multiple professions			Back specific function Pain		Work disability	Generic health status Patient satisfaction
Low back pain Chiarotto et al. 2015	Multiple professions	**X**	**X**	Physical functioning Pain Intensity Number of deaths			**Health related QoL**
VAPAIN Kaiser et al. 2015	Multiple professions	**X**	**X**	Pain (PI +PF) Physical activity	Emotional wellbeing	Productivity Satisfaction with social roles and activities	Health related QoL Patient Treatment goal achievement

COS for chronic low back pain
-the situation for MI-

Name of initiative/ Author	Recommendations of MI basing on SR to Psychometric properties
IMMPACT Turk et al. 2003 Dworkin et al. 2005	**No**
IMMPACT Survey with patient representatives Turk et al. 2008	**n.a.**
WHO back pain initiative Ehrlich 2003	**No**
ICF Core sets for low back pain Cieza et al. 2004	**No**
ICF/IMMPACT for vocational rehabilitation Reneman et al. 2013	**No**
Low back pain Deyo et al. 1998	**No**
Low back pain Bombardier 2000	**No**
Low back pain Chiarotto et al. 2015	**(Yes)**
VAPAIN Kaiser et al. 2015	**(Yes)**

COS for chronic low back pain
-the situation-

Different recommendations according to

- **Health condition**
- **Setting**
- **Methodological standards**
- **Patient involvement**
- **Outcome domains**
- **Measurement instrument**

COS for low back pain
-general considerations-

One fits all

Pain 106 (2003) 337–345

PAIN

www.elsevier.com/locate/pain

Core outcome domains for chronic pain clinical trials: IMMPACT recommendations

Dennis C. Turk[a,*], Robert H. Dworkin[b], Robert R. Allen[c], Nicholas Bellamy[d], Nancy Brandenburg[e], Daniel B. Carr[f], Charles Cleeland[g], Raymond Dionne[h], John T. Farrar[i], Bradley S. Galer[j], David J. Hewitt[k], Alejandro R. Jadad[l], Nathaniel P. Katz[m], Lynn D. Kramer[n], Donald C. Manning[o], Cynthia G. McCormick[p], Michael P. McDermott[b], Patrick McGrath[q], Steve Quessy[r], Bob A. Rappaport[s], James P. Robinson[t], Mike A. Royal[u], Lee Simon[s], Joseph W. Stauffer[v], Wendy Stein[w], Jane Tollett[x], James Witter[s]

COS for low back pain
-general considerations-

Implementation of IMMPACT primary recommendations (IMPT, 70 studies; example)

Core health areas	Superior outcome domains		Physical Health			Mental Health										Social Health		
			Symptoms	*Function*		*Affect*					*Behavior*	*Cognition*				*Function*		
			Pain as a symptom	*Disability*		*Fear*					*Coping*	*Self-efficacy*						
Health outcome domains based on different abstraction levels	Health-related quality of life	Sickness Impact	Pain intensity	Pain site	Disability in general	Pain-related disability	Physical function	Fear in general	Fear of pain	Avoidance of movement	Depressive symptoms	Psychological distress	Coping in general	Pain-related Coping	Self-efficacy in general	Pain-related self-efficacy	Pain-related catastrophizing	Work ability	Sick leave	Actual work Status
Schöps et al., 2000			●			●	●				●							●		
Chapman et al., 2000			●				●						○	○						●
Walsh and Radcliffe, 2002 [b]						●	●													
Lang et al., 2003	●		●				●				●								●	
Thieme et al., 2003			●									●				●				
Walsh et al., 2003 [b]						●	●								●					
Koopman et al., 2004						●	○	●			●			●						●
Michaelson et al., 2004			●																	
Watson et al., 2004			●			●	●	○	○	●	●	●								
Keogh et al., 2005		●	●				●		●		●	○					●			
McAllister et al., 2005			●			●	○													
Meyer et al., 2005	●		●				●											●		●
Neubauer et al., 2005			●				●											●		
Angst et al., 2006	●		●				●	●			●	●		●			●			
Buchner et al., 2006			●				●													●
Doleys et al., 2006			●																	
Smeets et al., 2006a [a]			●			●	●				●									

Psychological function

Pain

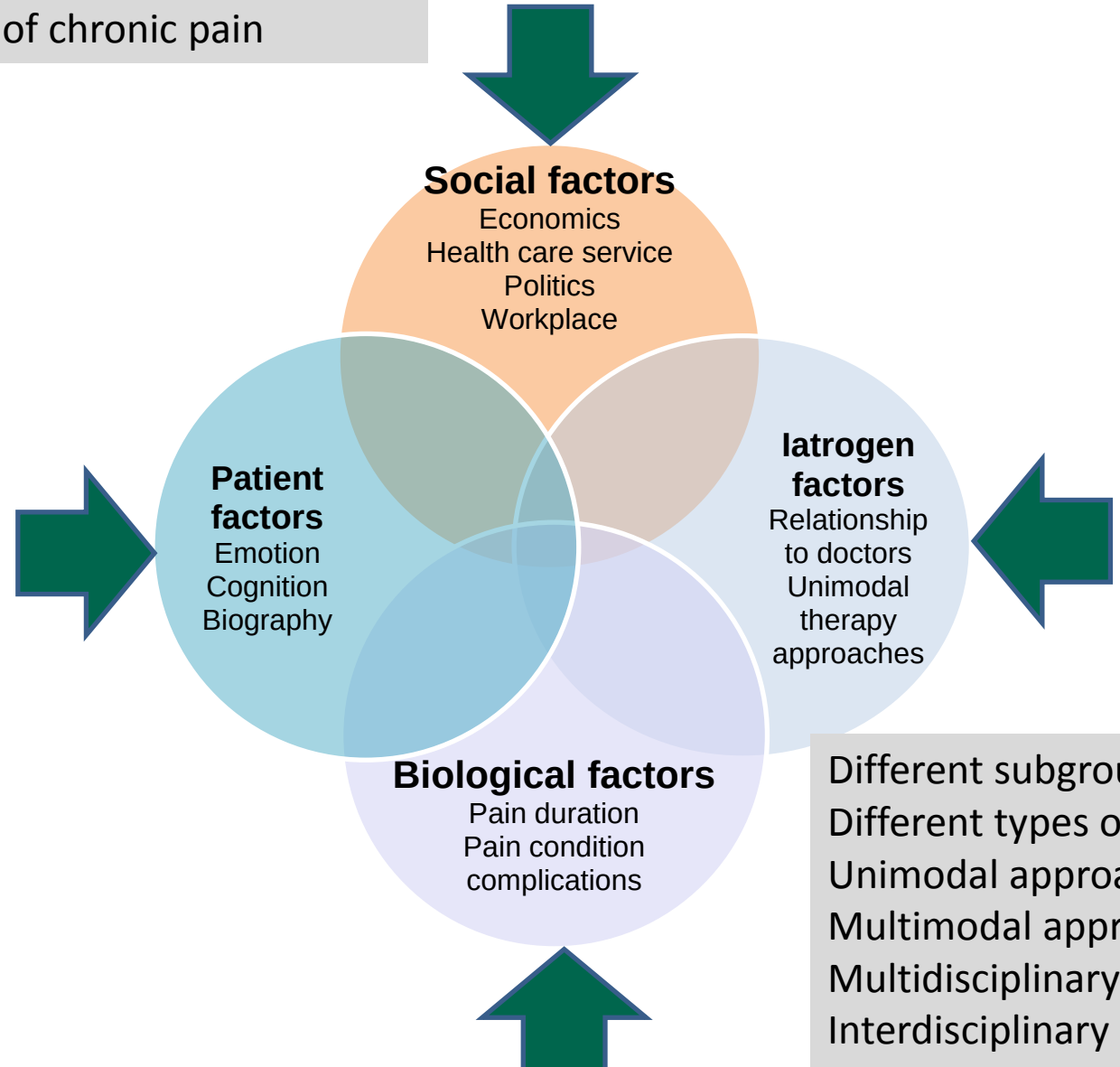
Physical function

Missing:
Adverse events
Patient global
Patient's disposition

Deckert et al., *Eur J Pain*; *2015*

COS for low back pain
-general considerations-

The challenge of chronic pain



Different subgroups of chronic pain
Different types of therapy
Unimodal approaches
Multimodal approaches
Multidisciplinary approaches
Interdisciplinary approaches

COS for low back pain
-general considerations-

We need to talk

- Collaborations between existing COS initiatives for chronic pain
- Meta COS

- Or do you have any idea?

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