<u>Title</u>: Node making process in network meta-analysis of complex intervention: a methodological systematic literature review and survey of authors.

Authors:

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INTRODUCTION

Clinicians should base their daily health related decisions on the best evidence. Because the medical literature production is constantly growing, methods to summarize evidence are strongly needed and systematic review with meta-analysis plays this role [1]. Traditional meta-analyses usually quantitatively compare only two interventions (pairwise) at a time and so have limited strength to assess the comparative effectiveness of several interventions or classes of interventions [2,3].

Network meta-analyses (NMA) allow combining both direct and indirect comparisons to estimate all possible pairwise comparisons between interventions for a single indication and placing them in rank order [4,5]. This method has experienced an incredibility fast expansion [6] and it raises several problems especially when it comes to assess non-pharmacological treatment (NPT) [7–9].

NPT include different type of intervention such as surgery, technical procedures, devices, rehabilitation, psychotherapy, behavioral interventions, and complementary and alternative medicine [10]. They are widely used in clinical practice and represent 24% of assessed interventions in RCTs published in 2000 [11–14]. They are often complex interventions involving several components and such interventions are known to be difficult to describe, standardize and reproduce [15]. One of the major issues of network meta-analysis assessing NPT is to gather NPT together in a homogenous group in order to allow for comparison.

This process, called *lumping*, increase the risk of in node heterogeneity and inconsistency [16,17] wich is known to bring limitations for further interpretation of the results [18] except if the variations in dose or co-treatment are so small that clinicians would agree that the variation has no material impact on efficacy [19]. The cochrane Handbook specifies that if this diversity becomes too great then the analysis might be meaningless because the true differences in the effects may be obscured [20,21]. An opposite process, called splitting is based on the individualization of all intervention.

Some publication show that the way interventions are lumped seems to be able to impact the result of the study [8,22] and that reporting remain a frequent problematic [23,24]. Based on this ascertainment, the PRISMA group has published in 2015 an extension dedicated to NMA [25]. The aim of this publication was to improve the

completeness this reporting. It is there specified that inclusion and exclusion criteria for each node must be specified and that a justification must be provided when different treatments are merged in similar nodes.

But although the node making process seems to be a crucial step in the creation of the network graph, methodological literature does not provide any consensual recommendation on the subject.

Objective:

We aim to examine how interventions are combined in network meta-analyses of NPT. Our objective is to identify the different methods available to build consistent node in NMA for NPT.

METHODS

We will proceed in 3 steps. First, we will describe the lumping process as reported in network meta-analyses assessing NPT from a methodological systematic review. Second, we will review methodological articles in order to provide a comprehensive overview of the recommendation about NMA of NPT. Third, we will survey experts and authors of NMA of NPT to identify all the possible process for node making.

1/ Methodological Systematic review

Search strategy

We planned to systematically search MEDLINE, Cochrane Central Register of Controlled Trials (CENTRAL) and EMBASE databases from their date of inception until March 2016. All databases will be searched using controlled vocabulary. Search equation is detailed in Appendix 1. The search strategy will be developed by the research team and an experienced information specialist. The search strategy for one of the main databases (Medline) will be peer reviewed [26] prior to any formal searches.

Eligibility criteria

We will include all published report of network meta-analyses assessing a NPT in human. We considered as NPT all intervention assessing surgery, technical procedures, devices, rehabilitation, physiotherapy, behavioral therapy, psychotherapy and alternative medicine [10]. We will include all NMA including 3 interventions or more which at least one is a NPT. We will not to apply language, publication status or date restriction.

We planned to exclude report of NMA evaluating only pharmacological treatments, editorial, technological assessment, non-human study, cost effectiveness assessment as well as prognosis and prognostic considerations. We will exclude ancillary study as duplicate.

Selection of articles

Authors will not be blinded to authors, institutions, journal of publication, or study results. One author (AJ) will examine each title and abstract identified in the search to exclude obviously irrelevant reports. 30% of the title will be done in duplicate.

Full text of eligible reports will be obtained, and the one author will then examine full text articles to determine eligibility. All selected articles will be assessed by a second author to confirm eligibility criteria. Authors will resolve disagreements by consensus or if necessary through a third author. The whole study selection process will be performed using the Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia. (Available at www.covidence.org)

Data extraction

Data will be extracted from published reports and protocols in duplicate using a standardized data extraction form (appendix 2). If both protocol and article are available for the same study, we will extract data based on the two reports.

The following data will be extracted:

- <u>General characteristics of the NMA</u>: Trial ID, first author, journal, year of publication, medical area, mail of the corresponding author.
- <u>Description of the intervention</u>: type of intervention, number of NPT intervention assessed, description of each intervention, reported inclusion or exclusion criteria, presence of lumping, is a justification provided for lumping, does the reviewer indentify issue with lumping, timing of the lumping and presentation of the network graph before and after merging intervention.

2/ Literature review of methodological article

Search strategy

We will perform a methodological review in NMA of NPT to identify different method for node making. For this purpose we will search in *pubmed* and Google Scholar (search equation in appendix). For Google Scholar, the first 100 references of each search will be investigated. This search will include main articles about NMA including methodological recommendations: Cochrane, PRISMA [21], IPSOR [22] as long as any article who discuss lumping in NMA.

Data extraction

We will identify and extract from these the situations that been considerate by authors as problematic on the node making process for NPT and what are the solutions identified by the different publications. These situations, proposed methodology to solve them and rational for the proposed solution will thus be assessed.

3/ Experts survey

We will plan an online survey in which participants will be asked to fill a questionnaire in order to bring their expertise about NMA methodology especially on the node making process. The aim of this part of the study is to be the most exhaustive concerning the different methods actually available to merge the different components before completing a network meta-analyses.

Participants:

• All corresponding authors of the articles included in the methodological review. We will use snowballing technique in order to enlarge the collective of the survey: if the corresponding author is not able to response or though it relevant, he will be will be proposed to transmit the survey to other authors.

- Network meta-analyses specialist including authors of the PRISMA extension for NMA [25], member of the *Cochrane Comparing Multiple Intervention* group and *Statistical Methods* Group, members of the IPSOR for network meta-analysis authors [27,28] and authors of the NICE recommendation [29].
- Experts of NTP and authors of the last recommendation of MRC for complex intervention [10,12,15,30,31].

Survey

A standardized and personalized email will be sent to potential participants to invite them to participate in an online survey about methodology of NMA. The email will contain a link toward an online survey. In case of absence of response after two week we planned to send a first reminder e-mail and a second two week later if needed.

Contact e-mail and survey are available in appendix 4 & 5.

Analyses

Quantitative variables data and frequencies will be described as means and standard deviations. Percentages will be used to describe categorical variables. All analysis will be performed in with R.

Qualitative data will be analyzed by content analysis, it will involve several steps [29]. First, all answers will be reviewed independently by two authors (AJ; AY) in order to identify literal terms used by participants to explain and describes their strategy. Secondly, during frequent meeting, authors will reach consensus on the terms that can be state as similar. Third, whenever a new idea will emerge, researchers will discuss the idea, thereby refining and enriching the list of themes.

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Appendix 1:

	Cochrane database Medline		Embase	
NMA	1	"network meta-analysis" OR "network meta- regression" OR "multiple treatment meta-analysis" OR "multiple treatments meta-analysis" OR "mixed treatment comparison" OR "mixed treatment comparisons"	"network meta-analysis" OR "network meta- regression" OR "multiple treatment meta-analysis" OR "multiple treatments meta-analysis" OR "mixed treatment comparison" OR " mixed treatment comparisons"	"network meta-analysis" OR "network meta- regression" OR "multiple treatment meta-analysis" OR "multiple treatments meta-analysis" OR "mixed treatment comparison" OR "mixed treatment comparisons"
	2	MTC AND meta-analysis	MTC AND meta-analysis	(mtc AND 'meta analysis'/exp)
	3	#1 or #2	#1 or #2	#1 or #2
	4	meta-analysis	meta-analysis[sb]	'meta analysis'/exp
	5	"Systematic review"	systematic[sb]	'Systematic review '/exp
	6	#4 OR #5	#4 OR #5	#4 OR #5
	7	"mixed treatment" OR "multiple treatment" OR "multiple treatments" OR "treatment networks" OR "multiple comparison"	"mixed treatment" OR "multiple treatment" OR "multiple treatments" OR "treatment networks" OR "multiple comparison"	"mixed treatment" OR "multiple treatment" OR "multiple treatments" OR "treatment networks" OR "multiple comparison"
	8	#6 AND #7	#6 AND #7	#6 AND #7
	9	#8 OR #3	#8 OR #3	#8 OR #3

Overview of reviews	10	"overview of reviews" OR "umbrella review" OR "overview of systematic reviews" OR "overview of meta-analyses " OR "multiple systematic reviews" OR "multiple meta-analyses " OR "overview of Cochrane reviews" OR "multiple Cochrane reviews" OR "overview of Cochrane"	(overview AND reviews) OR (umbrella AND review) OR (overview AND "systematic reviews") OR (overview AND meta-analyses) OR "multiple systematic reviews" OR "multiple meta-analyses" OR (overview AND "Cochrane reviews") OR (multiple AND Cochrane AND reviews) OR (overview AND Cochrane)	"overview of reviews" OR "umbrella review" OR "overview of systematic reviews" OR "overview of meta-analyses" OR "multiple systematic reviews" OR "multiple meta-analyses" OR "overview of Cochrane reviews" OR "multiple Cochrane reviews" OR "overview of Cochrane"
	11	"treatment networks" OR "network meta-analysis" OR "mixed treatment " OR "multiple treatments" OR "multiple treatment" OR "multiple comparisons " OR "multiple comparison" OR "indirect comparison"	"treatment networks" OR" network meta-analysis" OR "mixed treatment " OR "multiple treatments" OR "multiple treatment" OR "multiple comparisons" OR "multiple comparison" OR "indirect comparison"	"treatment networks" OR "network meta-analysis" OR "mixed treatment " OR "multiple treatments" OR "multiple treatment" OR "multiple comparisons" OR "multiple comparison" OR "indirect comparison"
	12	#11 AND #10	#11 AND #10	#11 AND #10
Equation of sear	rch	#12 OR #9	#12 OR #9	#12 OR #9

Appendix 2: Data extraction form for NMA

GENERAL CARACTERISTICS

1/ Trial ID:		
2/ Reviewer:	AJ 🗌	AY 🗌
3/ Journal: (complete name):		
4/ First author:		
5/ Year of publication:		

6/ Corresponding authors mail:

7/ Medical Area : including : Alternative Medicine, Anesthesia, Cardiology, Critical care, Dermatology, Endocrinology, Gastro-enterology, Geriatrics, Hemato/Immuno,, Infectious disease, Obst/Gynaeco, Oncology, Ophthalmology, Otolaryngology, Paediatrics, Pharmacology, Physiology, Psy/Psycho, Radiology, Respiratology, Rheumatology, Nephrology, Neurology, Surgery, Urology, Other.

8/ Authors include a statistician or methodologist?

No 🗌

Yes

Unclear

9/ Type and number of nodes describes in the network

a)	Surgery & Procedure:	nb:
b)	Devices:	nb:
c)	Behavioral:	nb:
d)	Physiotherapy:	nb:
e)	Pharmaceutical:	nb:
f)	Best supportive care	nb:
g)	Placebo	nb:

METHOD SECTION:

1.	Did the authors define the nodes (class of homogenous intervention) a priori in the method section? (e.g.: Barth, Plos Med)			
	Yes [No 🗌		
	If yes,			
	a.	Did they justify the choice of	of nodes? :	
		Yes	No 🗌	
	b.	Did they describe the metho	od used to build this nodes? :	
		Yes	No 🗌	
		If yes, describe:		
		Give references:		
	c.	Did they clearly define the	pre-specified nodes? ¹ :	
		Yes completely	Yes partially No	
	d.	Did they plan to explore in	node heterogeneity?	
		Subgroup analyses		
		Meta-regression		
		Other	Then describes:	

2. Did the authors describe an a priori method to a posteriori define nodes (class of homogenous intervention)? (ex Mosseri, PlosOne)

Yes No	
If yes,	
a. Did they justify the choice	ce of the method? :
Yes	No 🗌
b. Did they describe this m	ethod?:
Yes	No 🗌
If yes, describe: .	

Protocol Arthur James

Version 17 28/04/2016

¹ **Surgery:** expertise of the surgeon, incision, surgical technique, perioperative care, Device implanted

Device: expertise of the provider, description of the device, perioperative care, Co-intervention (e.g.: AAP for coronary stent)

Rehabilitation / physiotherapy/ Behavioral: Group or individual, supervision, Number and length of session

Give references:

c. Did they plan to explore in node heterogeneity?

Subgroup analyses	
Meta-regression	
Other	Then describes:

3. The authors did not clearly describe nodes nor a method to build them (meaning not 1 & not 2)

Yes	No 🗌
100	

	RESULTS SECTION
1.	Did the authors describe interventions in primary studies? (e.g. : table 1)
	Yes completely Yes partially No
2.	Did the authors change the definition of nodes compare to what was pre-specified? Yes No
3.	Did they present a network graph before lumping? (i.e.: a naïve network) Yes No
4.	Did they present a network graph after lumping (e.g. : grouped intervention)? Yes No
5.	Did they compare different network?
	Yes No
	If yes : Does the different configuration change the result of the study ?
	Yes No
6.	Did they explore in node heterogeneity?
	Subgroup analyses
	Meta-regression
	Other:
7.	Is there an evidence of lumping? (according to the reviewer)
	Yes No

<u>Appendix 3</u>: Authors contact e-mail

Dear "prefix" "first name" "Family name",

Given your expertise in the field of network meta-analysis, we would like to invite you to participate in an academic survey. Our aim is to identify all methods that could be used to define nodes in network meta-analysis.

In fact, the definition of nodes can be very complex particularly for non pharmacological treatment and complex interventions. According to the method used, we could obtain different network and different results.

The survey contains 11 questions, and should take less than 10 minutes of your time. Your answer will be treated confidentially. We will send you the final results of this survey. Further, we would like to acknowledge your participation in this survey in the final report. If you agree please provide your name at the end of the survey.

We also would like to propose you to transfer this e-mail to any colleague that might seems relevant.

To complete the survey, please click here, or copy and paste the following link into your browser: <u>http://www.gardesetastreintes.com</u>

If you have any questions or need technical help, please email me at: <u>arthur.james@cochrane.fr</u>

Yours faithfully,

Dr Arthur JAMES, Dr Amélie YAVCHITZ, Pr Isabelle BOUTRON, Pr Philippe RAVAUD Cochrane France - INSERM U1153 Hôpital Hôtel Dieu, Place du parvis Notre Dame 75181 Paris Cedex 4 Tel: 01 42 34 78 66 - Fax: 01 42 34 87 90

If you prefer not to receive future reminders regarding this study, please contact Arthur JAMES: <u>arthur.james@cochrane.fr</u>

<u>Appendix 4</u>: Expert Survey

"In network meta-analysis, often one has to decide whether to lump or split treatments that is, whether to combine different doses of the same drug, alternative forms of administration of the same drug, or varying durations of administration, or different controls."

"In network meta-analyses, authors should clearly describe inclusion and exclusion criteria for treatment regimens (that is, nodes) and should provide justification when treatment nodes are merged to form single comparators". The PRISMA extension for Network Meta-Analyses, B. Hutton et al. Ann Intern Med. 2015; 162:777-784

"In network meta-analysis of non pharmacological treatment this step can be very difficult because of the complexity of the intervention combining different component.

1. In the network meta-analyzes you have been involved in, have you been confronted to this problem?

	····· r-			
			Yes	No 🗌
			Never been involve	d in a NMA
	If yes	:		
	a.	How did you n	nanage it ?	
2.	Do yo	u think that the 1	nodes should be def	ined ?
	a.	Before the sele	ection of the primary	v studies, at the protocol stage?
			Yes	No 🗌
	b.	After the select	tion of the primary s	studies, according to the intervention
		described in the	e primary RCTs inc	luded?
			Yes	No 🗌
	c.	After the select	tion of the primary s	studies, according to the comparison
		retrieved in the	e primary RCTs incl	uded?
			Yes	No 🗌
	d.	According to s	tatistical considerati	on
			Yes	No 🗌

Protocol Arthur James - Version 17 - 3/05/2016

	e. According to	clinical consideration Yes	No 🗌
3.	Do you think that an	expert consensus is no Yes	eeded to build nodes?
	If yes, a. How do you 	think the consensus sl	nould be made?
	b. Who should h	Clinician Both	Methodologist or Statistician
	c. Do you thinkd. Do you thinkresults	that experts should be Yes that experts should be Yes Yes	 blinded of primary studies results? No be blinded of comparison of primary studies No
4.	Should a naive netwo intervention) ? Yes	ork graph be systemati No 🗌	cally presented (meaning before grouping
5.	Would you like to ad network meta-analys	d any free comments of is?	on the lumping process problematic in

Finally, please answer the following questions regarding your background and complete the identification form.

We will contact you again with the results of the survey.

Please indicate your e-mail so that we can send you the results, and your name and surname

If you accept to be acknowledge.

	Your answers will be analy	zed confidentially.		
6.	Identification (<i>optional</i>) a. Name: b. Email: c. Institution : d. E-mail address:			
7.	Where are you working:			
	N. America	S. America	Europe	
	Africa 🗌	Oceania 🗌	Non availabl	e 🗌
8.	Where are you currently lo Academic research	cated ?	actice	Both equally 🗌
9.	How many network meta-a	nalysis have you beer	n involved in?	
	0 🗌 1 🗌	2-4	5-10	>10
10	. Have you already been invo Yes 🔲	olved in a Non Pharma No 🗌	acological Treatr	nent assessment?
11.	. Have you ever been referer	nt statistician for a net	work meta-analys	sis?
	Yes	No 🗌		

18

Appendix 5

"network meta-analysis"

"network meta-analysis" AND "lumping"

"network meta-analysis" AND "non-pharmaceutical treatment "network meta-analysis" AND "complex intervention" "multiple treatment comparison" AND "lumping"

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