

Core Outcome Set (COS) registration guide

Step 1: Determine the health condition of interest

Use the International Classification of Diseases, Tenth Revision (ICD-10) system to classify symptoms/diagnosis.

Step 2: Identify whether there are potentially relevant core outcome sets (COS) published or in development

There are increasing concerns about the potential for unnecessary duplication where a well-developed COS already exists for a health condition and a new team wants to develop a COS for the same condition. Sometimes there are legitimate reasons for this duplication, for example if the methods used to determine the existing COS might be flawed or, if the existing COS is very old, it might benefit from being re-visited to see if an update would improve it. However, you need to give careful consideration to developing a COS for a health condition if one already exists, in order to minimise research waste. This might include considering who was involved in the development of the existing COS or whether you wish to focus on a particular population subgroup or intervention type, as discussed below.

Populations included in the COS development

Sometimes, the stakeholders involved in the development of the existing COS may not be considered to be sufficiently representative. One extreme situation would be where no patients or members of the public were involved. In this case, if the existing COS is otherwise well developed, you could undertake some work with patients to see whether any critical outcomes are missing. Less extreme would be where people in a particular region of the world were not involved in the COS development and there is uncertainty as to whether their views would be similar to the views of those who were involved. In this case, some researchers undertake an 'adopt or adapt' development, rather than starting completely from the beginning to develop a new COS specific to that region. Examples include the consideration of a COS for neonatal care developed by predominantly, but not exclusively, people from higher resource settings in terms of its applicability in Kenya (Karumbi et al, 2023).

Specific population subgroup for the COS

The research studies for some population subgroups may require additional outcomes specific to them, which are not relevant to a general COS for the condition being treated. We recommend that COS for a specific population subgroup should always include an existing COS for the health condition (excluding any outcomes that could not be measured in the specific population subgroup, such as pregnancy if the population is women who are not of child-bearing age), and that the focus of the development of the new COS should be to provide an add-on set of core outcomes. In developing the new population subgroup-specific COS, you should endorse the existing COS from the outset (if it was well-developed), and focus only on the specific outcomes of relevance to the population subgroup that you are interested in.

If you wish to develop a COS for a particular population subgroup and a general COS for the health condition does not yet exist, and is not ongoing, we recommend that you consider developing both a COS for the health condition as a whole as well as the add-on COS for the subgroup of interest. Your consideration should be based on whether you, as the COS developer, and the other people involved in developing your COS would be an appropriate group for developing the general COS.

Specific intervention for the COS

The research studies for some types of intervention may require specific outcomes to reflect the effect of the intervention, either as primary or secondary outcomes, which are not relevant to a general COS for the condition being treated. We recommend that COS for specific types of intervention should always include an existing COS for the health condition regardless of intervention type, and that the focus of the development of the new COS should be to provide an add-on set of core outcomes. In developing the new intervention-specific COS, you should endorse the existing COS from the outset (if it was well-developed), and focus only on the specific outcomes of relevance to the intervention type that you are interested in.

If you wish to develop a COS for a particular intervention type and a general COS for the health condition (regardless of intervention type) does not yet exist, and is not ongoing, we recommend you consider developing both a COS for the health condition regardless of intervention type as well as the add-on COS for the intervention type of interest. Your consideration should be based on whether you, as the COS developer, and the other people involved in developing your COS would be an appropriate group for developing the general COS.

Search the COMET database

To help avoid unnecessary duplication, COMET requires all those wishing to register a new COS to have searched the COMET database to identify whether a potentially relevant COS already exists, or is in development for the condition of interest. In a video (available [here](#)), of a talk by Professor Paula Williamson, who leads the COMET Initiative, at the Chinese COS Centre, she explains how we would like COS developers to focus first on the condition regardless of population subgroup or type of intervention, and then consider add-on modules for particular population subgroups or specific intervention types (e.g. traditional Chinese medicine).

If, when planning a new COS, you identify a potentially relevant COS, you should determine whether its scope is relevant to your target population/intervention type. To do this, you can use the framework developed by Saldanha et al. (see Figure 1), which describes various scenarios of degree of overlap. In terms of the *population*, four scenarios are possible: the existing COS may be narrower, exact in scope, or broader than the new target population, or may describe a different subgroup of the population (e.g., children only). In terms of the *intervention type*, four scenarios are possible: the existing COS may be narrower, exact in scope, or broader than the new intervention, or may describe a different intervention type (Saldanha et al., 2021).

Figure 1. COS scope comparison framework

		INTERVENTION			
		Core outcome set is narrower	Exact match	Core outcome set is broader	Different (but related) intervention
POPULATION	Core outcome set is narrower	A	B	C	D
	Exact match	E	F	G	H
	Core outcome set is broader	I	J	K	L
	Different population subgroup	M	N	O	P

	Core outcome set is very likely to be relevant.
	Core outcome set may be relevant.
	Core outcome set is unlikely to be relevant.

Step 3: Appraise relevant existing COS and provide rationale for the new one

- (a) For those COS which are very likely to be relevant, as the population and/or intervention type are an exact match or broader (i.e. scenarios f, g, j and k)

If the existing COS is completed and published, you should read its full paper and critically appraise the methods used to develop it. You can do this by applying the COS-STAD minimum standards (Kirkham et al, 2017). If the COS is deemed to be of sufficient methodological quality, the outcomes included in the COS should always be recommended, unless you can explain why any of those outcomes would not be relevant to your target population/intervention. If you think that outcomes of high importance for your target population/intervention are not included in the COS, you may wish to develop an add-on module to the existing COS and explain your rationale for doing so.

If you find an ongoing COS project in the COMET database, you should contact its lead person and discuss whether your proposed COS is needed, whether it should be an add-on module, and/or whether a collaboration is possible. You should then let COMET know what their reply is.

- (b) For those COS which may be relevant, because the population and/or intervention are narrower (i.e. scenarios a, b, c, e, i) or applies to a different population subgroup (i.e. scenarios m, n and o)

If the existing COS is completed and published, you should follow Step 3a to critically appraise it and consider whether all or any of the outcomes included in it would be relevant for your population/intervention. In some instances, you may be able to start from the existing COS and develop an add-on module, or alternatively, you should consider how to make details of the existing COS available to those you intend to include in your COS development process.

If there is an ongoing COS project in the database, you should follow the appropriate guidance in Step 3a and contact the lead person as above.

- (c) For those COS which are unlikely to be relevant, because they apply to a different intervention type (i.e. scenarios d, h, l and p)

If the existing COS is completed and published, you should follow Step 3a to critically appraise it and consider whether all or any of the outcomes included in it would be relevant for your intervention type. In some instances, you may be able to start from the existing COS and develop an add-on module, or alternatively, you should consider to make details of the published COS available to those you intend to include in your COS development process.

If there is an ongoing COS project in the database, you should follow the appropriate guidance in Step 3a and contact the lead person as above.

Developing an add-on COS

If you decide to develop an add-on COS module, the outcomes in the existing COS would already be included and so the methods you use would be solely to identify the outcomes applicable to your particular intervention and/or population subgroup. For example, there would be no need to undertake a full systematic review of existing research. Instead, you could check if the terms relevant to your population or intervention type were included in the search. If not, you could perform a new search limited to your specific population or intervention type. However, if the

original search was done some time ago, and even if it included the intervention and population of particular interest for the new COS, you may need to re-run the search.

During the consensus process, you only need to include outcomes that are specific to your population or intervention type. In the introductory material and information sheets that you would make available to those you intend to include in your COS development process, you should explain the outcomes that have already reached consensus for inclusion in the main COS for the condition.

When you report your add-on COS module, you should be clear that the existing COS for the health condition as a whole should always be measured and reported. Here is an example of an add-on COS module: <https://bmcgeriatr.biomedcentral.com/articles/10.1186/s12877-022-03395-8>

References

Karumbi J, Gathara D, Young B, Williamson P. To adopt or adapt an existing neonatal core outcome set in Kenya: A study protocol. *Trials*. 2023;24:806. <https://doi.org/10.1186/s13063-023-07821-z>

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Saldanha IJ, Dodd S, Gorst SL, Williamson PR. More than half of systematic reviews have relevant core outcome sets. *J Clin Epidemiol*. 2021;136:168-79. <https://doi.org/10.1016/j.jclinepi.2021.04.019>