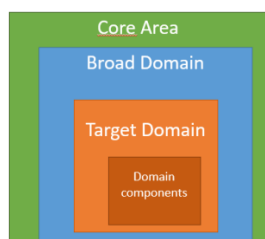


6.3 Domain definitions

While a domain label might be brief, the definition of the domain provides the rich description of what is included in that domain and what is not. If we use the metaphor of a domain being like a window in a house offering a certain view of an outcome, the right view will be when the window has the right breadth and depth. A rich definition accompanied by examples from qualitative or quantitative work helps us to describe that breadth and depth.

Earlier we introduced the idea of layers of definitions. Imaging outcomes have been using a layered approach to define their outcomes. They might start with a broad term like inflammation, but then they go to what they can measure, synovitis for example, and then they go even more specifically to blood flow and synovial tissue thickness

for example (14). We used this layered approach to develop a template for all definitions, not just imaging, and it worked. This layered definition captures the core area, the broad domain, the target domain (what we are trying to measure) and the domains' components (things that should be included in the domain). If you want to think about this some more, we highly recommend reviewing the whiteboard lesson #1 for OMERACT from Imaging - Detailed Domain Definitions (<https://youtu.be/omKD1z2MO78>)



	Description	Example	Example	Example
Core Area	One of the Core Areas as defined in Boers, 2019.	Pathophysiological manifestation	Life Impact	Pathophysiological manifestations
Broad Domain	Often there is a general term for an area.	Pain	Pain	Bone fragility
Target Domain	This is the more focused view of the domain that would be placed in the onion.	Intensity of pain	Pain impact on daily activities	Bone density
Target Domain: more detail in definition	In this section, we are at the same level as Target Domain, however we are asking for fleshing this out. This might fit in as the definition used for this domain in the Delphi survey	The daily average of the intensity of the sensation of pain expressed on a range from no pain to worst pain imaginable.	A sense of the amount of day people are impacted by pain in terms of the accomplishment of daily activities and roles other than work.	The volume of mineral bone structure in a given volume of bone. It is capturing the density of the bone component of the space-bone matrix that makes

				up cancellous bone.
Elemental components of the domain	What areas are essential to capture to measure this target domain well?	24 window of pain, average day not special events or activities. Provide numeric scale, higher number = higher magnitude of pain sensation	Should consider selfcare, leisure, social roles at home (parenting). Not work. Generalized over whole day rather than in morning or evening.	Proportion of bone in g/cl at femoral neck and specific settings/machine

Table 4. 2 Some examples of the layers of a definition.

This part of our template plays another important role. When consensus activities like a Delphi process begin, they need to have a name for the domain and a definition to its meaning. We suggest using the target domain as the label and the definition of the target domain as the definition. This template will be imported into excel and become the domain names and their definitions that are offered to respondents during the survey. So, it can serve both roles.

Our experience has told us that when groups evolve, or time passes we lose the detailed understanding of a domain and why it was important or considered. We need that to be held for the working group and other OMERACT groups who might be considering a similar domain.

OMERACT requires a clear definition of each of the potential domains in the Core Domain Set. This definition should be true to the work that uncovered it, and the experiences of people who generated the idea if it was found qualitatively. It is also possible to look for a theoretical or conceptual framework that includes the domain and could provide more insight into its definition and its relationship to other domains. An existing conceptual framework like this could define a concept adequately for the Working Group (i.e., self-efficacy from social cognitive theory and self-management literature). If it is a clear match to the domain as described by your literature review or qualitative work than you can use that conceptual framework’s definition and cite it as so. For example, if the concept is self-efficacy, the literature supported by Bandura’s definition (15) might be used to define self-efficacy as “an individual's belief in his or her capability to produce given attainments”. It might also be operationalized in Lorig’s work in arthritis (16) as a mediator of care utilization.

Working groups have often found it important to take a more complex definition to an OMERACT meeting so that you can get more input into how others are seeing the domain, or what might be impacting it’s meaning or measurement. For example, groups can reflect on the qualitative finding for a set of domains under ‘Life Impact’, discussing and documenting the breadth and depth of the experience in patients. In OMERACT, the work on the domain of fatigue (17) is an example of how breakout sessions during an OMERACT meeting paid considerable attention to the meaning of fatigue in persons with arthritis and led to a good discussion that vastly improved the domain definition for Fatigue. Several avenues can be used to improve the understanding of the domain.

Rheumatoid Arthritis (RA) Flare is another group where an emerging domain of patients’ experience of flare from a disease perhaps in remission is the management target for new therapies. This domain was developed and defined

through the OMERACT process (18). Early engagement and coordination with existing disease-focused Working Groups during the development of a domain that is relevant across several health conditions or might be new to a disease group is essential. Our Budapest meeting had a pre-meeting to discuss the measurement of pain and whether this was common across different disease groups (chronic versus episodic pain for example). As our sense of definitions evolved, and we realized the importance of having these detailed definitions for OMERACT working groups. We developed a domain definition report based on the work by d'Agostino (14). The table of examples above follows this report, and it in turn is following the layers of definition described. The table above describes several domains and is the first step in preparation for the Delphi process described in the prioritizing section below. But there are also two additional sections in this report: qualitative findings, and sources of variability.

Qualitative findings. A quote from a patient, or a clinician can really provide a lot more meaning than a synopsis of that in a domain name or even its definition. It provides a rich description of the experience of that domain. We ask you to collect some of those salient quotes from the qualitative work or even from the literature so that you will always have that salience with you when you talk about domains. It is in the domain phase that these qualitative findings will be available in the mind of the person who did those interviews and analysis and that is precisely why we suggest using this time to document and write down some of those quotes.

Sources of variability. As you learn more about a domain that you are considering, you will hear a lot about sources of variability in its measurement or interpretation. For example, in worker productivity patient research partners started telling them “Well it depends” (a key sign that there is an important contextual factor here). It depended if they could pace their own work, or if they could take time off for important appointments or if they had switched to a less demanding job. These are all things that could make them respond to a question about their work ability or their overall productivity with a different numeric choice. In 2020 the contextual factors group led by fellow Sabrina Mai Nielsen described these sources of variability as “measurement affecting” contextual factors, and their whiteboard video on their taxonomy of contextual factors is a great learning tool (<https://youtu.be/WZStbgNNftc>). From a domain definition perspective OMERACT feels that when you are in the literature about the domain definition you will also be finding out about these measurements affecting contextual factors or sources of variability. For example, in imaging we learned that these definitions are discussed a lot and often with reliability tests to see if the “measurement affecting” contextual factors, or sources of variability, are affecting a candidate outcome instrument score. This might be inter-rater differences, or a difference between brands of imaging machines. We suggest you document them as you go along in refining your definitions as you might forget them when you need them later!

Each domain nominated as part of your core domain set (inner layer of the onion) will require this domain definition sheet to be part of the report along with the OMERACT Onion and Workbook. We will hold a copy on the OMERACT website. Future groups would be well advised to search for existing definitions and see if they match an existing one. Such collaboration on definitions is exactly what we described around pain intensity.

Domain Definition Report

This is the one pager for each of your mandatory domains and any important but optional domains you feel you are ready to define. It will provide the domain definition in more detail than anywhere else and will be saved for future reference by OMERACT. In many situations this has become an invaluable resource when, perhaps years later, you are considering an instrument for your domain.

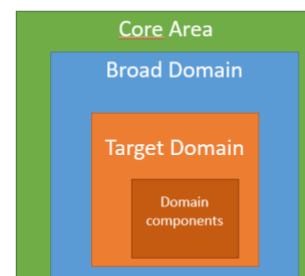
Working Group: _____

Target population _____

Intended use for this domain: _____ (e.g., RCT)

Intervention in trial: _____

Comparator in trial: _____



Core Area	<i>Life Impact</i>
Broad domain	<i>The general or broad domain, like “Pain Impact”</i> <i>Physical functioning</i>
Target Domain	<i>The name you are giving this more specific domain i.e., impact of pain on life activities in all realms of life- physical, social and role functioning. This is what we will be focusing on for measurement. Perceived physical functioning in daily activities</i>
Working definition of target domain	<i>Create a working definition in detail. Don’t just repeat the domain name, flesh this out, this is what people will see in your paper. Sometimes this is a definition from another conceptual framework – for example the definition of pain impact should range from periodic interference over the course of one week to inability to do any activities due to this pain.</i> <i>Specify difficulty or frequency of experienced limitation.</i> <i>Consider the context – dependence on others because of limitations, difficulties doing activities, or more objective, capacity versus performance</i> <i>Appraisal – how is the assessment being done?</i>
Domain components	<i>Outline here the components of your domain that are important for a good instrument to capture.</i> <i>e.g., pain impact on ADL’s, pain impact on work life, pain impact on social activities.</i>

	<i>Should not include pain impact on personality and personal relationships</i>
Qualitative or literature support	<p><i>Add in some quotes here from the qualitative work you have done. Consider examples of the breadth of the experience of this domain – high levels and low levels. Consider talking in more depth about what is included in this domain and what should NOT be considered part of this domain.</i></p> <p><i>This section is particularly important because it is easy to do as you work on your domains, and it will serve you well as a basis for your review of content validity when you start to look at candidate instruments. This definition sheet will be stored on OMERACT’s website.</i></p>
Sources of variability in score	<p><i>Please think through sources of variability or contextual factors that might impact the results (scores) when you measure this domain. For example, is there a large difference seen between people gathering the data? Is there a large difference between cultures or continents? Please see paper by contextual factors group Sabrina Nielsen et al, Ann Rheum Dis, 2020 (https://doi.org/10.1136/annrheumdis-2020-217237), and work on lessons from imaging outcomes lesson #2 (https://omeract.org/working-groups/improving-instrument-selection-lessons-for-omeract-from-imaging/)</i></p>