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Using common data elements to foster interoperability of research on health disparities

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Abstract

Common data elements (CDEs) are standardized questions, variables, or measures with specific sets of responses that are used across multiple studies. They are organized around a particular research topic or question, validated, and defined via a consensus building process. Their use fosters comparability of results and findings across studies. CDEs are more common in National Institutes of Health (NIH)-funded clinical and biomedical research than in social, behavioral, and economic (SBE) research. Yet the community-driven, consensus-building approach to defining CDEs makes them well suited to measuring complex social phenomena. The Social, Behavioral, and Economic COVID Coordinating Center at ICPSR (SBE CCC) is leading the effort to establish CDEs for SBE research into the effects of the COVID-19 pandemic. We are collaborating with fifteen NIH-funded research teams who are examining pandemic-related health disparities related to race, ethnicity, sex, geography, income, and other factors. In this article, we discuss ways in which CDEs support research into health disparities and describe our process for identifying, validating, and building consensus on CDEs related to COVID public health policies.

Keywords

Common data elements, health disparities, research interoperability, social science research

Introduction

Common data elements (CDEs) are standardized questions, variables, or measures with specific sets of responses that are used across multiple studies to ensure consistent data collection (National Library of Medicine, no date). CDEs originated in clinical health research, and they remain more widely used in some of the clinical sciences than in the social sciences (Sheehan et al., 2016). Initiatives such as the [PhenX Toolkit](#)³, [RADx-UP](#)⁴, and the [All of Us research program](#)⁵ have begun to expand CDEs from the clinical sciences into the social sciences. In particular, the COVID-19 pandemic has offered an opportunity to rapidly develop CDEs for understanding the experiences of COVID-19 (Krzyzanowski et al., 2021; Carrillo et al., 2022; Gleason, Tamburro and Signore, 2023). To date, however, CDEs are still less common within social, behavioral, and economic (SBE) research than clinical or biomedical research. This is particularly true when it comes to studying the effects of COVID-19 beyond diagnosis and symptoms, for example, the economic or educational impacts of mitigation policies implemented by federal, state, and local governments in 2020.

To support interoperability and consistency in SBE research into COVID-19, the National Institutes of Health (NIH) established the Social, Behavioral, and Economic COVID Coordinating Center (SBE CCC). Administered by ICPSR, a social science research data repository at the University of Michigan

Institute for Social Research, SBE CCC was established in 2021 as a coordinating center to foster collaboration across a consortium of 15 NIH-funded research teams (the SBE COVID Consortium) examining different social, behavioral, and economic outcomes related to the COVID-19 pandemic. A primary aim of SBE CCC is promote the use of CDEs in social science research on COVID, including the creation and establishment of new CDEs for SBE research.

In this article, we will provide an introduction to the purpose and structure of CDEs, discuss their potential applications to SBE research, and describe SBE CCC's process for establishing new CDEs for use in measuring COVID-19 mitigation policies.

About CDEs

The benefits of CDEs for standardizing data collection and improving reproducibility of studies are widely recognized, especially within the clinical sciences (Rubinstein and McInnes, 2015; Lapinlampi et al., 2017; Kush et al., 2020). In the absence of standardization efforts, it is common and likely for key concepts in scientific research to be measured differently across studies; examples can be found in a variety of topics such as human anatomy (Ioannou et al., 2011), social isolation in aging (Evans et al., 2019), and the COVID-19 era labor market (Maas, 2022). CDEs make it possible to compare results across studies, resulting in research that is more interoperable. In some cases, when using CDEs it becomes possible to combine results across small studies, making these studies collectively more meaningful and impactful. Also, they save time, money, and effort during data collection because they offer ready-made questions and responses instead of requiring researchers to create their own.

CDEs also have their limitations. For example, uptake is limited, and gaps in subject matter coverage exist. Also, because CDEs have arisen from different NIH-funded centers and initiatives, they can be siloed. Different CDEs from different sources may exist to measure the same concept, without accompanying guidance on how to select the most appropriate CDE for a given research question (Kush et al., 2020).

Despite these limitations, many researchers and funders recognize the value that CDEs bring to research studies. Several NIH centers encourage and sometimes require the use of CDEs in funded research (Meeuws et al., 2020; Wandner et al., 2022). In 2015, the National Library of Medicine (NLM) created a searchable [repository](#)⁶ of CDEs to bring together CDEs established by multiple different centers and initiatives across NIH.

Figure 1 illustrates a typical common data element from the NLM repository. A typical CDE might be a single question from a survey questionnaire or a component of a clinical protocol. Each CDE contains a definition, standardized wording for the question, a data type, and for value lists, a set of permissible responses. Concepts represented by the question itself and its permissible values are typically linked to concept identifiers found in controlled vocabularies like the [National Cancer Institute Thesaurus](#)⁷. Some CDEs are part of forms (also known as bundles) or sets of data elements that are only valid when asked as a set. If a CDE is part of a form, it is flagged that way in the CDE repository, with a link to the other questions in the same form.

Employment Status

This CDE is part of a bundle. All CDEs within a bundle must be used together. [Go to bundle](#)

Question Text

We would like to know about what you do-are you working now, looking for work, retired, keeping house, a student, or what?

Definition

A textual description of a person's employment status.

Data Type: Value List

Steward: Project 5 (COVID-19)

Origin:

Data Type Details

Data Type: Value List

Permissible Value

PV Labels	PV Definitions	PV Concept Identifiers	PV Terminology Sources	Codes for PVs	PV C Sysl
Working without pay	Exertion or effort directed to produce or accomplish something.: Used to indicate the absence or lack of something or someone.:Money or other benefits received in exchange for work. C74299:C25718:C180612	C74299:C25718:C180612	NCI Thesaurus		
Employed full-time	Employed for a standard number of hours of working time, at least 50% or 20 hours per week. C52658	C52658	NCI Thesaurus		
Employed part-time	Employment involving less than the standard or customary working time. C75562	C75562	NCI Thesaurus		

Figure 1. Screenshot from the NLM CDE repository showing a common data element for the concept "employment status." The screenshot shows the standard question text, definition, possible values, and links to controlled vocabulary.

The path from data element to NLM-endorsed CDE typically follows three steps. First, CDEs originate not as abstract concepts, but as variables in research studies. One common origin for CDEs is in existing instruments or scales which have already been validated and are widely used within a given discipline, such as the Kessler Screening Scale for Psychological Distress (K6) (Kessler et al., 2010). For measures of new and emerging concepts where validated measures do not already exist, as is the case for COVID-19, CDEs can be derived from other sources. One example is the set of CDEs for the study of COVID-19 taken from the [RADx-UP initiative](#)⁸ in 2021.

The next step in defining CDEs for a given research area is to convene a working group of individuals with expertise in that area. Working group members are subject matter experts and leaders in their fields. Their role is to establish consensus on which data elements are the best candidates to become CDEs for a given domain of study. This consensus building phase is typically followed by a process for gathering feedback on proposed CDEs. Redeker et al. (2015) provides a useful case study for the process of creating CDEs for the research domain of symptom science, a field of interest within nursing research. The authors describe how a group of experts from the National Institute for Nursing Research worked as a group to select a list of symptoms (e.g. pain, fatigue), identify validated measures for these symptoms (e.g. the PROMIS Pain and PROMIS Fatigue scales), and

establish consensus on which measures were best suited to become CDEs (e.g. based on appropriateness for study aims, cost, and participant burden).

The final step to becoming a CDE is review by NIH's CDE Governance Committee. Typically, this is initiated either by an NIH-sponsored project or within NIH. But in some instances, if there is a mission-critical gap and available funds, NIH-funded investigators could potentially work with their program officers to submit CDEs to the NIH CDE Governance Committee for review and inclusion in the NLM CDE repository as NIH-endorsed CDEs.

CDEs address the four key principles of open science and of good data management – findability, accessibility, interoperability, and reusability (FAIR)⁹ – at multiple stages of the research data lifecycle. During the study design phase, a researcher can search the CDE repository to find commonly used variables to incorporate into their study. Using measures that are common across studies improves the *interoperability* of their work and enhances the *reusability* of their study by making their data suitable for analysis in comparison with other studies or for use in meta-analyses. During the data sharing and preservation stage of a study, novel measures created or identified in study design can be submitted to the NLM CDE repository. This supports *findability* and *accessibility* by making new measures available for researchers while again supporting *interoperability* and *reusability* by promoting inclusion of those measures into new studies.

Potential for CDEs in studying health disparities

CDEs originated in clinical research and are more commonly found in some (though not all) clinical disciplines. They were not created for the purpose of measuring complex social phenomena. Figure 2 illustrates this history by showing the distribution of CDEs by their source – the center or initiative within NIH that was responsible for adding them to the NLM CDE repository. Of the centers and initiatives represented in this figure, many major contributors of CDEs – National Institute of Neurological Disorders and Stroke (NINDS), National Cancer Institute (NCI), and National Heart, Lung, and Blood Institute (NHLBI) – are in the clinical sciences. Only the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) has funded social and behavioral research that has helped establish CDEs.

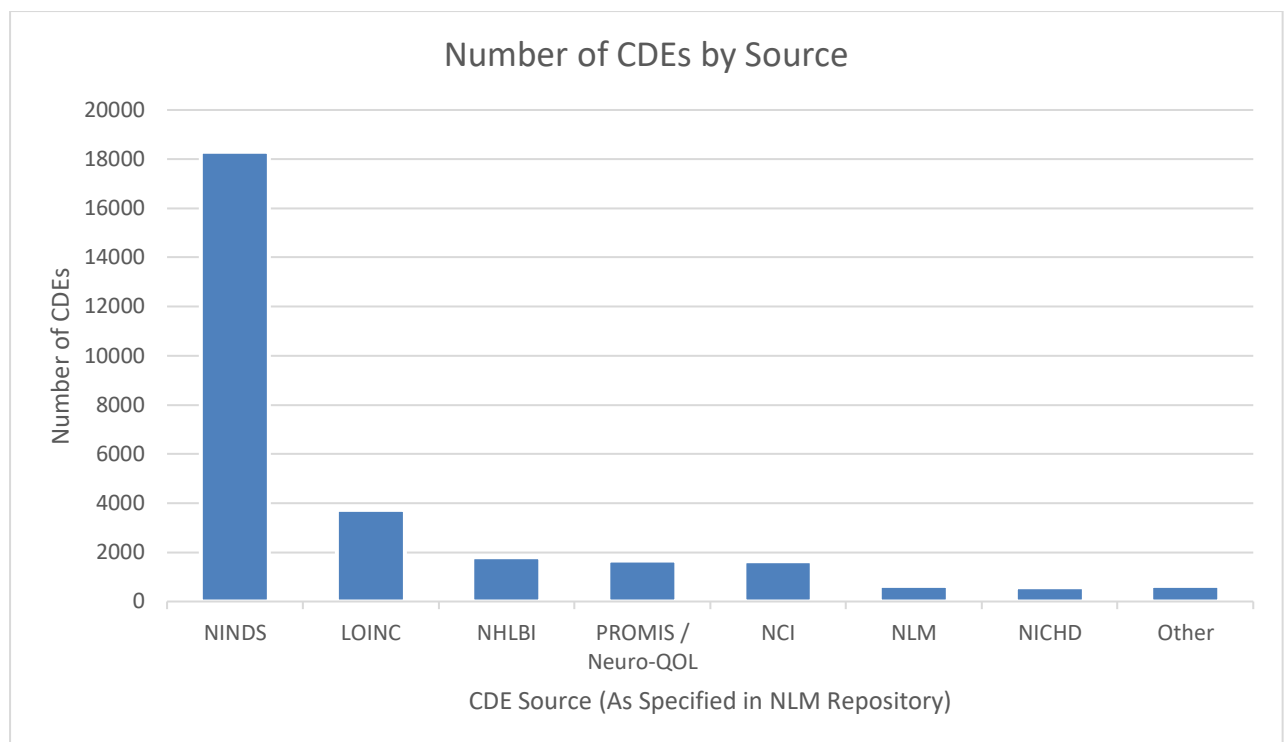


Figure 2. Bar graph illustrating the relative contributions of CDEs by source. Sources correspond to NIH centers or initiatives. (NINDS = National Institute of Neurological Disorders and Stroke. LOINC = Logical Observation Identifiers, Names, and Codes. NHLBI = National Heart, Lung, and Blood Institute. NCI = National Cancer Institute. PROMIS = Patient-Reported Outcomes Measurement Information System. NICHD = Eunice Kennedy Shriver National Institute of Child Health and Human Development)

This disparity in CDE uptake is understandable to a certain extent given the different nature of the concepts being studied in the clinical vs. social sciences. While biomedical concepts such as, for example, blood pressure and body weight pose their own challenges for measurement and interpretation, their definition is more straightforward than many concepts of interest in the social sciences, such as anxiety or wealth. Yet despite this challenge, social science researchers have recognized the benefits of standardized measures and worked to establish shared measures. Examples include the Diagnostic and Statistical Manual of Mental Disorders (DSM) in psychology and the North American Industry Classification System (NAICS) in economics. Similarly, CDEs bring value to the study of health disparities and the complex concepts that must be measured in social research into health disparities in several ways.

First, CDEs support interoperability in research, even when applied to hard-to-measure concepts. To consider a few examples, studies of COVID-related health disparities may entail defining and measuring sociodemographic characteristics (race, gender identity, essential worker status), mental or behavioral health outcomes (wellbeing, stress), and policy interventions (mask mandates, economic assistance). Each of these concepts represents one or more variables that needs to be defined and quantified before analysis is possible. Studies that measure concepts in incompatible ways may reach different and even conflicting conclusions simply because of those differences in measurement. To give an example, two studies of the impact of essential worker status on mental health during COVID-19 might reach different conclusions if one uses self-reported essential worker status while another uses job-based industry codes. Even if these two ways of defining essential worker status contain inherent limitations, use of the same CDE or shared measure can reduce the

likelihood that differences found by these two studies are due to differences in measurement of essential worker status.

Second, CDEs support specificity of research measures for a given research topic. Several of the examples provided above represent complex identities, such as race and gender identity, that require a great deal of nuance in definition and measurement. Measuring these topics in the same way across all research domains and contexts may not be appropriate. Because CDEs are domain-specific, they can help researchers identify the best measures for their research domain.

Finally, CDEs provide a mechanism for establishing and sharing consensus. Definitions of social phenomena shift in response to changes in consensus, understanding, and best practices. CDEs arise from consensus within a given research domain, offering a process for capturing current consensus on how to measure these concepts and disseminating it across studies. Furthermore, while efforts to date have focused primarily on creating new CDEs, it is possible in the long term to follow these same processes to revise CDEs in response to evolving research. For example, the National Institute of Neurological Disorders and Stroke (NINDS) maintains a [form](#)¹⁰ that can be used to recommend either new CDEs or substantial revisions to existing CDEs.

CDEs for social, behavioral, and economic COVID Research

One of the first projects launched by SBE CCC was to define a set of CDEs for capturing data about COVID-19 mitigation policies undertaken by state and local governments during the COVID-19 pandemic. These policies include mask mandates, school closures, business closures, and food and rental assistance programs. Defining CDEs for policy measures was a critical first effort because health policy in general, and COVID mitigation policies in particular, have been shown to affect health and to do so inequitably depending on race, income, employment, health insurance status, and other factors (Koppaka, 2011; Thompson, 1993; Nana-Sinkam et al., 2021; Park, 2021). COVID mitigation policies were also not equally distributed geographically during the pandemic.¹¹ Nor were they static, as policies changed over time. Finally, the tracking of these policies was done through many data sources, each measuring these policies in different ways. All of these factors undercut the ability to harmonize measures and reach consensus regarding the effectiveness of specific policy interventions.

The process to define CDEs for COVID mitigation policies was as follows:

1. Working with the 15 research teams that comprise the SBE COVID Consortium, SBE CCC conducted an inventory of policy measures used in their studies, focusing on:
 - a. types of policies being measured,
 - b. level of geography (usually state or county),
 - c. data source(s) used.
2. We searched published literature for other articles measuring similar concepts, identified additional COVID mitigation policy measures and data sources, and combined them with the inventory results to create a list of COVID mitigation policy measures and the data sources they were derived from.
3. We documented common concepts found across measures and data sources. For example, one study contained a variable “Days of Exposure to Gym Closure Mandate” measured in number of days. Another study contained a similar variable, “Gym Closure in Effect as of

[Date]” with values ranging from 0 (no restrictions) to 3 (closed). Both measures imply that the underlying data pertains to gym closures, has a start and end date, is a mandate rather than a recommendation, and is at the state level.

4. We held a meeting with SBE COVID Consortium members to review findings and obtain feedback on the completeness of our list of common concepts. Based on this discussion, we added some details to the list of concepts identified in the literature review; for example, a policy might apply to only a portion of the population (e.g. unvaccinated individuals) rather than everyone.
5. We drafted a list of CDEs based on the common concepts identified in steps 3 and 4. Each CDE included a variable name and label, question text, a predefined format, and possible values. For example, the CDE for “policy type” has question text that reads “What type of COVID-19 mitigation policy was enacted?” and possible values “mask policy,” “social distancing policy,” and “business closure policy,” among others.
6. Draft CDEs were shared again at a meeting of SBE COVID Consortium members and NIH stakeholders for final validation.
7. We worked with our NIH program officer to submit the CDEs to NLM’s repository.
8. NLM’s CDE governance committee approved the submission, and SBE CCC’s COVID mitigation policy CDEs were [published](#) in the NLM CDE repository in July 2024.

Table 1 lists CDE names, their brief definition, and an example of the format or some possible values for each. Detailed information about each CDE, including question text and a complete list of possible values, can be found in the [NLM CDE repository](#)¹². and on [SBE CCC’s website](#).¹³

Common Data Element	Definition	Example Values
Start date	The date on which a COVID-19 mitigation policy was enacted or went into effect.	4/1/2020
End date	The date on which a COVID-19 mitigation policy was repealed, superseded, or invalidated.	12/31/2020
Geographic level	The type of governing body or jurisdiction (in the U.S.) that is implementing the policy, e.g. state government, county government, or school district).	State government County government School district
Coverage area	The full name of the jurisdiction (e.g. the name of the state, county, or school district) to which the mitigation policy applies.	California Alameda [county] Oakland Unified [school district]
Policy type	The type of COVID-19 mitigation policy that may be enacted by governments and municipalities.	Mask policy Business closure Work from home policy
Target population	The population and/or group(s) for whom a COVID-19 mitigation policy is intended to affect.	All individuals Employees of businesses Unvaccinated people

Setting	The location or environment in which the COVID-19 mitigation policy applies.	All retail businesses Restaurants Schools
Regulation type	The type of regulation a reflected in a COVID-19 mitigation policy (i.e., a mandate, guidance, recommendation, or limitation/restriction on future policies).	Requirement Recommendation Restriction

Table 1. COVID mitigation policy CDEs created by SBE CCC.

Unlike many efforts to define CDEs, which employ existing questions or previously validated measures, SBE CCC's approach entailed identifying common concepts found in datasets used to collect data on COVID mitigation policies. We adopted this approach for two reasons. One practical reason is that COVID mitigation policies were a novel phenomenon and there were no previously validated measures or consensus on measurement best practices. Another reason was that this approach allowed us to identify commonalities across data sources and reveals some underlying harmonies across variables that differ in question text and possible values. SBE CCC found this approach useful and worth applying to future efforts to define new CDEs for social, behavioral, and economic disciplines.

Next steps and future research

Throughout the process of defining and publishing our COVID mitigation policy CDEs, SBE CCC has conducted outreach to researchers through social media, mailing lists, and presentations at conferences such as the Society for Epidemiological Research annual meeting. One opportunity for future research is to review data sources identified in the inventory of policy measures and compare how completely they capture the concepts outlined in our policy CDEs. SBE CCC's CDEs provide a framework for highlighting commonalities, differences, and harmonization challenges across data sources. A side-by-side comparison of the policy datasets identified during our inventory will help future researchers foresee harmonization issues and select policy datasets that are best suited to their research questions. Additionally, SBE CCC plans to review the existing CDEs in the NLM repository that relate to COVID, with the aim of identifying overlap and as a next step in establishing consensus on preferred measures. Finally, SBE CCC has launched a [COVID measures archive](#), a searchable database of variables used in social, behavioral, and economic studies of the COVID pandemic¹⁴. Measures come from the 15 SBE COVID Consortium members, as well as other major studies that incorporated questions about COVID. Measures in the COVID measures archive can be used to identify commonalities and differences across studies, and to identify more opportunities for novel measures to be promoted as CDEs in NLM's repository of CDEs.

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Endnotes

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³ <https://www.phenxtoolkit.org/>

⁴ <https://radx-up.org/>

⁵ <https://allofus.nih.gov/>

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- ⁶ <https://cde.nlm.nih.gov/>
- ⁷ <https://ncithesaurus.nci.nih.gov/ncitbrowser/>
- ⁸ <https://cde.nlm.nih.gov/cde/search?selectedOrg=RADx-UP>
- ⁹ For a summary of FAIR data principles, see <https://force11.org/info/the-fair-data-principles/>
- ¹⁰ <https://ninds.nih.gov/NINDS-CDE-Project-Request-Form>
- ¹¹ As an example, see the map of mask mandate policies by state as of November 9, 2020:
<https://abcnews.go.com/Health/states-mask-mandates-map/story?id=74168504>
- ¹² <https://cde.nlm.nih.gov/formView?tinyId=EUQJdXlf8k>
- ¹³ <https://www.icpsr.umich.edu/files/sbeccc/SBE-CCC-Common-Data-Elements-Policy.pdf>
- ¹⁴ <https://www.icpsr.umich.edu/web/sbeccc/search/variables>