

**REPORT DOCUMENTATION PAGE**

*Form Approved  
OMB No. 0704-0188*

The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Service Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

**PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ORGANIZATION.**

|  |                                 |  |
|--|---------------------------------|--|
| <b>1. REPORT DATE (DD-MM-YYYY)</b><br>30/04/2018 | <b>2. REPORT TYPE</b><br>Poster | <b>3. DATES COVERED (From - To)</b><br>04/30/2018-05/03/2018 |
|--|---------------------------------|--|

|  |                                   |
|--|-----------------------------------|
| <b>4. TITLE AND SUBTITLE</b><br>Common Data Elements: A Primer | <b>5a. CONTRACT NUMBER</b>        |
|  | <b>5b. GRANT NUMBER</b>           |
|  | <b>5c. PROGRAM ELEMENT NUMBER</b> |

|  |                             |
|--|-----------------------------|
| <b>6. AUTHOR(S)</b><br>Gardner, Cubby L, Maj | <b>5d. PROJECT NUMBER</b>   |
|  | <b>5e. TASK NUMBER</b>      |
|  | <b>5f. WORK UNIT NUMBER</b> |

|  |  |
|--|--|
| <b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b><br>59th Clinical Research Division<br>1100 Willford Hall Loop, Bldg 4430<br>JBSA-Lackland, TX 78236-9908<br>210-292-7141 | <b>8. PERFORMING ORGANIZATION REPORT NUMBER</b><br><br>17837 |
|--|--|

|   |   |
|---|---|
| <b>9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b><br>59th Clinical Research Division<br>1100 Willford Hall Loop, Bldg 4430<br>JBSA-Lackland, TX 78236-9908<br>210-292-7141 | <b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>       |
|   | <b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b> |

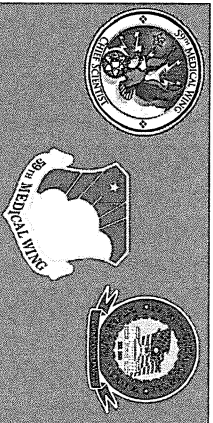
**12. DISTRIBUTION/AVAILABILITY STATEMENT**  
Approved for public release. Distribution is unlimited.

**13. SUPPLEMENTARY NOTES**  
TSNRP Research and Evidence-Based Practice Dissemination Course 2018, April 30 - May 3, San Antonio, TX

**14. ABSTRACT**

**15. SUBJECT TERMS**

|  |                    |                     |                                   |                            |  |
|--|--------------------|---------------------|-----------------------------------|----------------------------|--|
| <b>16. SECURITY CLASSIFICATION OF:</b> |                    |                     | <b>17. LIMITATION OF ABSTRACT</b> | <b>18. NUMBER OF PAGES</b> | <b>19a. NAME OF RESPONSIBLE PERSON</b><br>Clarice Longoria       |
| <b>a. REPORT</b>                       | <b>b. ABSTRACT</b> | <b>c. THIS PAGE</b> |                                   |                            | <b>19b. TELEPHONE NUMBER (Include area code)</b><br>210-292-7141 |



# Common Data Elements: A Primer

Maj Cubby L. Gardner<sup>1</sup>, CDR Lalon M. Kasuske<sup>2</sup>  
<sup>1</sup>59th Medical Wing, JBSA Lackland, TX; <sup>2</sup>Navy Medical Center, Portsmouth, VA

Approved for Public Release  
 Distribution is Unlimited

## Background

The National Institutes of Nursing Research (NINR) advocates data sharing across research efforts, strongly encouraging the use of common Data Elements (CDEs) in NINR-funded studies. Data operationalization and collection variability limits comparability and replication. One way to mitigate data variability is to standardize variable operationalization and collection. The CDE Resource Portal, managed by the National Library of Medicine, provides educational and resource to improve data quality and comparability across human-subjects research such as clinical trials and clinical registries.

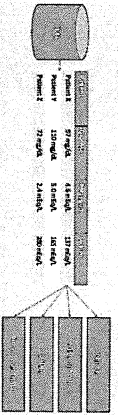
## Methods

A CDE is a data element mutual to multiple data sets across different studies operationalized and measured identically. Further, CDEs may extend to research protocol terms, data collection methods, as well as data obtained and analytic techniques common to a scientific domain. Consequently, development of standardized CDEs is a re-iterative process requiring community involvement and expert consensus. To maintain continuity, the NLM defines four distinct types of CDEs for use within the CDE Repository: universal, domain-specific, required and core.

## Findings

What is a common data element?

\* A "data element" is defined as "a logical unit of data pertaining to one kind of information, that includes a name, precise definition, and clearly enumerated values."<sup>1</sup>



\* "A data element mutual to multiple data sets across different studies operationalized and measured identically."<sup>2,3</sup>

| Element | Value      | Element | Value      |
|---------|------------|---------|------------|
| Patient | 1234567890 | Patient | 9876543210 |
| Patient | 1234567890 | Patient | 9876543210 |
| Patient | 1234567890 | Patient | 9876543210 |

What is a common data element?

## Findings

What is a common data element?

\* "A data element mutual to multiple data sets across different studies operationalized and measured identically."<sup>2,3</sup>

| Element | Value      | Element | Value      |
|---------|------------|---------|------------|
| Patient | 1234567890 | Patient | 9876543210 |
| Patient | 1234567890 | Patient | 9876543210 |
| Patient | 1234567890 | Patient | 9876543210 |

**Universal** - Universal data elements are those that exist across studies or conditions. These data elements are equally applicable to a clinical inquiry of cancer research as they are to the cultivation of health habits. Universal data elements commonly refer to attributes of a population, such as age, sex, race, education, health insurance, and occupation. Health history include demographics or medical history.

| Element | Value  | Element | Value   |
|---------|--------|---------|---------|
| Patient | 47 yrs | Female  | Single  |
| Patient | 11 mo  | Male    | Single  |
| Patient | 32 yrs | Male    | Married |

**Domain-specific** - Domain-specific data elements are unique to specified sphere of activity or knowledge. They are attributes of a particular phenomenon, topic, or other classification. For example, amputrophic lateral sclerosis (ALS) severity score - total score value is meaningful in the context of ALS investigation but is dramatically less useful outside that context.

| Element | Value | Element | Value |
|---------|-------|---------|-------|
| Patient | 4/20  | ALS     | 2/5   |
| Patient | 5/20  | ALS     | 3/5   |
| Patient | +3/5  | ALS     | 4/5   |

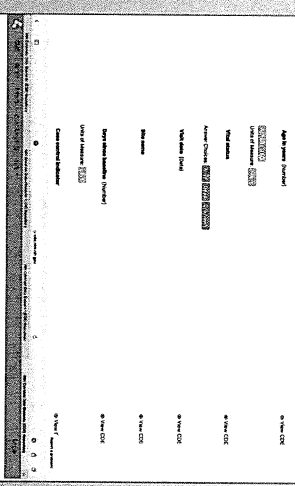
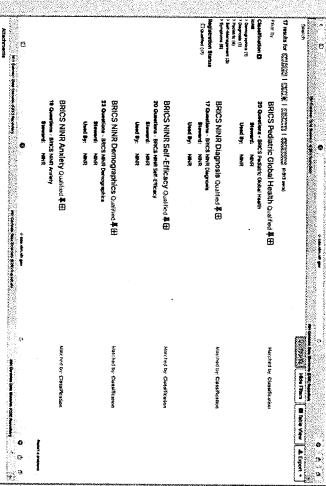
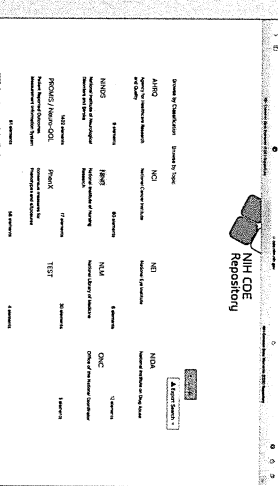
**Required** - Required data elements are those elements which must be included in the data set for a study to be conducted. Required data elements are often defined in institutional policy, such as those needed for a funding agency.

| Element | Value   | Element | Value   |
|---------|---------|---------|---------|
| Patient | 300234  | SCAD456 | 2001234 |
| Patient | 2456789 | SPR3211 | 2001234 |
| Patient | 7890123 | 7890123 | 2001234 |

**Core** - Core data elements represent fundamental attributes of a phenomenon. Required core data elements are necessary to provide sufficient data to adequately describe a phenomenon, while optional core data elements enhance the cognitive structures of a phenomenon's description or a phenomenon's critical the understanding.

| Element | Value | Element | Value |
|---------|-------|---------|-------|
| Patient | 118   | 71      | 53    |
| Patient | 154   | 91      | 54    |
| Patient | 128   | 76      | 53    |

## Findings



## Conclusion

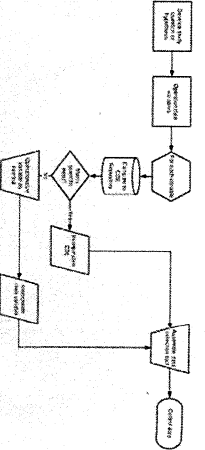
The NIH CDE Repository is not a stand-alone effort; instead, it is a multi-agency collaborative whereby research communities develop, contribute to, and monitor data definitions and collection standards that meet the needs of the respective community, incorporating 23,088 data elements across CDEs developed by consensus at the foremost centers of clinical inquiry.

Benefits of CDEs: reduced cost, improved data quality, consistency, timeliness, completeness.

Limitations of CDEs: suitability for purpose, accuracy, granularity, precision, maturity

## CDE Selection Logic

Consider integrating CDEs into your next research effort with following selection logic:



## Implications for Nursing

Nursing interests are represented in the NIH CDE Repository as contributions by the NINR which include 17 separate classifications incorporating: demographics, diagnosis, pediatrics, self-management, and symptoms, resulting 79 data element definitions.

## Acknowledgement

DISCLAIMER: The views expressed are those of the presenters and do not reflect the official views or policy of the Department of Defense or its components.

