

Developing Common Data Elements & An International Consensus For Their Use



Shän Ward, MD MAS

shan.ward@ucsf.edu

Definition: Common data element (CDE)?

A combination of a precisely defined question
paired with a specified set of responses

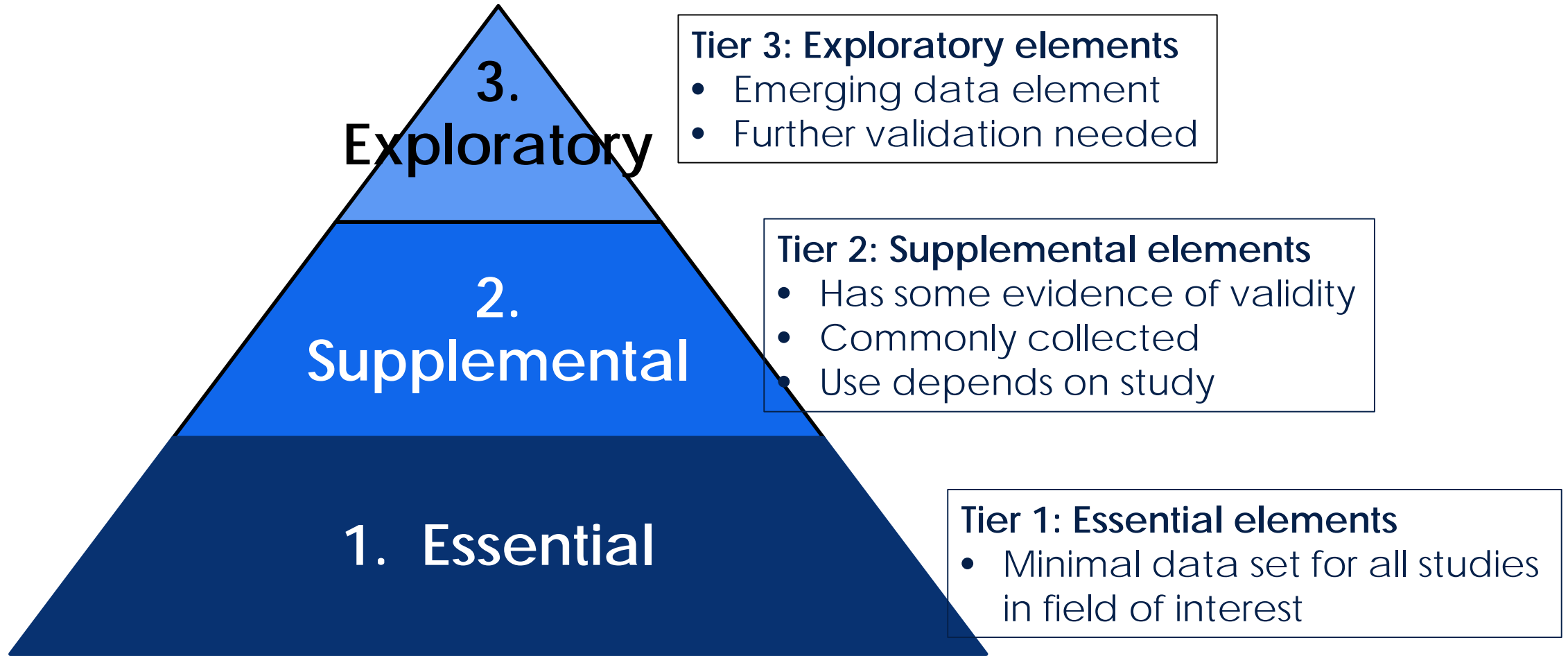
Value of CDEs

- Creating common data structure and definitions will:
 - ↑ efficiency with ↓ cost
 - Rapid study start up
 - Promotes collaboration
 - Maximizes the information learned after the years of initial enrollment
 - May promote better understanding at the population level
 - Customizable if the data entry criteria are robust and explicit

CDE Development Process

Executive Committee	Select core group of experts Develop first draft of CDEs
Review	Published definitions Prior data collections forms
Domains	Section data into domains of interest e.g. Demographics, Hospitalization Summary
Tiers of Importance	Hierarchical approach to data collection Creation of a standardized minimal data set

CDE Tiers of Importance



Example: ARDS

Domains of Interest:

1. Demographics
2. Admission Data & Severity of Illness
3. Prior Medical History
4. ARDS Diagnostic Criteria
5. Hospitalization Summary
6. Pertinent Daily Data

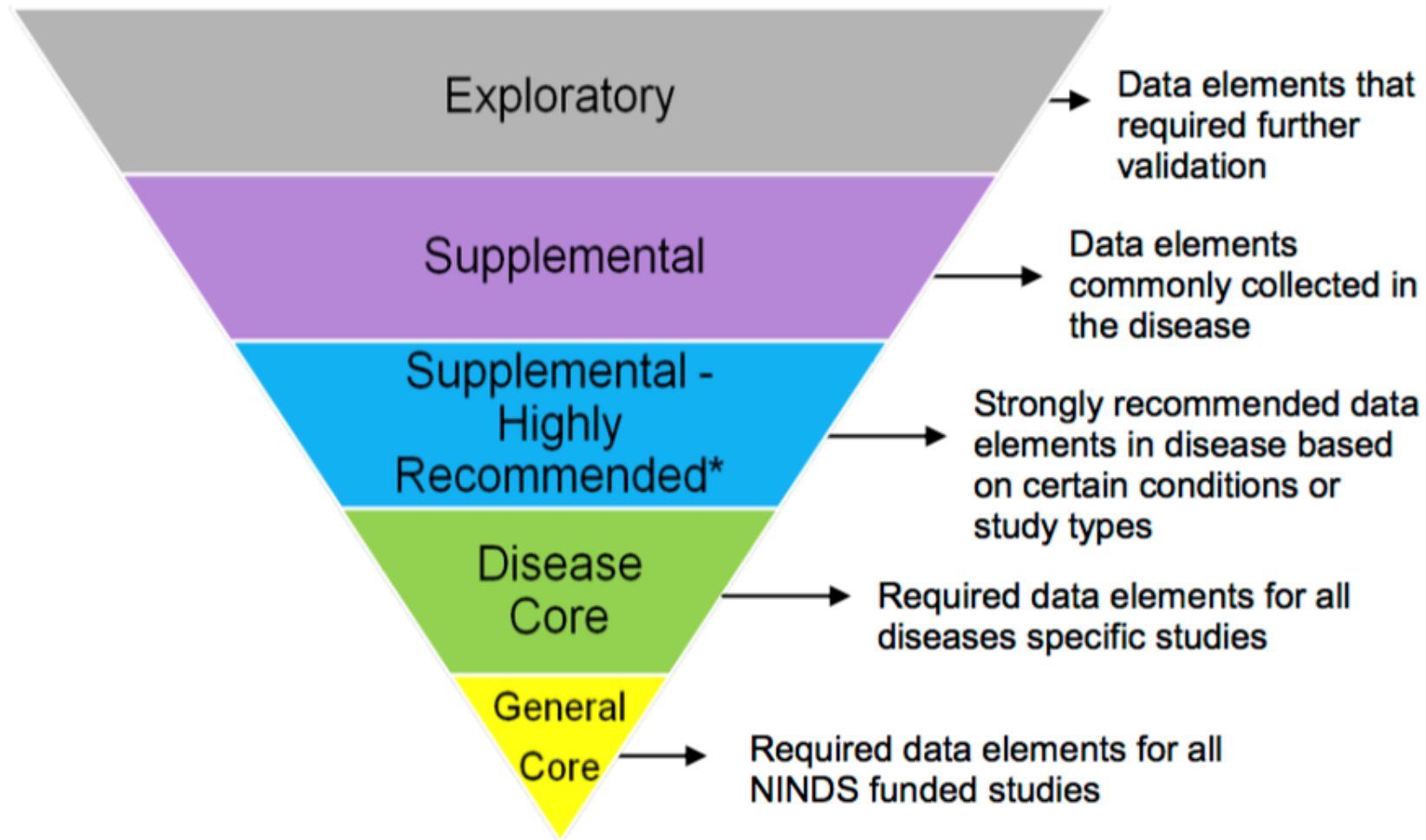
Sample Tier 1 and 2 CDE

☐ Y ☐ N Any history of chronic lung disease?
(Defined as any long term lung disease that requires daily medications or respiratory support)

Tier 2: If Yes, please document specific chronic lung disorder(s):

- ☐ 1. Asthma
- ☐ 2. Cystic fibrosis
- ☐ 3. Bronchopulmonary dysplasia
- ☐ 4. Interstitial lung disease
- ☐ 5. Pulmonary hypoplasia / dysplasia
- ☐ 6. Vascular ring or sling
- ☐ 7. Other, please specify: _____

NINDS Hierarchical Approach



* Classification term of "Basic" used for Traumatic Brain Injury CDEs

Consensus Process

Consensus Members	International Experts in the field Multidisciplinary
Delphi Round 1	Vote on all CDEs (tier of importance & format) Set acceptable level of agreement <i>a priori</i>
Delphi Round 2	Areas of disagreement Areas of major reformat
Lack of Agreement	Evaluate reason for lack of agreement Offer options (all Tier 2) Provide explanation for future users

Lessons Learned

Executive & Consensus Members must be:

- Experts
- Multidisciplinary
- Practical / logical
- Willing to donate time (lots of time!)
- Check egos and agendas at the door

Dissemination & Utilization

- Consensus conference findings published in appropriate journal
- Conversion of CDEs into REDCap friendly .csv (or other) format
- Access via web data hub
- Plan for future revisions

Thank You

Shan.ward@ucsf.edu

Methodology published:

Ward SL, Pediatr Crit Care Med. 2020 Nov;21(11):e1038-e1041

PMCID: PMC7609513