SESSION III: Training on Conducting the Informed Consent Process

Jennifer Lentz, Eli Lilly & Co.

March 10, 2015

CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

Session III Objectives

- Present examples of innovative informed consent training programs
- Solicit feedback and develop consensus on proposed recommendations related to informed consent process training programs

A Training Program for Improving the Informed Consent Discussion Between Clinical Researchers and Their Subjects

Mary Ellen Cadman (National Institute of Mental Health, NIH)

Julie Brintnall-Karabelas (National Institute of Mental Health, NIH)

March 10, 2015

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Based on a True Story: Using Re-Enactments of Actual Clinical Visits to Improve Oncologist Communication about Clinical Trials

Susan Eggly (Karmanos Cancer Institute)

March 10, 2015

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Proposed Recommendations for Informed Consent Training Programs

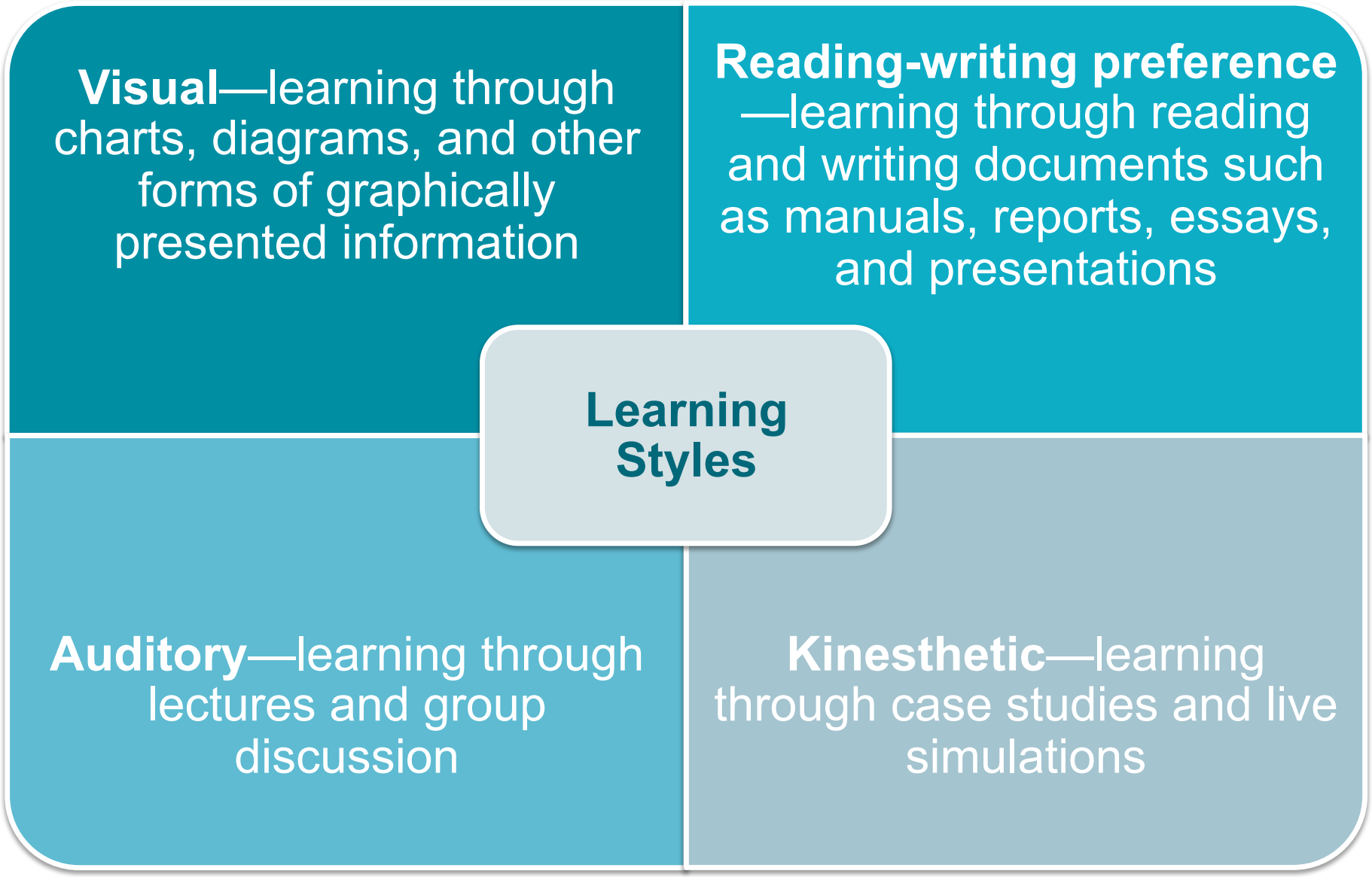
Michele Kennett, University of Missouri

March 10, 2015

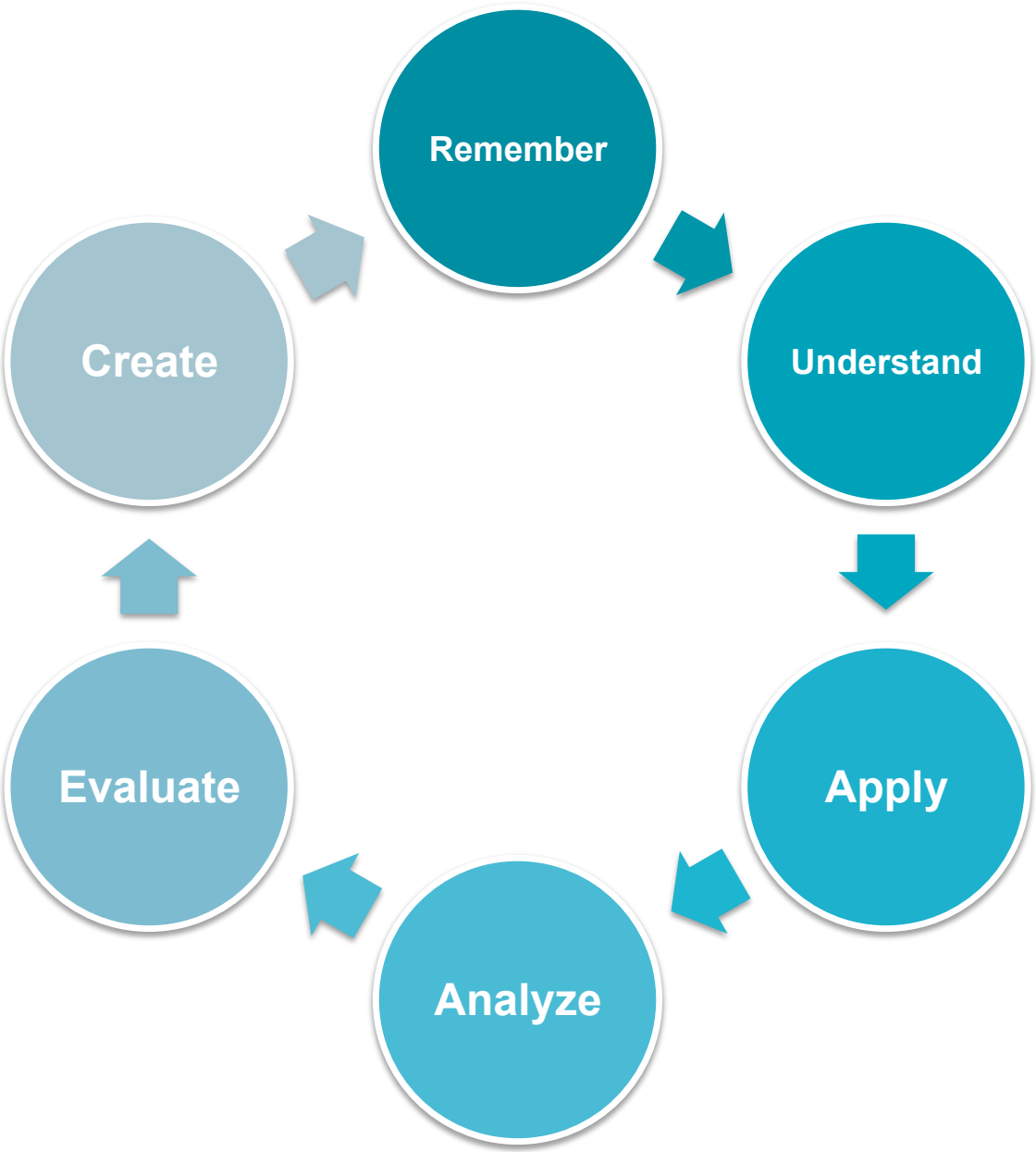
CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Training for the Informed Consent Process

- Not a “one-size-fits-all” scenario
- Not all people learn in the same way, at the same pace and/or are at the same level of skill development
- Should include
  - How to tailor messages to the individual participant’s needs
  - How to address possible challenges that may occur
  - How to encourage participant questions
  - How to prioritize information shared with the participant


Visual—learning through charts, diagrams, and other forms of graphically presented information
Reading-writing preference—learning through reading and writing documents such as manuals, reports, essays, and presentations
Learning Styles
Auditory—learning through lectures and group discussion
Kinesthetic—learning through case studies and live simulations

Bloom's Cognitive Development Process



Proposed Recommendations

- Strongly encourage study personnel participating in the ICP to take part in a formal training program
- May be required by individual research site, but should not be federally mandated
- Should be evaluated periodically and adjusted as needed to ensure they are meeting the needs of trainees

Proposed Recommendations

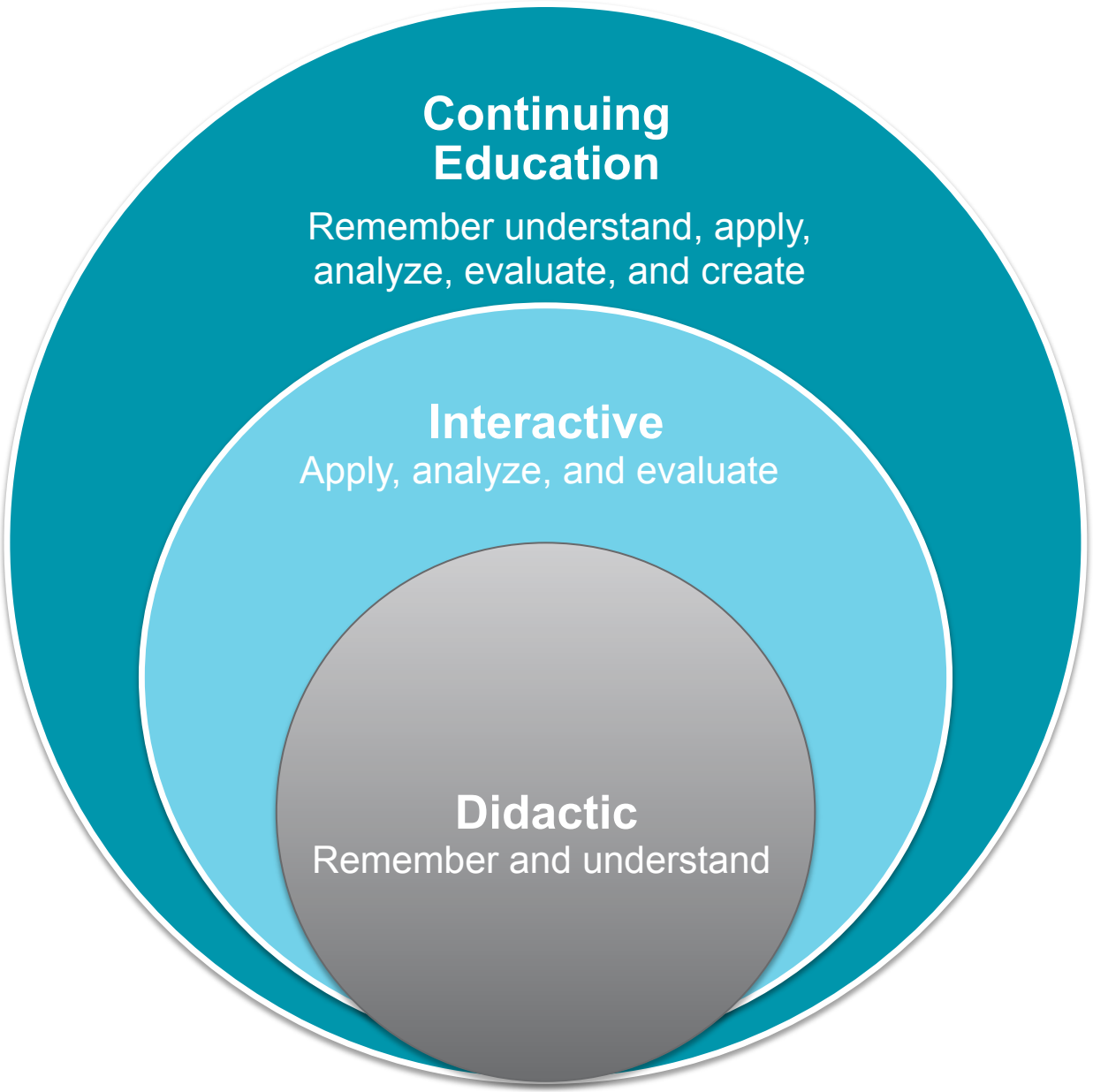
- Because no empirical evidence exists validating an IC training methodology correlated to improved ICP

  AND

- Because training programs should be flexible to fit the needs and local norms of investigative sites

  - Suggest a framework for training based on the 2 general educational principles described

  - Local sites may develop other methods for fulfilling the general training principles.


Continuing Education
Remember understand, apply, analyze, evaluate, and create
Interactive
Apply, analyze, and evaluate
Didactic
Remember and understand

Didactic Training

- Impart specific facts and information the learner should understand about the ICP
- Provides a foundation and framework for additional training
- May include lecture, video, and/or on-line training module

Didactic Training Content

Elements of a good consent process

Review of the federally mandated required elements of IC, including requirements for documenting the ICP

Guidance on effective health-communication behaviors

Writing a consent form, including health literacy issues and use of plain language

Interactive Training

- Provides an opportunity to think critically about real-world application of IC information learned during didactic training
- Allows the learner to practice or observe ICP best practices
- May include case study exercises via video or on-line module, small group discussion, role-playing, and/or proctoring with a researcher experienced in conducting the ICP

Interactive Training Content

Examples of different situations research staff may encounter during the ICP

Tools for managing challenging situations

Opportunity to practice effective health communication techniques

Continuing Education

- Allows the learner to reflect or receive feedback on his or her experience managing the ICP
- Allows the learner to consider ways to improve the process in future situations
- May include review of the ICP by IRB or research office staff; on-going opportunities for didactic and interactive learning for experienced research staff

Continuing Education Content

Any content necessary to address deficiencies identified during ICP audits

Constructive feedback for improving the ICP

New information or new training resources available about effective management of the ICP

Refresher sessions to remind research staff of the key principles of the ICP

Existing Resources and Programs

- Some training programs already exist and can be accessed as free resources for interested parties
- See the DRAFT Recommendations Document, Appendix E, for details

Additional Considerations

- **Policy Considerations**
  - Should there be policies requiring training?
  - Should there be accreditation of training programs?
- **Future Research Needs**
  - Determine staff and participant satisfaction with the ICP
  - Measure participant comprehension of the IC conducted by staff who had received formal training as compared with IC conducted by untrained staff
  - Evaluate the effect of research staff training on enrollment and retention of research participants
  - Compare different training models to evaluate effectiveness of training staff

Training Work Group

- Michele Kennett (University of Missouri)
- Kathy Kopnisky (NIH)
- Jennifer Lentz (Eli Lilly & Co.)

Discussion

Break 3:00 – 3:15pm