



### Evaluation in the context of lifecycles: "A place for everything, everything in its place"

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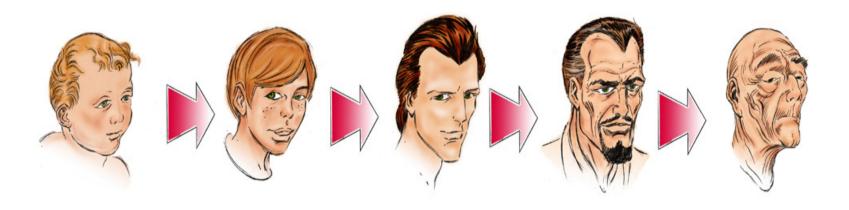
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### Ontogeny

- The origin and the development of an organism – for example: from the fertilized egg to mature form
- Programmatic ontogeny = Program lifecycle(s)
  - Programs are not static entities

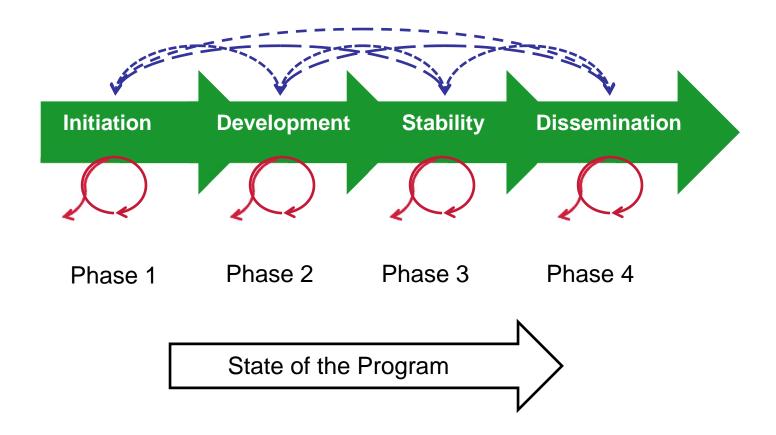








### Characterizing a Program's Evolution



Program evolution is a continuous dynamic process







### **Program Lifecycle**

Phase I nitiation

Program is in *initial implementation(s)*, either as a brand new program or as an adaptation of an existing program.

Phase IA

Program still undergoing *rapid or substantial change* or revision, after initial trials.

Phase IB

Phase II

Development

Scale and scope of revisions are smaller, most program elements are still developing while a few may be implemented consistently.

Phase IIA

Most program elements are implemented consistently; minor changes may still take place as some elements may still be developing.

Phase IIB

Phase III

Program is implemented consistently; participant experience from one implementation to the next is relatively stable (formal lessons or curricula exist).

Phase IIIA

Program has *formal written procedures/protocol* and can be implemented consistently by new facilitators.

Phase IIIB

Phase IV

Dissemination

Program is being *implemented in multiple sites*; adaptations to new contexts have been made.

Phase IVA

Program is fully protocolized and is being widely distributed.







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Phase IIB

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Phase IIIA

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### **Program Lifecycle**

Phase I

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Phase II

Phase II

Scale and scope of revisions are smaller, most program elements are still developing while a few may be implemented consistently.

Phase IIA

Most program elements are implemented consistently; minor changes may still take place

Phase IIE

Phase III Stability

Program is implemented consistently; participant experience from one implementation to the next is relatively stable (formal lessons or curricula exist).

Phase IIIA

Program has formal written procedures/protocol and can be implemented consistently by new facilitators.

Phase IIIB

Phase IV ssemination

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Phase IVA

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Phase IV **Dissemination** 

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Phase IVA





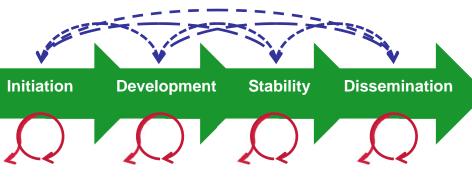


Phase 4

### Role of Evaluation in Program Evolution

Phase 1





Phase 3

Phase 2







### **Phased Clinical Trials**

**PHASE 0 TRIALS:** Whether the drug affects the human body, determine what should be further developed.

Target/Focus = Exploratory on humans.



PHASE I TRIALS: Assess safety, find safe dosage range, identify side effects.

Target/Focus = Test on small groups.

PHASE II TRIALS: Determine effectiveness, evaluate safety. Target/Focus = Larger group testing

PHASE III TRIALS: Fully examine the risk/benefit. Seek FDA approval.

Target/Focus = Broader, longer-term testing

**PHASE IV TRIALS:** Assess how it can be used optimally, further provide evidence on the risks and benefits.

Target/Focus = Post-marketing

English, R., Lebovitz, Y. & Griffin, R. (2010) Transforming clinical research in the United States: Challenges and opportunities: Workshop summary, from Forum on Drug Discovery, Development, and Translation. National Academies Press.



### **Phased Clinical Trials**

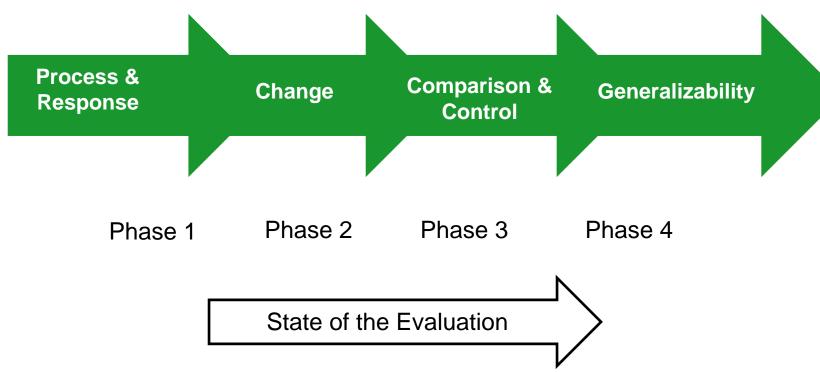
- In true evolutionary fashion, not all treatments survive
  - Nearly 3/4 of all treatments are abandoned before a Phase III randomized experiment is ever mounted (Mayo Clinic, 2007)
- This strategy of phased clinical trials embeds the principle that different designs are appropriate at different phases of a treatment's development







### Application to Program Evaluation



**Evaluation is a continuous dynamic process** 







### **Evaluation Lifecycles**

Phase I Process & Response Phase IA

Examines *implementation*, *participant* and *facilitator* satisfaction. Uses process and participant *documentation* and assessment and *post-only* evaluation of reactions and satisfaction.

Focuses on *implementation*, and increasingly on *presence or* absence of selected outcomes. Evaluation is post-only; outcome measures are under development with attention to internal consistency (reliability).

Phase II Change

Phase IIA

Phase IB

Examines program's association with change in group outcomes, for these participants in this context. Uses unmatched pre- and post-test of outcomes, quantitative/qualitative assessment of change, assessment of measure reliability and validity.

Phase IIB

Examines program's association with change in group (and/or individual) outcomes, for these participants in this context. Uses matched pre- and post-test of outcomes, quantitative/qualitative assessment of change, verifying measure reliability and validity.

Phase III Comparison & Control

Phase IIIA

Assesses effectiveness using design and statistical controls and comparisons (control groups, control variables or statistical controls).

Phase IIIB

Assesses effectiveness using controlled experiments or quasiexperiments (randomized experiment; regressiondiscontinuity.)

Phase IV Generalizability

Phase IVA

Examines *outcome effectiveness across wider range of contexts*. Multi-site analysis of integrated large data sets over multiple waves of program implementation.

Phase IVB

Formal assessment across multiple program implementations that enable general assertions about this program in a wide variety of contexts (e.g., meta-analysis).

**Evaluation Special Projects** 







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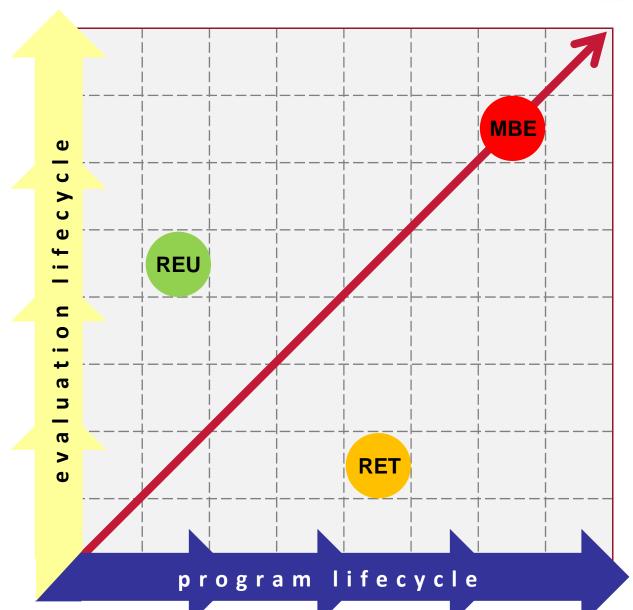
### Relationship between Program and Evaluation Lifecycles

- Program evolution driven, in part, by evaluation evolution
- Evaluation evolution driven, in part, by program evolution

For any given program lifecycle phase or state of the program, there is an appropriate evaluation lifecycle phase - ALIGNMENT











### Program and Evaluation Lifecycle Alignment

- Moving toward alignment should be treated as a key goal of evaluation planning
- Alignment does not necessarily happen after one evaluation cycle
- Evaluations and programs are developmental and grow over time





### Conclusions

- Evaluation methods have a particular time and place when they are appropriate depending upon a program's lifecycle phase
- There are advantages to the co-evolution of programs and evaluations
  - Evaluation and program lifecycle alignment promote successful program evolution
    - Effective use of resources
    - Societal well-being







This material is based upon work supported by the National Science Foundation under Grant No. 0814364.

Any opinions, findings, and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the National Science Foundation

