The Economic Evaluation of Implementation Strategies

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Road Map

- Need for Economic Evaluation in D&I Research
- EE Methods in Implementation Context
- An Example Illustration Throughout
- Mixed-methods
A Story Sounding All So Familiar...

Innovation effectiveness DOES NOT guarantee its uptake into routine usage
Gap!

- ~10-27% individuals receive scientifically validated care (IOM 2006)

- ~17-20 years for clinical innovations to get integrated into usual practice (Balas and Boren 2000)

- ~80% of medical research $ do not make a public health impact (Chalmers and Glasziou 2009)!
New Trend

- Evaluate interventions in environment where they will potentially be used
  - Practical clinical trials / Pragmatic clinical trials
  - Comparative effectiveness trial
  - Large simple trials
Why?: individual-level

- Food Cost
- Time Cost
- Acceptability
- Food Sufficiency
Why?: organization-level

- Audience: practitioners, provider organizations etc.
- Product of consideration:
  - Efficacious and effective interventions
  - Processes/strategies that help the intervention to be spread to / adopted by target providers → IS
- IS: complex endeavors and NOT FREE
  - No research funds
  - No existing personnel fit for the intervention executions
  - Current reimbursement do not cover all IS costs
  - Institution/Organization level contextual issues
At the launch of the initiative, President Barack Obama signed a Presidential Memorandum creating the first-ever Task Force on Childhood Obesity to conduct a review of every single program and policy relating to child nutrition and physical activity and develop a national action plan to maximize federal resources and set concrete benchmarks toward the First Lady’s national goal. The Task Force recommendations focus on the five pillars of the First Lady’s Let’s Move! initiative:

1. Creating a healthy start for children
2. Empowering parents and caregivers
3. Providing healthy food in schools
4. Improving access to healthy, affordable foods
5. Increasing physical activity
A Specific Example

Serving Healthier School Food

- $10 billion over 10 years to improve the quality of NSLP and SBP
Economic 101: Demand
Economic 101: Supply
Key concept: opportunity cost (OC)
- The potential benefits might have been accrued through B are forgone due to support of A instead.

Central question:
- Is the support of A the best possible use of available resources given its OC? [efficacy; effectiveness]
- Is the A strategy making the most economic sense to deploy?

Goal of EE:
- Quantify costs and outcomes of both A and B
- Then compare
EE Components in IS: Costs

- Costs by Implementation Components
  - IS execution
  - Program tailoring/adaptation: e.g., excess cost of service delivery as uptake or implementation changes
  - OC of practitioners’ and participants’ engagement

- Types of Costs
  - Direct costs: e.g., cost of purchasing new equipment to monitor fidelity
  - Indirect costs: e.g., time away from other duties
  - Overhead: e.g., utilities, administrative support
EE Components in IS: Outcomes

- Traditional EE focuses on efficacy outcomes only
- Outcome Measurements by Types of Trials:
  - Efficacy: extensive battery of health outcomes (comprehensive)
  - Effectiveness: focused battery of health outcomes
  - Implementation: process related outcomes (may also include health outcome measures similar to effectiveness studies)
    - Implementation ones: e.g., fidelity; reach
    - Service ones: e.g., equity; patient-centeredness
    - Clinical ones: e.g. functioning; symptoms

All types of outcomes are intertwined!
Standard EE Methods

- Compare costs only: cost offsets; budget impact analysis
- Cost-Effectiveness Analysis [benefit: natural units]
  - Incremental Cost-Effectiveness Ratio: $ per unit outcome gained
    \[ ICER = \frac{Cost_A - Cost_B}{Outcome_A - Outcome_B} = \frac{\Delta C}{\Delta E} < R_T \]
- Cost-Utility Analysis [benefit: quality of life/preference]
- Cost-Benefit Analysis [all in $]
- Net Health Benefits:
  \[ NHB = \Delta E - \frac{\Delta C}{R_T} > 0 \]
The CE Plane
Standard EE Methods

- The CE Acceptability Curve (CEAC):
  - The probability that A is CE compared with B, given the observed data, for a range of maximum WTP values (thresholds) for a particular unit change in outcome.
  - Nonparametric bootstrapping of IC and IE jointly

- The CE Acceptability Frontier (CEAF)

- Modeling and simulation
Figure 1. The Cost-Effectiveness Acceptability Curve

EE Adaptation to Evaluate IS

- Explicitly account for resources used in developing and executing IS as a cost of ensuring appropriate delivery


Table 1 Overview of forms of economic evaluation

<table>
<thead>
<tr>
<th>Form of evaluation</th>
<th>Use for decision making</th>
<th>Measurement of health effects</th>
<th>Economic summary measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost-consequences analysis</td>
<td>Comparison of implementation strategies that have disparate outcomes</td>
<td>Any measure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Cost-effectiveness analysis</td>
<td>Comparison of implementation strategies that produce a common outcome</td>
<td>Process measures (e.g., professional guidance adherence, patient compliance to medication) or health effects (intermediate or final), measured in natural units</td>
<td>Cost-effectiveness ratio (e.g., cost per case averted, cost per life-year saved), at patient or population level</td>
</tr>
<tr>
<td>Cost-utility analysis</td>
<td>Comparison of implementation strategies that have morbidity and mortality outcomes</td>
<td>Final health outcomes, including health status, patient preferences, utilities</td>
<td>Cost per quality-adjusted life-year, at patient or population level</td>
</tr>
<tr>
<td>Cost-benefit analysis</td>
<td>Comparison of implementation strategies with different units of outcome (health and nonhealth)</td>
<td>Monetary units</td>
<td>Net health benefit or net monetary benefit, at patient or population level</td>
</tr>
<tr>
<td>Cost analysis</td>
<td>Comparison of net cost of implementation strategies with equivalent outcomes</td>
<td>Not applicable</td>
<td>Net cost or cost of illness, at patient or population level</td>
</tr>
</tbody>
</table>
Challenges in EE of IS

- Find better ways for the following:
  - The full economic costs and consequences of alternative IS
    - Economies of scale and scope when target larger groups and/or multiple behaviors and practices
    - Degree of data collection: focused vs. extensive
  - System/contextual factors: uncertainty; relevant perspectives
  - ROI Threshold for IS outcomes: i.e., fidelity; wait time
  - Ethical issues: e.g., equity; confidentiality
Issue 1: Relevant Perspective

- Perspective → what costs to capture
  Example: what is cost of a day of hospital care
  - Health plan perspective:
    $ paid to the hospital by the plan
  - **Organizational perspective:**
    total hospital expenditure on that patient that day (labor + medicines + overhead)
  - Patient perspective:
    out-of-pocket payments, OC of time
  - **Societal perspective:** all costs (irrespective of who incurs them), including OC of all resources and time used
Issue 2: Costs

- Consider costs across multiple domains and throughout the full implementation process
- Discounting’s relevance varies with time horizon

Issue 2: Costs (cont.)

- Across Domains: Comprehensive cost measurement
  - Example: IS → group education for clinician
    - Direct costs: costs of IS directly relevant resources
e.g., training materials; trainer labor costs; equipment
    - Indirect costs: costs of indirectly related ones
e.g., OC for participants: foregone clinical revenues due to the loss of those billable hours
    - Overhead: cannot be directly assigned to a particular clinician
e.g., administration; facility and utilities
Issue 2: Costs (cont.)

- Types of costs:
  - One-time fixed costs
    e.g., costs of initial training; equipment purchase
  - Regular scheduled fixed costs
    e.g., costs of ongoing supervision/auditing
  - Variable costs increasing with services provided
    e.g., administration; fidelity assessment
- IS: activity-based costing strategy
Issue 3: Outcomes

- IS outcomes encompass intervention outcomes
  - Example: Dopp et al. 2017 → CE of Learning Collaboratives
    - Implementation outcome: Clinician Competence → not favorable
    - Clinical outcome: youth mental symptoms → favorable
  EE on implementation outcomes in isolation can be misleading

- Practice nature of IS limit the ‘rigor’ of measurement
  - Less controlled methods: e.g. Pre-post design
  - Pragmatic self-report measures
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Economic evaluation of interventions</th>
<th>Economic evaluation of implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant costs</td>
<td>Discrete costs of intervention</td>
<td>Expansive costs of intervention (i.e., costs for replication) + implementation strategy</td>
</tr>
<tr>
<td>Relevant benefits</td>
<td>Clinical outcomes</td>
<td>Implementation, service, and clinical outcomes</td>
</tr>
<tr>
<td>Time horizon</td>
<td>Variable, but can be brief (&lt; 1 year)</td>
<td>Often multi-year, can include short-term implementation and long-term sustainment</td>
</tr>
<tr>
<td>Perspective</td>
<td>Variable, but full societal perspective often encouraged</td>
<td>Health care system perspective is often most relevant</td>
</tr>
<tr>
<td>Study design</td>
<td>Research methods are chosen to maximize internal validity, rigor, comprehensiveness</td>
<td>“Minimum acceptable” research methods; must be pragmatic, feasible for practice settings</td>
</tr>
<tr>
<td>Impact of context</td>
<td>Minimized; often standardized interventions delivered in ideal settings</td>
<td>Variable; often multi-site studies with variability in intervention, implementation across settings</td>
</tr>
<tr>
<td>Relevant decision-makers</td>
<td>Health care payers (invest in clinical care)</td>
<td>Health system payers (invest in infrastructure)</td>
</tr>
</tbody>
</table>
Example

Gillespie et al. Trials 2014, 15:227
http://www.trialsjournal.com/content/15/1/227

Cost effectiveness of group follow-up after structured education for type 1 diabetes: a cluster randomised controlled trial

Paddy Gillespie1*, Eamon O'Shea1, Mary Clare O'Hara2, Sean F Dinneen2 for the Irish DAFNE Study Group
Example: Intervention

- The Dose Adjustment for Normal Eating (DAFNE)
  - Group-based structured education program for type I diabetes
  - It is cost effective as compared to conventional program

The DAFNE course is delivered over 5 consecutive days to groups of up to 8 individuals who are using a basal/bolus insulin regimen to manage their diabetes. It involves 38 hours of structured education covering all aspects of diabetes self-management with an emphasis on carbohydrate estimation and matching of quick-acting insulin to food.

The course is delivered by a DAFNE-trained diabetes nurse, dietitian and doctor, who are regularly peer reviewed to ensure that the education is consistently delivered according to the curriculum.

All groups are invited back to a 3 hour review session at 6 weeks post-DAFNE to consolidate skills learned and to review targets and goals.
Example: Implementation Trial

- Remaining question → follow-up care for maintenance
- Cluster RCT: post-DAFNE
  - Individual follow-up (usual care) vs. Group follow-up
  - 6 hospital clinics with 437 patients w/ type I diabetes
  - Individual follow-up (usual care) arm: 3 clinics, 221 patients
    - Outpatient one-to-one visit
    - 6 and 12 months post-DAFNE
  - Group follow-up arm: 3 clinics, 216 patients
    - “booster” education sessions in original DAFNE group
    - Structured curriculum
Example: Implementation Trial

- Group follow-up details:

Intervention arm participants met at 6 and 12 months post-DAFNE in the original group to which they were assigned. Group follow-up sessions lasted approximately 3 hours.

Sessions were facilitated by trained educators using a structured curriculum, which included topics such as principles of insulin dose adjustment, carbohydrate estimation and managing hypoglycaemia. Groups identified their own priorities for discussion while the educator used the curriculum to guide the session.

Participants were encouraged to reflect on progress and difficulties with their original self-management goals and to produce an updated action plan.
Example: EE overall plan

- Time horizon: 18 m (12-m trial + 6 m trial follow-up)
- Discounting: no discounting was considered due to short length of trial follow-up
- Perspective: healthcare provider
- Effectiveness outcome: HbA1c change
- Health outcome: QALYs
- Threshold value: over a range that healthy system may be willing to pay per additional QALYs
- Multivariate multilevel model (cluster, correlation)
Example: EE – Costs

- Expressed in 2009 Euros
- Direct costs: sessions costs
  - Educator’s and administrator’s time; education materials, consumables, packaging, telephone and travel expenses [P]
- Indirect costs: capture cost savings
  - Primary and secondary healthcare services and medications used [S] (unit cost estimates were based on national data)
- Overhead: Administrator’s time
- What else are missing?
  - e.g., retention protocol and costs?
Example: EE – Costs (cont.)

- Missing resource costs at individual respondent level
  - Multiple imputation controlling for age, gender, illness length, treatment arm, clinic cluster

- Incremental total healthcare costs estimation
  - Linear mixed effects regression on each MI data set then generate to overall coefficients of interest
  - Control for baseline cost, age, gender, illness length, treatment arm, clinic cluster, HbA1c, BMI, heart disease status, high blood pressure status, chest/lung disease status, smoking status, insurance, marital status, education, employment
Example: EE – Effectiveness

- QALYs: EuroQol EQ5D 3L
- Use a UK population based algorithm to transform it into a single health index range from 0 to 1
- Similar MI procedure for missing values as costs

- Find: no statistically significant differences in effectiveness between two arms
<table>
<thead>
<tr>
<th>Variable/time point</th>
<th>Baseline: 12 months</th>
<th>Follow-up 1: 0 to 6 months</th>
<th>Follow-up 2: 6 to 12 months</th>
<th>Follow-up 3: 12 to 18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Individual follow-up</td>
<td>Group follow-up</td>
<td>Individual follow-up</td>
<td>Group follow-up</td>
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<td><strong>Healthcare resources</strong></td>
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<tr>
<td>GP visits: diabetes</td>
<td>25 (68)</td>
<td>19 (46)</td>
<td>12 (38)</td>
<td>9 (30)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>16 (50)</td>
<td>16 (50)</td>
</tr>
<tr>
<td>GP visits: other</td>
<td>68 (98)</td>
<td>58 (86)</td>
<td>73 (122)</td>
<td>56 (72)</td>
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<td></td>
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<td>16 (50)</td>
<td>16 (50)</td>
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<td>Diabetes nurse visits</td>
<td>29 (28)</td>
<td>24 (28)</td>
<td>20 (33)</td>
<td>16 (21)</td>
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<td>15 (33)</td>
<td>15 (33)</td>
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<td>Diabetes nurse calls</td>
<td>21 (48)</td>
<td>17 (48)</td>
<td>20 (38)</td>
<td>15 (29)</td>
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<td></td>
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<td>15 (33)</td>
<td>15 (33)</td>
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<tr>
<td>Dietitian visits</td>
<td>9 (14)</td>
<td>8 (18)</td>
<td>7 (15)</td>
<td>7 (13)</td>
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<td></td>
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<td>4 (9)</td>
<td>3 (8)</td>
</tr>
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<td>Dietitian calls</td>
<td>1 (5)</td>
<td>1 (5)</td>
<td>7 (26)</td>
<td>2 (8)</td>
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<td></td>
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<td></td>
<td>1 (6)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Outpatient visits: diabetes</td>
<td>143 (128)</td>
<td>139 (110)</td>
<td>85 (99)</td>
<td>60 (98)</td>
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<td></td>
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<td></td>
<td>83 (101)</td>
<td>50 (89)</td>
</tr>
<tr>
<td>Outpatient visits: other</td>
<td>49 (122)</td>
<td>66 (262)</td>
<td>76 (282)</td>
<td>55 (149)</td>
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<td>72 (158)</td>
<td>83 (198)</td>
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<tr>
<td>Inpatient days: diabetes</td>
<td>228 (1199)</td>
<td>139 (716)</td>
<td>131 (792)</td>
<td>19 (160)</td>
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<td>50 (362)</td>
<td>90 (533)</td>
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<td>Inpatient days: other</td>
<td>195 (860)</td>
<td>324 (1913)</td>
<td>242 (1230)</td>
<td>80 (350)</td>
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<td>161 (882)</td>
<td>124 (593)</td>
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<tr>
<td>A &amp; E visits: diabetes</td>
<td>23 (104)</td>
<td>17 (74)</td>
<td>10 (53)</td>
<td>6 (56)</td>
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<td>8 (47)</td>
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<tr>
<td>A &amp; E visits: other</td>
<td>20 (79)</td>
<td>30 (105)</td>
<td>20 (80)</td>
<td>41 (138)</td>
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<td>17 (69)</td>
<td>29 (100)</td>
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<td>Chiropodist visits</td>
<td>7 (13)</td>
<td>6 (15)</td>
<td>8 (15)</td>
<td>5 (10)</td>
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<td>8 (17)</td>
<td>6 (14)</td>
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<tr>
<td>Diabetes centre visits</td>
<td>229 (187)</td>
<td>211 (194)</td>
<td>172 (225)</td>
<td>136 (156)</td>
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<td>133 (180)</td>
<td>122 (156)</td>
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<td>Quick-acting insulin</td>
<td>111 (55)</td>
<td>102 (53)</td>
<td>93 (50)</td>
<td>88 (50)</td>
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<td>94 (48)</td>
<td>94 (50)</td>
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<td>Background insulin</td>
<td>94 (42)</td>
<td>89 (52)</td>
<td>77 (33)</td>
<td>69 (36)</td>
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<td>80 (39)</td>
<td>74 (42)</td>
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<td>Blood glucose tests</td>
<td>270 (169)</td>
<td>265 (141)</td>
<td>317 (136)</td>
<td>290 (102)</td>
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<td>327 (145)</td>
<td>301 (145)</td>
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<td>Lipid lowering therapy</td>
<td>76 (113)</td>
<td>79 (114)</td>
<td>78 (114)</td>
<td>87 (117)</td>
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<td>80 (115)</td>
<td>89 (117)</td>
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<td>Antiplatelet therapy</td>
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<td>34 (48)</td>
<td>31 (47)</td>
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<td>Antihypertensive therapy</td>
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<td>26 (54)</td>
<td>49 (65)</td>
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<td>28 (55)</td>
<td>49 (65)</td>
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<tr>
<td>Total cost</td>
<td>Health outcome</td>
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<td>------------</td>
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<tr>
<td>Total healthcare cost</td>
<td>QALYs gained</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>1,597 (1,549)</td>
<td>0.44 (0.09)</td>
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<tr>
<td>1,643 (2,416)</td>
<td>0.43 (0.09)</td>
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<tr>
<td>1,413 (1,347)</td>
<td>0.45 (0.08)</td>
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<tr>
<td>1,189 (840)</td>
<td>0.44 (0.07)</td>
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<td>1,348 (1,588)</td>
<td>0.46 (0.05)</td>
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<td>1,246 (1,021)</td>
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<tr>
<td>1,274 (1,181)</td>
<td>0.46 (0.06)</td>
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<tr>
<td>1,283 (1,105)</td>
<td>0.44 (0.08)</td>
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</tbody>
</table>

**Table 6 Incremental cost effectiveness analysis results**

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Intervention Group follow-up N = 216</th>
<th>Control Individual follow-up N = 221</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost analysis</strong></td>
<td></td>
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<tr>
<td>Total healthcare cost (€)</td>
<td></td>
<td></td>
<td>0.016</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>3,551 (566)</td>
<td>4,337 (551)</td>
<td></td>
</tr>
<tr>
<td>Incremental analysis (difference in means; intervention versus control)</td>
<td>−772 (95% CI, −1,415 to −128; P = 0.020)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Effectiveness analysis</strong></td>
<td></td>
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</tr>
<tr>
<td>QALYs gained</td>
<td></td>
<td></td>
<td>0.033</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>1.31 (0.12)</td>
<td>1.35 (0.12)</td>
<td></td>
</tr>
<tr>
<td>Incremental analysis (difference in means; intervention versus control)</td>
<td>−0.04 (95% CI, −0.08 to 0.01; P = 0.052)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Example: EE – CE

**Cost effectiveness analysis (probability that treatment is cost effective at \( \lambda \))**

<table>
<thead>
<tr>
<th>Threshold value (( \lambda ))</th>
<th>1.000</th>
<th>0.000</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \lambda = €0 )</td>
<td>1.000</td>
<td>0.000</td>
</tr>
<tr>
<td>( \lambda = €5,000 )</td>
<td>0.996</td>
<td>0.004</td>
</tr>
<tr>
<td>( \lambda = €10,000 )</td>
<td>0.762</td>
<td>0.238</td>
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<tr>
<td>( \lambda = €15,000 )</td>
<td>0.400</td>
<td>0.600</td>
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<tr>
<td>( \lambda = €20,000 )</td>
<td>0.204</td>
<td>0.796</td>
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<tr>
<td>( \lambda = €25,000 )</td>
<td>0.119</td>
<td>0.881</td>
</tr>
<tr>
<td>( \lambda = €30,000 )</td>
<td>0.078</td>
<td>0.922</td>
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<tr>
<td>( \lambda = €35,000 )</td>
<td>0.049</td>
<td>0.951</td>
</tr>
<tr>
<td>( \lambda = €40,000 )</td>
<td>0.033</td>
<td>0.967</td>
</tr>
<tr>
<td>( \lambda = €45,000 )</td>
<td>0.000</td>
<td>1.000</td>
</tr>
</tbody>
</table>

\( \lambda \) or threshold value of the maximum that the health system would be willing to pay per QALY gained. ICC, intra-class coefficient; QALY, quality-adjusted life year.
Example: EE – CE
Mixed-Method Approach

- Integrate two types of data & analyses (quant & qual) in parallel/sequential phases to address specific questions
- Why is it useful in IS?
  - IS: activity-based with the goal of integrating an efficacious innovation into normal practice in local settings
  - The IS uptake and sustainability are human decisions
  - Local decision makers and individual program participants are institutionally and socially embedded
  - Qual help to bring the perspectives, experiences and understanding of research subjects into assessment
Mixed-Method Approach

- Quant vs. Qual:
  - closed-end vs. open-end ways to gather data
  - Quant: representativeness, statistical power, concise
  - Qual: depth, complexity, contextually relevant

- MM helps IS in:
  - Inform equity impact of IS
  - Inform choice of WTP threshold and perspective
  - Interpret and triangulate CEA findings
Mixed-Method Approach

- Example: sequential Quant-Qual-Quant
  - First: quantify relative costs of group follow-up vs. individual follow-up and relative quantifiable intermediate outcomes
  - Second: qualitatively assess fidelity outcome and patient satisfaction outcome
  - Third: examine if those qualitative outcome improvement lead to improvements in distal outcomes such as QUALYs etc.

- Example: Qual-Quant
  - First: interview to assess follow-up barriers from patients to identify distinct subgroups
  - Second: quantify CE by subgroups
THANK YOU!
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