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Implementation Science: What is it? Is it worth it?

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Active Implementation Research Network

What is science?

In his book *The Invention of Science*, Wootton (2015, p. 393) says "What makes it science is not that it provides an explanation but that it provides reliable predictions." According to Popper (1963, 2002), who defined the philosophy of science, predictions must be testable and refutable. Predictions are made in the form of if-then statements. If reliable predictions define science and testing predictions is the work of scientists, then implementation science is a science to the extent that 1) predictions are made and 2) those predictions are tested in practice.

How does science develop?

Wooton (p 393) notes that reliable predictions "move the problem of explanation to another set of factors." That is, how to explain the factors that cause predictions to be valid. Metaphorically, instead of peeling the onion accurate predictions add layers to the onion with the realization that independent variables are dependent variables when viewed from the perspective of a higher order set of conditions. In implementation science, every independent variable must be viewed as a dependent variable in a cascading series of causes and effects.

In physics, chemistry, biology, and other "hard sciences" scientists can study natural phenomena that exist everywhere (e.g. every living thing has chromosomes that can be studied at any time; chemical elements already exist and are waiting to be observed; gravity is everywhere). The independent variable exists in nature and the task is to develop measurement tools (powerful lenses, particle colliders and detectors) to assess relationships and outcomes of what is. In the so-called "soft sciences" things are much more difficult: to study the outcomes of an independent variable the independent variable must be produced by the scientist in highly interactive and reactive environments. Unlike waiting for an expected solar eclipse to produce an independent variable for study, implementation scientists cannot wait for an expert implementation team (a postulated implementation independent variable) to form and begin to function then assess the outcomes. This may never happen in any predictable and assessable way. This is an important distinction because implementation scientists must be able to produce the independent variable on demand so that predictions of its effects can be measured (if this, then that). It is ironic that implementation practice is required to produce variables to advance implementation science.

What is the role of theory?

Theory is a source of predictions (if-then) and hypotheses (explanations of if-then relationships) that lead to observations to confirm or disconfirm those predictions and hypotheses. Theory is shaped by the results of prediction testing so that more precise theory-based predictions can be made and tested in the future. Theory provides explanations for predictions and concept labels for discrete but related facts. Theory is generalizable and robust across variable conditions.

Implementation Science

Implementation science is the study of factors that influence the full and effective use of innovations in practice. Implementation is defined as a specified set of activities designed to put into practice an activity or program of known dimensions. When thinking about implementation the observer must be aware of two sets of activities (intervention-level activity and implementation-level activity) and two sets of outcomes (intervention outcomes and implementation outcomes) (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005, p. 5).

In the descriptions provided below, the cited authors language is used to describe innovations and implementation supports. When it is not obvious, the elements that relate to the Active Implementation Frameworks (a mid-range theory) are noted in brackets […] to provide conceptual labels and a common language to describe implementation and its effects.

Predictions

Prediction: if innovations are used as intended (i.e. with fidelity), then innovations will produce improved outcomes. This prediction is fundamental to implementation science. If an innovation can be used a little bit or a lot or not at all and still produce intended benefits, then innovation science is sufficient and there is no need for implementation science.

In the following examples, note that the prediction that the use of innovations with fidelity improves outcomes is confirmed repeatedly in a broad range of programs, human service domains, countries and circumstances ("generalizable and robust"). Also note the information related to how fidelity is produced and supported ("move the problem of explanation") by assuring Usable Innovations and using Implementation Drivers, Implementation Stages, Improvement Cycles, Implementation Teams, and Systemic Change (i.e. the Active Implementation Frameworks). This small sample of many studies confirms Implementation Science as a science that can help improve the wellbeing of people in every country.

Adult Mental Health

Problem: Beginning in the 1960s federal policies focused on closing down institutions where systemic abusive practices and lack of treatment were well documented. There was not an equal emphasis on developing community-based alternatives (Stein & Santos, 1998; Test, 2010). Effective intervention practices began to be developed and be supported by implementation best practices.

- Assertive Community Treatment: The Program of Assertive Community Treatment (PACT), a multidisciplinary team approach, delivers integrated community-based treatment, rehabilitation, and support services to help persons with severe and persistent mental illness to avoid psychiatric hospitalization and to live independently in natural community settings.
    - Twenty five randomized clinical trials of PACT and its close adaptations, conducted over three decades in several countries, demonstrate its effectiveness for this population in reducing use of inpatient psychiatric services and sustaining tenure in normalized housing (Gold et al., 2003)
    - Higher-fidelity uses of PACT had support from effective administrative and program leadership, sound personnel practices, [Implementation Drivers], low staff turnover, and skilled staff, and they allocated sufficient resources in terms of staffing, office space, and cars [Facilitative Administration] (Mancini et al., 2009).

- Individual Placement and Support (Supported Employment) model:
    - Supported employment for people with severe mental illnesses is an evidence-based practice, based on converging findings from four studies of the conversion of day treatment to supported employment and nine randomized control trials comparing supported employment to a variety of alternative approaches. The outcomes of this research suggest that about 3 times more recipients enrolled in supported employment obtain competitive employment compared to similar recipients who are not enrolled in supported employment (Bond, 2004).
    - Higher fidelity to the supported employment model is associated with better employment outcomes (McGrew & Griss, 2005).
    - The benefits of participation in support employment persisted for several years with 75% of the participants continuing to work beyond the initial study period, and 33% who worked at least five years during the ensuing ten-year period (Salyers, Becker, Drake, Torrey, & Wyzik, 2004).
    - Supported employment saves $3.04 for every dollar spent to provide the individual placement and support services (http://www.wsipp.wa.gov/BenefitCost).

Fidelity, an implementation outcome, is an important contributor to the outcomes achieved for this vulnerable population. These programs are being scaled up in New York state with attention to fidelity (Covell et al., 2014) to impact the entire population of adults with severe mental health disabilities.

Delinquency

Problem: Delinquent youths have been incarcerated in abusive residential care facilities that provide little care and little hope for the future. The deinstitutionalization movement for this population left many children in foster care, mental health facilities, or on the streets (Wooten, 1976). In the ensuing decades effective innovations have been produced and supported by effective implementation.

- In a meta-analysis of 548 experimental studies, three factors emerged as major correlates of program outcomes: a 'therapeutic' intervention philosophy, serving high risk offenders, and quality of implementation. With regard to implementation, “the quality with which the intervention is implemented [Fidelity] has been as strongly related to recidivism effects as the type of program, so much so that a well-implemented intervention of an inherently less efficacious type can outperform a more efficacious one that is poorly implemented” (Lipsey, 2009).
    - Recidivism (delinquency) outcomes for the best most efficacious programs were 2 times better when used with fidelity. Outcomes for the less efficacious programs were infinitely better with an average effect size of 0.24 when used with fidelity and an average effect size of 0.00 when not used with fidelity.
- Multisystemic therapy (MST) is an evidence-based home-based treatment model for youth with serious delinquent behavior who are at high risk for out-of-home placement. With more than 100 peer-reviewed outcome and implementation journal articles published as of January 2016, the majority by independent investigators, MST is one of the most extensively evaluated family based treatments.

- Outcome research has yielded almost uniformly favorable results for youths and families (Henggeler & Schaeffer, 2016)
- Implementation research has demonstrated the importance of treatment and program fidelity in achieving such outcomes, and the importance of coaching for supporting high fidelity use of MST by therapists (Schoenwald, Sheidow, & Letourneau, 2004).
- Implementation research has demonstrated the links between organization change and high fidelity use of MST where the outcomes for youth were 2 times better when MST was conducted in a purposefully supportive organization context (Glisson et al., 2010).
- MST saves $2.43 for every dollar spent to provide intensive MST services (http://www.wsipp.wa.gov/BenefitCost).

Coaching and facilitative administrative practices support high fidelity use of effective innovations and improved outcomes for the difficult to treat population of youths in the delinquency system. Given these implementation data, MST has established "network partners" [Implementation Teams] who support the high fidelity use of MST by practitioners in the US, Canada, Europe, and Australia. A fidelity assessment for network partners has been developed (Brunk, Chapman, & Schoenwald, 2014).

- For network partners in the top quartile, nearly 3 times more of their treatment teams provided sustained services that were 2 times more effective in terms of youth outcomes when compared to the network partners in the lowest quartile. MST used with fidelity is more effective and high fidelity supports for MST by network partners magnifies those outcomes (Brunk et al., 2014).

The Teaching-Family Model developed "regional partners" called Teaching-Family Sites [Implementation Teams] and developed a fidelity assessment for Sites that support high fidelity use of the Teaching-Family Model by practitioners (Blase, Fixsen, & Phillips, 1984).

- With Implementation Teams embedded in each Site, treatment program sustainability for 5 or more years increased from 23% to 84% (Fixsen & Blase, 2018).
- The time to develop a Teaching-Family Site was reduced by about half while the success of developed Sites almost doubled (Fixsen & Blase, 2018).
- The use of the treatment model was scaled and sustained for over 50 years with a focus on Site Development [Implementation Teams] and fidelity assessment at the Site and practitioner levels provided by the Teaching-Family Association (Fixsen & Blase, 2018).

Health – Tuberculosis (TB)

Problem: The drugs required to cure TB must be taken on schedule each day for the prescribed number of days. Failure to follow the regimen results in relapse and the development of a more virulent and drug resistant strain of TB. The Directly Observed Treatment System (DOTS) was developed by the global health community to help assure high fidelity intake of the medications. The DOT system engages neighbors to visit TB patients at the assigned times to visually witness the ingestion of the medications [Fidelity]. The DOTS strategy is effective but not easy to use in practice. Diagnosis requires multiple visits to a health facility. Use of microscopy requires trained technicians, a regular supply of reagents of good quality, a satisfactory microscope, and, ideally, a reliable electricity supply. Treatment requires the availability of a range of drugs for at least six months. Minor adverse effects of

drugs are common. Recordkeeping is simple but requires training and supervision. Thus, although TB control is inexpensive and effective, it is more complex than some other public health programmes, e.g. immunization (Khatri & Frieden, 2002).

- In 1998 India established clinics and included DOTS in their treatment for rural populations. After four years the clinics reached nearly 1 million people with TB and saved 200,000 lives (Khatri & Frieden, 2002).
- Khatri and Frieden (2002) describe how DOTS [Fidelity] depends on (1) getting the science right and ensuring technical excellence [Usable Innovation], (2) building commitment and ensuring the provision of funds and flexibility in their utilization[Exploration and Installation Stages]; (3) maintaining focus and priorities [Leadership]; (4) systematically appraising each area before starting service delivery [Exploration Stage]; (5) ensuring an uninterrupted drug supply [Facilitative Administration]; (6) strengthening the established infrastructure and providing support for staff [Implementation Drivers]; (7) supporting the infrastructure required in urban areas [Leadership]; (8) ensuring full-time independent technical support and supervision, particularly during the initial phases of implementation [Initial Implementation Stage; Implementation Drivers]; (9) monitoring intensively and giving timely feedback [Fidelity; Decision Support Data System; Improvement Cycles]; and (10) continuous supervision [Coaching].

Health – Neonatal Care

Problem: Little is known about the coverage of services to prevent transmission of human immunodeficiency virus (HIV) from mother to child. All clinical sites in African countries used at least single-dose nevirapine to prevent mother-to-child HIV transmission and some sites used additional prophylaxis drugs.

- Population nevirapine coverage was measured in a random sample of 43 clinics. High fidelity use was defined as the proportion of HIV-exposed infants in the sample with both maternal nevirapine ingestion (confirmed by cord blood chromatography) and infant nevirapine ingestion (confirmed by direct observation). Using fidelity of the use of nevirapine as a metric, the authors found only 51% coverage for at risk babies across the participating countries (Stringer, Ekouevi, Coetzee, & et al., 2010).

Problem: Neonatal death remains a global challenge contributing to 45% of under-five deaths. With rising institutional delivery intended to accelerate a decline in neonatal mortality rate (NMR), improvement in the quality of perinatal care requires attention.

- The intervention package included improving facility readiness for newborn care [Exploration Stage], training of the birth attendants (on essential newborn care and newborn resuscitation using the modified 3 days module), establishment of skill laboratories for practice (4 units in each district) and supportive supervision [Implementation Drivers]. All the birth attendants in the district including the doctors, nurses, and auxiliary nurse midwives (ANMs) were trained on essential newborn care and newborn resuscitation using the modified 3 days module. The supporting team members, at these facilities including the pharmacy, store, data, supervision,

and administrative team members, were also orientation on the system strengthening components directed at perinatal and newborn care [Systemic Change] (Das et al., 2018).

- The results showed there was marked improvement in newborn service availability: skilled birth attendants (51%), resuscitation (30%), and kangaroo mother care (27%) at these facilities. A multifold rise in newborn resuscitation efforts and documentation (n = 4431 vs. n = 144 in preintervention period) with high success rate (98.6%) was observed. There was also improvement in obstetric care services including partograph use (31%) and active management of third stage of labor (46%). However, several infrastructural indicators (electricity, water supply, toilets, and sanitation) remained unchanged (Das et al., 2018).

Problem: Basic emergency obstetric and newborn care (BEmONC) is a primary health care level initiative promoted in low- and middle-income countries to reduce maternal and newborn mortality. Access to BEmONC has improved but the services provided are still lacking.

- Tailored support, including BEmONC training to providers, mentoring [Coaching] and monitoring [Fidelity] through supportive supervision [Coaching], provision of equipment and supplies, strengthening referral linkages [Facilitative Administration], and improving infection-prevention practice [Training, Coaching], was provided in a package of interventions to 134 health centers, covering 91 rural districts of Ethiopia to improve timely BEmONC care (Tiruneh et al., 2018).
- The BEmONC implementation strength index score [Fidelity], which ranged between zero and 10, increased statistically significantly from 4.3 at baseline to 6.7 at follow-up. Correspondingly, the health center delivery rate more than doubled (24% to 56%). For every unit increase in BEmONC implementation strength score [Fidelity] there was a corresponding average of 4.5 percentage points increase in facility-based deliveries; in addition, a higher score for BEmONC implementation strength [Fidelity] of a health facility at follow-up was associated with a higher met need (Tiruneh et al., 2018).

Problem: In low resources settings handwashing with soap is an existing but erratic practice; around 25% of residents washed their hands with soap after defecation and cleaning a child's anus and less than 1% practiced before preparing food. Open defecation is not extensively practiced by adults; around 11% found ever practiced during baseline. However, only about half the population has access to improved sanitation facilities that hygienically separate human excreta from human contact. Malnutrition in Bangladesh is still high and estimated that approximately 36% of children under 5 are stunted (Masud Parvez et al., 2018)

- Community health workers (CHWs) delivered individual and combined water, sanitation, handwashing (WSH) and child nutrition interventions to 4169 enrolled households in geographically matched clusters. Households received free enabling technologies [Facilitative Administration; Technical Leadership] (insulated water storage container; sani-scoop, potty, double-pit, pour-flush latrine; handwashing station, soapy-water storage bottle), and supplies (chlorine tablets, lipid-based nutrient supplements, laundry detergent sachets) integrated with parallel behavior-change promotion. Behavioral objectives were drinking treated, safely stored water, safe feces disposal, handwashing with soap at key times, and age-appropriate nutrition behaviors [Usable Innovation]. We administered monthly surveys and spot-checks to households [Fidelity] from randomly selected clusters for 6 months early in the trial. If any

fidelity measures fell below set benchmarks, a rapid response mechanism was triggered [Improvement Cycles] (Rahman et al., 2018).

- In the first 3 months, functional water seals were detected [Fidelity] in 33% (14/42) of latrines in the sanitation only arm; 35% (14/40) for the combined WSH arm; and 60% (34/57) for the combined WSH and Nutrition arm, all falling below the pre-set benchmark of 80%. Other fidelity indicators met the 65 to 80% uptake benchmarks. Rapid qualitative investigations determined that households concurrently used their own latrines with broken water seals in parallel with those provided by the trial. In consultation with the households, we closed pre-existing latrines without water seals, increased the community health workers' visit frequency to encourage correct maintenance of latrines with water seals, and discouraged water-seal removal or breakage [Improvement Cycles]. At the sixth assessment, 86% (51/59) of households were in sanitation only; 92% (72/78) in the combined WSH; and 93% (71/76) in the combined WSH and Nutrition arms had latrines with functional water seals (i.e. fidelity more than doubled in each arm of the trial). (Rahman et al., 2018).

Education

Problem: Education outcomes in the U.S. have remained virtually unchanged since the 1960s, hovering around a mediocre mean literacy score of 215 on a 500-point scale for 9-year old children. This is in spite of decades of massive investments in improvement initiatives at local, state, and federal levels and investments in educational research and evidence-based interventions.

- The U.S. Department of Education Office of Special Education Programs funded a National Implementation Team to develop implementation capacity in state education systems to support the use of evidence-based instruction in classrooms.
- The National Implementation Team set a benchmark at 60% for "acquisition" of implementation knowledge, skills, and abilities and at 80% for "proficiency" of state Implementation Teams developed and embedded in state education systems (Fixsen, Blase, Ward, & Ryan Jackson, in preparation; Ryan Jackson et al., 2018).
- In Study 1 (2008-2012), engagement in implementation and scaling capacity development was conducted in 5 states. The work ended by mutual agreement in two states after 20 and 23 months (States 2 and 3 respectively). Semi-annual State Capacity Assessment (SCA) scores in those 2 states were under 30%. SCA scores in State 1 remained low at about 20% for all 5 years. SCA scores in States 4 and 5 improved over 5 years from baseline scores in the 20-40% range to the 60% acquisition benchmark after 45 months. SCA scores at or above 60% sustained for 2 consecutive administrations (one year) for one state (State 4).
- In Study 2 (2013-2017) with 5 more state education systems, the National Implementation Team used improved methods learned during Study 1 to produce relatively rapid and reliable development of implementation capacity. Each state moved from baseline scores in the 20 – 40% range and reached the 60% acquisition goal within 24 months. The 80% proficiency goal was approached (e.g. 75% or more) by the 36 month mark.
- The data are a) the first repeated assessments of state capacity development in education, b) the first to show that purposeful development of implementation capacity is possible in complex state education systems, c) the first to show the deliberate use of data-based Improvement Cycles by a National Implementation Team so that effectiveness and efficiency increased from

one cohort to the next, and d) the first to show that purposeful capacity development can be replicated across state departments of education that are unique and highly variable with respect to history, size, and operations.

In 2018 the Carnegie Foundation recognized this program as a national example of education improvement and invited presentations to the Carnegie Board of Directors and to Congressional Committees to "spotlight" the seminal contributions to education.

Lack of effect

The lack of predicted outcomes in large scale studies point to lack of attention to providing implementation supports for fidelity of the use of innovations as the problem.

- In education, $2 billion spent over 5 years to support the use of evidence-based programs in 8,000 schools produced no difference in student outcomes. The authors found the teachers were not supported with adequate training and coaching and high fidelity use of the programs occurred in only 10% of the schools (Vernez, Karam, Mariano, & DeMartini, 2006).
- In another example, a study of facilitation of the use of evidence-based programs in 24 long-term nursing care sites [Systemic Change] in four European countries found no difference in use of those programs (Seers et al., 2018). Post hoc analyses found it was likely because the researchers did not provide adequate supports for high fidelity use of the prescribed facilitation strategies (Harvey, McCormack, Kitson, Lynch, & Titchen, 2018).

These are two examples of many studies such as these dating back several decades (Rossi & Wright, 1984; Watkins, 1995) and the problem is not going away. Kruk et al. (2018) conducted an extensive analysis of data from the 2016 Global Burden of Disease study. They calculated mortality amenable to personal health care for 61 United Nations Sustainable Development Goals conditions by comparing case fatality between each LMIC with corresponding numbers from 23 high-income reference countries with strong health systems.

- 15.6 million excess deaths from 61 conditions occurred in LMICs in 2016. After excluding deaths that could be prevented through public health measures, 8.6 million excess deaths were amenable to health care of which 5.0 million were estimated to be due to receipt of poor-quality care [Active Implementation Frameworks] and 3.6 million were due to non-utilisation of health care.
- Poor quality of health care [Fidelity] was a major driver of excess mortality across conditions, from cardiovascular disease and injuries to neonatal and communicable disorders.

Fidelity matters when attempting to improve outcomes and the investment must be made in Implementation Teams who have the expertise to improve fidelity and, therefore, outcomes.

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