

INSTITUTE FOR HEALTHCARE IMPROVEMENT
SUMMARY REPORT: 90-DAY PROJECT

Clinical Effectiveness
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I. Research and Development Team:

- John Whittington

II. Intent:

How can we improve clinical effectiveness? This is the question we are trying to answer in this report. There continues to be a gap between what patients experience and the best feasible outcome for them. Health care at times may have been too focused on safety to the exclusion of clinical effectiveness. And presently we may be thinking too much about population health in health systems and not enough about effectiveness at the individual level. We need, among other things, “a production system that contains reliable problem solving and improvement methods that help patients and their families find individual solutions to the challenges posed by their diseases”¹

III. Background:

IHI has spent many years working on the idea of how to improve clinical effectiveness. Reviewing our innovation activity shows that we have already had 6 cycles of work; 2,4,8,17,18, and 19. Wave 18, titled Outcomes and Effectiveness II,² provides the clearest insight into this work and we will summarize that work. For a more in depth knowledge we recommend you read the original paper.

Wave 18 can be divided into three parts: *outcome measures, application of improvement methods to outcomes, and integrating research methods and improvement methods.*

Outcome measures

The core of what the authors propose for measurement is captured below.

¹ **Outcomes and Effectiveness II** Wave 18 November 1, 2010 - January 31, 2010 IHI innovation series.

² **ibid**

“Michael Porter in an article in the New England Journal of Medicine suggested a hierarchy of measures for determining the outcome component of value in health care. He defined value as a function of the outcomes that were obtained for an individual patient and the cost for the entire episode. The hierarchy has three tiers: 1. Health status achieved or retained 2. Process of recovery, and 3. Sustainability of health. We found this an effective measurement framework for outcomes by studying forty published randomized control trials and determining how the authors measured their outcomes. The list of outcome measures is contained in this report and fits well with Porter’s framework. It is the work of quality improvement to take these research measures and make them useful for routine clinical care. “

The idea is to use this three-tier measurement strategy in direct clinical care

Application of improvement methods to improve outcomes and effectiveness of health services

Because of gaps in health care science and the complexity of individuals, which includes so much more than just health care needs, the authors of wave 18 suggest building improvement methods into daily patient interaction. The core of which is captured below.

“Improvement of outcomes as defined by one or more of these measures will come from effective treatments and interventions. In some cases strong medical evidence will dictate how to proceed. However, in many cases medical science and technology are unable to provide a cure and only partial mitigation of the burden of a disease. The outcome measures may still be the same but the interventions must be a combination of medical interventions and customized problem solving methods that help patients and families find individual solutions to challenges brought on by their disease.” ...

“One model that is used extensively in health care improvement is The Model for Improvement developed by Associates in Process Improvement. The model starts with three questions related to aims, measures, and changes:

- What are we trying to accomplish?*
- How will we know that a change is an improvement?*
- What changes can we make that will result in improvement?”*

“Experienced clinicians of course see many different patients and recognize patterns and thus refine empirically the medical knowledge for choices about a course of care for an individual. However, it seems that in most cases the learning method is not made explicit

and the learning among clinicians is informal and reverts to discussing the evidence at the population level. We believe the PDSA method of small scale tests documented on the graph containing the time series data would be a substantial improvement on this learning system and would result in improved outcomes. These PDSA cycles would take into account the available medical knowledge as well as the values, preferences of the individual patient and the costs. Use of the PDSA cycle might be the scientific cornerstone of what it means to be patient centered.”

Building Knowledge by Integrating Research Methods with Methods for Improvement.

This is the third and final section for the work done during wave 18.

“We need both research evidence at the population level and PDSA learning at the level of the individual but we need them integrated to get the best outcomes. Two important questions arise when considering this integration: 1. How can learning at the population level from research trials provide better guidance for decisions by individual patients and their clinicians? 2. How can action and learning at the individual level be harvested for learning at the population level?

From population based learning to effective individual decisions and action

We propose two areas for further study and testing. The first is subgroup analysis in research trials and the second is providing guidance for the start of a sequence of PDSA cycles for an individual patient.

See paper for more details about subgroup analysis

“A starting point will be to decide what treatment to start patients off on. For example this may be informed from evidence reviewed according to current population perspective approaches. This will likely identify a ‘best’ treatment. In some situations, there may also be information available to inform whether particular groups of patients may benefit from one particular treatment more than another.”

“A signal to switch (treatment) may be provided through the use of run charts or control charts of key patient-level data that is highly correlated with the patient-level outcome of concern”

The original paper also included a section on “*action and learning at the individual level to be harvested for learning at the population level*” which we did not include.

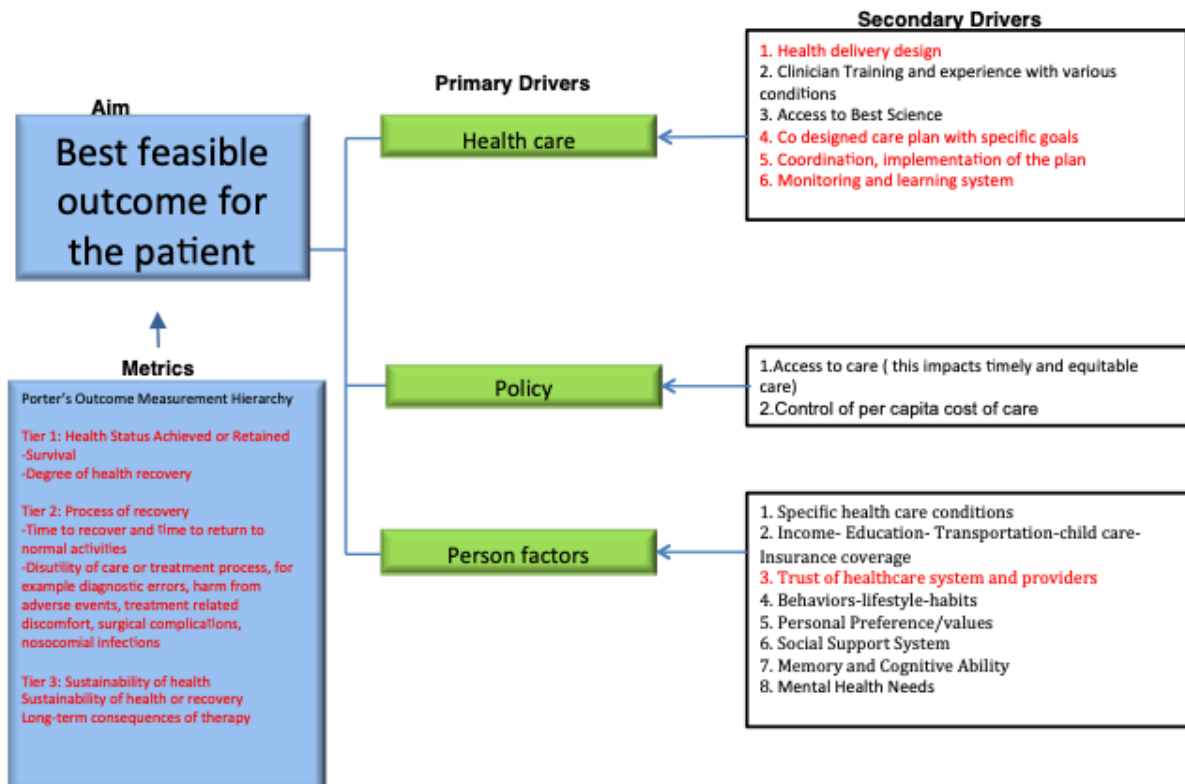
IV. Description of Work to Date:

This cycle of innovation work was built upon the foundation of innovation ideas from all of the preceding cycles of IHI innovation activity that were related to improving clinical outcomes and effectiveness. As mentioned earlier that includes papers from the IHI Innovation waves 2,4,8,17,18, and 19. In reviewing this past work, we have been thinking about why we failed to move this work into the field. So all of this has influenced the output of this work.

V. Results of the 90-Day Scan:

The main output of this work was to identify the primary and secondary drivers of effective clinical care.

Drivers of Clinical Effectiveness for a Patient



Clinical Effectiveness

*Anything that is in red in the driver diagram is an area that IHI should be able to impact.

In the following sections we will attempt to explain the thinking behind this driver diagram. The key for this work is: what problem are we trying to solve and who is going to use it? There has been and continues to be a gap in effective care for patients.³ The IOM report defined⁴ effective care as: “providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.” Add to this that care also needs

³E.A. McGlynn et al., “The Quality of Health Care Delivered to Adults in the United States,” *New England Journal of Medicine* **348**, no. 26 (2003): 2635–2645.

⁴ Committee on Quality of Health Care in America. *Crossing the Quality Chasm, A New Health System for the 21st Century*. Washington, DC: National Academy Press. 2001

to take into account at least social and economic realities for the patient. *Therefore we define our aim as the best feasible outcome for the patient* in our driver diagram. All clinicians strive to achieve this for their patients. If we can develop a meaningful and practical way to help them better achieve this, then many clinicians in health care would want to use this work.

As mentioned in wave 18, the authors recommended we use Michael Porter's measurement strategy⁵ to measure clinical outcomes. That strategy consists of the following three tiers of measures:

Porter's Outcome Measurement Hierarchy

Tier 1: Health Status Achieved or Retained

- Survival
- Degree of health recovery

Tier 2: Process of recovery

- Time to recover and time to return to normal activities
- Disutility of care or treatment process, for example diagnostic errors, harm from adverse events, treatment related discomfort, surgical complications, nosocomial infections

Tier 3: Sustainability of health

- Sustainability of health or recovery
- Long-term consequences of therapy

Here is an example of how that could be applied.

Table 1: Outcome Measures for Knee Replacement

Tier	<u>Measure</u>
1. Health status achieved or sustained	<ul style="list-style-type: none"> • Pain relief • Improved function • Improved quality of life

⁵ What Is Value in Health Care? Michael E. Porter, Ph.D. N Engl J Med 2010; 363:2477-2481
December 23, 2010 DOI: 10.1056/NEJMp1011024

2. Process of recovery	<ul style="list-style-type: none"> • Time to reach treatment goals for Tier 1 • Infections • Discharge to home
3. Sustainability of health or recovery	<ul style="list-style-type: none"> • Tier 1 measures after 6 months

The driver diagram is broken down into three primary drivers and multiple secondary drivers. We are using this driver diagram to give us an overall theory of what impacts clinical effectiveness and to focus specifically on areas where IHI can make a difference, those in red font.

Health care is one of the primary drivers and that seems self-explanatory.

In the secondary drivers, *health care delivery design* refers to how health care is organized. The patient centered medical home is one example of health care design. Anthony DiGioia, Orthopedics at UPMC, is another example of health care design. It uses the idea of a focused factory, where there is a specific focus on a specific condition to improve the outcome significantly. IHI has done work on a concept called production system design that could support focused factory work for health care.

Core clinical training is not a focus for IHI. Our support for clinical students has been mostly in the areas of safety and quality. Both of these are important, but do not represent the heart of medical training.

Providing *access to the best clinical science* also is not a focus for IHI at this time. Clinical science is provided through guidelines either with stand alone access or embedded into electronic medical records. In addition, there are proprietary electronic tools like UpToDate and others that support clinicians.

Co-designing a care plan, along with *coordination and implementation* of the plan, are all areas where IHI could play a role. Maren Batalden et al⁶ figure 3 described a model of health care coproduction that is very helpful for this work. Coproduction may be a way to level the power differential between health care providers and patients.

⁶ Batalden M, Batalden P, Margolis P, et al. Coproduction of healthcare service BMJ Qual Saf Published Online First: 16 September 2015 as 10.1136/bmjqs-2015-004315

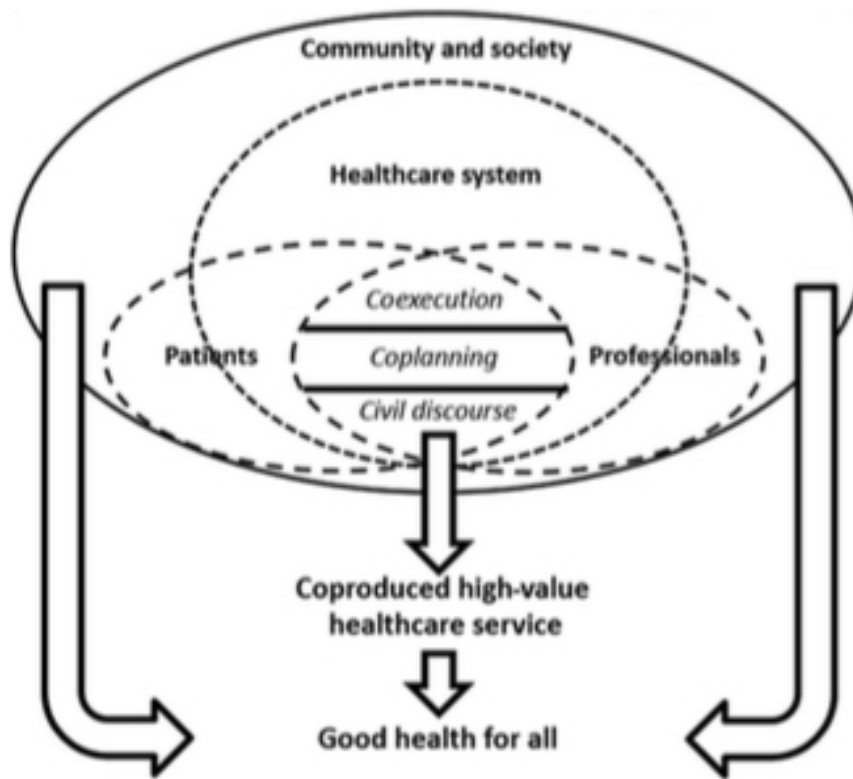


Figure 3 Conceptual model of healthcare service coproduction.

Monitoring/ learning system are particularly unique areas for IHI to make a contribution. Health care science tends to focus at the population level. In health care we have a slow learning research system that learns at the population level. We also need a faster learning system that operates at the patient level. The approach is to learn for the population and let the patient and his or her clinician try to figure it out for the individual. A central tenet of the work in wave 18 was to use the model for improvement to learn at the individual patient level by starting with the best population science as a starting point. However, realize that even with the best science, it is often difficult to know the impact of therapy at the individual level if the event you are trying to prevent or delay is a long way off in the future. “The percent of waste in a treatment is $(\text{NNT}-1)/\text{NNT}$ ” where NNT = number needed to treat.

The next primary driver to achieve our aim is policy.

Policy plays an important role in clinical effectiveness. Barriers to health care access can lead to delays in diagnose and treatment that can impact the health of individuals.

The per capita cost policies may not be as intuitive as access. Public money supports over 50% of health care cost primarily through the public programs of Medicaid and Medicare. As health care costs rise, they burden society through tax dollars either now or in the future. If per capita health care cost get prohibitively costly, that might prompt either a reduction in health care services that are covered under public insurance or a decrease in the number of people covered by these policies. Either one of these scenarios can impact care to individuals. Therefore policy that can help control the increase in health care cost is important.

The third primary driver deals with the person.

Specific health conditions refers to the severity of any given health condition and the constellation of health conditions that a person might have, all of which create a unique profile for that person.

Income-education-transportation-child care-insurance coverage represent the influence of financial status on the outcomes of health.⁷ Overall, healthcare seldom considers this in creating a health plan for an individual.

Trust of the health care system and providers is a driver that needs some explanation. Trust is always part of any health care interaction. The patient needs to trust that the clinician is up to date on knowledge and will act in the patient's best interest. However, because of some exploitations like the 1932 Tuskegee Institute "Study of Syphilis in the Untreated Male"⁸ and genetic research among the Havasupai Tribe in Arizona,⁹ among other incidents, populations of color have a deeper, more fundamental lack of trust in health systems. This is a secondary driver where IHI may be able to play a role. Within our health equity work, we are focusing on this issue.

⁷ Chetty et al The Association Between Income and Life Expectancy in the United States, 2001-2014 AMA. doi:10.1001/jama.2016.4226 online April 10, 2016.

⁸ Jones JH. Bad Blood: The Tuskegee Syphilis Experiment. Free Press; 1993.

⁹ Sterling RL. Genetic research among the Havasupai: A cautionary tale. AMA Journal of Ethics. 2011;13(2):113-117.

Behaviors-lifestyle-habits are another example of multiple determinants of health that contribute to the production of the best feasible outcome for the patient. These at least need to be considered when co-developing a health care plan.

Personal Preference/values all make a contribution to determining what is the best feasible outcome. A woman dying of cancer is on chemotherapy. She can gain a short amount of extra life span but the holidays are coming up and she wants it to be a better time for herself and family so she decides not to continue her chemotherapy. The best feasible outcome for this patient is to spend time with her family without the side effects of chemotherapy.

Social support system also impacts the best feasible outcome for a patient. For example, a reliable healthy caregiver may have significant impact on the health of a frail elderly patient.

Memory and cognitive ability of the patient play a role in designing care to provide the best feasible outcome.

We have included *mental health needs* as a separate secondary driver. Perhaps we could have lumped this with specific health care conditions. However, because of the large impact mental health has on other health outcomes and health care cost we felt that this should be a stand-alone driver.

VII. Conclusions and Recommendations:

In this manuscript we have attempted to summarize the work from prior waves of innovation on clinical effectiveness and introduce a driver diagram to highlight opportunities where IHI can help make progress.

We need to focus on developing comprehensive health plans for individuals that are well executed over time. Start with the best science, but recognize the extreme limitations of population-based science when we apply it to the individual. The execution of an individual's health plan will require the use of quality improvement at the individual patient level. This will be part of an effective learning system where Porter's three tiered measurement strategy can be tested at the patient level. Both patients and physicians will need training to implement quality improvement at the individual patient level.

All that we propose is not new and we should seek examples that come as close to this as possible, and at the same time we should work with organizations that want to advance clinical effectiveness in a systematic manner.

We are concerned that the vast majority of patients with multiple chronic diseases and challenging social situations receive far less than the best feasible outcome for their situation.

VI. Open Questions:

1. What organizations would like to collaborate with us in this work?
2. Are we doing enough to address the power differential between clinicians and patients to enable patients to be on equal footing?

VIII: Appendices:

Measurement sources

- PROMIS- <http://www.healthmeasures.net/explore-measurement-systems/promis>
- International Consortium for Health Outcomes Measurement (ICHOM) <http://www.ichom.org/>
<http://www.oecd.org/els/health-systems/health-care-quality-indicators.htm>