Demonstrating Medical and Economic Value through Outcomes Studies

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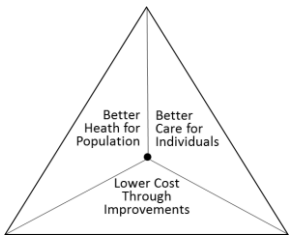
1

Without economic evidence, it is becoming very difficult to show value for any new solution: drugs, diagnostics, devices, or behavior-change programs. This is understandable, because healthcare needs and expenditures are growing worldwide, placing great pressure on providers and suppliers alike to deliver better care at lower cost.

Retrospective outcome studies help healthcare systems, as well as manufacturers of drugs, diagnostics, and devices, or suppliers of behavior-change programs, to create the rationale for adopting new products, solutions, and treatment protocols on the basis of both medical and econometric evidence.

More demanding healthcare environment

Healthcare reform in the US, in the form of the Affordable Care Act (ACA), is calling for increasing accountability of Providers to optimize the components of the "*Triple Aim*": lower cost of treatment, better health outcomes, and higher patient satisfaction. Similar evolutions, in different forms, occur in numerous countries in the world.



In many cases, these reforms involve a decentralization of decision-making (medical protocols, formularies, procurement). Local authorities and other decision makers are often unprepared for such responsibilities and need convincing, trustworthy information delivered by easily understandable tools to help them evaluate and compare (a) Medical Value, (b) Econometric Effectiveness, and (c) Expected Patient Satisfaction.

Manufacturers of drugs (Rx), medical devices and diagnostics (Dx), as well as providers of behavior change programs (Bx) bear the "*burden of the proof*". The winners will be those providing clear evidence for the holistic value of the solutions they propose.

A new technology that is backed by a strong retrospective clinical outcome study – conducted at a first-rate academic institution under proper Institutional Review Board (IRB) approval, with a well-known Principal Investigator (PI), and utilizing a statistically significant patient population – is likely to have superior acceptance, and correspondingly greater diffusion rate.

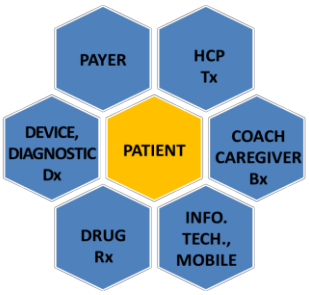
For example, once the superiority of Digene's genetic test over the traditional Pap smear was demonstrated in studies by Kaiser, diffusion throughout US healthcare was dramatically fast. On the other hand Troponin-T, Roche's presumably superior cardiac marker, languished for years and never succeeded in replacing the earlier marker, Troponin-I.

What can you learn from retrospective outcomes studies?

Retrospective outcomes studies offer a fact-based starting point to (a) build and validate models of ex-

isting and future treatments, and (b) combine therapies utilized, medicines, diagnostics, and behavior-change interventions (e.g. coaching for treatment adherence or tele monitoring) to reduce hospital readmissions.

These validated models provide the rationale in terms of medical benefit, economic benefit, and potentially patient satisfaction benefit, to justify a change of medical protocol. Such change could be a simple addition (e.g. patient coaching post discharge) or a complete modification (e.g. using diagnostics to decide what anti-infective strategy to use).
In other words, if your Dx creates an intrinsic value of $1.00, its price of $0.20 may be readily accepted.
Retrospective outcome studies are also used as a foundation for better Integrated Care.



Where do you start?

Patient data. The starting point is patient data. A hospital system with good electronic records is a good base. More interestingly, the electronic records in a system combining the functions of Provider and of Payer will allow combining analyses of medical value and of economic value.

Example of pathway: 8,500 patients with heart symptoms selected from 34,600 admitted at an Emergency Department.

What are the foundational Key Success Factors?

If you can demonstrate that your new diagnostic, drug, or behavior change intervention saves $1.00 to the healthcare system, you made a start.

If you …

- conducted the study at a first-line academic medical center,
- had access to a broad and deep clinical data repository (CDR) or Electronic Health Record (EHR),
- retained the services of a respected clinician to act as the Principal Investigator (PI),
- used real historical patient data of a volume that was statistically significant,
- had your PI design a Clinical Protocol and define the appropriate care pathway,
- had your PI obtain the approval of the local Institutional Review Board (IRB),
- made the study compliant with all regulations such as patient privacy (HIPAA), and
- assembled a database that truthfully reflected the data retrieval part of the study,

then, you have made two important accomplishments:

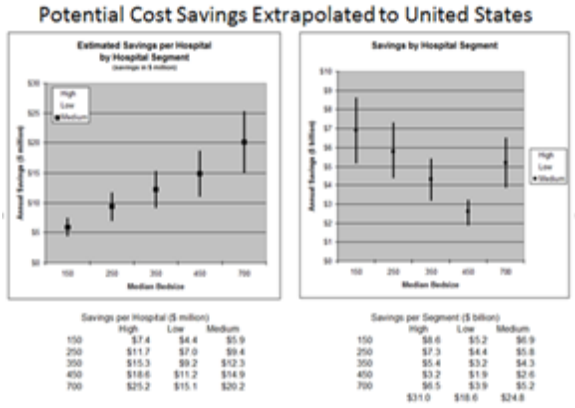
(a) you completed a medically recognized retrospective outcome study,
(b) you successfully established the foundation for the intrinsic value.

How do you organize a successful retrospective outcome study from there?

If you collaborated with the PI in the analysis, and derived PI-approved estimates in the retrospective outcome study for the impact your technology was likely to make on the care pathway for medical outcomes and improvement in the quality of care, you have successfully established two of the three critical metrics required, and completed the third step.

Example of evidence for medical impact. Extract from a poster presented at IDWeek of a retrospective study conducted at Intermountain Healthcare, Salt Lake City, Utah on hospital acquired infections.

If you, your PI, and the institution's IT compiled the required volume of the third metric, the cost reductions delivered by your technology, you succeeded, and you have the *intrinsic*, *inherent, true, fundamental* value for your technology.

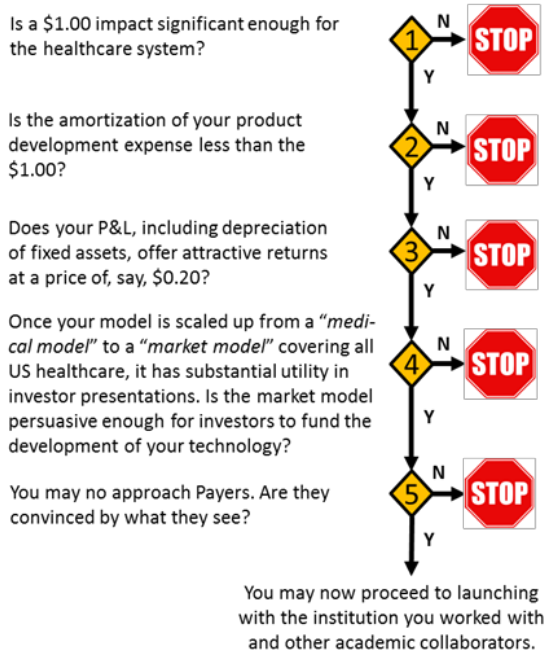


Example of savings calculated for different types of hospitals.

You now have a validated, objective claim that the technology's intrinsic value is indeed $1.00, supported by repeatable and sustainable improvements in medical outcomes and quality of care, and the attendant reduction in cost. You have completed the third and final step.

How do you evaluate your solution in this context?

The retrospective outcome study provides your company with a clear guidance about the value that your solution may provide to the healthcare system. This is the starting point to help you decide if and how to build this solution, according to the following logic.



The institution with which you collaborated for you retrospective clinical study will likely be your "*launch customer*". You may discuss with them a prospective clinical study to validate the solution and gather data for regulatory submission. The institution will likely want to publish the results of the objective retrospective outcome study; a clearly helpful result. Other academic institutions that collaborate with your launch institution are likely to accept the results of the studies and in turn express interest in the solution.

How is it impacting your Sales approach?

The time-honored practice of completing the development project, securing regulatory approval, training a sales force, and making sales "*cold calls*" on healthcare provider institutions is less than optimal. Walking in with only the modest prospective data in hand used to secure regulatory approval, offers the provider slim proof of the medical and econometric effectiveness of a new technology. Providers are

likely to request trials, some extensive, in an effort to develop a larger volume of trustworthy clinical evidence and cost metrics. Such requests might come from several prospects at the same time. Prospective studies have three undesirable properties: (a) they take considerable time, (b) they are expensive, and (c) they use small patient populations.

Having in hand a retrospective clinical outcome study as described here – conducted at a first-rate academic institution under IRB approval, with a known PI, and utilizing a statistically significant patient population – is likely to have superior impact.

Why EAC?

EAC is your indispensable partner for Retrospective Outcomes Studies.

- EAC has developed a unique expertise over the last 30 years in building medical-value models and economic-value models
- EAC leverages its networks of 30,000 experts around the world, many of them potential Principal Investigators for retrospective outcome studies.
- EAC has developed an efficient working relationship with renowned institutions that manage high quality databases of patient electronic health records: Intermountain Healthcare, Massachusetts General, Geisinger, NHS (UK), Kantonspital Basel (Switzerland).

Established in 1985, EAC offers strategic consulting, clinical studies, fact-based market research, and executive advisory services.
EAC has deep expertise in the diagnostic sciences and in those domains that diagnostics touches: clinical medicine, the intersection of pharma and diagnostics, bioscience, and food-chain efficiency and safety.

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