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Determining the "*Intrinsic Value*" in Diagnostics

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Abstract

Over the past few years EAC has made a concerted effort to develop a set of tools that can be deployed to estimate the intrinsic value of a new biomarker or diagnostic test. The intrinsic value represents the savings that a new diagnostic would deliver to the healthcare system. The tools involve clinical studies, specifically retrospective outcome studies, in which the records of a significant population of relevant patients – on the order of 30,000 to 100,000 – are used to prepare a picture of care pathways. A mathematical model is then built upon the results and utilized to estimate the beneficial impact of a hypothetical (or existing) diagnostic test in the context of that treatment pathway.

Determining Intrinsic Value for a Test – a Case Study

A few years ago, a client asked EAC to establish the value of biomarkers intended for the Emergency Department (ED) setting. Their request was: "*Hypothesize a set of new biomarkers that would have strategic impact on emergency medicine; biomarkers which could be used at the Point of Care in Emergency Departments. Determine their intrinsic economic value.*"

To answer the question, EAC conducted a retrospective outcome study (ROS) at an integrated healthcare network (IHN) in the US. Although EAC had developed and tested the ROS methodology in an earlier and smaller project, the ED ROS turned out to be the largest test case to date; it involved a cohort of 34,600 retrospective ED admissions, 892 of whom met the "*admission criteria*." The ROS project entailed the major steps described in the table below.

Steps	Tasks
Determine and describe "*best practices*" treatment pathway	• Monitor overall disease development and specific, event-related treatment • Observe the use of diagnostic tools along the pathway
Extract historical patient data for treatment along the pathway	• Label the use of diagnostic tools, decision points and treatment applications
Graphically depict the pathway and convert it to a mathematical model	• Aggregate data along the pathway, accumulating time and costs • Compare and apply actual data to model and adjust model accordingly
Hypothesize treatment changes based on availability of new markers or tests	• Evaluate this parameter in the framework of a model (multiple scenarios are possible)
Extrapolate hypothesis to establish value for new treatment pathway	• Forecast better medical outcomes at better economic terms
Derive implied economic value for markers	• Calculate difference between actual and extrapolated retrospective data

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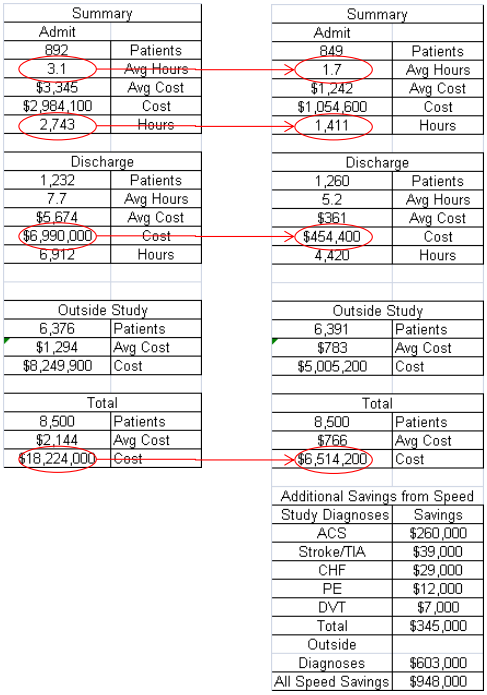
The model is built of a series of steps and links describing a "*best practices*" care pathway. Each step is an identified clinical intervention that involves a care provider assessment, a diagnostic or monitoring tool, or a pharmaceutical or other treatment application. All of these are associated with a specific outcome. When institutional experience cannot be captured from the data, the distribution of occurrence is pulled from principal investigator (PI) experience augmented by national statistics.



Summary	
Admit	
892	Patients
3.1	Avg Hours
$3,345	Avg Cost
$2,984,100	Cost
2,743	Hours

Discharge	
1,232	Patients
7.7	Avg Hours
$5,674	Avg Cost
$6,990,000	Cost
6,912	Hours

Outside Study	
6,376	Patients
$1,294	Avg Cost
$8,249,900	Cost

Total	
8,500	Patients
$2,144	Avg Cost
$18,224,000	Cost

Summary	
Admit	
849	Patients
1.7	Avg Hours
$1,242	Avg Cost
$1,054,600	Cost
1,411	Hours

Discharge	
1,260	Patients
5.2	Avg Hours
$361	Avg Cost
$454,400	Cost
4,420	Hours

Outside Study	
6,391	Patients
$783	Avg Cost
$5,005,200	Cost

Total	
8,500	Patients
$766	Avg Cost
$6,514,200	Cost

Additional Savings from Speed	
Study Diagnoses	Savings
ACS	$260,000
Stroke/TIA	$39,000
CHF	$29,000
PE	$12,000
DVT	$7,000
Total	$345,000
Outside	
Diagnoses	$603,000
All Speed Savings	$948,000

In the model, each step is linked to its immediate prior step and its immediate succeeding step. Links can be reassigned at any step. Decision points are assigned specific labels and associated with underlying tables that capture time, people, and costs. Master tables contain cost data associated with specific services, levels of patient acuity, and length of stay (bed occupancy either in days or hours). Decision points along a pathway accumulate data from the prior points.

Total cost, time, and patient numbers can be associated at each outcome (e.g. admission, discharge, readmission, diagnosis). When the mathematical representation of the current practice pathway is complete, a number of hypothetical improvements (e.g. the impact of new markers) can be tested at various points in the flow and the resulting cost improvement seen. The model begins with patient "*admission*" and ends with the grand total of costs.

In the case of the ED study, the results showed a substantial reduction in ED costs, as depicted in the illustration to the left. The IHN was impressed that the pre-study annual cost of nearly $3 million, for caring for these ED admissions, would drop to something close to $1 million. The second indication for value was the decrease of 2,743 ED hours to 1,411 ED hours, and the coincident decrease in the average length of stay from 3.1 hours per patient to 1.7 hours. A subsequent modest extension to this intrinsic study put further emphasis on this length-of-stay time parameter: "*The sooner a patient is sent from the ED to the ICU, the shorter the length of stay in the ICU…*"

Broader ROS Applications

EAC believes that with adjustments the ROS methodology works in a broad variety of settings, from in-patient to out-patient domains.

In EAC's view, the key requirements for ROS success include:

- Availability of a database of clinical patient records (CDR - Clinical Data Repository or EMR - Electronic Medical Record)
- Availability of a strong PI at the institution (a noted physician of appropriate rank)
- Adequate population of patients (IHNs are excellent in this respect)
- The institution's reputation for clinical excellence, quality of care, and record of outcomes
- Reasonable institutional approach to external collaborations
- Confidentiality, protection of sponsor IP and interest in publication