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- Foster sharing of ideas, challenges, and learning to increase overall level of knowledge and skill in this area
- Provide a training opportunity to ensure continual growth with Pharmaceutical Management Science
- Encourage interaction and networking among peers in this area

Please submit correspondence to:

Pharmaceutical Management Science Association

446 E High Street, Suite 10
Lexington, KY 40507
info@pmsa.net
(877) 279-3422

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sczuhajewski@pmsa.net

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PMSA Journal: Spotighting Analytics Research

Welcome to the fourth edition of the *Journal of the Pharmaceutical Management Science Association (PMSA)*, the official research publication of PMSA.

The purpose of the Journal is to promote and embody the mission of the association, by:

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The Journal publishes manuscripts that advance knowledge across a wide range of practical issues in the application of analytic techniques to solve Pharmaceutical Management Science problems, and that support the professional growth of PMSA members. Articles cover a wide range of peer-reviewed practice papers, research articles and professional briefings written by industry experts and academics. Articles focus on issues of key importance to pharmaceutical management science practitioners.

If you are interested in submitting content for future issues of the Journal, please send your submissions to *PMSA Journal* editor **Devesh Verma** at dverma@pmsa.net.

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Summary of manuscript structure: An abstract should be included, comprising approximately 150 words. Six key words are also required.

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Industry submissions: For practitioners working in the pharmaceutical industry, and the consultants and other supporting professionals working with them, the Journal offers the opportunity to publish leading-edge thinking to a targeted and relevant audience.

Industry submissions should represent the work of the practical application of management science methods or techniques to solving a specific pharmaceutical marketing analytic problem. Preference will be given to papers presenting original data (qualitative or quantitative), case studies and examples. Submissions that are overtly promotional are discouraged and will not be accepted.

Industry submissions should aim for a length of 3000-5000 words and should be written in a 3rd person, objective style. They should be referenced to reflect the prior work on which the paper is based. References should be presented in Vancouver format.

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Industry, academic and expert opinion authors are invited to contact the editor directly if they wish to clarify the relevance of their submission to the Journal or seek guidance regarding content before submission. In addition, academic or industry authors who wish to cooperate with other authors are welcome to contact the editor who may be able to facilitate useful introductions.

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Fox School of Business
Temple University

Sudhakar Mandapati
Principal
Strategic Research Insights

Devesh Verma, Ph.D.
Brand Director, Hypertension and Welchol
Daiichi Sankyo, Inc.

David Wood, Ph.D.
Senior Principal
Atria

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Tele-Detailing: How a Late-Stage Pharma Brand Combats the Loss of Field Sales Force Coverage

Jane Portman, Sr. Director, Analytics, Merkle; Alice Liang, Associate Director, Analytics, Merkle; Paul Spiegler, Senior Director, Strategy, Merkle Health

The rep is likely pharma's most effective weapon. Many companies consider the pharma rep the quarterback of a brand's marketing efforts, and they leverage reps in numerous ways to enable or assist with communications to key customers.

It is widely agreed in performance marketing circles that a robust and constantly evolving multi-channel marketing plan is the most effective way to achieve brand success. This type of strategy may better enable a rep to gain access to key healthcare practitioners (HCP), deliver key messaging to them in vacant territories, or even increase awareness and response by activating user-preferred channels and/or content mix.

Typically in a brand lifecycle, we are at one time or another forced to scale back resources and dollars, especially at times when loss of exclusivity (LOE) is approaching. Because rep-coverage is usually the largest expense, sales teams are often reallocated to support new inline or launch products. On the front lines, the field sales force begins to lose much of the HCP access they once had. So it begs the question: Is a semi-personal tele-detail approach the next-best tactic, once you lose access?

Some arguments against telemarketing programs may include limitations on reach and access – and of course, cost per reached call tends to be higher than other non-personal tactics. That said, there are telemarketing approaches that are highly effective in the right circumstances. Let's look at some examples:

1. **High potential writers who are not on the call plan**

A deep analysis of your key audience and segmentation will identify physicians who are high potential writers but currently reside in your white space. These gaps, like rural areas, can easily be picked up by a trained inside sales team.

2. **Low-see and no-see physicians**

A primary detail equivalent (PDE) gap analysis will identify under-detailed physicians. A telemarketing approach can help fill in those gaps to maximize script lift. Often times, this is achieved using a nurse champion in the office to communicate messages with the physician(s).

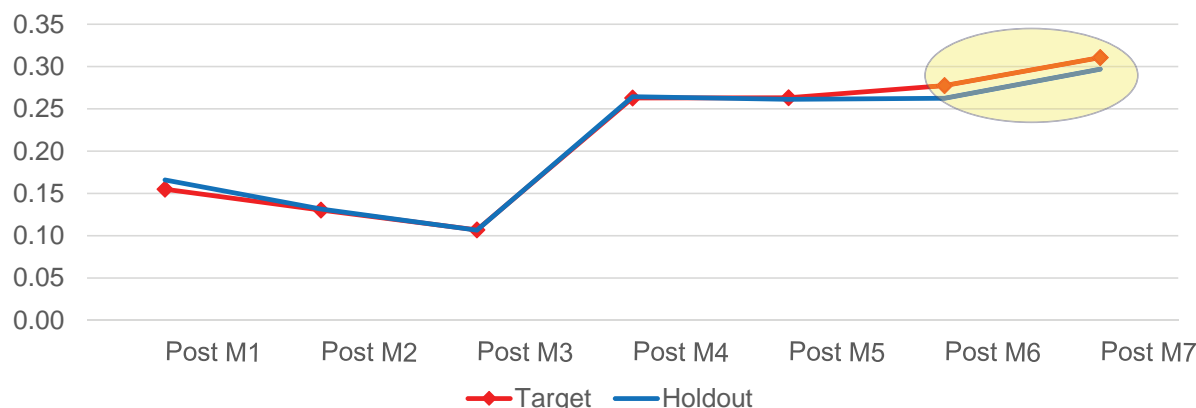
3. **Managed care pull through**

The call point here does not have to be the physician, which makes telemarketing an ideal way to quickly communicate tier status wins. The business manager can easily spread the news and deliver co-pay card initiatives.

4. **Brands with high awareness levels**

When calling an office for a brand that's mature, awareness is high and the customer is very receptive to your message. If they have written for the product over the years, these tele-details are seen as relevant and the offices welcome any support materials you have available to help their patients become more adherent.

Figure 1: Personal Details Per Month Per HCP (Post-Campaign Period)



Following is a case study involving a mature cardiovascular brand with declining sales force coverage that employed a tele-detailing program to fill the newly created gaps. The program yielded excellent results with high tactical response rates across key engaged specialist HCPs, and slowed the brand’s Rx decline with a positive program ROI. There are many insights that will provide you with a better perspective of tele-detailing best practices.

The Business Challenge:

A late-stage cardiovascular brand from a top 10 pharmaceutical company was losing sales force coverage, as reps were being redeployed to another drug with greater upside. With the removal of the sales force, the brand was experiencing a decline in prescriptions. The initial strategy was to counter this loss in volume by increasing the Rx price. On a positive note, the brand had high market awareness and recognition, which made it a perfect candidate for leveraging other marketing channels to compensate for the gap in sales force calls.

Our Approach:

When losing PDEs, it is important to somehow maintain top-of-mind awareness with the HCP. A targeted semi-personal, or “inside sales,” approach serves well to accommodate this need.

We engaged with a leading pharmaceutical tele-detailing organization to run an eight-week call cycle on 5,000 cardiologists. Each cycle would include a new message and/or a new offer such as samples, co-pay cards, or patient education materials. Understanding that most presentations are made to the office staff, messages were non-technical.

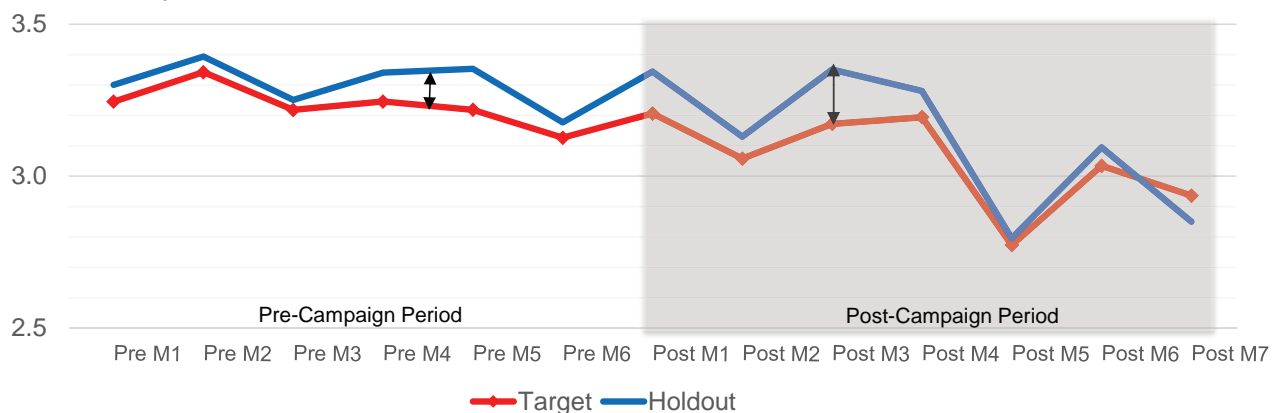
Who received the tele-details?	% of Total
Office Manager	1.1%
Medical Assistant	4.0%
Non Clinical Office Staff	36.1%
Office Influencer	44.9%
Nurse	12.5%
Mid-Level Prescriber	0.8%
Physician	0.6%

We set up a randomized test with holdout groups to accurately measure the results for program optimization opportunities and to quantify any recognized financial gains.

Measurement Methodology:

Lift analysis is an analytical approach that employs the analysis of covariance (ANCOVA) statistical method to measure performance of the marketing campaign. ANCOVA-adjusted

Figure 2: Monthly Brand TRx/HCP



“Gap” is the difference in Rx comparing test vs. control group, noted by the black arrows. The difference between two gaps is the “Double Difference”.

lift analysis estimates the incremental lift of the campaign. It compares the change in Rx between pre and post-campaign periods for targeted and holdout/control physicians, while controlling the impact of other promotion factors.

In a randomized test design, the holdout/control physicians closely resemble the targets during the pre-campaign period, but there are differences in details, samples, etc. in the post period. This means that some of the Rx difference between the test and holdout/control groups could be due to details, samples, or any other promotional efforts that occurred during the campaign period. (Figure 1)

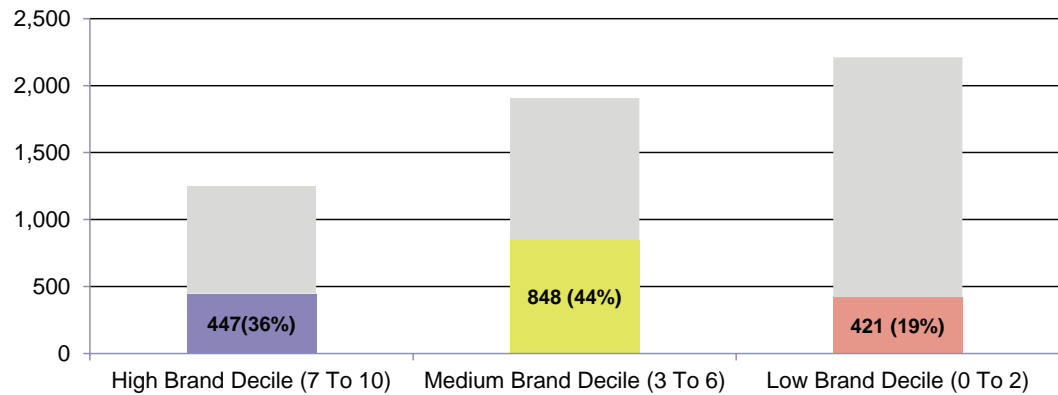
Using ANCOVA techniques to account for these post-period differences can help control the impacts from promotional factors outside of the program of interest. Least squared means of Rx difference between test and holdout groups are estimated after removing these covariates’ effects; their difference is the estimated incremental lift of the campaign. This is often referred to as “double difference.” Essentially, it is to compare the gap between test and holdout/control group pre- vs. post-campaign period.

Has it increased or decreased and by how much? By using this approach, the incremental lift of the program is estimated, with a statistical confidence level associated with it, to determine whether the read is statistically significant or not. (Figure 2)

Measurement Segments

Segment-level analysis is a crucial part of any program evaluation as it pin points to pockets with success vs. pockets that underperformed. This is helpful to derive insights to drive actionable recommendations to the next implementation of the program. In this analysis, targeted physicians in the test group were split into two segments: engagers vs. non-engagers. Engagers were those who received communication followed by responses to samples and/or co-pay cards offers. The remaining targets who didn’t receive communication or didn’t respond were considered as non-engagers. Rx behavior change after program implementation between engagers and non-engagers was observed and compared to help understand the baseline Rx behavior on engagers, as well as provide initial

Figure 3: Tele Engagers by Brand Decile (n=1,716)



# Tele Targets	1,250	1,907	2,144
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direction on the program effectiveness. This comparison had suggested that the program is more impactful on engagers. Further details and evidence on the program impact on engagers were revealed in the engager lift analysis.

Engagement Results:

Just seven months into the program, senior leadership requested an early read on it. This is always a bit risky as there needs to be a reasonable “in market period” before seeing response metrics and being able to accurately measure impact.

Following three separate campaigns (call cycles) with 5,000 targeted physicians, the tele-detailing program received the highest unique engagement rate the brand had ever experienced from any one tactic outside the field sales force. Cumulatively, 32% of the targeted physicians requested samples or co-pay cards, proving that messages and offers were relevant. In fact, they were more effective for physicians in medium to high deciles than low deciles, with the highest engagement rate for mid-decile physicians at 44%. (Figure 3)

The relationship between tele-engagement and PDEs

High-decile writers receive the most attention from the field sales force. However, 447

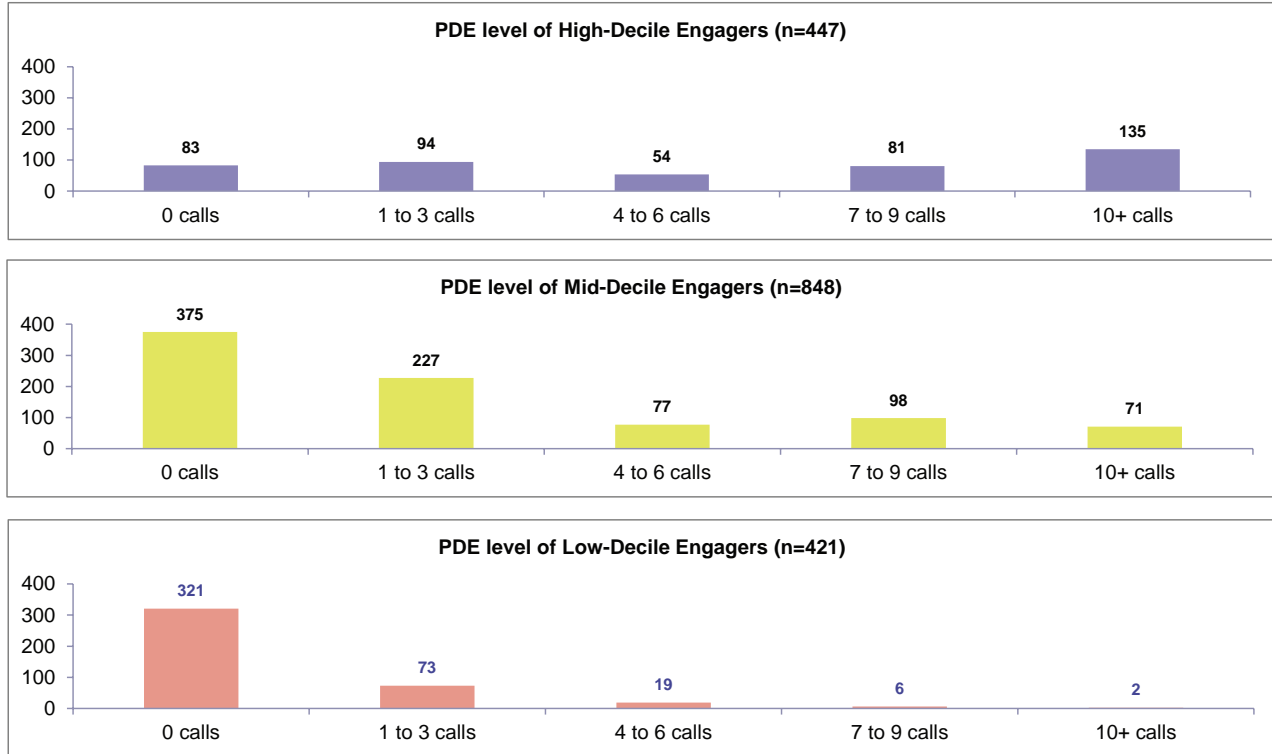
physicians or 36% from the high-decile group, responded to tele with requests for samples and co-pay cards. It did not make a difference how many PDEs were delivered, high-decile writers were very interested in what was being presented to them via the tele-detail.

However, the story changes a bit for the mid- and lower-decile physicians. The vast majority of these physicians engaged only when PDEs were under-delivered. For mid-decile physicians who engaged, 74% of them received just 0-4 PDEs over the seven-month period. With lower-decile physicians who engaged, 93% of them received only 0-4 PDEs in the seven-month period. It can easily be concluded that most of the mid- to lower-decile tele physician engagers really needed more attention than what they were receiving out in the field, and this program helped to fill these gaps. (Figure 4)

Financial Results:

When measuring the financial impact and script writing behavior from engagers, we found significant differences over the holdout group. The incremental lift of the program was significant for targeted physicians who requested samples or co-pay cards, regardless of their decile values and the level of sales

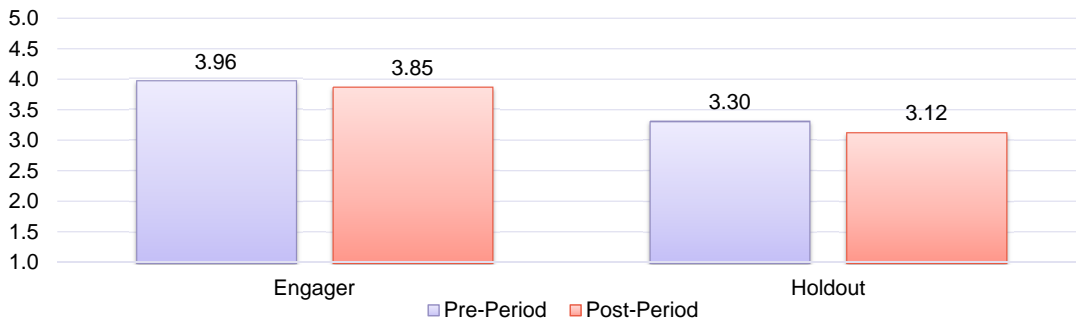
Figure 4: Tele Engagers by Level of Sales Force Support



force details they received. Since this brand was experiencing a decline in prescriptions, the monthly average prescriptions in post-period was smaller than pre-period. As a result, the total number of prescriptions (TRx) change from pre-to-post period was negative. However when comparing the pre-to-post change between

engager and control/holdout group, we saw a slower decline for engagers. The estimated “double difference” from ANCOVA analysis was 0.84 per physician, after adjusting the impacts from other promotional factors. Within the seven-month period, we saw an overall 3.3% lift in TRx from engagers which in turn paid for the cost of

Figure 5: Average Monthly Brand TRx per HCP



Audience	TRx Lift per HCP	%TRx Lift	P-Value	# HCPs	7-month Incr. Revenue	7-month ROI
Engagers	0.84	3%	0.06	1,716	\$ 550k	3:1

Figure 6: Tele Engagers Lift Summary

Audience	TRx Lift per HCP	%TRx Lift	P-Value
High-Decile Engagers	2.24	3%	0.11
Mid-Decile Engagers	0.63	3%	0.16
Low-Decile Engagers	0.35	8%	0.15

the entire 12-month tele-detailing program spent on all targeted physicians with a 3:1 ROI. In other words, the program cost is paid for with a positive return at month seven out of the entire 12-month period. (Figure 5)

How Valuable Are the Engagers?

We dug a little deeper to better answer critical business questions to optimize the tele-detailing tactic moving forward. We took a deeper dive into the 32% of the targeted physicians who are engagers to see just how valuable they really are.

- We observed directional script lift across all decile groups for engagers who responded to samples and co-pay cards. (Figure 6)

- When comparing TRx trends through the seventh month of the program, high-decile engagers significantly outperformed holdout/control group. We anticipate seeing a significant difference between the two groups following the conclusion of the program’s first year as the gap widens. (Figure 7)
- There were more high-value targets in the engager group than in the non-engager group. On average, engagers prescribed 1 more script per month than non-engagers. TRx trends demonstrated a slower decline in engagers than non-engagers in the campaign period.

Figure 7: Monthly Brand TRx/HCP Trend (High Brand Decile 7 to 10)

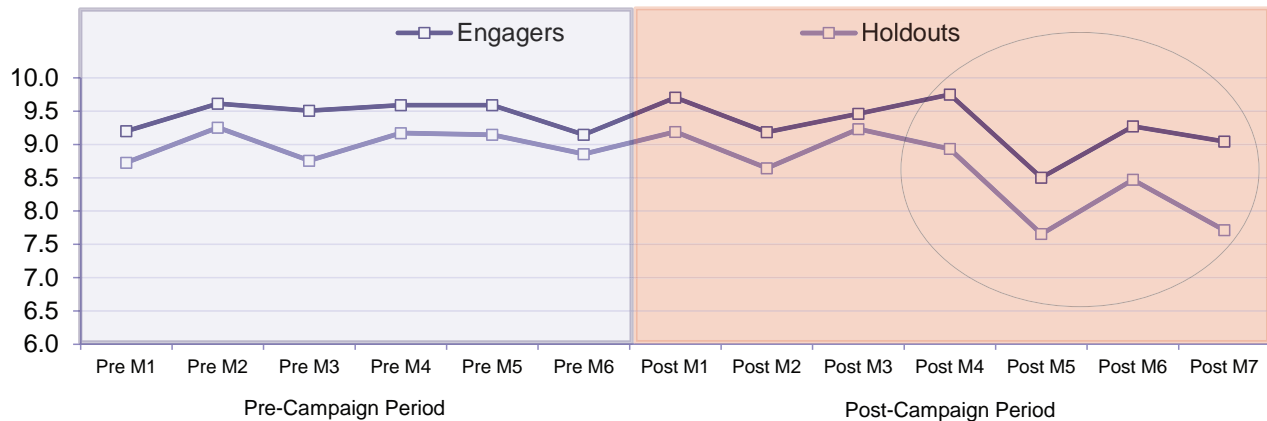
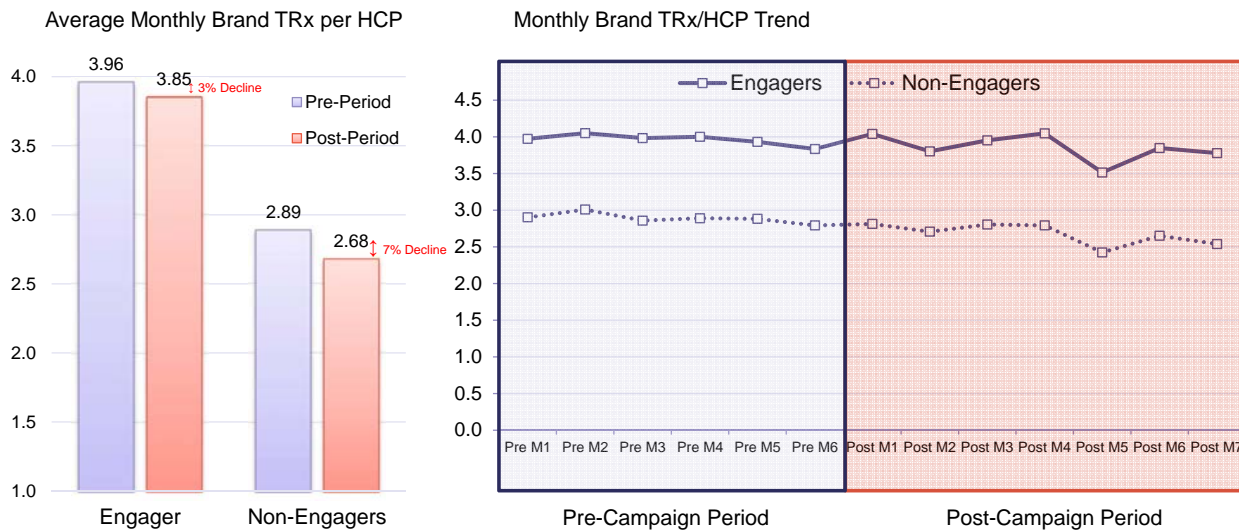


Figure 8: TRx Change Comparison: Engagers vs. Non-Engagers



This also directionally proved the effectiveness of the program on engagers at minimum. (Figure 8)

One other interesting note comes from a group of non-writers receiving zero field sales calls. These cardiologists had not written for the brand in the six months prior to the start of the tele-detailing program. Following three call cycles, 42% of these physicians had begun to write for the brand again, pulling away share from generic competition. These physicians wrote an average of .72 scripts per month during the seven-month campaign period.

In summary, for brands who are in similar situations, it is important to understand the impact tele-detailing could have on your ROI and consider the following:

- Use tele-program to complement low-see and no-see physicians
- Rotate physicians within call cycles and continuously add new targets while replacing non-engagers
- Adopt tele-detailing for vacant territory coverage
- Consider a franchise approach by adding an additional cardiovascular brand to help shoulder the costs and improve financial returns
- Scale up and enhance the tele-program to complement the increasing gap of rep details by adding new, lower-cost tactics to create buzz and incremental response rate across other preferred HCP channels

About the Authors

Jane Portman, Senior Director, Analytics, Merkle Health Jane Portman is an established analytics professional with more than 10 years of experience in the financial, publishing, and healthcare sectors. At Merkle, Jane specializes in multi-channel marketing strategy, bringing customer insights and innovative analytics solutions to address client needs. Jane is a subject matter expert in digital analytics, with extensive experience in digital and media optimization and measurement. Prior to joining Merkle, Jane worked at Publicis Healthcare Communications Group, where she created and implemented the analytics framework for multiple pharmaceutical consumer and physician marketing programs. Jane also consulted for DraftFCB, handling a variety of digital healthcare strategy client engagements. Jane also has extensive client-side experience, having led the audience development efforts at Newsweek.com and media measurement and optimization efforts at E*TRADE Financial.

Alice Liang, Associate Director, Analytics, Merkle Health Alice has 10+ years of experience in Data and Marketing Analytics in pharmaceutical/medical industries. She has been with Merkle for six years. She is well versed in our multi-channel marketing approach and has worked on a number of clients for us including Abbvie, Endo, GSK, Novartis, Sanofi, Sunovion etc. besides assisting clients in other industries (Citizens Bank, The Limited, and AARP etc.) Since joining Merkle in Jan 2010, she has successfully lead analytic projects for pharmaceutical clients, including non-personal promotion targeting waterfall, test design and measurement, physician relationship marketing performance analysis and

reporting, patient CRM program development and analysis, regionalized optimization analysis for product launch, customer behavioral segmentation analytics and sales force analysis. Prior to joining Merkle in 2010, Alice worked as a Clinical Development Data Analyst in Health Dialog Analytics Solutions, and Data Analyst in Center for Outcomes Researches in U Mass Medical School, and as Associate Biostatistician for Keck Biotechnology Laboratory in Yale University. Alice holds a MS degree in Biostatistics from Yale University and a BS degree in Biometrics from National Taiwan University.

Paul Spiegler, Senior Director, Strategy, Merkle Health Paul has over 25 years of experience in healthcare marketing and business development. For the past four years, he has been leading customer centric digital promotion strategies for multiple therapeutic areas with key clients in the Health industry, leveraging Merkle's core values in people based performance marketing.

Prior to joining Merkle, Paul spent 21 years at Abbott Laboratories, where he is best known for turning around a declining Ensure Institutional business – His work led to a gain of 39 share points in 3 years to retake the number 1 share position in all institutional and retail channels. He led the launch of 2 pharmaceutical brands for involuntary weight loss and wound debridement. In addition, he championed physician segment marketing strategy. Paul later became a Regional Manager of Strategic Accounts where he was in front of key Hospital, Long Term Care and Homecare executives helping to guide strategy in today's challenging Affordable Care Act environment.

Using Predictive and Prescriptive Analytics to Inform Pharmaceutical Market Forecasting: Insights from a Nationwide Lab Test Database

Jason Bhan, MD, Executive Vice President and Co-Founder, Medivo; Tatiana Sorokina, MSc, Sr. Manager, Advanced Analytics and Insights, Medivo; Karry Calderon, Medical Affairs, Medivo; Carol Smyth, MB, Medical Director, Medivo

Abstract

For pharmaceutical brand teams, data analytics provide vital business intelligence and unique advantages in the highly competitive pharmaceutical market. Predictive analytics is an emerging tool that can further hone these insights, and provide early indications of emerging trends in physician behaviors. Prescriptive analytics can help marketing teams identify the best course of action in order to reach a desired outcome. This paper examines case studies in hepatitis C to illustrate the power of analytics run on a nationwide, clinical laboratory database to offer critical insights to brand teams on existing hepatitis C market trends, physician behaviors, and relevant patient populations.

Key words: Marketing strategy, health informatics, lab test database, predictive analytics, prescriptive analytics, forecasting

Introduction

With multiple sources of healthcare data available to marketing and analytics groups in the pharmaceutical industry, the ongoing challenge is how to use data sources most effectively in order to inform and develop a brand's strategic plan.¹ Predictive and prescriptive analytics offer new opportunities for insights into market trends, namely using known and estimated variables to forecast the best route to selected outcomes.² Being able to anticipate change based on probabilities is a distinct advantage in the increasingly competitive pharmaceutical market, and prescriptive analytics offers key information, based on the quality of the data used in the analysis.³ This paper shows how predictive and prescriptive analytics using data on hepatitis C (HCV) tests and testing rates from a nationwide lab test database offered important insights on current and future market trends following the recent launch of new oral therapies.

Predictive and Prescriptive Analytics

Descriptive analytics are the tools used to

translate big data sources into useful insights, studying what has already happened.⁴ Predictive analytics differ in that tools such as data mining, statistical modeling and machine learning are used to study current and historical data in order to make predictions about future trends based on probabilities, in other words, the different scenarios likely to happen if current patterns in data continue.⁴ In contrast, prescriptive analytics involves the use of algorithms to identify one or two recommended courses of action and to show the likely outcomes of these actions.⁴

The rise of various sources of big data in healthcare has resulted in increasing interest in the use of predictive analytics to examine multiple variables that impact patient outcomes.⁵ These variables include those that remain constant over time, such as patient demographic information including gender and location, and those that change over time (temporally) such as lab test results and office visits.⁵ These different types of variables require varying analytical techniques to generate data-driven responses to specific hypotheses.⁵

Analysis of lab test data can validate current physician behaviors, as well as identify new accounts with specific patient groups for whom the physician is considering treatment options.⁶ However, lab data can be difficult to analyze, due to complexity, volumes and rapidly changing results. About 7 billion lab tests are performed each year in the US, making it the single highest-volume medical activity, even higher than the annual number of prescriptions written (an average of 4 billion).^{7, 8, 9} The development of a nationwide, lab test database gives brand managers, marketers and data analysts a new source of actionable data from earlier in the patient journey than other data sources, namely pre-diagnosis and pre-treatment. This allows for patient identification earlier and can result in improved sales force efficacy compared with traditional data sources.^{1, 6}

The Hepatitis C Virus Marketplace 2011 - 2014

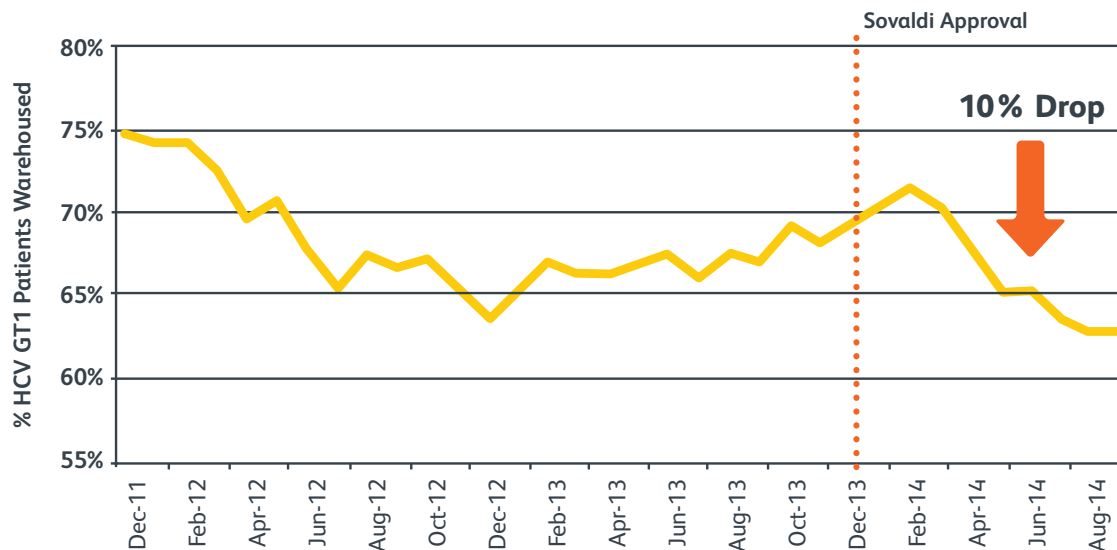
One of the conditions where lab data is playing an important role in studying marketplace dynamics is hepatitis C. Almost 4 million Americans are chronically infected with the hepatitis C virus (HCV).¹⁰ In the United States, approximately 65% of those infected belong to the Baby Boomer generation born between 1945 - 1965, and now aged 50-70 years.¹¹ Hepatitis C remains a major cause of morbidity, mortality, and resource utilization in the United States.¹² The virus is primarily transmitted by exposure to infected blood, mostly through intravenous drug use (60-70%), blood transfusions, and other medical and surgical procedures.¹³ Some of the main complications of HCV infection involve hepatic fibrosis, which may ultimately result in cirrhosis, hepatocellular cancer (HCC), and liver failure, resulting in a need for liver transplant.^{12,13}

Prior to 2014, physicians “warehoused” many HCV patient populations (warehoused patients are those who are diagnosed with HCV but

not yet actively treated) in anticipation of the availability of new treatments, given that older therapies (interferon and ribavirin) had lower response rates and a high rate of adverse side effects, such as fatigue, flu-like symptoms, hematologic abnormalities, and neuropsychiatric symptoms.¹³⁻¹⁵ With the approval in December 2013 and launch in 2014 of the direct-acting, oral HCV agents SOVALDI[®] (Gilead) and OLYSIO[®] (Janssen), followed quickly by the approval of four more drugs (Gilead’s HARVONI[®], AbbVie’s VIEKIRA[®] Pak and TECHNAVIE[®], and Bristol Myer-Squibb’s DAKLINZA[®]), dramatic changes occurred rapidly in the hepatitis C market. Given the high cure rate associated with the new drugs, physicians quickly moved patients with HCV from being warehoused to being actively treated.¹⁶ Through analysis of HCV data, our team helped client pharmaceutical companies study the new market dynamics and inform marketing strategy.^{1, 17}

We determined the rate at which patients with the most common HCV genotype in the US (genotype 1(GT1)) stopped being warehoused and moved to active treatment following the launch of new therapies in 2014. Our database has access to over 150 million lab test results from 200,000 practices through its nationwide network of partner labs. The Data Science and Medical Affairs teams analyzed results from 770,593 HCV patients who tested positive for HCV antibody, HCV genotype, or HCV viral load between August 2010 and September 2014, identifying the warehoused HCV GT1 population through analysis of patients who had baseline HCV tests (RNA testing), but no follow up tests such as genotype or viral load, indicating that treatment had not begun.¹⁷ We observed a cumulative volume of 181,035 patients with HCV who had been warehoused since December 2011 and tracked them longitudinally to understand the rate at which they exited warehoused status and started treatment.¹⁷

Figure 1: Longitudinal View of Genotype 1 “Warehoused” HCV Population



Longitudinal analysis showed that the rates of warehoused patients increased in the 12 months prior to the approval and launch of Sovaldi, as expected with a revolutionary, anticipated new therapy, and then declined 10% within 4 months after launch of the new drug in 2014 (Figure 1).¹⁷

characteristics such as oral therapy vs. injectable or improved side effect profiles, enter the market. For drugs that enter the market following the launch of a first-in-class agent, analysis of lab test data can reveal populations that have not yet been treated, or those who are refractory to previous treatment.

The dynamics suggest that there is faster adoption as new therapies with breakthrough

Following the launch of the new drugs, physicians started to actively test their previously

Figure 2: Longitudinal View of Genotype 1 Patients Tested for HCV Genotype Alone or Genotype and Viral Load Tests

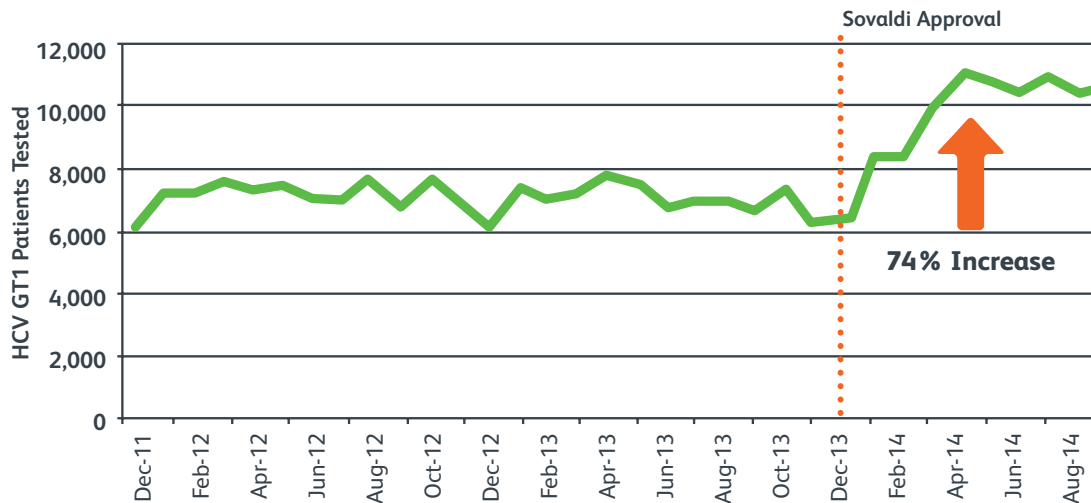


Figure 3: Longitudinal View of HCV Patients Tested for Genotype and Started on New HCV Therapy

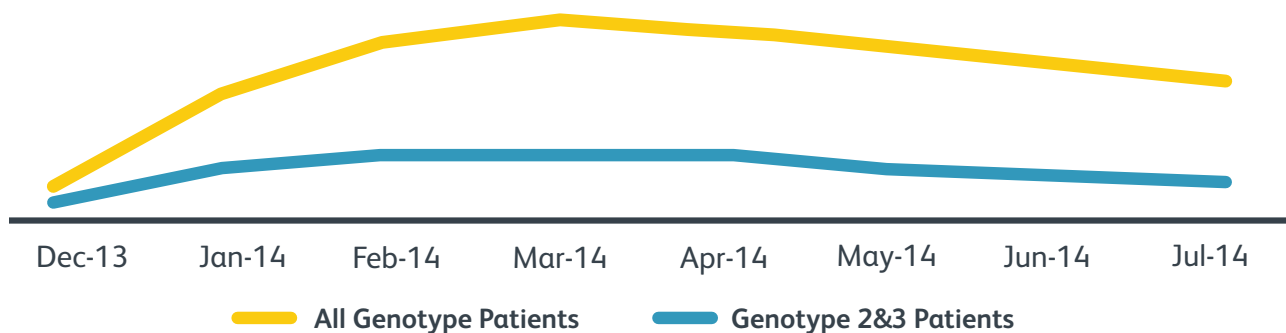
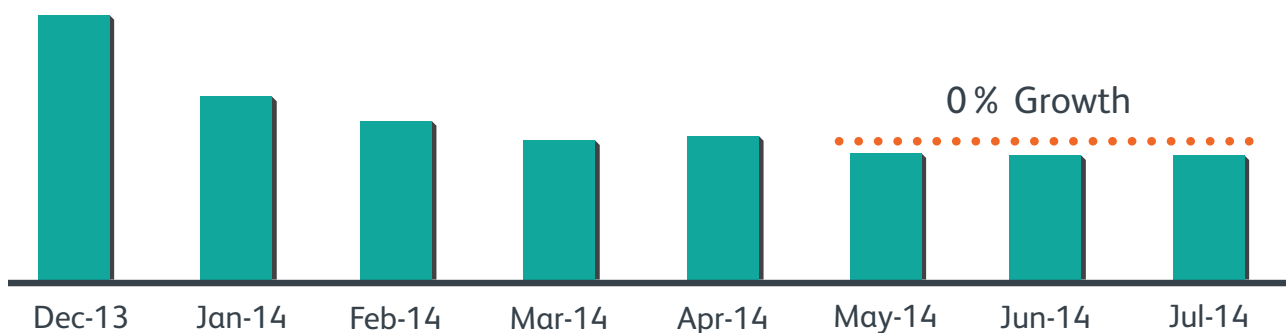


Figure 4: Month-by-Month View of GT1 Share of New HCV Patient Starts

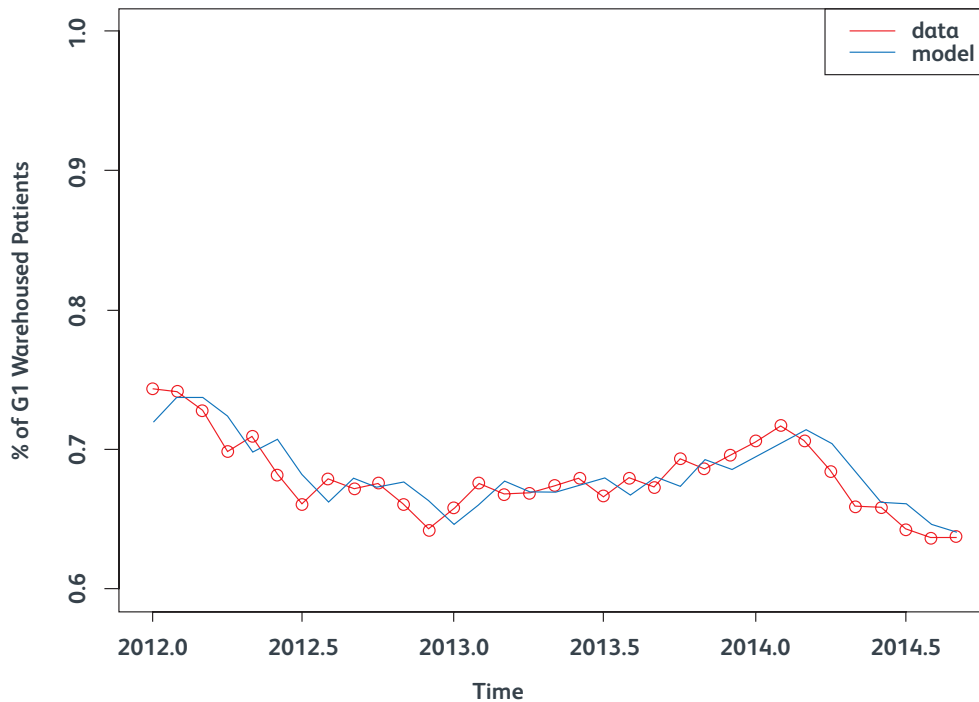


untreated patients for HCV genotype, a factor that helps determine treatment regimen, and HCV viral load tests, a biomarker used to monitor disease baseline levels, showing an intention to actively treat the condition. Our study observed a cumulative volume of 266,061 HCV GT1 patients who were tested for HCV genotype alone or both HCV genotype and viral load between December 2011 and September 2014.¹⁷

An increase in the volume of HCV testing followed the launch of Sovaldi in the US, with a 74% increase in the number of HCV GT1 patients tested, increasing from 6,202 patients in November 2013 to 10,786 patients in May 2014 (*Figure 2*).¹⁷ This period spans the time from pre-launch of Sovaldi to post-launch, likely indicating patients who were tested in preparation for starting treatment once the drugs became available.

In order to confirm the HCV market dynamics seen in this analysis, we created an integrated HCV data warehouse working with a client pharmaceutical company and a claims database partner, combining lab and prescription data by linking both datasets at the patient level.¹⁷ Using this dataset permitted tracking of patients with HCV who were tested for genotype and initiated treatment between December 2013 and July 2014. No actual patient volumes were disclosed in this study due to confidentiality reasons. Trend analysis showed that there was a noticeable increase in patients tested for genotype in HCV new-to-brand prescriptions (NBRx) between December 2013 and March 2014.¹⁷ However, starting in April 2014, the volume of patients who initiated treatment plateaued (*Figures 3 and 4*).¹⁷

Figure 5: Actual Historical Trend and ARIMA (1,0,0) Model



Similarly, HCV patients with genotypes 2 and 3 did not show any increase between April 2014 and July 2014, when their share stabilized at approximately 30%.¹⁷ This finding suggests that a forecasted increase in all HCV patients who initiate treatment will most likely be due to HCV patients with GT1 and not patients with other genotypes. As a result, there was an increased opportunity for our pharmaceutical client to target their marketing activities to the relevant patient population.

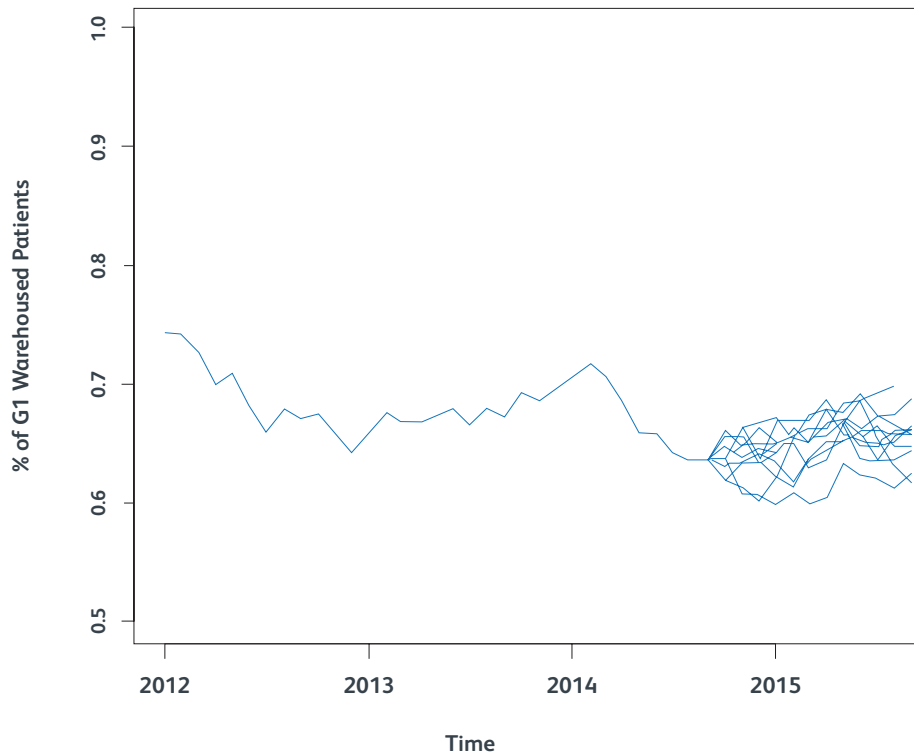
Forecasting the HCV Market

In addition to analyzing the current market in HCV, our data scientists also work with clients to forecast trends in the market, using testing rates and lab test results as variables in simulations aimed at predicting the market in the future. One of the tools used in predictive analytics for short term forecasting is building autoregressive integrated moving average (ARIMA) models, models involving at least 40 historical data points.¹⁸

The models used in this analysis of tests conducted in patients with HCV GT1 showed set functions, such as auto correlation function remaining constant over time (where correlations with its own variations from the mean remain constant) and Akaike Information Criterion (AIC), a way to compare different models looking at the same outcome.¹⁸ Running this analysis, the model with the lowest AIC score emerges as the best one to use to determine the outcome using the available variables.¹⁹

The data analysis conducted on HCV data collected between 2012 to 2014 found that the model was stationary, and also that it showed a mean-reverting process, centering around 0.68 (coefficients of the model $(y_t - 0.68) = 0.91*(y_{t-1} - 0.68) + \epsilon_t$) (Figure 5). Regression to the mean is a statistical concept that states when an extreme data point occurs, the next one is likely to be less extreme.²⁰

Figure 6: Monte Carlo Simulation from Oct 2014 to Sept 2015



As shown in Figure 5, predictions made based on ARIMA model followed the actual trend fairly closely with one data point lag, which confirms accuracy of the model.

Further analysis on the HCV GT1 data using ARIMA time series forecasted a positive (upward) trend in the number of patients being warehoused (treatment deferred) for the following year, starting in October 2014. Because the ARIMA model does not show distinct paths, a different model using prescriptive analytics is required to generate paths using random factors. This allows for calculation of the probability of a particular pattern detected in the past.

Using a Monte Carlo simulation, the graphs in Figure 6 show an example of ten simulated paths taken from the analysis. This simulation

was performed with 100,000 iterations. In about 23,000 cases, the result exhibited a 6% or greater increase in the next year. Therefore, the result of the simulation was a prediction of a 23% probability of a 6% or greater increase in the rate of patient warehousing over the next year (2014 – 2015).

In summary, using predictive and prescriptive analytics, our Data Science team predicted that the rate of new warehousing of patients with HCV would start to rise in the second half of 2014, using ARIMA time series model forecasts showing an upward trend in warehousing, and a Monte Carlo simulation that indicated a 23% probability for the same magnitude (6%) or greater increase in warehoused patients over the projection period of October 2014 to September 2015. News reports indicate that patients with HCV are in fact being warehoused

again, as insurers and Medicaid institute restrictions on which patients will receive coverage for the new oral drugs.²¹

Conclusion

Analytics are increasingly important in both determining current trends in the pharmaceutical market and forecasting future trends in the short term. Analysis of HCV testing rates and results confirmed the warehousing of patients prior to the launch of new HCV drugs in early 2014, and also predicted new warehousing of patients with HCV starting in late 2014. The use of an integrated database using lab test and claims data showed an association between an increase in HCV testing and new-to-brand prescriptions following the launch of new drugs for HCV in the US market. Analytics based on data provides critical insights to forecasters on

the dynamics of patient care, including the transition of patients infected with HCV in and out of warehousing status depending on drug availability prior to the launch of new drugs and again 6 - 12 months after the launch, perhaps due to restrictions on insurance coverage for the new drugs. Having this important information available informs pharmaceutical strategies and allows brand managers to more accurately plan marketing programs over specified time periods to targeted audiences.

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About the Authors

Jason Bhan is a family physician and serves as the Chief Medical Officer and Co-Founder of Medivo. He is regarded as a national expert in the applications of technology to healthcare and medicine, a topic on which he speaks regularly at institutions and conferences, such as Health 2.0, mHealth, New York's eHealth Collaborative, and Health Datapalooza. He also has done extensive strategy consulting with pharmaceutical companies. From 2007-2010, he worked with Clinovations and managed several large hospital system EHR implementations, outcomes measurements and data analysis. Jason obtained his Doctor of Medicine at the University of Miami School of Medicine and he is board certified in Family Medicine.

Tatiana Sorokina is an Advanced Analytics & Insights Lead at Medivo with experience in market research, experimental design and analytics as well as passion for healthcare and biotechnology. Tatiana holds B.Sc. degree in economics from Moscow State University (Moscow, Russia) and M.Sc. degree in marketing and analytics from Columbia Business School (New York, NY). Tatiana joined Medivo in a market research role in 2012 and transitioned to advanced analytics in 2013. Currently she leads a team that helps Medivo clients understand provider behavior

through lab data and draw insights that enable pharmaceutical brands to improve their targeting strategies and increase ROI of their programs.

Karry Calderon is a Clinical Affairs Intern at Medivo, and assists in the development of medical and business publications based on the company's lab test database. She is currently a senior at Bryn Mawr College, where she studies Psychology, Neuroscience, and Health. Karry joined Medivo in 2015, and worked as an intern to help develop manuscripts and abstracts across therapeutic areas based on insights from Medivo's lab test database.

Carol Smyth is Medical Director at Medivo, and leads development of the company's medical publications. She holds a medical degree from Trinity College, Dublin, Republic of Ireland, and a certificate in Health Information Technology from Columbia University, New York, NY. Carol has an extensive background in medical communications across media platforms. She joined Medivo in 2013 and works across therapeutic areas to publish findings from research conducted using Medivo's lab test database.

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The Value of EMR Data: Unlocking Insights That Drive Pharma Sales

Steve Love, Principal, ZS Associates; Sudhanshu Bhatnagar, Business Consulting Manager, ZS Associates; Greg Rickman, Business Consultant, ZS Associates; Jedy Wang, Business Associate Consultant, ZS Associates

Abstract

Each step in the physician workflow creates data – and more of it is being created every day. EHR data vendors can now capture, aggregate, access, and analyze more data than ever before. New and different de-identified sources of data provide new and compelling insights and research capabilities, including real-world evidence, which enhances findings beyond those from the original small-scale FDA-approval trials. Real-world case studies reveal that by applying deeper data analytics than ever before, pharma can use this new realm of data to uncover insights that help guide them toward more-successful sales and marketing efforts.

The pharma industry has an endemic challenge. It has a complex and circuitous sales process involving drug manufacturers, physicians, pharmacies, patients, and insurance companies. Each step in the buying process creates data – and more of it is being created every day.

Arguably, pharma companies have always had access to these data through a variety of sources, including primary market research, but only some of the data have been readily available in large quantities. For instance, back in the 1990s, they had access to prescription and co-pay data through reimbursement claims. In the 2000s, they gained access to longitudinal claims data by tracking clinical visits, diagnoses, and prescriptions.

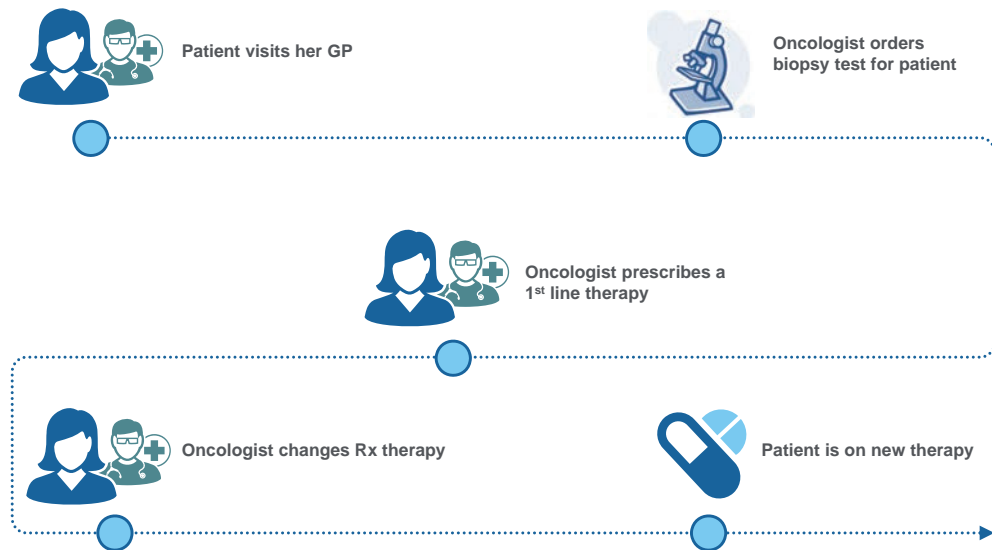
In truth, though, even having access to some of the data in large quantities from these sources has been problematic, because it's been siloed, fragmented, incomplete, and in differing formats. Getting a holistic view of the entire patient journey through primary market research has been expensive, time-consuming,

and potentially subjective or idiosyncratic (because of small sample sizes).

But there's a new opportunity for pharma, one that will change the way they think about data, its aggregation, and its analysis. The proliferation of EMR analytics and software platforms and the data vendors that now aggregate and sell the electronic health records (EHR) data warehoused in them, now give pharma companies greater visibility than ever into its marketplace of buyers, consumers, and decision-makers – and the factors that drive sales. Now pharma can research its markets by combining EHR data with traditional secondary data to see the entire buying process at a much larger scale than ever before. For the first time, pharma can use EHR data to supplement primary market research, taking advantage of the latter for its nuanced insights and the former for its breadth.

EHR data vendors can now capture, aggregate, de-identify, access, and analyze more data than ever before. New and different sources

Figure 1: Examples of Patient Level Data Available From Claims



of data provide new and compelling insights and research capabilities, including real-world evidence, which enhances findings beyond those from the original small-scale FDA-approval trials.

Consider these opportunities of EHR data:

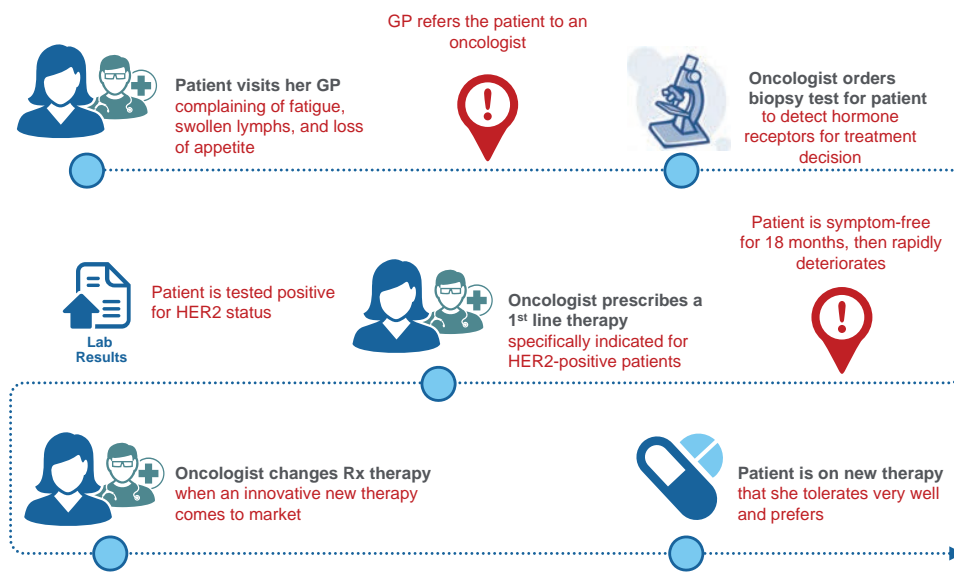
- The ability to better understand when products are used, including how, when, where, by whom, in what circumstances, dosage, and frequency
- The ability to understand when products are *not* used, why not, and which competitor made the sale
- The ability to transform insights gained by analyzing EHR data to make better strategic decisions, including how to identify and win against competitors, and how to identify which segments (indications, patients and MDs) to target for highest profitability
- The ability to make better tactical decisions; that is, what actions to take to execute strategic plans, and to identify best sales and marketing methods

Pharma finally has a new way to collect and view information that was previously very expensive to obtain manually or only available on a much smaller scale. The industry now has the unprecedented opportunity to understand testing and treatment decisions, patient outcomes, the decisions being made at each step, and determine – finally – how it might influence in its favor.

What's New: The EHR Data Vendor Landscape

Two important advances are helping pharma discriminate a new generation of marketing insights. In addition to using primary market research and claims information, pharma now has access to anonymized patient-level EHR datasets. These records include other data points with greater granularity. The spectrum of data is almost unprecedented: lab results, diagnoses, prescriptions, patient compliance, physician notes, and follow-on or replacement prescriptions. Overall, these results can map the entire course of a disease and its treatment through cure or death.

Figure 2: Examples of Patient Level Data Available From EHR



While there are more data sources, there are also more ways to make the data useful. Thanks to technological advances, it's now easier to (1) capture, (2) aggregate and de-identify, (3) standardize, and (4) analyze more volume of data. New analytic tools and capabilities allow better ways to aggregate and integrate both claims and EHR data, for deeper analysis. These tools can convert unstructured data (i.e. physician's written notes) into structured data to expand the depth of information captured. As a result, companies can increase the breadth of the information they use for analysis.

A Sample Scenario

To better understand the ways in which pharma can use both new information and new analysis techniques, consider the example of a patient visiting a primary-care physician. A claims data study would only reveal certain aspects of her treatment: that the patient initially visited her primary care physician; that a pathologist ordered a subsequent biopsy; and that one or the other prescribed medication. (*Figure 1*)

But there is a large amount of important additional data that EHRs can add to that picture, more simply and economically than via primary market research. For example, the EHR would likely reveal what prompted the patient to make the initial visit: complaints of fatigue, swollen lymph nodes, and loss of appetite. It would also reveal how the primary care physician responded, whether by running diagnostics tests or by referring her to an oncologist. (*Figure 2*)

EHR data also reveals why the pathologist ultimately ordered the biopsy test, such as to detect hormone receptor status and other genetic biomarkers, which would influence the treatment decision. It would reveal the results of the lab test, including a positive test for HER-2 status (a diagnostic biomarker for breast cancer), which would in turn give insight into why the oncologist prescribed the drug therapy: because it was specifically indicated for HER-2 positive patients, and because its safety profile was the best fit for the patient's comorbidities.

In this scenario, EHR data also reveals that the patient responded to first-line therapy for a duration of 18 months, after which the patient's condition deteriorated. It also illuminates the thought process behind why the oncologist changed the drug therapy; it could have been in response to multiple issues, whether a new drug launched, patient characteristics, disease characteristics, or non-clinical (i.e., financial) reasons.

Finally, the EHR would also show how the patient responded to the new therapy, revealing such details as either patient preference (based on different, or lack of, side effects) or the fact that the disease did not progress for 18 months. All that information is now accessible across thousands of patients to provide a market level (vs. patient level) view of that therapy area's marketplace.

The previous scenario is for illustrative purposes, but vendors are already creating opportunities for data usage based on four different business models:

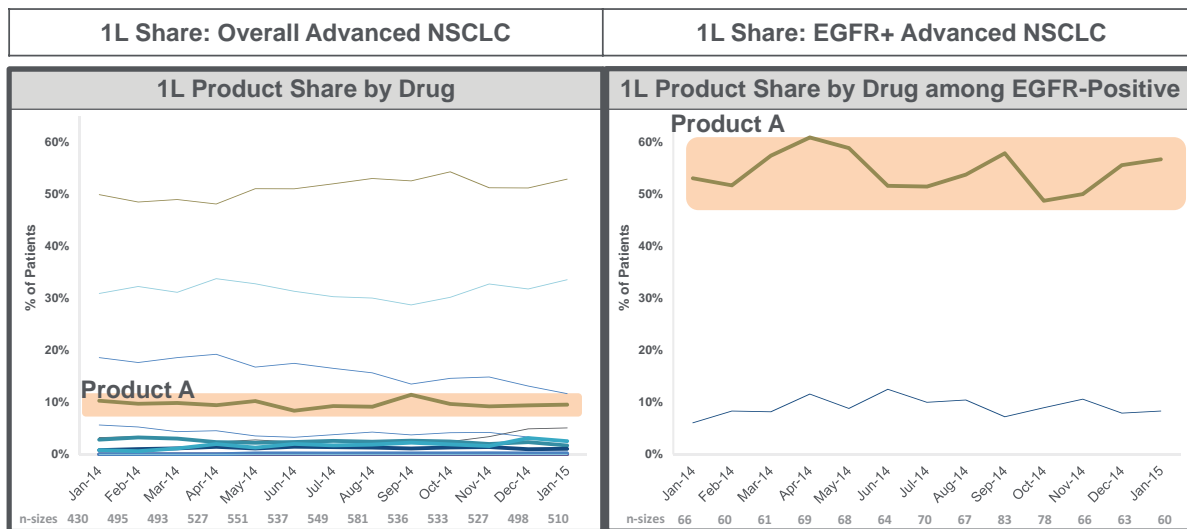
- Some vendors source their data exclusively from their own proprietary (or leased) EMR platforms themselves. Other vendors are EMR-agnostic and integrate EHR across multiple EMR platforms.
- Vendors may differ in their focus on therapy areas — looking only at primary care diseases, specialty areas, or a combination of the two.

- They may also differ in their emphasis on data provision only, analytics, and/or providing point-of-care information services.
- Some companies sell discrete data sets designed to answer specific questions at a point in time, while other vendors sell subscriptions to entire databases that allow for perpetual analyses of the subscriber's choosing.

Efficacy in Three Case Studies

There are many actual examples of transformative applications for EHR data. Consider these three real world case studies in which EHR data vendors delivered valuable market insights for their pharma manufacturer clients. They come from three leading data vendors: EHR data vendor Flatiron Health processes both structured and unstructured EMR data for considerably improved accuracy in patient and disease characterization and completeness of data elements provided; EHR data vendor Practice Fusion offers clinical guidelines and best practices to providers specifically for patient encounters, allowing practitioners to search on critical patient metrics within their records; EHR data and analytics vendor Optum-Humedica focuses on health economics and patient-report outcomes research, especially in the area of pharmaco-epidemiology.

Figure 3: Example No.1



By analyzing monthly updates of longitudinal patient-level EMR data that included access to deep biomarker testing and results over a twelve-month period, a pharma company was able to determine that its product had a much larger market share within a specific patient sub-segment.

Example No. 1

Context: A pharma company wanted to understand patient share within the population of EGFR mutated advanced non-small cell lung cancer patients. Historic data sources presented challenges with regard to completeness of biomarker data and/or data recency. (Figure 3)

Action: The patient level data provides a complete view of each patient with resolution into diagnosis, stage, histology, testing, test result, treatment and patient outcomes. Based on analysis of Flatiron’s data, the customer was able to determine that the patient share for the therapy was 50-60% in the target biomarker population.

Recommendation: The delighted client was able to conclude that they were the market leader for the indicated patient population, but also that there was still a significant growth opportunity in its target segment. The client used the EMR data output to improve the company’s understanding of testing, treatment

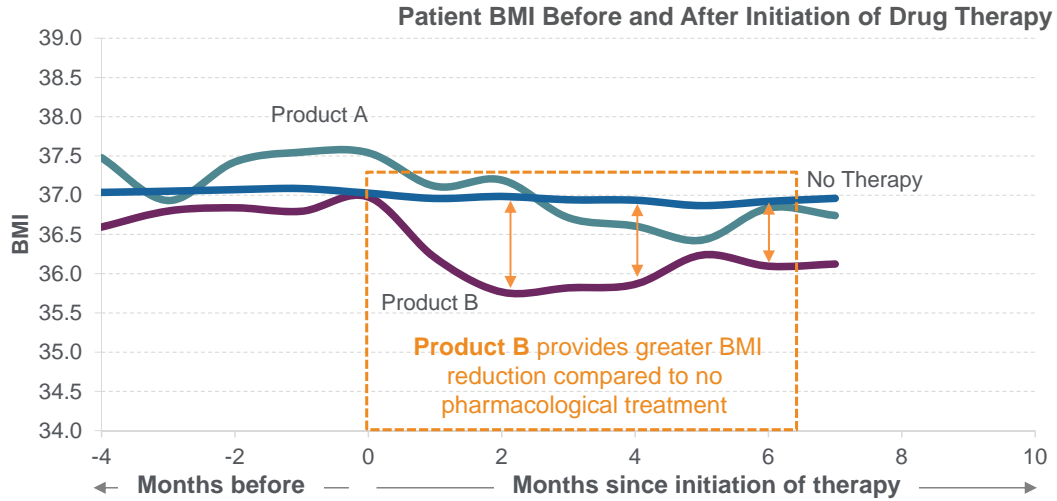
and outcomes for specific patient segments, and improve quality of its forecasting model for the indicated patient population.

Example No. 2

Context: A pharma company wanted to prove the efficacy of an obesity medication compared to competitor’s drugs and non-pharmaceutical interventions alone. (Figure 4)

Action: Practice Fusion used its own research database and compiled the results from the following samples: 2,003 patients using Therapy A; 3,104 patients using Therapy B, and 16,200 non-therapy patients with high BMIs. Analysis revealed that after two months, the company’s obesity drug reduced patients’ average BMI by 1.5 points. EHR data also revealed that the client company’s drugs were more effective than its competitor’s drugs and a non-therapy solution. The data illustrated the real-world results at different time intervals both before and after initiation of therapy.

Figure 4: Example No.2



By analyzing data from thousands of patients in its research database, data vendor Practice Fusion was able to show that Product B provided greater BMI reduction than both a comparative product and no pharmacological treatment at all.

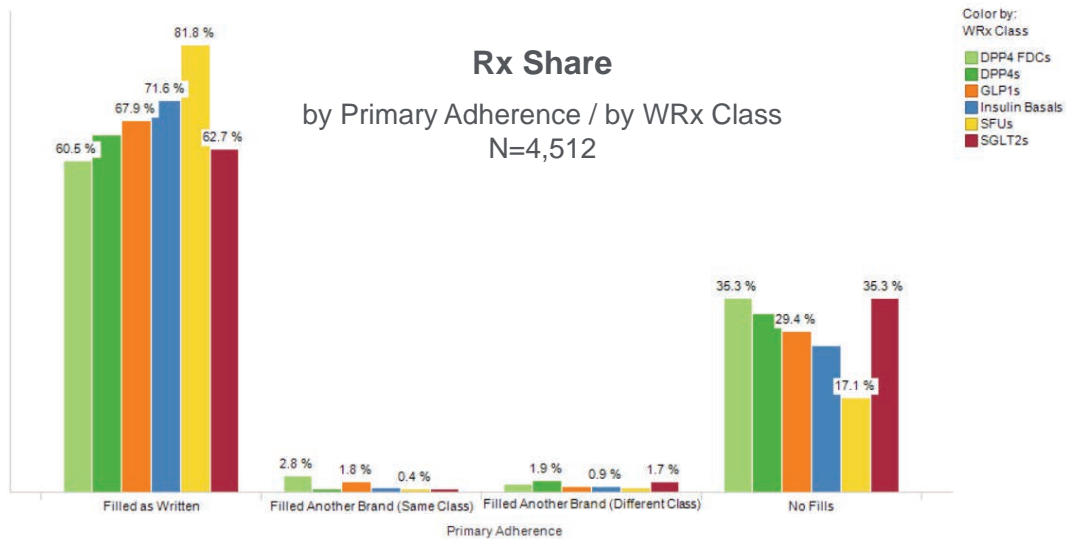
Recommendation: These results enable a drug manufacturer to demonstrate to payers the real-world efficacy of its drug and improve its business case for higher formulary status. In addition, these results could also be combined with other results, such as A1c, cholesterol, and blood pressure, to show how holistic the impact

of the drug can be in real-world settings.

Example No. 3

Context: A pharma company wanted to study whether diabetes patients were adhering to the therapy regimens prescribed by their doctors. (Figure 5)

Figure 5: Example No.3



Analysis of claims data in conjunction with chart information revealed that within three months, as many as half of patients had stopped taking the diabetes medication, indicating a need for reallocation of marketing resources.

Action: Optum-Humedica combined claims and patient-level chart information from a de-identified sample size of 4,512 to discover an intriguing fact. Although high percentages of patients filled the initial prescriptions as written – especially in comparison to other brands – within a three month period, as many as half of patients had stopped refilling their prescriptions. This insight wasn’t available in claims data, because claims only show what happened, not what the physician intended to happen. The analysis revealed that although the pharma company thought it had achieved its sales goals, it had actually only accomplished part of them.

Recommendation: The data revealed that although the physician wrote the prescription, and the payer reimbursed for the drug, the patient didn’t continue taking the medication as prescribed. The data helped the pharma company reallocate its marketing resources to solve a problem that it didn’t even know it had! The vendor was able to compare physician intent versus prescriptions actually filled, and adjust payer outreach and/or patient marketing accordingly. The results also showed that the longer a patient took to fill a prescription, the less likely they would fill it with the prescribed brand. By understanding how frequently patients turned to generics, the vendor was able to address the opportunity for increasing first fills of its own product.

A Caveat: Challenges Remain Before Getting To This Level of Insight

Though pharma companies have high potential to gain new insight, there are some caveats to remember, in the form of distinct limitations.

Data limitations. Even in this data-driven age, the capture rates of practices can be limited, depending on the disease area. Biases toward collecting data may exist, based on

types of practices, their geographies, or other issues. At the same time, data sets can be incomplete and difficult to analyze due to a lack of standardization in how workflow inputs are collected or how EMR platforms exchange data. And robust longitudinal data can be difficult to find because patients move to different HCPs – and their different EMR systems.

Technology limitations. The challenge of integrating data has baffled experts for years, and while new analytic tools available under the rubric of “big data” represent a step forward, they are new and not yet perfected (ditto natural language processing systems used for data extraction from unstructured fields). It’s only recently that companies are able to wrest meaningful insights from the piles of data, and it may take a while to get proficient at it.

Vendor limitations. EHR data vendors have unique focus areas and data sets, as well as different products and sales models (subscription to real-time data platform vs. discrete data set; raw data vs. analytics).

Moving Forward

In the face of this potential – and potential pitfalls – what can pharma companies do to increase the value of EHR data in the future?

In the short term, they can be better informed about both the benefits and tradeoffs of EHR data, and they can also start building up their EHR data analytics capabilities. In the long term, they can identify EHR partners best suited to answer their business questions, and incorporate EHR data insights to drive better sales and marketing decisions.

Either way, the key is to start thinking about these issues now. Only those who understand its ramifications and value early will derive a strong competitive advantage in the long term.

Sidebar: Q&A: What Pharma Needs to Know About EHR Data Vendors

When pharma companies embark on programs to understand the value they can derive from the analysis of EHR (electronic health records), it's important to understand the data vendors and how the market is changing. Here's a Q&A to help pharma understand what it needs to know about the current state of the EHR data market.

Q: What changes can we expect to see in the market?

A: The market will continue to undergo shifts in business models and technology. Vendors who sell EMR platforms will be particularly affected the most, especially from the standpoint of market consolidation. Historically, some platform vendors had difficulty accommodating Stage II meaningful use requirements, which led to a wave of consolidation, and the Stage III meaningful use standards are even higher. From a technology standpoint, most EMR companies are moving to the cloud-based operating model (data managed centrally on the cloud) and away from an on-premises model (data resides on the EMR instance on local office/hospital); this is operationally more cost effective and also scalable from a data management perspective.

Q: How are pharma companies collaborating with companies that sell EHR data?

A: Companies are actively innovating with pharma manufacturers to provide new data analytics and point of care services. For example, two companies have partnered to invest significant effort and resources on NLP techniques to systematically extract information from unstructured physician notes and other text-based fields. Another is the creation of

EMR patient portals (patients opt-in by default) that collect patient feedback on issues such as reasons for discontinuing treatment.

In addition, EHR data vendors are collaborating with ACOs to provide real-time data at point of care to improve the ACOs' quality metrics. For instance, at least one health intelligence platform can also help pharma leverage EMR data to analyze performance relative to ACO measures. For example, if one of the ACO measures looks at the percentage of diabetic patients with A1c who are not reaching their goals, pharma can both proactively identify those specific patients (in order to get them into a more-intensive diabetes management program) and then segment that data across the entire health system, taking into account sites of care, regions, and individual providers.

Q: Why is it important for pharma to have a better understanding of these applications?

A: The line between commercial and medical applications is blurring. Datasets used by health economics and outcomes research (HEOR) and commercial groups at Pharma companies are becoming one and the same, i.e., commercial groups are getting more sophisticated and mindful of outcomes, while HEOR groups are more interested (or concerned) about aligning with the commercial impact.

EHR data companies, in particular, believe that their data, although only a partial sample, is fairly representative of overall national trends, based on comparisons with other data benchmarks. Insights from these applications could be used for national level metrics estimation, although the ability to execute

sub-national analysis depends on the therapy area and how quickly the n-counts decrease.

Q: What other value can pharma derive from these applications?

A: EHR data vendors are continuously looking to integrate their data with other external datasets and potentially with other EHR vendors' data — if there is a significant push from the manufacturers. This integration and increasing subscriber base will make EHR data significantly more valuable to pharma companies commercially as well as for outcomes research.

For instance, companies are collaborating with claim data vendors to de-identify patients and link their information – to make more robust longitudinal datasets (more so with closed claims vs. open claims vendors). This integrated data overcomes one significant drawback of EHR data when patients change insurance companies, because EMRs using a unified patient ID will still be able to track anonymized patients. Neither EMR platform companies nor EHR data vendors are actively looking to make this investment without sufficient incentives, but are open to try if the pharmaceutical consortium will help carve a path forward.

About the Authors

Steve Love is a Principal with ZS Associates in the San Francisco, CA office and the Tracking Practice Area Leader for ZS. His experience at ZS over the last 14 years has focused on a variety of market research studies and business analytics using secondary data such as EMR. Steve has led many marketing engagements with emerging and large biopharmaceutical companies, particularly in oncology. Steve holds an HBA from the Richard Ivey School of Business at the University of Western Ontario and an MBA from the Haas Business School at the University of California Berkeley.

Sudhanshu Bhatnagar is a Business Consulting Manager with ZS Associates in the San Francisco, CA office since 2007. His primary focus is on the biotech and medical device verticals and he has advised clients on improving their commercial effectiveness including sales organization design and enablement, launch planning, marketing operations and business processes optimization, including focus on commercial data analytics. Sudhanshu holds a Bachelor

of Engineering from University of Pune (India) and is pursuing his Executive M.B.A. from the Wharton School of the University of Pennsylvania.

Greg Rickman is a consultant with ZS Associates in the San Francisco, CA office and has 3 years of experience in healthcare consulting, including working in PWC's Health Industries Advisory practice prior to joining ZS. Since joining ZS, Greg has focused on qualitative and quantitative primary research and commercial strategy for large, global biotechnology clients. Greg earned his BA from Princeton University and an MBA from UCLA Anderson School of Management.

Jedy Wang is a business associate consultant with ZS Associates in the San Francisco, CA office. She has worked as a consultant in the healthcare industry for 4 years with a focus in market research, secondary data and EMR analytics for emerging and industry-leading biopharmaceutical clients. Jedy holds an HBA from the Richard Ivey School of Business at the University of Western Ontario.

