Proceedings of the Annual General Donald R. Keith Memorial Conference
West Point, New York, USA
April 28, 2022
A Regional Conference of the Society for Industrial and Systems Engineering

Applying a Generalized Logistic Function to Pharmaceutical Globalization: Introduction of Johnson & Johnson Fibrin Sealant to the Chilean Market

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Abstract: In 2021, Johnson & Johnson's subsidiary, Ethicon, launched a new fibrin sealant product, VeraSeal. Though profit is their primary determinant of success, Johnson & Johnson is committed to improving medical conditions for communities globally. The purpose of this report is to effectively communicate the application of a logistic function to the introduction of the VeraSeal product to Chile. With the application of the Generalized Logistic Function, a qualitative and quantitative methodology commonly used to forecast the progression of medical technology, the West Point Capstone team was able to model and analyze the potential revenue earned by introducing VeraSeal into the Chilean market. The resulting application of the model enabled the recommendation of not moving VeraSeal into Chile due to lack of profitability. The only viable adjustment that justifies moving VeraSeal into Chile would be a renegotiation of the minimum order quantity with the manufacturer to only 550 units per order.

Keywords: Johnson & Johnson, VistaSeal, VeraSeal, Pharmaceutical, Fibrin Sealant, Generalized Logistic Function, Chile, Biosurgery

1. Introduction

1.1 Johnson & Johnson

Johnson & Johnson is a Fortune 50 publicly traded healthcare company and is "the world's largest and most broadly-based healthcare company committed to using [their] reach and size for good" ("About Johnson & Johnson," n.d.). Johnson & Johnson's decision-making is "guided" and "spelled out" by their Credo which challenges the company to "put the needs and well-being of the people [they] serve first" ("About Johnson & Johnson," n.d.). Johnson & Johnson is split into three primary sectors: consumer products, pharmaceuticals, and medical devices. Although people tend to recognize the company from their consumer products such as Band-Aids, Johnson & Johnson's pharmaceutical sector brings in 55% of its overall revenue and this sector will be the primary focus of the investigation ("About Johnson & Johnson," n.d).

1.2 VeraSeal/VistaSeal Fibrin Sealant

VeraSeal is a fibrin sealant product produced by Grifols and distributed by Ethicon (a subsidiary of J&J). A fibrin sealant is used by medical professionals to create blood clots during surgery to prevent excessive bleeding, decreasing recovery time and the decrease the likelihood of complications (DiMeo and Schaffer, 2019**)**. Ethicon previously distributed a similar fibrin sealant product known as Evicel that has been discontinued and is now being replaced by the new VeraSeal product (DiMeo and Schaffer, 2019). The product nomenclature is VistaSeal in the United States and Canada but is rebranded as VeraSeal in the rest of the world (DiMeo and Schaffer, 2019). For this paper, the product will be referred to as VeraSeal. VeraSeal is a much safer alternative to its Evicel predecessor because Evicel required carbon dioxide gas to apply the product

onto the patient. In contrast, VeraSeal uses a "malleable drip/spray tip to provide a rapid, adherent clot without a gas source" (DiMeo and Schaffer, 2019). Ethicon is "the only company providing airless spray technology for open and laparoscopic surgery" (DiMeo and Schaffer, 2019). The product is safer than its predecessor, and it is also more appealing to medical professionals. This is due to its increased precision and complete pre-packaging of the product. VeraSeal is made possible through a partnership between Johnson & Johnson and Grifols, a Spanish pharmaceutical and chemical manufacturing company ("Grifols," n.d.). Grifols is the "world's largest, most advanced plasma fractionator" and VeraSeal contains byproducts of plasma (DiMeo and Schaffer, 2019).

Figure 1. VeraSeal Product (DiMeo and Schaffer, 2019)

1.3 Evicel Phase-Out Plan

In anticipation of the VeraSeal launch, Johnson & Johnson has decided to discontinue the sale of Evicel in Chile in April of 2022. They have developed a phase-out plan that began in 2021 to clear their inventory while maintaining their current commercial commitments through the first quarter of 2022. In preparation for the complete phase-out of Evicel, Ethicon has completed three specific tasks. First, they have excluded Evicel from the special publication metrics of the wound closure and biosurgery, oncology, and company reports. Second, Ethicon has increased the penetration of their product Surgiflo, a complementary thrombin-based product that aids in hemostasis, thus, repositioning it as the soul biosurgery hemostatic that Ethicon offers. Third, they have prepared to launch another product, Surgicel Powder, in the second quarter of 2022 to replace Evicel and acquire a third of its current consumers. The main question here is whether or not VistaSeal or VeraSeal will be accessible in Chile come the discontinuation of Evicel. The answer to that question is no. The plasma manufacturer, Grifols, requires a minimum order that is equivalent to eight years of inventory for the consumers of Chile. Currently, Johnson & Johnson is attempting to bypass this requirement and is hoping to negotiate a minimum stock with the option to re-export the orders from the United States. The discontinuation of Evicel forces Ethicon’s clients to find a new product that is comparable in quality and ease of use. Ethicon is bound to lose a portion of their consumer base to competing companies during this transition period, thereby limiting the initial profit VeraSeal would generate when it is ready to be introduced to the market.

1.4 Challenge of Distributing VeraSeal into Chile

Johnson & Johnson has successfully launched VistaSeal in the United States and Canada. However, they still face the issue of whether the company should pursue the Latin America Market. Johnson & Johnson partnered with a capstone team from the United States Military Academy at West Point to receive a simulation model that can accurately predict forecasting, costs, and revenue of VeraSeal in the Chilean market to allow Johnson & Johnson to make an informed decision on whether to launch VeraSeal into Chile. The task presents additional challenges compared to a release in developed countries such as the United States or Canada due to cultural differences and general national organization. There are countless measures to review when deciding the launch of a product, such as stability within the country, the need for the product within the country, and the country's ability to support the necessary space or equipment to store the product. This paper will explain the processes and problem-solving strategies utilized by the West Point capstone team to provide a recommendation regarding the decision to launch VeraSeal into the Chilean market.

2. Initial Background Research

2.1 Chilean Economic Status

Along with the challenges of market entry and globalization, Johnson & Johnson must consider the economic health of the country it wishes to enter. Over the past few decades, Chile has done a tremendous job of increasing its economic progress and decreasing poverty rates. Still, Chile's policy frameworks seem to stand in the way of an increase in productivity and economic diversification (World Bank). Like other countries worldwide, Chile's economy suffered severe repercussions from COVID-19 and contracted the GDP 6% (World Bank). The fiscal deficit increased to 7.5% of GDP in 2020 (World Bank). Poverty is expected to grow from 8.1% to 12.2% (World Bank). Despite the fact these statistics indicate the Chilean economy is in decline, growth is expected to rebound to 5.5% given current projections (World Bank). The economic prospects for growth predict that Chile has a strong growth potential making it a potentially profitable sector.

The research conducted by the World Bank Group creates the context for understanding the current and future expectations of the Chilean economy. Not only would the population benefit from the product through better medical care, but the predicted economic development may facilitate the potential growth of VeraSeal.

3. Model Design

3.1 Generalized Logistic Function

The first step to creating the model was finding a forecasting method that would adequately estimate the number of units of VeraSeal sold in the next five years. The forecasting model would need to demonstrate the complexities of multiple variables and reflect the expected growth rate of the product**.** The generalized logistic function is typically used to study forecasting changes. The S-curve of the generalized logistic function "represents the growth or decline" of system interactions within a particular "environment" (Rządkowski, G. & Sobczak, L.(2020)). Therefore "S-shaped curves are applied for projecting the performance of technologies, to foresee population changes, market penetration analyses, micro and macroeconomic studies, diffusion mechanisms of technological and social inventions, and many others" (Rządkowski, G. & Sobczak, L.(2020). Johnson & Johnson's intention of market penetration and tracking the growth of the usage can be accurately represented with the use of the generalized logistic function. As VeraSeal becomes more established in the market annually, the forecasted sales increase. However, as innovative technologies and fibrin sealants emerge, VeraSeal will become less valued, and the sales will plateau and slowly decline. The generalized logistic function accounts for the introduction of VeraSeal in Chile and its decline. The generalized logistic function equation used is seen below as well as a base visualization of the generalized logistic function:

$$u(t) = \frac{u_{max} - u_{min}}{1 + e^{-s(t-c)}} \tag{1}$$

$$c = \frac{1}{s} \log\left(\frac{u_{max} - u_0}{u_0 - u_{min}}\right) \tag{2}$$

Table 1. Logistic Function Variables and Definitions

Variable	Definitions
$\boldsymbol{u(t)}$	*Forcasted Units of VeraSeal Sold in Each Year*
$\boldsymbol{u_{max}}$	*Number of Clients* $*$ *Number of Surguries Preformed per Year per Surgeon*
$\boldsymbol{u_{min}}$	0; *minimum amount possibly sold*
$\boldsymbol{u(0)}$	*Initial launch Based on Evicel * .75; assuming 75% of Evicel Clients try VeraSeal at the launch*
$\boldsymbol{s}$	*Growth Rate of the Product; based on prior Evicel Product*
$\boldsymbol{t}$	*Time in Years*

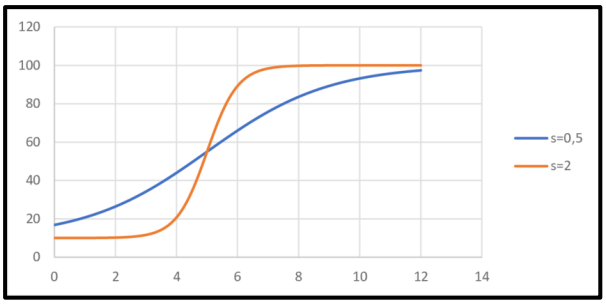

Figure 2. Basic Logistic Function (ResearchGate, 2020)

3.2 Historical Model

As part of J&J's globalization process of VeraSeal, Ethicon conducted country-specific investigations. These investigations analyzed the validity of all VeraSeal product sizes and the anticipated use if implementation into the country occurred. Our model expands the study conducted by Ethicon. The country analysis focused on the breakdown of costs based on historical data in conjunction with long-term projections for sales. The historical sales were based on the previous Ethicon product sales of Evicel. The historical sales were then fit into possible batch sizes negotiated with Grifols. The amount of wasted product was calculated and incorporated into total profitability calculations based on the batch sizes. Information such as the price breakdown per unit and pricing contingencies, including the cost of delivery and additional costs related to cold supply chain movement were supported by historical Evicel data. When Ethicon evaluated the possible entry into various countries, it analyzed sales for all sizes of the VeraSeal product. VeraSeal is available in three different sizes, 2 ml, 4ml, and 10 ml. To narrow the focus, the 4mL size is the only product size to enter Chile. In addition to narrowing the focus to only one product size, the model accurately reflects the delivery costs based on information provided by the Chilean ground team. The most influential aspect of the historical model was the minimum order quantity (MOQ) from Grifols. The current contract with Grifols dictates that the minimum order quantity for VeraSeal is 5000 Units, which is classified as a single "batch" (Mezer and Mack, 2020). However, it is also possible to order a "half batch," meaning the order quantity would only be 2500 units. Since the MOQ is the most influential part of the gross profit calculation, given accurate forecasting could be used as a negotiation element to acquire small order quantities.

3.3 Assumptions

The assumptions made to create the logistic function are the growth rate of the product and the percentage of Evicel users switching to VeraSeal. The estimated growth rate was found by creating a linear regression between the relationship between the price and willingness to buy provided by Ethicon. Also estimated is that 75% of Evicel Users will use VeraSeal at the time of the launch due to the Ethicon local team's estimation. The price estimate is $200 based on stakeholder and minimum order quantity analysis provided by the stakeholders. However, this can change to increase profitability, demand changes over time, or changes to deals with Grifols.

4. Findings

4.1 Model Result

4.1.1 Revenue Forecasting Findings

As previously described, the generalized logistic function is used to forecast the expected units purchased in Chile over the next five years. Since the model assumes the product's pricing to be $200, the model is then able to calculate the expected revenue. The initial value in the function is the amount of Evicel sales in the last year multiplied by 75% to show the expected forecasted units at the launch. Evicel data showed 672 units sold in the previous year. The expected units sold and total revenue per year are in Table 2 below.

Table 2. Forecasted Units and Revenue from 2024-2029

Year	**1**	**2**	**3**	**4**	**5**
Forecasted Units	504	515	526	536	545
Revenue	$100,800	$103,016.63	$105,129.49	$107,137.75	$109,041.45

4.1.2 Profit Margin Findings from Historical Model

Based on the forecasted units sold generated by the generalized logistic function, after applying them to the modified historical model to compute the gross profit for each year. The table below shows the expected gross profit for each year of the five years across varying minimum order quantities. The order quantities analyzed were the traditional full batch of 5000 units, the half batch of 2500 units, and the minimum viable batch size to produce a profit of 550 units. The values that correspond with the batch size and year are the gross profit percentage. The only profitable batch size is a batch size of 550, and only following the third year.

Table 3. Profit Percentage Based on Batch Size

Batch Size	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
5000	**-590%**	**-576%**	**-557%**	**-545%**	**-535%**
2500	**-265%**	**-257%**	**-236%**	**-230%**	**-225%**
550	**-3%**	**-2%**	**14%**	**16%**	**17%**

4.1.3 Profit Margin Findings from Maximized Variables

After finding that the variables currently in place in Chile did not allow the product to meet the desired profitability of 60%, the model was used to find the maximum threshold the variables would need to reach in order to make the stakeholder's goal of 60% profitability. The first adjustment to the model was increasing the price from $200 to $800. Although many hospitals are not likely to pay this much higher price it allows the stakeholders to understand the high variability of price on the model and the predicted forecast. Another variable changed was the number of clients and growth rate. The number of clients was increased from 24 to 250 and the growth rate increased from 9% to 100%. Once again, the likelihood of these two events occurring is very low and near impossible, but after corresponding with the regional Chilean J&J team they believe that with an increase in sales representatives in the region allowing for more exposure of the product, it is likely that these two variables could drastically improve. The last variable changed was the number of clients that would transition from Evicel to VeraSeal. In the initial model it is believed that only 75% of the clients would transition at the initial launch of VeraSeal. The maximized model includes all the pervious clients transitioning to VeraSeal, or 100% transition. This should be made possible by creating a more efficient phase out plan for the current Evicel product to VeraSeal. The maximized model profitability is seen below:

Table 4. Profit Percentage for Maximized Variables

Batch Size	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
5000	**-117%**	**-2%**	**46%**	**61%**	**67%**
2500	**-17%**	**40.90%**	**67.88%**	**75.67%**	**78.53%**
550	**62%**	**71%**	**85%**	**87%**	**87%**

ISBN: 97819384962-2-6

5. Recommendation

5.1 Recommendation to Johnson & Johnson

The given minimum order quantity set by Grifols hinders Ethicon's ability to enter the Chilean market and be profitable. J&J's clients only order the amount of VeraSeal they expect to use, regardless of the order contract between J&J and Grifols. Thus J&J will have to take losses on the VeraSeal units that are not used. There are three alternatives to make the entrance into Chile feasible: add additional sales representatives, decrease the minimum order quantity set by Grifols, or sell the VeraSeal 2mL.

Chile does not currently have sales representatives and a budget to focus on the fibrin sealant market solely. Johnson & Johnson increasing their annual budget in Chile allows the Chilean Team to find additional clients outside the capital, Santiago. This will increase the number of accounts open for VeraSeal and all J&J's biological products. However, it is doubtful that additional resources would drive the demand to levels of order full batches or products.

The second option is to create a smaller minimum order quantity. This option is less feasible due to the current agreements between J&J and Grifols. Decreasing the minimum order quantity will mean fewer units of VeraSeal not used. If the minimum order quantity decreases, J&J will have to increase the price of VeraSeal to account for the surcharge Grifols will emplace. The price increase will limit the number of clients in Chile that will be willing to purchase their units. If they model was applied to several smaller countries it is possible that J&J will identify enough evidence to approach Grifols to renegotiation the batch sizes.

5.2 Critical Influences

Critical influences are the variables within a model that have the most weight on the model's outputs. The project modeled the outcome using nine variables when determining whether Ethicon should launch VeraSeal in Chile. Of those nine, the most critical variable is the minimum order quantity due to the lack of sales in the region. If J&J is able to create a new deal with Grifols both companies would likely see profit. Although order quantity is the most sensitive variable, the price of the product also has a large impact on the profit margin. If Ethicon is able to increase the price by even $150 they would eventually see the profit margin increase. The presence of the product also needs to increase in the market. What this means for Ethicon is that they could see a rise in sales if their dedicated sales reps can increase the usage of VeraSeal within Chile. Lastly, there is over $150,000 worth of slow-moving and obsolete units (DiMeo and Schaffer, 2019). The minimum order quantity (MOQ) poses a significant risk to Ethicon. If Ethicon cannot sell the MOQ they purchase from Grifols, Ethicon will incur a loss due to wasted materials because of the temperature requirements and self-life of VeraSeal.

6. Improve

6.1 Model Improvements

The model could improve by directly correlating with Ethicon's original forecasting methods that the company used for Evicel. This would have been an improvement from the adjustments to the MOQ and general logistic function. Utilizing more historical data would have proved to be more helpful in finding sales amounts when using our model. The model could improve by comparing other J&J products processes and movement into Latin America to gain insight as to the growth rates of products as well as the costs associated with market entry.

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