An alternative to the use of analogues for estimating market share and uptake of new products

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An alternative to the use of analogues for estimating market share and uptake of new products

One of the main events that pharmaceutical market forecasters are asked to forecast is that of new product launches. A critical question is then asked regarding the assumptions around prediction of market performance for this new product launch. What share will the product achieve? How quickly will share be gained?

The temptation for most is to reach for an "analogue". That is, a product that ***has already launched***, and use its share path over time to mimic the new product launch event.

However, use of analogues in this way is not a particularly useful way of estimating or modelling new product uptake launches. Selection of an analogue predicates that the situation for the historical product is **EXACTLY** the same as the situation for the product now under consideration. This is rarely the case.

Implicit within the data for an analogue is a whole host of information & factors which determined the product utilisation & uptake within its particular segment. These are factors such as (in no particular order):

- Company launching the product – equity, trust & image in the product / therapy area
- Sales representative & promotional spend on the brand during the launch period
- Pre-market conditioning (both in terms of awareness & environmental situation)
- Strength of clinical data underpinning the brand
- Ability for the product to fulfil an unmet need
- Differentiation of the product vs. other same class products (if present)
- Side-effect profile & adverse events
- Tolerability, dosing regimen and formulation
- Physician segment / specialty that the product is to be used by
- Patient segment that the product is to be used for
- Primary vs. secondary care setting, critical care etc

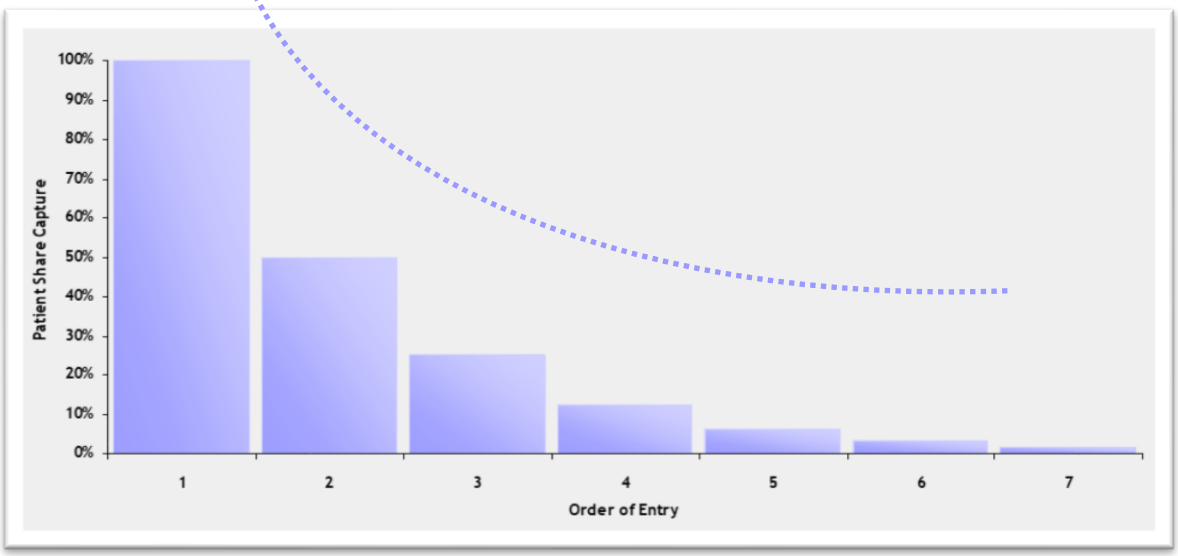
While straight application of the analogue has its limitations, product launch data can be mined & analysed for consistent trends & higher-level predictive elements which can then be used to estimate how a new product is likely to perform. Applying the central limit theorem, taking multiple samples & deriving a distribution of 'benchmark' values converging around a mean, is a more robust methodology to apply than taking just one or two analogues upon which to base one of the most critical assumptions in any new product forecast model.

This higher-level analysis of multiple product launch curves forms the basis of the "**Order of Entry"** effect.

Order of entry

Order of entry is a well-documented phenomenon whereby various product performance variables are dictated by the order in which a product launches into a given market space.

Identical products within a class perform within a narrow range of predicted results on certain performance variables such as expected market share and speed to achieve peak. Products perform according to Benford's law (sometimes interchanged with Zipf's law) with regard to frequency of patient share capture as follows:



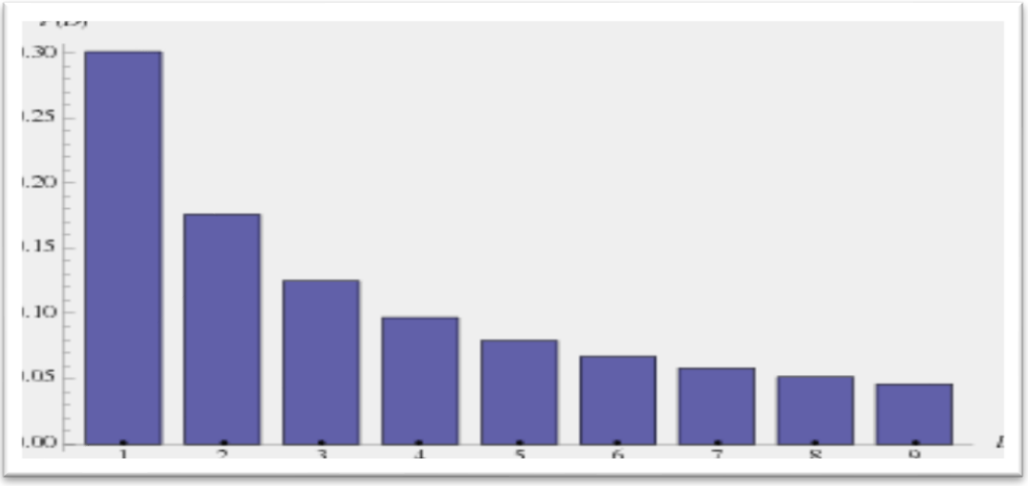
Of course, with each subsequent entrant the market has to 'normalise' back to 100%, thus the shares get compressed, but the **ratio** remains evident.

For example:

In a two-product market, the second to market establishes a share which is in the ratio of 2:1 with the market leader – for every two patients that the first to market product has, the second to market has one patient. This yields shares in the range of 66%:33%.

In a three-product market, the third to market achieves a share which is half that of the product entering prior to it, i.e. the 2nd to market product. The ratio now stands at 2:1:0.5, or 4:2:1. When 100% patient share is reallocated, the shares now stack up as follows: 57%:29%:14%. This pattern continues as new products launch.

For a market with ~9 products, these would be the relative shares produced using Benford's law:



Thus, in a market where products are NOT differentiated in terms of decision or rationale to use, this law of entry should hold.

Bucking the trend

It is actually very difficult to override the effects of order of entry, even where companies try to differentiate their products. A residual element will still remain to anchor a product to its launch order potential.

However, that said, the order of entry share should be used as a **starting position** – the share which the product could capture when perceived as equivalent to the market leader or being identified with the product **class**.

Ability to compete

Within any market, the gold standard (normally the market leader) sets the benchmark against which all other products, targeting the same patient segment, are compared in the mind of the physician.

By understanding the drivers of treatment selection in the minds of the prescribing physicians, the relative importance of those drivers & how the gold standard meets the needs of the physician when treating the patient, it is possible to anticipate how a new product could perform within this decision framework.

The new product can now be scored against the gold standard to generate an ‘ability to compete’ index

				Gold Standard		Competitor 1		Competitor 2	
Benefit Sought	Benefit Weight	Critical Capability	CC Weight	Rating (1-10)	Score	Rating (1-10)	Score	Rating (1-10)	Score
Benefit 1	15		10	8	80	7	70	6	60
			5	5	25	5	25	7	35
Benefit 2	10		8	5	40	7	56	7	56
			2	7	14	4	8	8	16
Benefit 3	30		16	8	128	4	64	5	80
			14	8	112	5	70	5	70
Benefit 4	25		15	9	135	3	45	3	45
			10	2	20	5	50	4	40
Benefit 5	20		10	3	30	5	50	4	40
			10	3	30	5	50	3	30
	100		100		614		488		472

Market shares as predicted by order of entry laws can now be modified according to the new product's "ability to compete" (formalisation of product differentiation) against other products within the market that are already being used by the prescribing physician. The index value is used as a multiplier to the order of entry market share to generate a more predictive share value, reflective of the individual product characteristics and clinical benefits.

Of course, that is only the first part of the story with regard to estimating performance of a new product in the market. Although the estimated share undoubted has the greatest impact on product sales, the other parameters should not be forgotten.

When forecasting a new product launch event in a forecast model, it is necessary to not only estimate the anticipated market share but also to include assumptions regarding rate of adoption and time to achieve peak share.

Let's look at using a Bass diffusion algorithm to model the new product launch event.

Deconstruction of the Launch Curve

In order to model a new product launch event, we will need to make the following assumptions for the new product:

Launch date

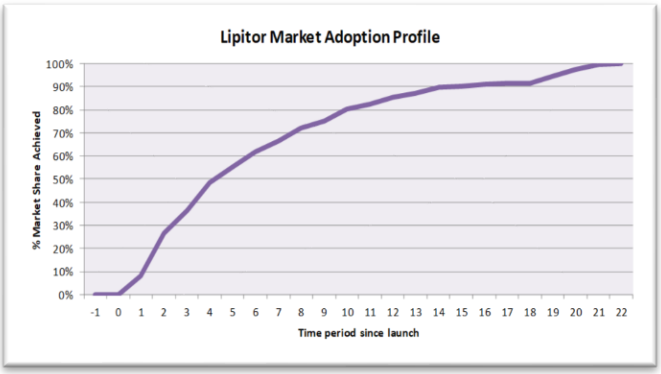
- Simplest of the parameters to determine, although delays can significantly impact other parameters if entry launch sequence changes

Rate of adoption – uptake 'profile'

- Mostly dictated by order of entry, but can be modelled discretely based on physician education & influencer pathways – see **Diffusion of Innovation**
- Needs to be considered in conjunction with Time to Achieve Peak, order of entry is a strong determinant based on physician segment targeting order and existing knowledge base in the market
- As a rough rule of thumb, new MOA products have a lagged tail denoting requirement for education of the market, initial targeting of true innovators (most likely key opinion leaders in their field), staying true to the order of influence required in the medical arena

(e.g. general practitioners take the lead from specialists, specialists take the lead from KOLs)
- Follow-on / me-too products can often bypass the KOLs and early adopters, fitting straight into the armamentarium of the early or late majority prescriber types leading to loss of the lag tail on the uptake curve

The following chart shows an example of an uptake profile for a statin – Lipitor. Lipitor was launched after several other statins. Its peak share is an example of where order of entry trends did not hold true since the product was able to differentiate itself from the other statins in the market and thus shift the gold standard, making Lipitor ***more competitive*** and able to meet the physician perceived need than the first to market statin.



The rate or profile of uptake demonstrates a fast-follower market product launching into a well-developed marketplace where the benefits of statins, as a class, had been established.

Peak market share

- Predicted through **Order of Entry** law, modified with **Ability to Compete** benchmarking against market gold standard *at time of launch*

Time taken to achieve peak share - *speed of adoption*

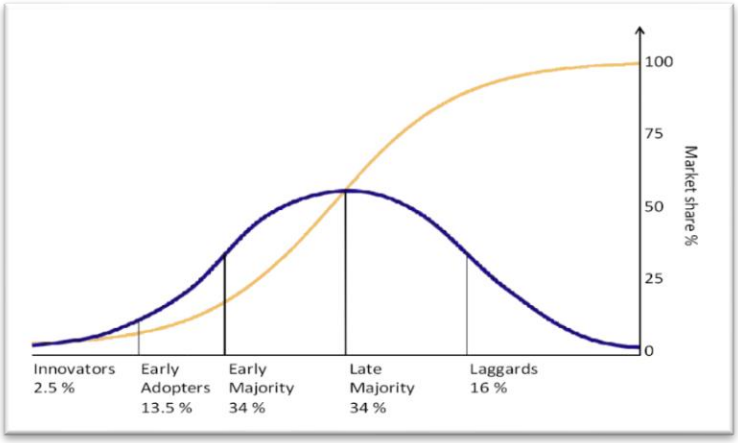
- Function of the order of entry (subsequent market entrants take a shorter time to achieve peak share), but also awareness activities & market education (depending on launch order). This is a general rule of thumb and should be modified according to factors such as market access, territory expansion etc.
- Time to peak is a function of marketing activities generating awareness coupled with order of entry to market – level of physician segment targeted.

Diffusion of innovation

In 1958, Everett Rogers (Rogers, 1962) empirically standardized the “innovativeness” of individuals and social systems and organized it into adopter categories. Adopter categories are a descriptive method for classifying the members of a system based on their adoption of

new innovations in relation to their peers. In a normal-frequency distribution, there are five adopter categories:

- Innovators (2.5%)
- Early adopters (13.5%)
- Early majority (34%)
- Late majority (34%)
- Laggards (16%)



Rogers suggests using these five categories of adopters in order to standardize the usage of adopter categories in diffusion research. It should be noted that the adoption of an innovation follows an S-curve when plotted over a length of time.

Top-level Diffusion Curve

The diffusion for an innovation would therefore be composed of several adoption curves, each representing a different segment of the target population

So, if we now look at how order of entry interacts with physician segments, education within the market place and how knowledge is transferred throughout a group, we can start to see how the rate of adoption profile & time to achieve peak share is affected by order of entry…

Innovator category and influence cascade

1st to market – having to start with the innovators in order to influence the early adopters. Early majority follow on from the early adopters and in turn influence the late majority. Education base must be established within the innovators & early adopters to create advocates to recommend product usage within broader, less specialised or thought leading physician segments. Whilst uptake into the innovators is relatively rapid, rate of adoption slows with progressive roll out to subsequent market segments.

Thus, for a true first to market product, the adoption profile will be exactly as shown on the chart above in yellow, a lag period followed by a period of exponential growth plateau-ing off once market has reached saturation in terms of the user base.

2nd to market – do not have to educate the marketplace as much as the first to market. Depending on how close in time they launch to the 1st to market, they can target the early adopters or early majority. This significantly speeds up the time to achieve peak share; rate of adoption is also quicker / steeper, starting to lose the tail lag. Subsequent entrants to market

lose more of the lag tail, entering directly into the exponential growth section of the uptake curve.

Eventually, the lag tail disappears altogether (see chart for Lipitor).

Of course, there are products and markets where these rules work in reverse. Let's now consider a market with a high degree of unmet medical need, where there is less risk for trialling a new product.

Oncology products and other markets with high unmet need

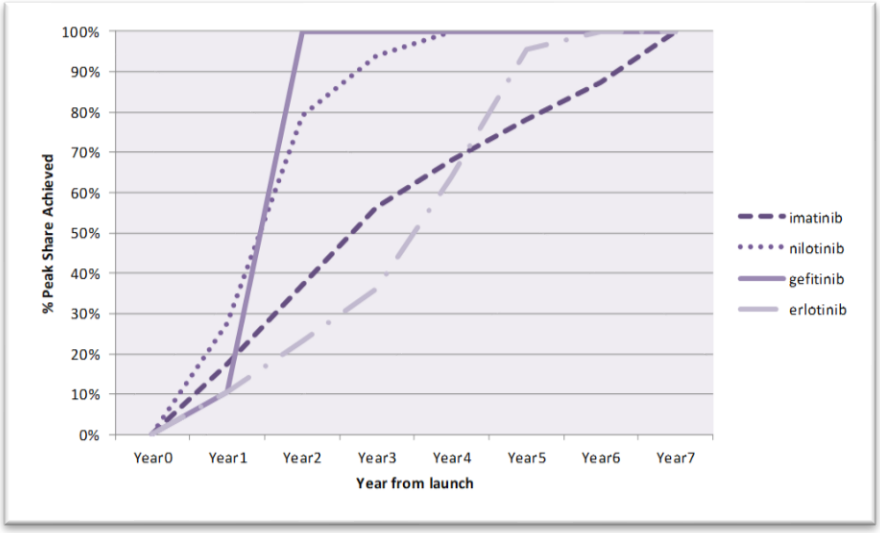
Conversely, there are markets where these rules for order of entry breakdown or are reversed entirely. These tend to be markets where significant breakthroughs are happening or where the risk of trialling a new medication far outweighs the risk to the patient of not trying it. The most common example of this can be found in the oncology sphere.

Traditionally, products aimed at treating cancer were widespread in use, non-specific and not very effective in improving patient outcomes. With the development of different classes of oncology product, with more targeted, focused areas of use, big changes in patient outcomes were seen. Maybe the first and most notable of these new oncology products was imatinib (Gleevec) – a tyrosine kinase inhibitor initially licensed for the treatment of chronic myeloid leukaemia (CML). Prior to the launch of imatinib, patients with CML had a life expectance of 2-3 years. Today, CML patients on treatment can expect a life expectancy in excess of 10 years. Similarly, in autoimmune associated vasculitis, rituximab has extended life expectancy from 3-4 years to over 12-15 years.

In markets such as these, there is a clear benefit to the patient in taking these drugs, thus uptake is far more rapid than would ordinarily be expected for a first to market, first in class innovative product.

It could also be argued that the physicians treating conditions such as these are a more conserved group with a different distribution of adopter categories. Physicians treating specific groups of cancer patients or those with rare auto-immune conditions are likely to be small in number, more likely to be involved with clinical trials (and therefore more likely to be key opinion leaders in their field), and since the groups of physician are quite small, dissemination of information is likely to happen much quicker than for, say, a general practitioner group.

Below are some examples of uptake profiles for oncology drugs, including imatinib. While there are tails on some of the uptake curves, these products tend to reach peak much quicker. Interestingly, the first in class (imatinib), has less of a tail than subsequent product entrants.



Other aspects of the market that affect product uptake

Of course, all of this is in the context of free access to patients – in other words, the 'demand' side of the market.

It is also critical to factor in other market parameters that may limit or constrain product usage within a market – these we can group under the general term of 'market access'.

These factors can be applied in two ways:

1. Suppression of overall market potential and uptake - i.e. demand leads you to believe that your share of the market should be 30%, however, with market access constraints, this will be reduced to 25%. This could be the case if, for example, the target market is the UK, but Scotland does not allow use of the product at all.
2. Time-delay on market adoption / uptake. This could be the case where reimbursement or other discussions are required. Often, this slows the rate of market uptake rather than reducing overall product opportunity.

Regardless of the impact of the market access issues in the market, the clinical demand should remain as the basis for estimating product opportunity in a given market since it is routed in the clinicopathological aspects of the disease / patient population.

Summary

So, although analogues are difficult to find and apply, there are data that can gleaned for modelling purposes. This coupled with the additional techniques and tools outlined above can give a firm steer on likely adoption profiles for new products.

Remember to disaggregate demand vs. market constraint. Once market constraints have been removed, the full potential of the product should be achievable.

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