Forecasting Price Escalation

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The Context for a Conversation

As with most good life cycle cost estimates (LCCEs), the content of this paper and its findings derived from an open and collegial conversation with the client, where we traded ideas back and forth on the best cost estimation approach for each major aspect of the program in question. The conversation was in May of 2021, only three months after the author had started, for the first time, evaluating costs for capital investments in medical developments. The topic at hand was the program whereby the Army was developing a vaccine to protect deployed personnel from E-Coli infection.

Here is a quick background on this program, from the pubic website of the sponsoring materiel developer (MATDEV) of this vaccine, the US Army Medical Research and Development Command[i] (https://usammda.health.mil/index.cfm/project_management/pharm/other_infectious):

> "Enterotoxigenic *E. coli* Vaccine (ETECV)
>
> The ETECV is intended to be an FDA-approved multivalent vaccine indicated for active immunization of adults against enterotoxigenic E. coli to prevent bacterial diarrhea. Prevention of diarrhea would curtail a considerable source of lost duty days, particularly in the first month of deployment, while minimizing antibiotic treatment in theater and the possibility of long-term gastrointestinal issues. Infectious diarrhea is repeatedly the most common illness reported by travelers visiting low- and middle-income countries abroad, and among U.S. troops deployed overseas. The impact of bacterial diarrhea on unit readiness caused it to be ranked the number one infectious disease threat by the Combatant Commands Infectious Diseases Threat Prioritization Panel (through the Military Infectious Disease Research Program) in 2019. Approximately 80 percent of infectious diarrhea cases are caused by bacterial agents, of which ETEC causes the greatest proportion. Although the military has developed extensive capabilities for the provision of clean food and water, diarrhea has continued to be a problem for deployed personnel. The ETECV is intended to prevent ETEC-attributable diarrhea using a multivalent strategy to achieve strain coverage.
>
> A research and development contract was awarded to Scandinavian Biopharma on September 25, 2020, for manufacturing of clinical trial material suitable for a Phase 3 clinical trial. Scandinavian Biopharma is developing the lead candidate, a whole cell killed vaccine comprised of 6 different immunogenic components. Technical batches of vaccine have been produced at-scale and are undergoing testing."

The Army would potentially acquire the vaccine and make use of it once the product is approved for this use by the Food and Drug Administration. But by the time the Army were to start acquiring the vaccine at scale, it will be a ***commercial product***. At the time of the conversation in 2021, it was unclear under what contractual terms and conditions, or for what term, the drug would be acquired by DOD from the manufacturer. It seemed the product's initial price per unit and, once the initial acquisition contract had been met, its on-going price at contract renewals, would be exposed to the normal price movement of the commercial marketplace.

This is where the conversation then focused, and how memory roughly recalls it:

> "Cost Analyst: Once it's commercially available, other than normal inflation, what would be the expectation for this medical product's price movement over time?
>
> Team: Well, our usual expectation for price movements if for them to go from an initial high point, and then on a downward ramp. We expect as manufacturing ramps up, you'd see economies of scale kick in, and with a lower cost to produce each unit, we ought to see in negotiation the price to start to come down.
>
> Cost Analyst: Over a lot of years, watching medical procedures and drugs being reported in the press as commonly rising faster than inflation, I'm not so sure we'd find this would be the case here.
>
> Team: What you've seen might be applicable to this specific product, but maybe not. How could you find out one way or another, in a way that would apply to this specific product?
>
> Cost Analyst: I used to work for the Centers for Medicare and Medicaid, and I seem to recall their having information on drugs and drug prices. Let me see if I can find any relevant data there. *The one thing I promise is that if I can't find information that would be applicable and useful, right away – in a day or so – then I will let you know.* If so, then we'll figure out some way to model the expected price movement in line with your experience or other data.
>
> *Above all, we need to avoid paralysis by analysis*, especially since we're preparing the estimate for an early milestone in the program, and we will have time and room for corrections at later milestones, if we find it warranted.
>
> I'll dive in and see what I can find."

(We note the DOD Joint Capabilities Integration and Development System (JCIDS[ii]) defines DOD decision milestones, and depicts a process of increasing precision in LCCEs, matching to the maturation of project plans over time, as each decision milestone is achieved.)

Committing to a quick data search on my part was intended to build confidence in the client, that their new cost analyst was keeping their interests in meeting tight delivery schedules in mind.

It turned out the Centers for Medicare and Medicaid Services (CMS) has indeed been tracking drug price movement: "All Part B drug manufacturers report Average Sales Price (ASP) data for Part B-covered drugs and biologicals and related items, services, supplies, and products that are paid as drugs or biologicals." Available quarterly reports for a large basket of pharmaceuticals go back as far as 2005, and are available here: https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files

A sample of the relevant data can be found in the collection on the webpage labeled "2005-2020 ASP Drug Pricing", in the downloadable file "Jul 2019 ASP Pricing File updated052920.xls", which contains updated ASPs for the period January-March of 2019, for a basket of 590 drugs.

The elements in the basket of drugs reported each quarter do shift a bit over time, as new drugs come on the market and old drugs are discontinued by their manufacturers, but by and large this is a stable population of products, reported in standardized dosages – so little data normalization is required. The ASP series is from a reputable, statutorily mandated source, covering as many years as we might find useful, and we verified each report was in then-year dollar values.

For our purposes this was a grand slam of a pricing data find. May all your searches for relevant data end so fortunately.

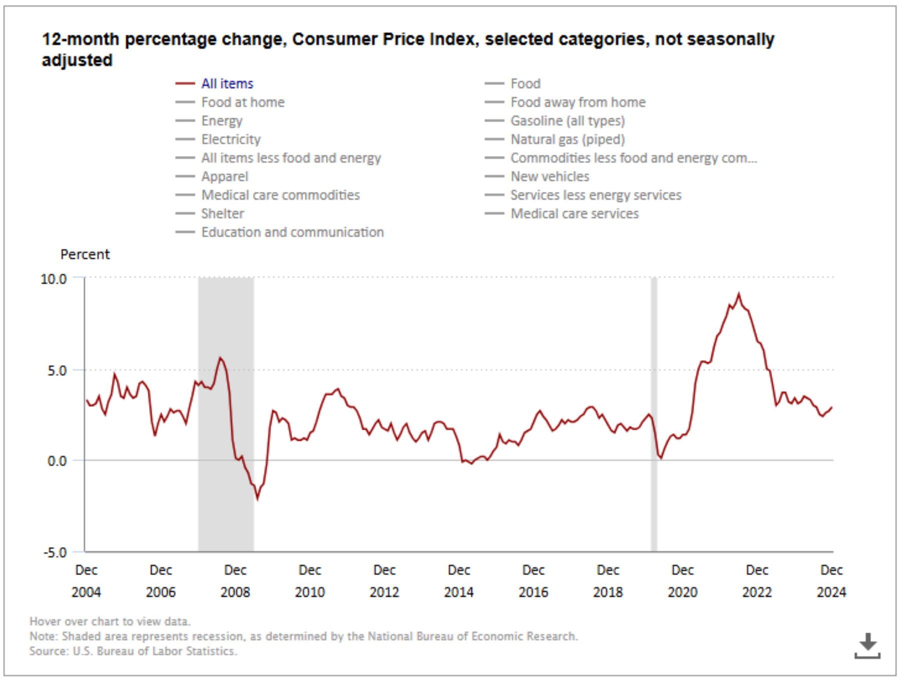
Data Preparation & Analytical Process

We first selected the eleven-year period 2011-2021. We downloaded each year's Q1 file. We verified each report was in then-year dollar values. We consolidated all the files into one Excel master file. We did some data cleaning, paring from the collected values those for drug items which were not reported in every Q1 report for the series. We then calculated the percentage of increase in price year-on-year for each drug in the series. This gave us, for each product, starting with 2011 prices as our base year 0, ten successive annual price increase percentages in then-year prices.

Since this is a series of commercially available products ultimately sold to US consumers, we then pulled, for each year, the over-all Consumer Price Index (CPI) annualized inflation, as reported by the US Department of Commerce's Bureau of Labor Statistics (BLS) on their

CPI website, here: https://www.bls.gov/cpi/. We recognize the CPI series, as a measure of inflation, has limitations and features of which the general public might not be aware. The series uses a statistical technique known as "hedonic modeling", which accounts for price movements in products over time due to their changing quality, as opposed to their changing supply/demand curve or a change in purchasing power of the dollar. CPI is based on surveys of households and businesses, and is specific to geographic regions or census areas, and the most commonly reported of the series is that for Urban Consumers[iii].

That said, we opted to use the BLS CPI as a basis for comparing drug price movement, calculating those changes over or under CPI's measured national inflation rate. The CPI annualized series is available in graphic form here: https://www.bls.gov/charts/consumer-price-index/consumer-price-index-by-category-line-chart.htm.



Show table

The "Show Table" link on BLS's webpage above will take you to a downloadable table of the values.

We then subtracted from each drug's annual percentage change in the CMS' drug price data series, the BLS CPI change for each particular year. This gives us a year-on-year price change after accounting for CPI-measured inflation.

We did this for all the drugs continuously present in the basket over the period, and then zeroed in on just the 17 vaccines in the basket. The results are reported on the next page.

HCPCS Code	Short Description	Decade Price % Change *	Decade Price Change After Inflation *	Mean % annual price change	Average Annual price change after inflation	Standard Dev in % annual price change after inflation
90585	Bcg vaccine, percut	23.38%	-0.85%	2.18%	0.43%	0.0276268
90586	Bcg vaccine, intravesical	25.45%	0.81%	2.24%	0.58%	0.0194722
90632	Hep a vaccine, adult im	23.82%	-0.50%	2.45%	0.18%	0.0470381
90656	Flu vaccine no preserv 3 yo & >, im	59.78%	28.40%	5.14%	3.36%	0.0877879
90662	Flu vacc prsv free inc antig	108.75%	67.75%	7.75%	5.94%	0.0516834
90670	Pneumococcal vacc, 13 val im	94.93%	56.64%	6.67%	4.63%	0.0281461
90675	Rabies vaccine, im	68.06%	35.05%	7.37%	3.77%	0.1039109
90691	Typhoid vaccine, im	106.35%	65.83%	9.89%	8.41%	0.2336023
90714	Td vaccine no prsrv >/= 7 yo, im	48.05%	18.97%	3.86%	1.54%	0.0641624
90732	Pneumococcal vaccine	153.18%	103.46%	8.79%	7.48%	0.0537855
90740	Hepb vacc, ill pat 3 dose im	17.87%	-5.28%	1.67%	-0.05%	0.0190898
90743	Hep b vacc, adol, 2 dose, im	7.92%	-13.27%	0.78%	-0.93%	0.0181281
90744	Hepb vacc ped/adol 3 dose im	16.53%	-6.35%	1.56%	-0.16%	0.0225289
90746	Hep b vaccine, adult, im	16.65%	-6.26%	1.56%	-0.16%	0.0171536
90747	Hepb vacc, ill pat 4 dose im	17.87%	-5.28%	1.67%	-0.05%	0.0190898
J9031	Bcg live intravesical vac	23.47%	-0.78%	2.08%	0.42%	0.0206961
Q2037	Fluvirin vacc, 3 yrs & >, im	33.44%	7.24%	2.96%	1.22%	0.0268774

* For reference, the total actual inflation effect as measured by changes to the Consumer Price Index during this period was:

Year	CPI	Annual Inflation Over Prior Year
CPI 2010	218.1	
CPI 2011	224.9	3.12%
CPI 2012	229.6	2.09%
CPI 2013	233	1.48%
CPI 2014	236.7	1.59%
CPI 2015	237	0.13%
CPI 2016	240	1.27%
CPI 2017	245.1	2.13%
CPI 2018	251.1	2.45%
CPI 2019	255.7	1.83%
CPI 2020	258.8	1.21%
CPI 2021	271.4	4.87%
Total US Inflation 2011-2021:	24.44%	

Portfolio Price Change **Over Ten Years** after Inflation
20.33%

Mean Portfolio Annual Price Change after Inflation
2.15%

Portfolio Annual Price Standard Deviation
5.06%

Coefficient of Variation (Standard Deviation/Mean): 235%

The market basket of 17 vaccines, all drugs continuously available over this period – over and above our accounting for general inflation – rose in price a total of 20.33% over the ten-year period, with a mean portfolio annual increase of 2.15%, after inflation.

The Typhoid Analog

Of particular note was the typhoid vaccine, highlighted in yellow, the portfolio price increase leader, and the one vaccine that stood out as the closest analogous product to that of the developing E-Coli vaccine.

Typhoid vaccine was first developed in 1896 and licensed in the US in 1914. The current version of the vaccine was approved by FDA in 1994[iv].

At the time of this analysis, global typhoid vaccine demand had been rising by about 10% per year for the last decade, and that demand was estimated to continue rising for the foreseeable future at about that same annual rate. One of the drivers of this increased demand – other than demographics – are the increasing effects of global climate change, in particular, the increasing variability and intensity of rainfall distribution.

When rainfall suddenly increases following a period of sustained dry weather, it results in a steep increase in the osmotic pressure of untreated ground water surrounding in-ground water distribution pipes. In many countries, including the US, ground water distribution pipes can be aged and leaky, and even though these pipes carry nominally treated, safe water, under these conditions of sudden increases in osmotic pressure, untreated ground water – which can and does carry both typhoid and e-coli infectants – can be forced into the distribution pipes.

When typhoid subsequently breaks out, demand from local authorities for typhoid vaccines surges[v].

As both typhoid and E-coli follow this same increasing vector of infection, it is reasonable to extrapolate to some degree a rise in demand fueling price increases in the one, as they have for the other.

But would this necessarily result in an additional pricing factor that mirrors for E-Coli, once it is approved, the expected past and future experience with typhoid?

Bear in mind the more than a century of successful and now global history of the application of typhoid vaccines to this problem of public health, and the intense interest on the part of an established, extensive network of non-governmental organizations, the World Health Organization, and governments in propagating the vaccine. None of these organizations, funding, or distribution channels exist as yet for any E-Coli vaccine, as this product, as of this writing, is not commercially available.

It will take some time for global demand and distribution for E-Coli vaccines to emerge and begin to make itself felt in an effective demand upward pull on the expected price for the product, once it becomes commercially available. Further, a large global market demand would necessarily be gated by first the large numbers of countries other than the US approving the commercial distribution of the product.

Accordingly, as close an analogy as we have to the E-Coli vaccine in the typhoid vaccine, we concluded it would be an overreach to insert a price factor increasing the total cost of the product over and above inflation of 8.41%, as we found for typhoid over the last ten years.

We arrived at establishing the principle for this LCCE that the over-all price effect post-FDA approval would be upward, not downward, and recommended expressing this likelihood by using the 2.15% annual price increase factor we derived for the whole vaccine portfolio.

Using the "Pricing Factor" in the Estimate

- *We use a standard DOD-approved process of incorporating the information from our study into the LCCE.*

Application of this price increase factor within the LCCE is governed by the procedure called for by the relevant guidance document, "Inflation and Escalation Best Practices for Cost Analysts", the latest version of which is dated December 2021, and published the Office of the Secretary of Defense Cost Assessment and Program Evaluation Office (OSD CAPE). We note this document in this version is not publicly available; the previous version, dated from 2017, is for our purpose substantially the same as the current version, and is publicly available, here:

https://www.govinfo.gov/content/pkg/GOVPUB-D-PURL-gpo156849/pdf/GOVPUB-D-PURL-gpo156849.pdf.

This guidance document makes a few key observations and definitions useful for DOD cost estimates using the analytical approach outlined here.

"Real Price Change" (RPC) is the real change in prices otherwise not explained by measures of inflation, and usually driven by sustained imbalances between supply and demand. *Our recommended pricing factor of 2.15% is an RPC.*

"Inflation" is the relevant metric of change in the general price level, as an economy-wide average over all goods and services transacted, reflecting a generalized loss of purchasing power of the dollar. In our study, we refer to the broad Consumer Price Index for all products as our relevant measure of inflation.

"Price Escalation" refers to the combined effects of inflation and RPC, the price changes over and above inflation observed here for our market basket of vaccines.

For our LCCE, prepared using Tecolote Research's ACEIT software, we would add the 2.15% RPC as an Input Variable, and include that variable in formulas calculating the cost element for each year's planned purchases. We would also load the latest approved inflation tables provided for ACEIT by OSD CAPE.

In a Then-year report, ACEIT would then apply the relevant inflator from the inflation tables and the RPC value, giving us the cost for acquisition that includes the combined price escalation effect of the RPC and inflation.

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[i] The US Army Medical Research and Development Command has since been transferred from the US Army into the Defense Health Agency's Program Executive Office Operational Medical Systems (Provisional), also known as PEO OPMED.

[ii] Described in DOD Instruction 5000.85, Major Capability Acquisition, public link here: https://www.dmi-ida.org/knowledge-base-detail/dodi-500085)

[iii] A useful guide to common misperceptions regarding CPI and how it is calculated is available here: https://www.bls.gov/cpi/factsheets/common-misconceptions-about-cpi.htm

[iv] https://www.immunize.org/vaccines/vaccine-timeline/

[v]The Global Alliance for Vaccines and Immunization (GAVI) tracks global demand and supply of a large market basket of needed vaccines.
Their 2018 report – what was available at the time of this analysis – is available here: https://www.gavi.org/progress-report-2018
GAVI's current report for 2024 is available here:
https://www.gavi.org/our-alliance/market-shaping/vaccine-demand-forecasting
An NIH article discusses typhoid immunization efforts here:
https://www.ncbi.nlm.nih.gov/sites/books/NBK470571/