Preliminary Design of a Light Attack Aircraft for Austere Airfields

The Causes of the Steadily Increasing Price of Insulin

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

The technical topic in this paper is an AIAA competition for the preliminary design of a light attack aircraft for austere airfields. This aircraft's intended use is as a cheap, efficient alternative to modern fighter aircraft or attack helicopters in uncontested airspace. It is intended to operate on short runways with limited servicing and maintenance. The goal of this design is to provide deliverables describing the aircraft configuration, sizing, and concept of operations. The goal of a preliminary design is to provide a baseline proof of concept before more resources are invested into the program. The ethical implications for any military design are complicated, but I believe the use of a light attack aircraft is worthwhile due to the reduction of waste from manufacturing and fuel use compared to fighter aircraft or attack helicopters.

In July 2019, Bernie Sanders' 'Caravan to Canada' travelled to Canada with a group of people who had diabetes in order to buy thousands of dollars' worth of insulin at one tenth the price of the same drug in the United States (Hoskins, 2020). Insulin is a life-saving medicine for many people and its price has steadily increased since 2002, becoming a substantial burden on those who require it. This STS prospectus aims to examine the causes of high insulin prices in the United States. I am hypothesizing that the pricing of insulin is not a result of cost of production, but of complex price politics. I will examine how the relevant parties communicate with each other in order to set the price of insulin. My goal is to use insulin as a case study to explain increasing pharmaceutical and healthcare prices in the United States as a whole.

The technical subject of the STS prospectus and the technical topic for the Dept. of Aerospace Engineering are not related.

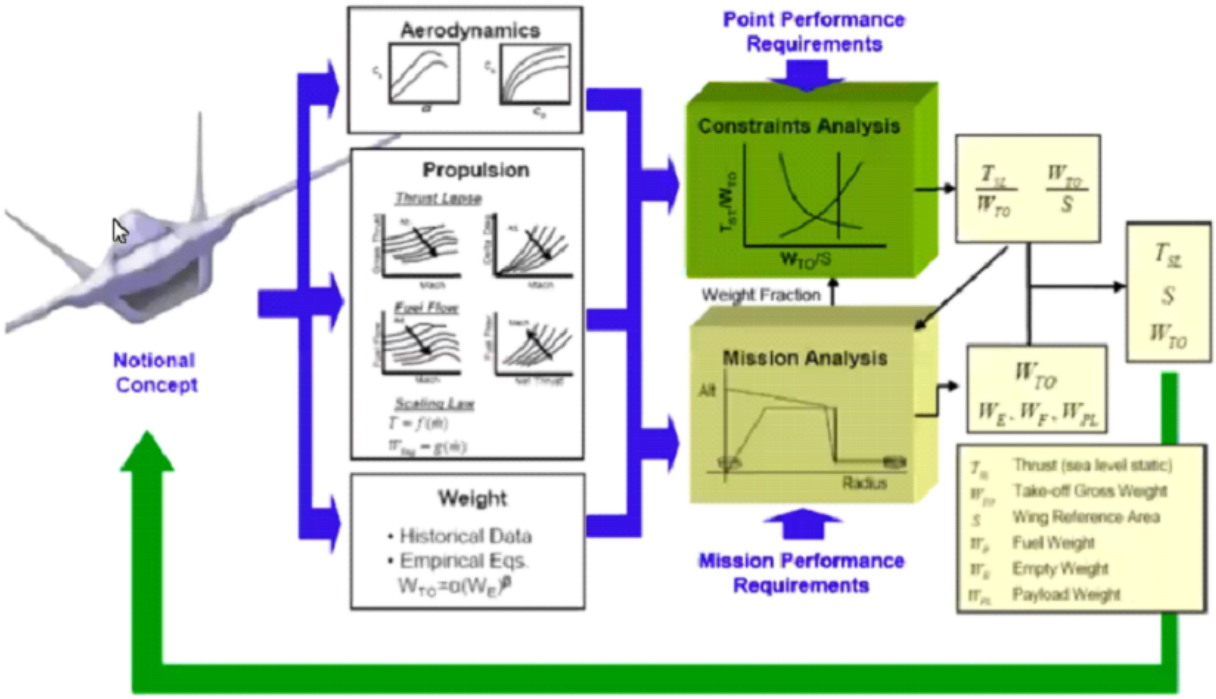
Technical Topic

A modern light attack aircraft is designed to provide close air-to-ground support and counterinsurgency. There is a gap in the arsenal of the U.S. Air Force because it has no light attack aircraft. This aircraft is typically a turboprop and is both slower and quieter than the jet-powered aircraft that are typically used by the U.S. Air Force. The prop-driven aircraft can serve better as stealth and surveillance air support. It is both cheaper to make and more efficient to run than an advanced fighter jet or attack helicopter. Per hour use of a light attack aircraft compared to a high-end advanced fighter can be as low as 2%-4% (Weisgerber, 2010). As a result, the light aircraft can be available for a longer period of time to ground forces. The light attack aircraft can also run on short notice on austere airfields, which require short take offs and landings on somewhat rough terrain. Light attack aircraft can serve as a substitute for attack helicopters, which are expensive to run and maintain. However, there are downsides to the light attack aircraft. The lower speed of the light attack aircraft makes it more vulnerable to attack from fighters, therefore it is only useful in permissive, uncontested airspace. The light attack aircraft's advantage lies mostly in cost. Therefore, when designing one of these aircraft a primary concern should be limiting the costs of manufacture, maintenance, and service.

The scope of this project is a preliminary design. The objective, requirements, and two design missions are given in a Request for Proposal from the AIAA (Design Competitions: Light Attack Aircraft, 2020). This technical project is collaborative with team members Alfredo Basile, Andrew Kraemer, Caleb Mallicoat, Riley Assaid, Ryan Hughes, Robbie Sorrentino, and myself, Benjamin Hamer. Robbie Sorentino is serving as the team leader, and the group is working under the supervision of Professor Jesse Quinlan.

The first step in the design process is concept generation. Each team member makes individual design decisions based on mission requirements to generate initial designs for the aircraft. The team then down-selects from the designs to find a consensus concept to the light attack aircraft problem. Finding this initial design is only the beginning. Aircraft design process is iterative. Figure 1 shows the design process. First, a concept is made (CAD/OpenVSP). Then, the aerodynamics (XFOIL/VSPAERO), propulsion system (XROTOR), and weights (FLOPS) of the design are solved for. Finally, the capability of the design to complete the mission is analyzed (FLOPS). The concept is altered and the process repeats until the aircraft completes the given requirements. The deliverables of the preliminary design include complete geometric description, analysis of performance, aircraft weight statement, material selection, cost estimates, and others.

Figure 1: Overview of preliminary design process.



The ethical implications for an engineer designing a device for military applications are complex and have been debated since the creation of the military-industrial complex. The most pressing ethical concern is the likelihood of a light attack aircraft to be used in military conflicts which result in loss of life. Generally, it is morally bad for humans to die, but it is unclear if the use of light attack aircraft would lead to more deaths due to military operations. However, looking at ethics through a conservation of resources perspective makes the design of an efficient light attack aircraft more appealing. The light attack aircraft needs fewer resources to build, less fuel to fly, and operates from smaller, cheaper bases. Overall, the use of light attack aircraft would likely provide an overall benefit in terms of my own ethical perspective.

STS Prospectus

Introduction

In 2015, Martin Shkreli, then CEO of Turing Pharmaceuticals, increased the price of the Daraprim, a life-saving drug for AIDS and cancer patients, from $13.50 a pill to $750 overnight (Shefali, 2018). An ever-rising healthcare concern in the United States is cost, particularly for life-saving pharmaceutical drugs. The most widespread example of this is insulin. In 1921, Frederick Banting discovered the ability to extract insulin from a cow pancreas. He refused to sell the patent, and his co-inventors sold it to the University of Toronto for $1. Today, more than 34 million people (~10%) in the United States have diabetes. Insulin is a life-saving drug for people with Type 1 or 2 diabetes. For the average person using insulin in the United States, the daily cost went from $7.80 in 2012 to $15 in 2016. Insulin's price has increased consistently since 2002. This price is often cited to be a result of innovation and providing the best medicine possible. The causes of the rising price of insulin could be an insightful case study into rising prescription costs, and medical costs, in the United States as a whole. The relevant stakeholders, which contribute to the price politics of insulin, are pharmaceutical companies, the U.S. government, insurance providers, physicians who prescribe, and the people with diabetes who need insulin. High insulin prices are an issue that has been investigated thoroughly by others, however it has been primarily from the perspective of healthcare professionals. An investigation from an STS point of view could provide further insight into the causes and solutions to this problem.

Research Questions

The United States has a free market approach when it comes to healthcare. In theory, this means the price of pharmaceutical drugs are set freely, based on supply and demand principles.

The price of insulin has been steadily increasing since 2002. There may be free market explanations for this: increased manufacturing costs, increased cost of materials, or increased demand. But do these explanations apply, or is the price increase related to exploitation of a market of consumers who have no choice but to buy the product: insulin.

A common argument in favor of the free market approach to insulin is that allowing the market to regulate itself promotes innovation. One measure of innovation is patents, and in the US four companies have filed over 200 patents on insulin technology since 1995 (Kaplan and Beall, 2016). However, I want to quantify the benefit of this innovation. And, if its resultant increased cost is what patients want and can afford.

Literature Review

This literature review focuses on the themes that have led to the increasing price of insulin. Some sources address several of these themes, but this prospectus compiles the different themes and connects the sources. The identified themes are patient choice, technological exclusivity, price negotiation, and government policy.

The first theme is patient choice. Patients lack choice in insulin pricing, as their options are limited (Hayes, 2020). The patient's choice is in the physician, who prescribes the medication and patient involvement in the physician's choice is variable. The physician's choice can also be affected by gifts and targeted ads from pharmaceutical companies (Schwartz and Woloshin, 2019). The most well-meaning physicians can be influenced by misleading research financed by pharmaceutical companies such as "Insulin Analogs- Are They Worth It? Yes!" (Gunberger 2014). Grunberger asserts analog insulin is superior to human insulin, but has a clear conflict of interest due to his funding coming from a major insulin provider, Novo. He overstates the benefits of analog insulin and other researchers such as the World Health Organization disagree

in the generalization that analog insulin is better (Kaplan and Beall, 2016). Studies funded by large pharmaceutical companies can affect the decision making of the physicians who prescribe the medications. The patient also has a lack of choice in insurance due to many Americans' insurance being provided through their employer. This limits their options and incentivizes insurance companies to lower the cost of insurance for the business, instead of lowering the cost for the patient.

The second theme is technological exclusivity. Pharmaceutical companies are constantly making new patents to push the technology forward, but more importantly, to keep insulin technology under intellectual copyright. Many new patents on insulin technology have been filed in the last few years, and market exclusivity for these products lasts 12 years (Hayes and Barnhorst, 2020). This prevents generic brands from competing with alternatives. The second part of technological exclusivity is pharmaceutical companies sending gifts to and lobbying physicians in order to convince them to primarily prescribe only new products. The World Health Organization has asserted that this new technology has negligible benefit to the patient, especially when compared to increased cost (Kaplan and Beall, 2016). I would like to delve particularly deep into this theme because it seems the most relevant to engineers and would be an interesting study of the trade-off between innovation and affordability.

The third theme is price negotiation. Most drugs in the United States are priced with a free market approach, but the principle of supply and demand does not work for a life-saving drug like insulin. The consumer for insulin has no choice in the demand, they must buy the drug to survive, and this need can be abused. Four pharmaceutical companies, Eli Lily, Novo, Sanofi and, Pfizer, provide a vast majority of prescribed insulin and insulin delivery systems and they seek to maintain an oligarchy-monopoly system over the prices of insulin (Kaplan and Beall,

2016). The companies can have a “handshake” deal where they take advantage of a market on which they have all leverage. There is also a lack of transparency in cost for manufacturing and creation of new technology which affects drug prices (Schwartz and Woloshin, 2019). This makes negotiating difficult for the party lacking information. In addition, the consumer has no direct access to negotiation.

The fourth theme is government policy. The government could do more to control drug prices, but actively makes policy which leads to further increases in price (Engelberg, 2015). An example is the FDA being prohibited by law from negotiating prices through Medicare. Pharmaceutical companies also receive millions of dollars a year in funding for research and development from the government (through taxpayers). However, patients do not see any reduction in their cost from this funded money. These companies also spent $171 million in 2017 lobbying politicians to have favorable policy (Lucas and Hancock, 2018).

STS Framework and Method

Actor-Network Theory can be used to simplify the large groups of people which make up the groups of interest: patients, physicians, pharmaceutical companies, insurance companies, and the United States government. This will allow me to examine communication between the groups and determine why one group, the patients, is experiencing high prices.

The network for producing insulin for human use has been fully integrated into society for a long time. In 1982, the Eli Lilly Corporation produced a human insulin that became the first approved genetically engineered pharmaceutical product. Without needing to depend on animals, researchers could produce genetically engineered insulin in unlimited supplies (Insulin, 2020). The insulin pricing system actor network features the actants of pharmaceutical companies, the U.S. government, insurance providers, physicians who prescribe, and the diabetics who need

insulin. Pharmaceutical companies manufacture insulin and thus are a key component to its pricing. Diabetics purchase this insulin and provide the demand for the medicine. The U.S. government makes law and policy for drugs and medicine in general which apply to insulin. Insurance providers negotiate prices of insulin with pharmaceutical companies. Some overlap occurs between the insurance and government actants as the government also provides insurance for some through Medicare and Medicaid.

Actor-Network Theory will be used to investigate the effect of newly patented technology on the system of insulin production and distribution. The actants in this a system include recently patented technology; older, unpatented technology; patients who make choices in what products they use; physicians who make prescription decisions; insurance companies who contribute to what product is used; pharmaceutical companies which create new technology and push for its use; and government which regulates insulin related patents. These actants work together in a complex way to price insulin. I will quantify the benefits of recently patented technology relative to older, unpatented technology in terms of both cost and health outcomes. Actor-Network Theory will be used to connect the insulin technology actants – both patented and older – to the groups of people in the system to explain each actants role in the consistently increasing price of insulin. The research for Actor-Network Theory will be strictly data gathering and analyzing or visualizing that data.

"The Social Construction of Facts and Artefacts" (SCOT) can be used to categorize people who use insulin into different social groups. One social group of people can afford insulin. This group likely has good insurance or is wealthy and can afford insulin costs. Another group of people cannot afford insulin; 26% of these people ration their use of it. This group is composed of people who may have insurance, but cannot afford out-of-pocket costs. It may also

include people who have no insurance at all, including those who are in a lower income bracket but not poor enough to qualify for Medicaid. People who are poor have insulin paid for through Medicaid, and people over the age of 65 have coverage through Medicare. Increased wealth will generally correlate with being able to afford insulin. The exceptions to this rule are often people who make too much money to have Medicaid, but have poor insurance or no insurance through their employer and trouble with out-of-pocket costs. This group of people is of the highest interest because they are likely to struggle paying for insulin.

SCOT relies on knowing the needs of the relevant social groups. To determine this, I will survey the patient groups identified using SCOT. The survey will ask questions to categorize patients by differentiating factors such as wealth, age, and insurance coverage. It will also ask what each group of people prioritize in their use of insulin: price, effectiveness, ease of use, etc. I will consider how the phrasing of questions can bias answers and note that people can be biased by how the survey is administered: at a hospital, online, etc. This survey will help solidify the assertion that communication between patient and provider has broken down which contributes to increasing cost.

By obtaining some measure of patient needs, the analysis using Actor-Network theory can be improved by comparing patient needs to the product that insulin companies provide. I expect that the patient need will be lower costs of insulin, while the pharmaceutical companies' main focus is providing the most technologically advanced insulin delivery. The existence of these conflicting goals would indicate a breakdown of communication between the groups.

Timeline

Milestone	2021				
	January	February	March	April	May
Write Survey					
Contact physicians to post survey in clinics and/or post survey on online forums					
Research relative benefit of new patents					
Receive survey results					
Analyze survey results and integrate data with other research					
Write first draft of STS Research Paper					
Revise as necessary					

Conclusion

This STS project will address the causes of the increasing price of insulin in the United States. The paper will be centered around the themes of patient choice, technological exclusivity, price negotiation, and government policy. Actor-Network Theory will be used to analyze the network which produces insulin and the communication between actants in that system and how they contribute to insulin pricing. SCOT will be used to break the patients down into groups based on wealth, age, and insurance plan. These two frameworks can be connected to see if the needs of the patients are accurately communicated to pharmaceutical companies. At the conclusion of this project, there will be a complete explanation of the cause of the high price of insulin. The role of patents in insulin price will be investigated in detail, since this is of particular concern to the engineer.

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