



# Alternative Methods to Deliver Epinephrine

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# Executive Summary

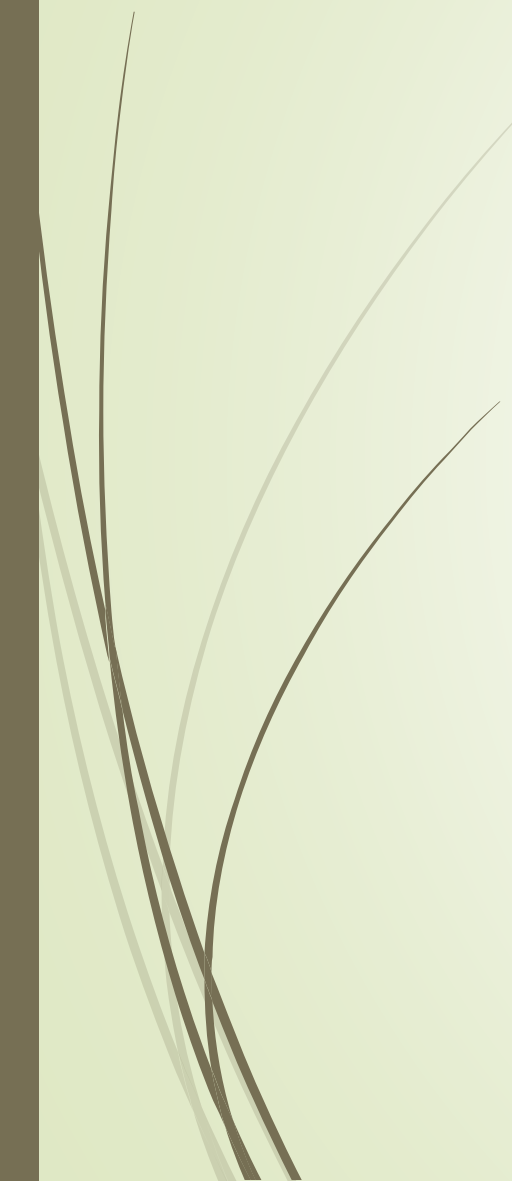
- Anaphylactic shock has an estimated prevalence of around 1.6%
- Only solution we currently have are intramuscular Epinephrine auto-injectors (EpiPen)
  - Expensive (~\$600), pre-specified dosage, inconvenient, needle, etc.
- \$4B market that is stuck to this design



**Goal is to research alternative delivery methods and design a commercially viable product with the needs of the patient and physician in mind**



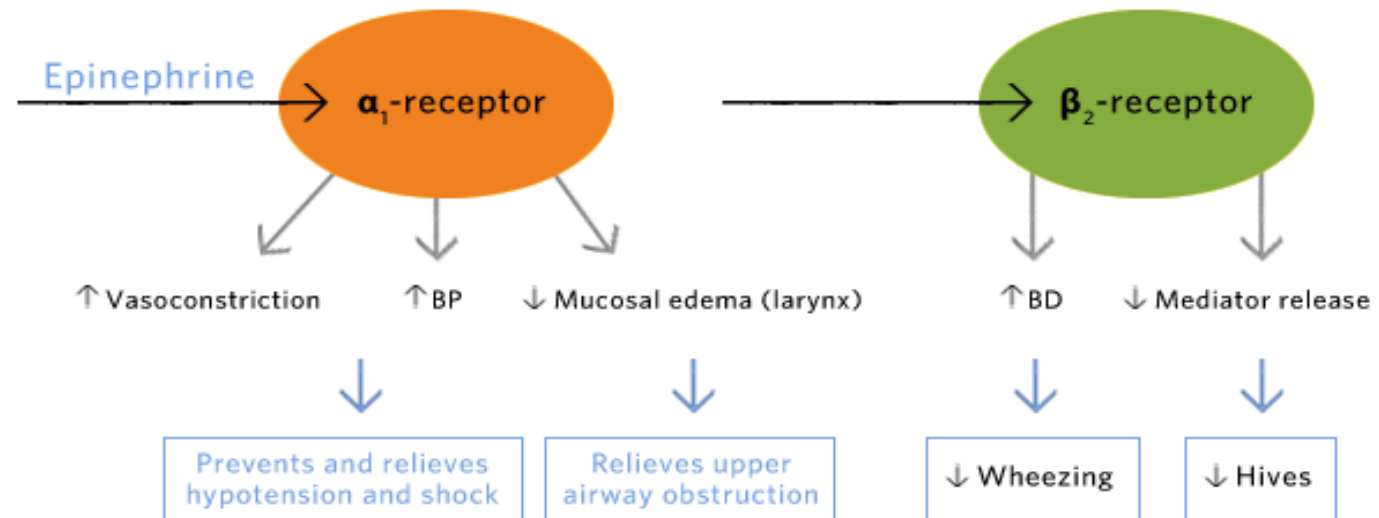
# Outline

- Background
  - Existing Solutions
  - Alternative Delivery Methods
  - Project Scope and Team
  - Design Schedule Timeline
  - Conclusion
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# Epinephrine & Anaphylactic Shock

Figure 1: Epinephrine is the Cornerstone of Emergency Treatment for Anaphylaxis

Epinephrine's  $\alpha_1$ - and  $\beta_2$ -adrenergic effects prevent and relieve *life-threatening symptoms* of anaphylaxis in most organ systems.

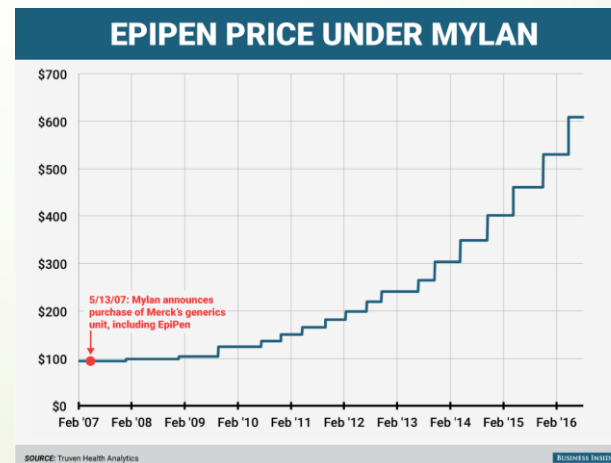


**Additional pharmacologic effects:** at  $\beta_1$ -receptor:  $\uparrow$  heart rate;  $\uparrow$  cardiac contraction force

BP = blood pressure; BD=bronchodilation

# Existing Solutions

- Intramuscular Auto-Injectors are the only solution currently
  - EpiPen by Mylan
  - Adrenaclick, generic EpiPen without retractable needle (hard to get hold of)
  - Auvi-Q, more portable device with a mixing chamber to reduce temperature sensitivity; repealed in 2015

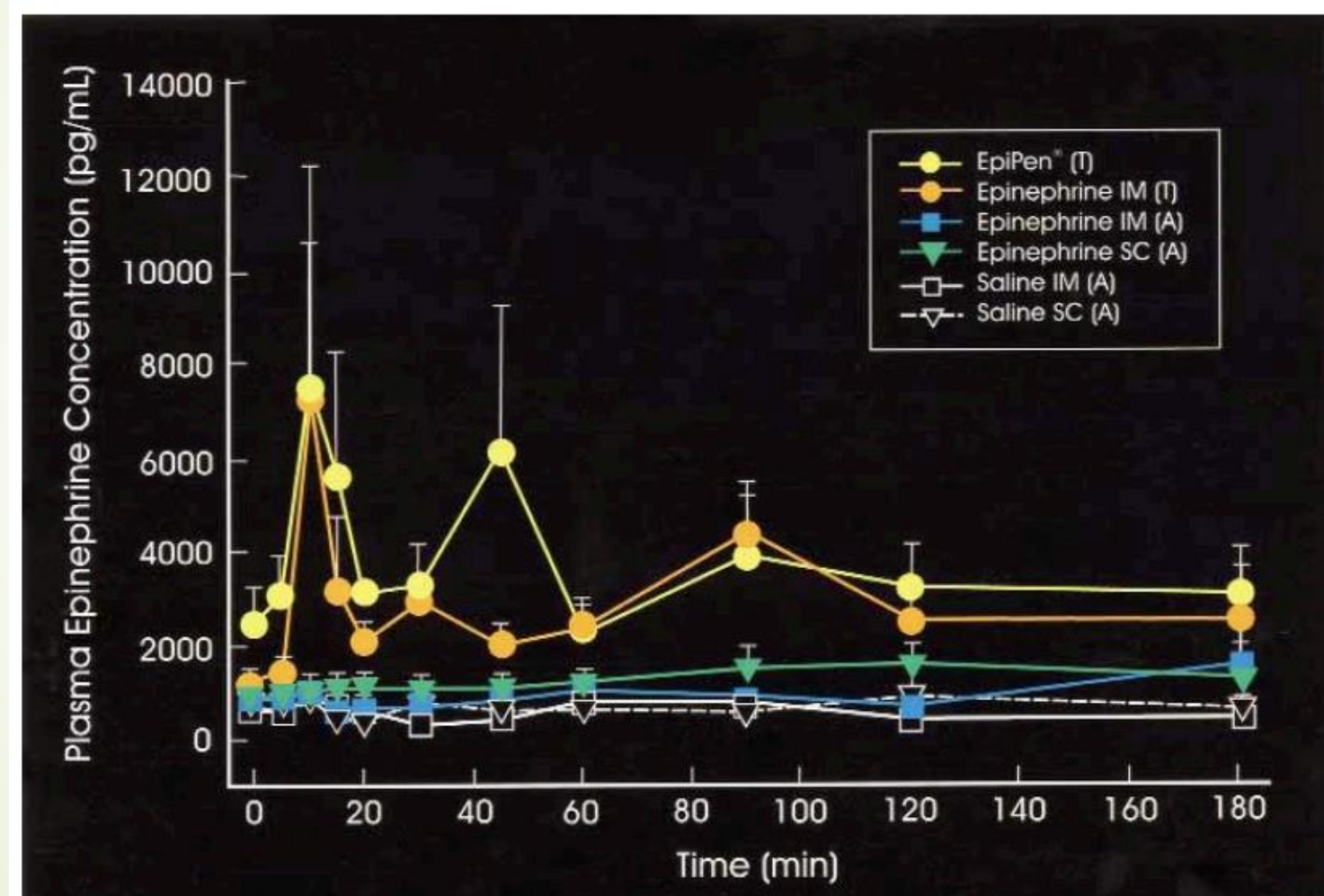




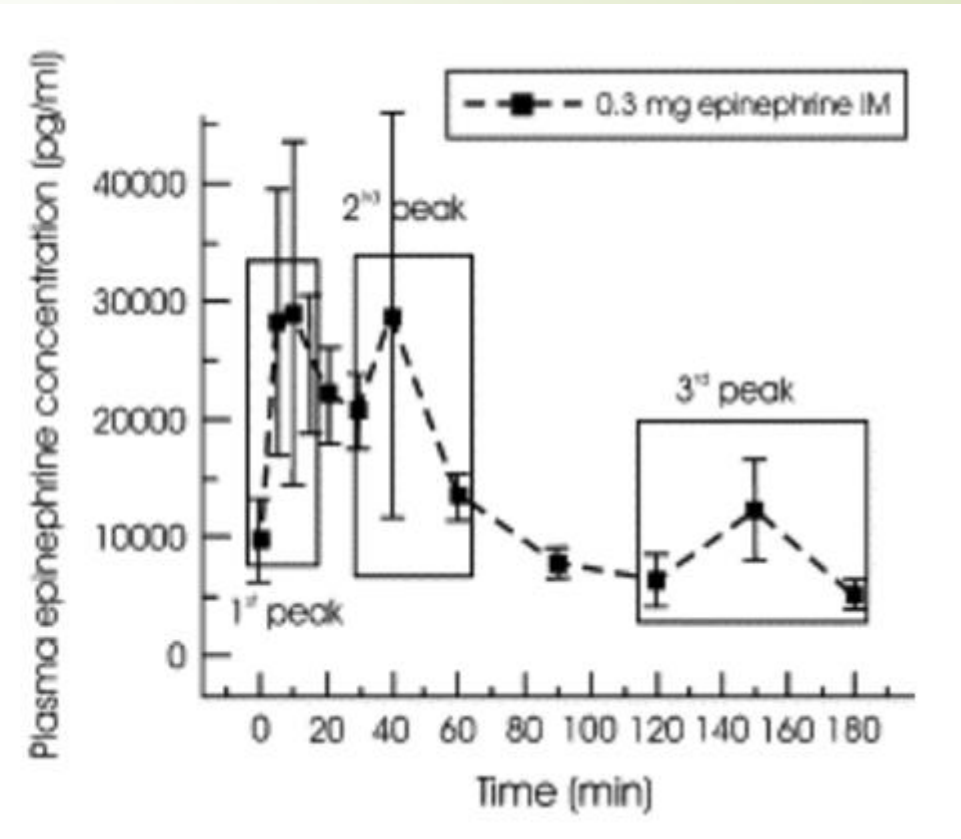
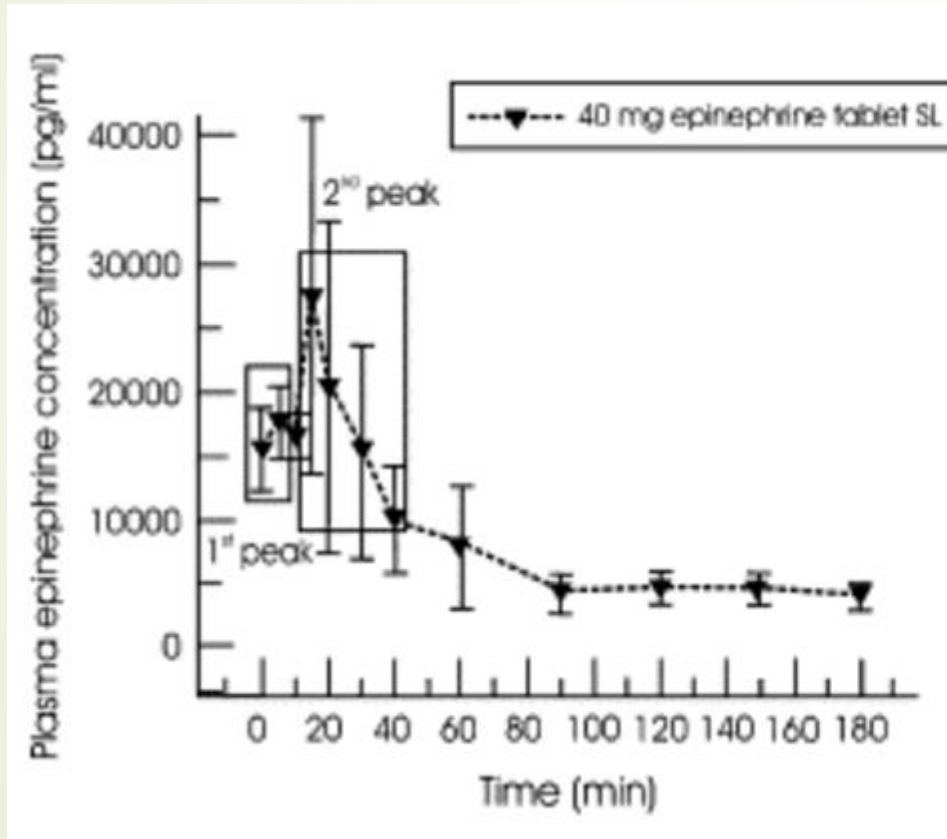
# Alternative Delivery Methods

- ▶ 3 Potential Delivery Methods:
  - ▶ 1. Subcutaneous (SC), under skin
  - ▶ 2. Sublingual (SL), under tongue
  - ▶ 3. Intranasal (IN), through nasal passages

# Intramuscular vs. Subcutaneous



# Intramuscular vs. Sublingual







# Intramuscular vs. Intranasal

- Limited data has been collected on Intranasal
- Preliminary studies show that epinephrine can be significantly absorbed via the IN route in humans
  - Higher IN dose (5 mg) than the usual IM dose (0.3 mg) required



# Project Scope

- Based on the industry research, we have determined that a revised design using Intramuscular delivery will be the best approach
- Goals:
  - Priced < \$300
  - Lightweight (<140g), portable (12.7 cm x 2.54 cm x 2.54 cm), and not threatening
  - Consistent adrenaline dosage, .300 +/- .015 mg

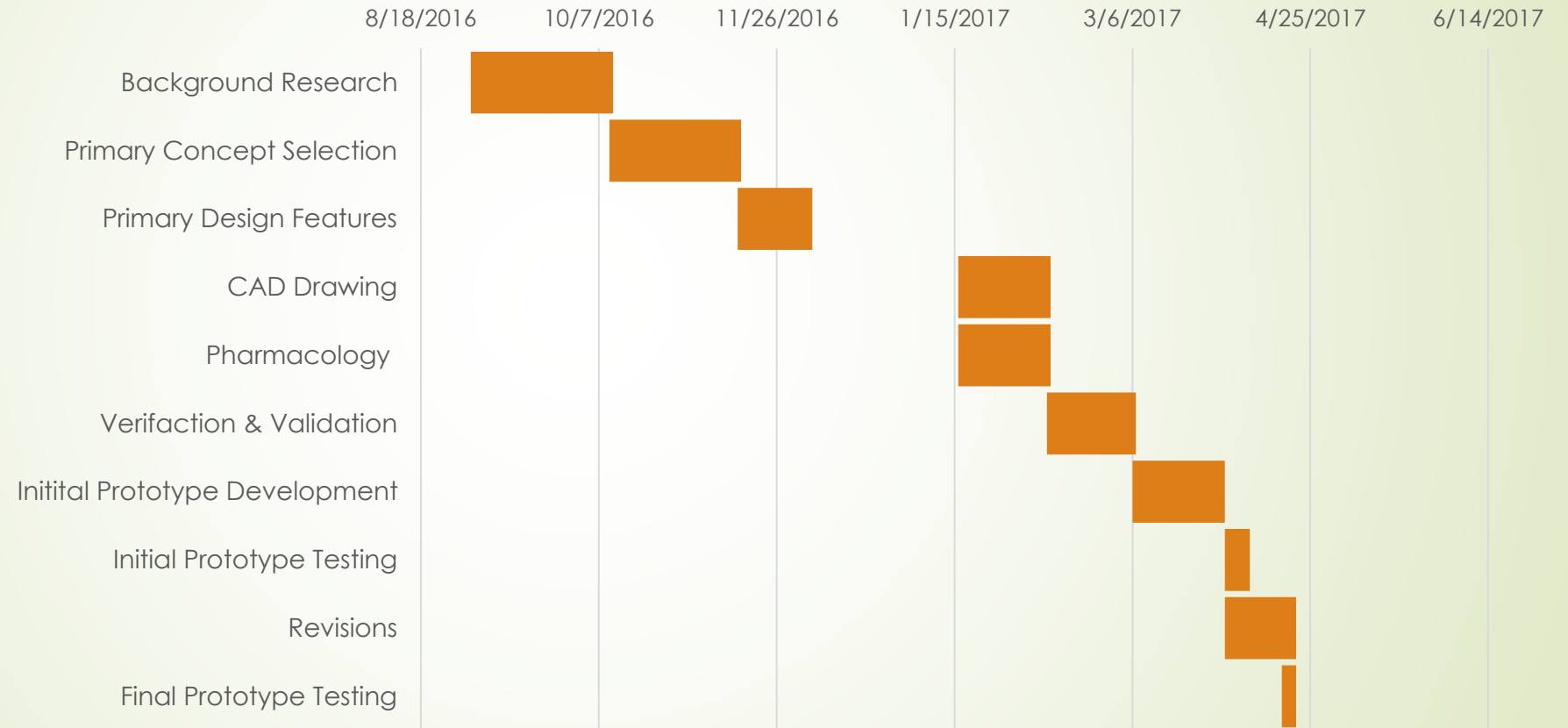


# Team



- ▶ WashU BME Undergraduate Students
  - ▶ Vikram Arun: Point-of-contact, research
  - ▶ Ben Katzman: CAD, prototype creation
  - ▶ Luke Ziolkowski: Pharmacology, prototype testing
- ▶ Division of Pediatric Allergy, Immunology & Pulmonary Medicine Washington University, School of Medicine
  - ▶ Dr. Caroline Horner
  - ▶ Dr. Avraham Beigelman
  - ▶ Dr. Kitcheroensakkul

# Design Schedule





# Conclusion

- There is a huge need and market for alternatives to the EpiPen
- Intramuscular (IM) is still the most trusted mode of delivery
- Our focus will be on making our product reasonably priced, portable, and reliable



Thanks!

