MediSaver: An EpiPen Alternative

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Outline

- Project Scope
- Design Specifications
- Explored Designs
- Chosen Design
- Updated Schedule
- Updated Team Tasks

Project Scope

1. Problem: Anaphylaxis -> Solution: Epinephrine administration
2. Design a device that can be used to deliver an emergency dose of epinephrine for individuals undergoing anaphylaxis
   a. More practical, safe, and efficient alternative to existing devices
   b. More durable and portable design with a shelf life of more than one year, minimally invasive epinephrine administration method, and an accurate and precisely delivered dose of epinephrine
   c. The route of epinephrine administration will ensure safe and effective patient use along with accurate and rapid drug absorption to treat customers.
3. January: Complete design for a device
4. End of April: Completed project, produced prototype of this device that will be tested to deliver a consistent amount of epinephrine.
   a. Device will be accompanied by mechanical design diagrams, risk analysis, and testing results that provide evidence for the product as a temporary but reliable treatment in the case of anaphylaxis.

Design Specifications

Design specification	Design Specification goal
Weight	Less that 1.0 kg
Portability	Volume Constraints: less than 82 cubic centimeters
Temperature dependence	Functional between 10 degrees and 40 degrees celsius
Onset of absorption	<= 5 minutes
Plasma concentration over time	20,000 pg/mL after 40 minutes
Dose Accuracy	95% of epinephrine dose
Cost to produce	<$300
Preparation + delivery time	Can be applied in under 10 seconds, does not require electrical power
Dose variability	Dose for children and adults
Invasiveness	Penetrates skin minimal amount needed to apply dose
Accidents	Safety mechanism to prevent accidental use
Instructions	Printed largely on device

Design Specifications (continued)

Epinephrine dose	Small amount (<= 5 milligram)
Repeatability	Can replace device/dose and re-use
Safety after use	Retractable needle/no sharp parts revealed
Ease of use	Can be administered by someone else if not breathing/conscious
Longevity	Lasts > 1 year
Trackability	Strap/key chain
Application site side effects	Minimals scarring/redness/bleeding
Delivery Obstacles	can be applied with clothes
Concentration	Less than 90% by weight epinephrine
Width	less than 2.54 cm
Force of Activation	10-30 Newtons
Fall durability	Can be dropped 2 meters and still function
Weight durability	Can withstand 400 Newtons of applied force and still function

Designs

Injectors

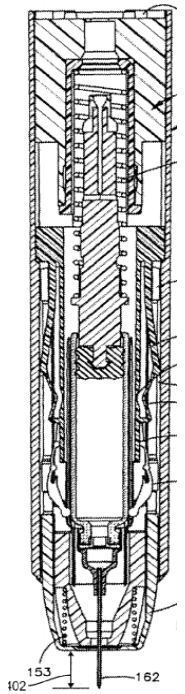
1. (Reference) IM Autoinjector
2. Subcutaneous Injector
3. Improved IM Injector
4. Intravenous Injection
5. Jet injector
6. Magnetic Jet injector
7. Wearable Injector Pack

Non-injectors

8. Epinephrine Inhaler
9. Sublingual delivery
10. Intranasal Spray
11. Epinephrine Patch
12. Implantable pump

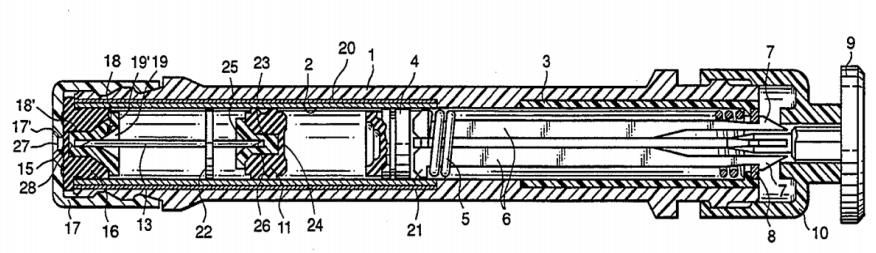
1. IM Autoinjector (Reference)

- Only current existing FDA approved solution
- EpiPen, the “Gold Standard”
- Activation (via force on needle cover) releases a spring which forces the needle into the leg and forces a plunger into a prefilled cartridge, injecting the epinephrine solution
- Estimated 89 Newtons of dynamic force on plunge
- IM offers best onset of absorption (less than 5 minutes to peak), best plasma concentration over time, and is easy and quick to use
- 15 mm 22 gauge needle, causes risk of wrong injection length
- Failed static load of 400 N



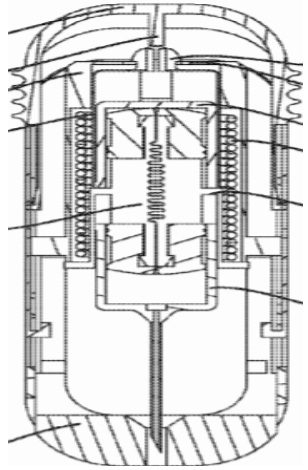
2. Subcutaneous Injector

- Similar to IM injector, uses a spring-plunger mechanism to drive needle into tissue
- Small needle (1 to 4 mm), less force needed to drive it



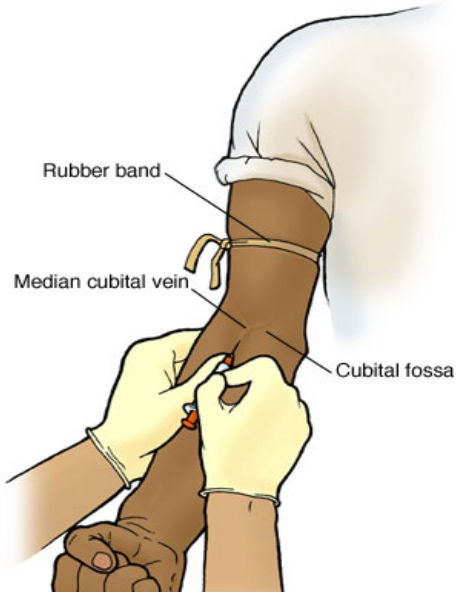
3. Improved IM injector

- Smaller, portable, voice guided walkthrough
- Separation of dry and wet ingredients that are mixed together during activation and injected as one solution
- Adjustable needle length, replaceable cartridges



4. Intravenous injection

- Direct injection into bloodstream
- Less epinephrine (.1 mg)
- Injection given at an angle and must pierce vein

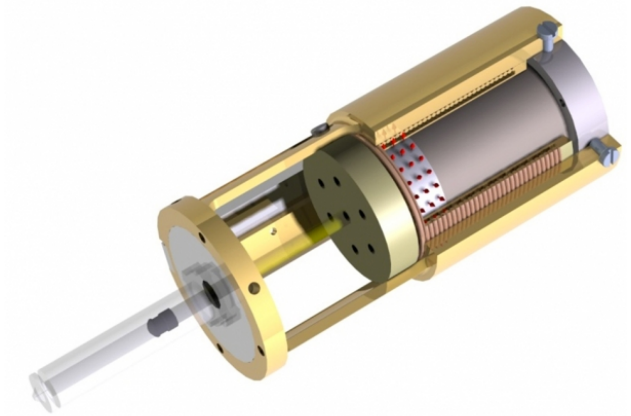


5. Jet injector

- ”Needle-free”
- Previously used in mass vaccination to avoid needle-stick injuries and cross-contamination
- Large pressures (4-40 MPa) created by spring to shoot solution
- Small needle to assist injection

6. Magnetic Jet injector

- Uses electromagnetic actuator to create mechanical force (instead of spring or gas)
- 200 Volts applied to a coil actuator moves a plunger, creating 20 MPa that drives fluid beneath a patient's skin.



7. Wearable Injector Pack

- Device that can be attached to the body and deliver epinephrine by pushing a button (like insulin packs)
- Button causes needle to inject tissue and deliver medication
- Portable, worn around leg

8. Epinephrine Inhaler

- Inhalable solution, similar to treatments for asthma
- Applied pressure sprays solution which is breathed in and absorbed in alveoli

9. Sublingual Delivery

- 40 mg tablet
- Absorbed through mucus membrane under tongue

10. Intranasal Spray 11. Epinephrine Patch 12. Implantable Pump

- Insufflation, absorbed through mucus membrane in nasal cavity
- Downward force on the top causes pressure differential which shoots fluid out a small opening

- Skin patch coated with epinephrine designed to diffuse across skin
- Difficult to make epinephrine transfer subdermally

- Invasive, pump surgically placed on muscle
- Automatically apply medication (sensing histamines) or apply on command by patient

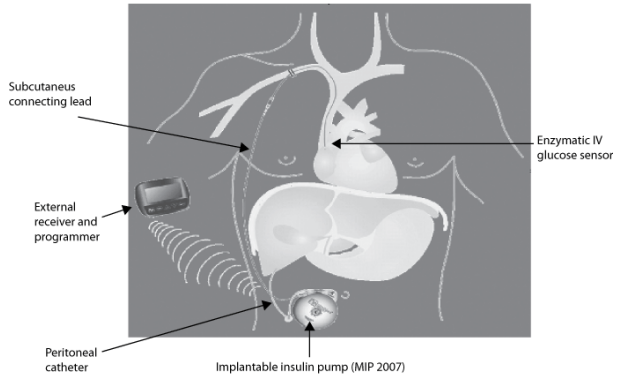


Figure 1. Scheme of human implantation of the Long-Term Sensor System® (LTSS, Medtronic-MiniMed), a prototype of implantable artificial beta-cell.

Design Analysis

Ranked lowest on Pugh Chart

2. Subcutaneous Injector- Poor absorption and plasma concentration

4. Intravenous Injection- Preparation too long, negative health effects

7. Wearable Injector Pack- Not portable, IM injection not feasible

11. Epinephrine Patch- Poor absorption, plasma concentration, and accuracy

12. Implantable pump- too invasive, risk of safety and longevity

Ranked highest on Pugh Chart

1. IM Autoinjector (REFERENCE)

3. Improved IM Injector

5. Jet injector

6. Magnetic Jet injector

8. Epinephrine Inhaler

10. Intranasal Spray

Design Analysis (continued)

- Injector designs outperformed non-injectors for absorption, accuracy, and plasma concentration
- Inhaler ease of use very low- can't apply if not breathing
- Non-injectors had less invasiveness and better safety
- Best design options from whole Pugh Chart were Jet injector and improved IM injector

Abbreviated Pugh Chart

Design specification	Design Specification goal	Specification weight	IM injector (EpiPen)	Improved IM injector (Auvi-Q)	Intranasal Spray	Epinephrine Inhaler	Jet injector (IM)	Magnetic Jet Injector
Onset of absorption	<= 5 minutes	10	10	10	5	10	10	10
Dose Accuracy	95% of epinephrine dose	10	9	9	5	7	8	8
Preparation + delivery time	Can be applied in under 10 seconds, does not require electrical power	10	8	7	9	8	9	5
Ease of use	Can be admnistered by someone else if not breathing/conscious	10	8	8	9	1	8	7
Plasma concentration over time	20,000 pg/mL after 40 minutes	9	9	9	5	5	9	9
Longevity	Lasts > 1 year	8	5	7	5	9	6	6
Weight durability	Can withstand 400 Newtons of applied force and still function	8	4	4	4	4	6	6
Invasiveness	Penetrates skin minimal amount needed to apply dose	7	3	3	9	9	5	5
Safety after use	Retractable needle/no sharp parts revealed	7	8	8	10	10	9	9
		Total	1213	1245	1144	1153	1273	1167
		Rank	REFERENCE	2	5	4	1	3

Chosen Design

JET INJECTOR

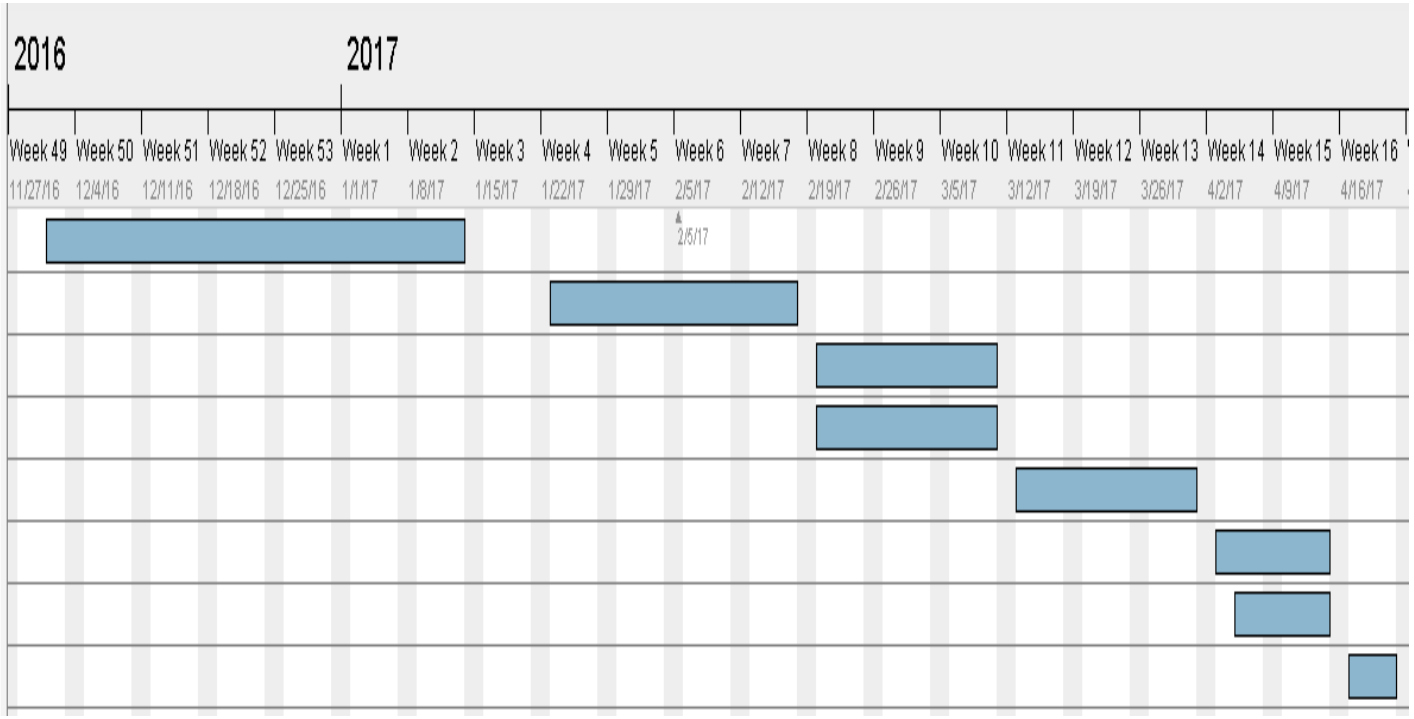
- small needle to assist injection (less than 10 mm)
- Spring mechanism with large spring constant to reach intramuscularly
- Safety to prevent accidental use, needle cover, straight-forward instructions
- Plastic with steel reinforcement for durability
- Portable design (size of a cell phone)

Component	Price ($)
2 3CC syringes + 22G needles	14.99
Stainless Steel tube	8.25/ft
Various plastic pieces	Varies (3D printed)
Knox gelatin 16 oz (For ballistic gel testing)	12.00
Compression spring	25

Estimated costs were very low; we will not be requesting any funds.

Current Design Schedule

Name	Begin date	End date
Design Brainstorming	12/1/16	1/13/17
CAD Drawing	1/23/17	2/17/17
Verification and Validation	2/20/17	3/10/17
Material Acquisitions	2/20/17	3/10/17
Initial Prototype Development	3/13/17	3/31/17
Prototype Testing	4/3/17	4/14/17
Revisions	4/5/17	4/14/17
Final Prototype Creation	4/17/17	4/21/17



Team Responsibilities remained the same

Thanks

Questions?