Case studies from classes led by Dr. Ron Fulbright, University of South Carolina Upstate.

INNOVATIVE ANALYSIS

VISCOUS INJECTIONS

BRIEF DESCRIPTION OF THE SITUATION

Controlled-release pharmaceuticals deliver active ingredients over a period of days, weeks, or even months but many require subcutaneous delivery of high viscosity (thick) formulations. Unfortunately, the high viscosities required for these formulations cause significant problems when administering the dose with traditional injection devices (hypodermic needles). For example, injection of a high viscosity formulation will typically exhibit significant back-pressure as the formulation is forced through a hypodermic needle causing excessive fatigue on the part of the administrator accompanied by discomfort in the recipient. Lack of accuracy in the administered dose is often commonly encountered due to the difficulty of minimizing residual product remaining in the dosing device.

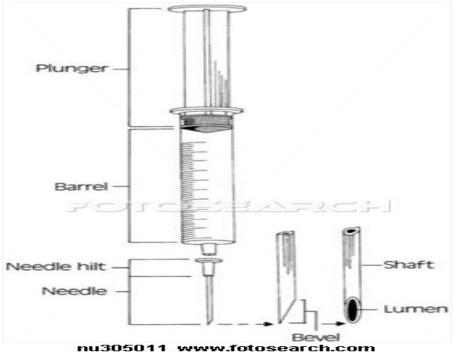
The challenge is for a way to allow accurate and precise, subcutaneous delivery of a highly viscous formulation. A traditional syringe pump is not practical because of the expense (on the order of thousands of dollars), bulk, and requirement for alternating current (AC) electricity. Direct injection of the formulation by air pressure will probably not be effective. It is anticipated that such a process would result in a "donut effect" – only the formulation in the center of the device would be delivered, and the formulation around the outer edges would remain in the device. Also of concern is the problem of bending and breaking the device given the anticipated higher stress forces.

The device should be capable of handling formulations with viscosities up to 20,000-25,000 centipoise. (For comparison, at room temperature water has a viscosity of ~1 centipoise and honey has a viscosity of 2,000-10,000 centipoise.) The formulation is a Newtonian fluid (viscosity is constant regardless of shear force). For additional analogous liquids, please consider glycerin, heavy oil, or corn syrup (low end of the viscosity range) to higher viscosity liquids such as would be found in a thick (sugar) syrup or commercial glue formulation. The device should be capable of delivering volumes as low as 0.1 mL and as high as 5.0 mL.

The amount of trauma to the patient should be no more than that experienced with a traditional syringe equipped with an 18 gauge needle. For instance, delivering the formulation through something as large in diameter as a drinking straw would not be an acceptable solution. The physical effort required to administer the dose should be kept to a minimum, as a single person may be required to administer as many as 100+ doses in the course of a day without suffering undue fatigue. The device should be portable and as small as possible. While this device may be used in a modern, clinical setting, it would ideally be amenable to use under more rudimentary conditions (e.g. remote locations without AC electricity).

2. DETAILED DESCRIPTION OF THE SITUATION

2.1 SUPERSYTEM/SUBSYSTEM ANALYSIS



Needles are hollow, slender, sharp-pointed instruments used for injections or aspirations. They are made simple and disposable in recent years but there are several different kinds of needles such as: aneurysm needles, aspirations needles, cataract needles, discussion needles, hypodermic needles, stop needles, and transseptal needles. They all have the same general parts, a hollow point needle which can detach, the body of the needle, and the syringe which includes the plunger. The needle has 3 parts: the shaft, lumen, and bevel. The shaft is the long, hollow body of the needle. The lumen is the actual interior diameter of a needle. The lumen measurement is variable depending on the thickness of the catheter material. In general, the higher the needles gauge, the smaller the diameter of the lumen. The bevel is the slanted shape of the tip that helps prevent splintering. The middle piece that connects the needle with the syringe is called the needle hilt. The hilt is used more to administer medicines through an IV that doesn't require a needle. The syringe is made of a barrel and a plunger that is inserted inside the barrel to cause the liquid to be pushed through or pulled out of something.

2.2 INPUT/OUTPUT ANALYSIS

In the past needles were more complex and not disposable so more effort was put into cleaning and keeping up the needles to prevent infection from patient to patient. They would have to soak them in alcohol and sterilize them before each use. Once they came up with plastic disposable needles, the effect put into injections was cut in half. More training is needed for the person administering the injection than on how to use it.

Needles and syringes are simple instruments. Not much is needed to go in or out of it other than the needle with the syringe, medicine, a patient, and a nurse/doctor or properly certified phlebotomist. The medicine is pulled through the needle to the appropriate level. Once injection is prepared, insert the needle into desired spot on body then push the medicine through with as little movement as possible. Medicine gets put into the needle as well as put out. Doctors and nurses also use these syringes to draw blood or other liquids out of the body.

2.3 CAUSE/EFFECT ANALYSIS

Needles and syringes can only perform certain task. Needles will either go in you to administer some sort of liquid or draw liquid out of you. The needle itself doesn't actually do the pulling and pushing of the liquid into the barrel. The needle is attached to a syringe that the medicine is kept in. If the plunger is pushed all the way in towards the needle hilt, dip the tip of the needle into whatever liquid you're wanting. Once the tip is submerged into the liquid, pull the plunger slowly up to the desired amount labeled on the barrel. The suction will pull the liquid through the hollow needle and into the barrel of the syringe.

Pushing the liquid out of the syringe is much easier than pulling it in. Just place the needle into desired object then slowly push the plunger back into the barrel of the syringe until no liquid is left inside the barrel.

2.4 PAST/FUTURE ANALYSIS

Needles are slender, usually sharp-pointed instrument used for puncturing tissues, suturing, or passing a ligature around an artery. Needles and syringes have changed over time. Before the hollow point needle was invented they used to have to cut a hole into someone's body wherever they wanted the medicine administered. They would then place a tube into their body at the hole and push medicine through. It is obvious that would be a very painful way to receive a shot, luckily in 1844 an Irish physician Francis Rynd invented the hollow needle.

The hollow needle allowed the doctor to push liquid through something much smaller than a tube which would be less painful for the patient. Two physicians developed the first practical hypodermic syringes in 1853, which put together a metal syringe and the hollow pointed needle that could penetrate the skin without the need to cut an opening. These two physicians were Alexander wood (Scottish) and Charles Pravas (French).

The needles were made of glass and metal which was expensive to make and had to be sterilized and reused. Infections were being spread from patient to patient at a rapid rate. The needle companies were beginning to worry that this up rise in hospital acquired infection would hurt their future business. An improvement needed to be made.

Arthur E. Smith received eight U.S. patents for a disposable syringe from 1949-1950 even though it was Becton, Dickinson and Company (BD) who eventually mass produced the first glass disposable syringes in 1954, called the BD Hypak. In 1955 Roehr Products worried about the litigation that could arise from infection caused by the use of their syringes, they put their heads together and came up with the world's first plastic disposable hypodermic syringe called the Monoject, which they sold for only 5 cents each. Doctor were very skeptical to use the new plastic syringes, they still believed sterilizing them was a safer, cleaner approach. Nowadays needles are made in all different sizes, all disposable, thinner, shorter, and safer to make receiving them much easier on the patient.

3. RESOURCES, CONSTRAINTS, AND LIMITATIONS

3.1 AVAILABLE RESOURCES

– Needle (metal ingredients vary, metallic, metal ore)

– syringe (plastic or glass ingredients vary, carbon, hydrogen, oxygen, petroleum, sulfur, acetone, styrofoam, polystyrene, polyvinyl chloride, nylon, etc.)

– plunger (plastic/rubber ingredients vary, hydrogen, oxygen, petroleum, sulfur, acetone, styrofoam, polystyrene, polyvinyl chloride, nylon, rubber tree, rubber sap)

– person that administers the injection

– patient

– liquid medicine (ingredients vary depending on the medicine)

– patient's skin

– pressure created inside the syringe by the plunger

3.2 ALLOWABLE CHANGES TO THE SYSTEM

Replacing parts of the syringe is allowable.

Changing the chemical makeup of the medicine is probably unreasonable.

Making changes to the administrator of the injection or the patient is allowable.

How the medicine is injected could be changed.

3.3 CONSTRAINTS AND LIMITATIONS

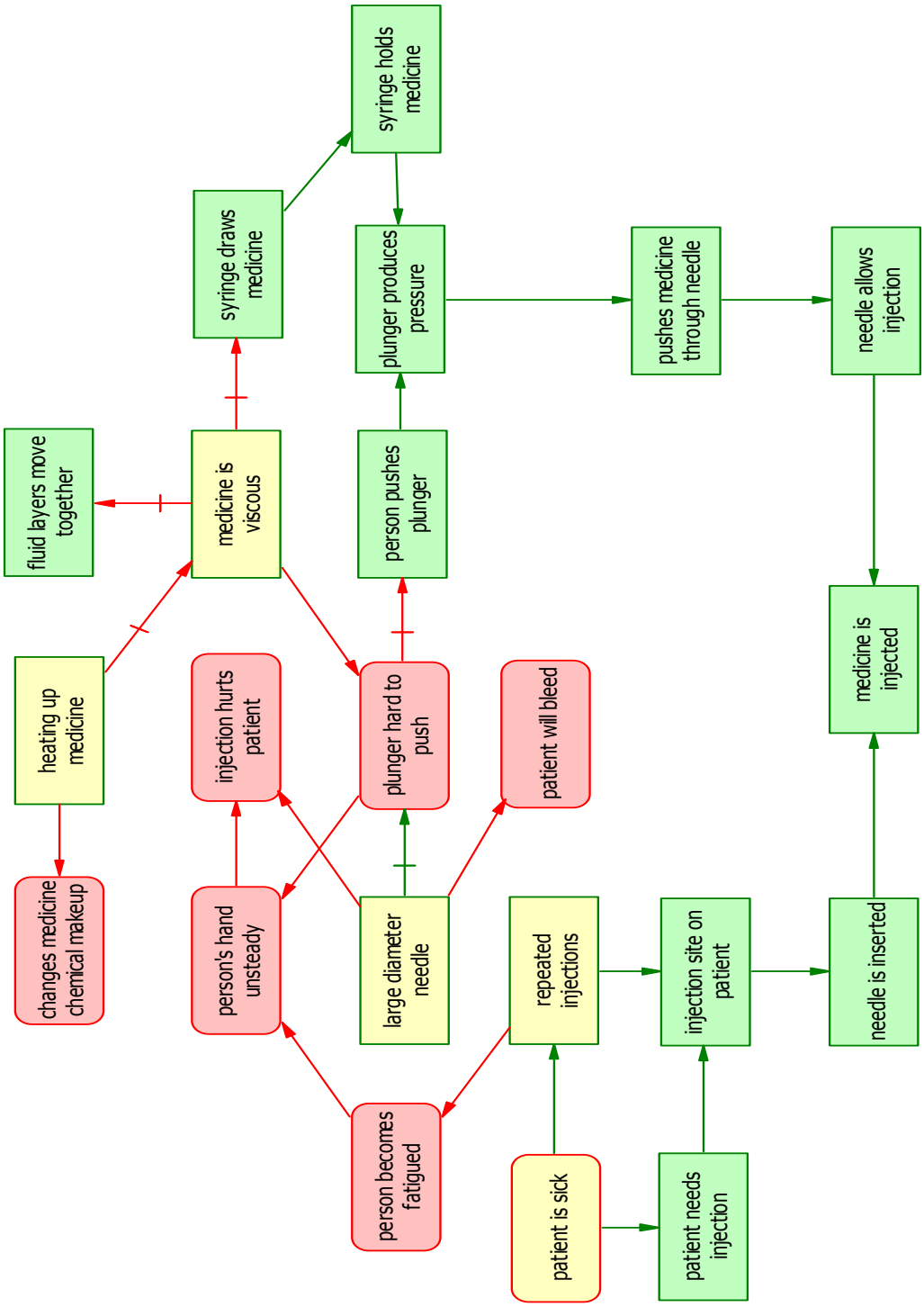
The patient must not feel a lot of pain.

The chemical makeup of the medicine must be kept intact.

The administer must not become fatigued.

The injection must be rather quick.

4. PROBLEM FORMULATION



5. IDEAS

1. **Find a way to eliminate, reduce, or prevent *plunger hard to push* in order to avoid *person's hand unsteady* under the conditions of *medicine is viscous*.**

    Introduce an additive with stored energy - Eliminate the plunger and have the syringe hooked up to a mechanical pump that administers the medicine.

2. **Find an alternative way to obtain *needle allows injection* that offers the following: provides or enhances *medicine is injected* does not require *pushes medicine through needle*.**

    Use other systems - The medicine can be put in a patch that is put on your arm and the medicine is absorbed through the skin.

3. **Find a way to eliminate, reduce, or prevent *injection hurts patient* under the conditions of *person's hand unsteady* and *large diameter needle*.**

    Introduce an isolating substance - The injection site on the patient can be numbed before the injection to eliminate the pain.

4. **Find an alternative way to obtain *heating up medicine* that offers the following: does not cause *changes medicine chemical makeup* does not influence *medicine is viscous*.**

    Integrate to obtain new properties - The medicine can be heated, but careful not to overheat and breakdown the medicine, then injected easier.

5. **Find a way to eliminate, reduce, or prevent *plunger hard to push* in order to avoid *person's hand unsteady* under the conditions of *medicine is viscous*.**

    Introduce an isolating substance - The rubber end of the plunger can be changed to reduce the friction that is caused by it rubbing on the sides of the syringe, allowing for it to be pushed easier.

6. **Find an alternative way to obtain *medicine is injected* that does not require needle is inserted and needle allows injection.**

    Use other systems - The viscous medicine can be put into pill form which when taken will absorb into the blood stream.

7. **Find a way to eliminate, reduce, or prevent *injection hurts patient* under the conditions of *person's hand unsteady* and *large diameter needle*.**

    Introduce an isolating substance - The patient can be put to sleep during the injection to eliminate pain.

8. **Find an alternative way to obtain *pushes medicine through needle* that offers the following: provides or enhances *needle allows injection* does not require *plunger produces pressure*.**

    Substitute a field - The syringe can be spinning which could drawn the layers of liquid out

into the needle by centrifugal force, allowing for easier flow of the liquid.

9. **Find a way to eliminate, reduce, or prevent *injection hurts patient* under the conditions of *person's hand unsteady* and *large diameter needle*.**

Use other systems - The viscous medicine can be administered through and IV to slowly inject the medicine, reducing pain on the patient and strain on the nurse.

10. **Find an alternative way to obtain *medicine is injected* that does not require *needle is inserted* and *needle allows injection*.**

Remove a substance or a part - Remove the straight needle and the syringe and create a flat strip that has very small fiber glass ridges and a small compartment for the medicine to be stored within the strip. Place it on the skin and it will create tiny painless cuts in the skin that will allow an opening for the medication to seep through.

11. **Find an alternative way to obtain *medicine is injected* that does not require *needle is inserted* and *needle allows injection*.**

Remove a substance or a part - Needle- less injections, the medicine is turned into shape changing crystals that can be inserted through the skin by a needle-less syringe that uses air pressure.

12. **Find an alternative way to obtain *needle allows injection* that offers the following: provides or enhances *medicine is injected* does not require *pushes medicine through needle*.**

Integrate for new properties - A small flat strip that is made entirely of the medication. Create one flat side and then one ridged side that can cut into the skin at a microscopic level so there is no pain. Place a band aid over the flat strip and with the heat from your skin, the medicine will slowly dissolve. Within a day the band aid can be removed and nothing is left. (Similar to dissolvable stitches or dissolvable staples)

13. **Find a way to eliminate, reduce, or prevent *changes medicine chemical makeup* under the conditions of *heating up medicine*.**

Pulverize - Freeze the medication until it becomes a solid. Crush it up into powder and administer either as powder or change to gas.

14. **Find an alternative way to obtain *syringe draws medicine* that offers the following: provides or enhances *syringe holds medicine* is not influenced by *medicine is viscous*.**

Change the state of the system - Separate the liquid within the barrel to make the pushing easier.

15. **Find an alternative way to obtain *needle allows injection* that offers the following: provides or enhances *medicine is injected* does not require *pushes medicine through needle*.**

Use a disposable object - Create a needle that has a dissolvable tip so when inserted it acts as the medicine and stays in the body.

16. **Find an alternative way to obtain *fluid layers move together* that is not influenced by *medicine is viscous*.**

Add object with required properties - Inside the hollow needles put ridges along the sides to help break down the thick liquid.

17. **Find an alternative way to obtain *large diameter needle* that offers the following: eliminates, reduces, or prevents *plunger hard to push* does not cause *injection hurts patient* and *patient will bleed*.**

Introducing an isolating substance - Separate the medication within the syringe so that it doesn't become thick until in the body. (Drano bottle)

18. **Find a way to eliminate, reduce, or prevent *injection hurts patient* under the conditions of *person's hand unsteady* and *large diameter needle*.**

Integrates for new properties - Have the tip of the needle be dipped in lidocaine to numb the skin before puncturing it.

19. **Find an alternative way to obtain *person pushes plunger* that offers the following: provides or enhances *plunger produces pressure* is not influenced by *plunger hard to push*.**

Use inexpensive objects - Have a rubber band holding the plunger to create the pressure behind the syringe to eliminate the nurse's shaky hand.

20. **Find an alternative way to obtain *needle is inserted* that offers the following: provides or enhances *medicine is injected* does not require *injection site on patient*.**

Use other systems - Change the medicine to a dissolvable strip that you can place on your tongue and it dissolve.

21. **Find an alternative way to obtain *syringe holds medicine* that offers the following: provides or enhances *plunger produces pressure* does not require *syringe draws medicine*.**

Add an object with required properties - Cloth heating sleeve that goes around the syringe to heat the medicine so to make it thinner and also will help with creating pressure.