The DIY approach in T1 diabetes

Abstract: In this project, we aimed to develop a deep insight into how the type-1 diabetic(T1D) community works to solve their issues without institutional experts. This led to our research question: "How do the type-1 diabetic community create their own knowledge and solve their own issues."

Background:
T1D is a medical condition where the body doesn't produce insulin, as the beta cells that produce insulin are destroyed. T1D doesn't have any cure as of now. People need to take insulin externally, through injections, or by insulin pump. The insulin pump has two types of insulin: bolus and Basal. Bolus is the one which is taken before every meal, so 3 times a day. The Basal is the one that goes in the body for 24 hours, like an artificial pancreas. The main organs affected by diabetes are the eyes(diabetic retinopathy), the foot(diabetic foot), and the kidney. It comes under disability.

T1 diabetics have been solving their issues using the knowledge they created. A significant example is the hashtag #WeAreNotWaiting, which represents OpenAPS. This DIY looping community created their self-looping insulin pump to rival the medical companies as the cost was very high. This is a type of lead user innovation.

Tidepool, a lead user innovator company, came up with their looping system, which got approved by the FDA, making it a historical moment where a lead-user innovator got approved by an authority. After this, another company called beta-bionics got their pump approved by the FDA.

Journey:
1) Self-introspection
We started this project by me describing type-1 diabetes from my personal experience. We first covered the basics of T1D, including the impact of high sugar and low sugar, how insulin is calculated based on food and blood sugar levels, exercise and its effects, and puberty and its impact on glucose levels.

Next, we compared t1d in India vs t1d in the US. In India, Medtronic is the only company that sells insulin pumps and CGM(Continuous glucose monitoring device). CGMs are very expensive devices in India. In the US, people have more options like Omnipod, t:slim in insulin pump, and in CGM options like Dexcom. The main problem in the US is cost, too. **Cost is also the main factor for many innovations in T1D.**

One of the main questions we were looking for was the challenges, especially the challenges faced by the T1D in India vs in the US. For me, the biggest challenge was patch site infection caused by the insulin pump, a very typical insulin pump issue.
Then, we looked at different design framings & processes of this approach:
- **Tech-driven** – design and build something – put it out there - "build and they shall come."
- **Human-centered** – study people to identify their needs, then get back to the whiteboard to solve the "critical" issues (sometimes these might not be what people say/think are the critical issues)
- **Lead user** – study people to identify their challenges AND their attempts at fixing them.

Major Directions:

Make a system that gathers information from a community forum(informal people) and helps the people with their experience, including formal people(doctor, dietician, diabetologist).
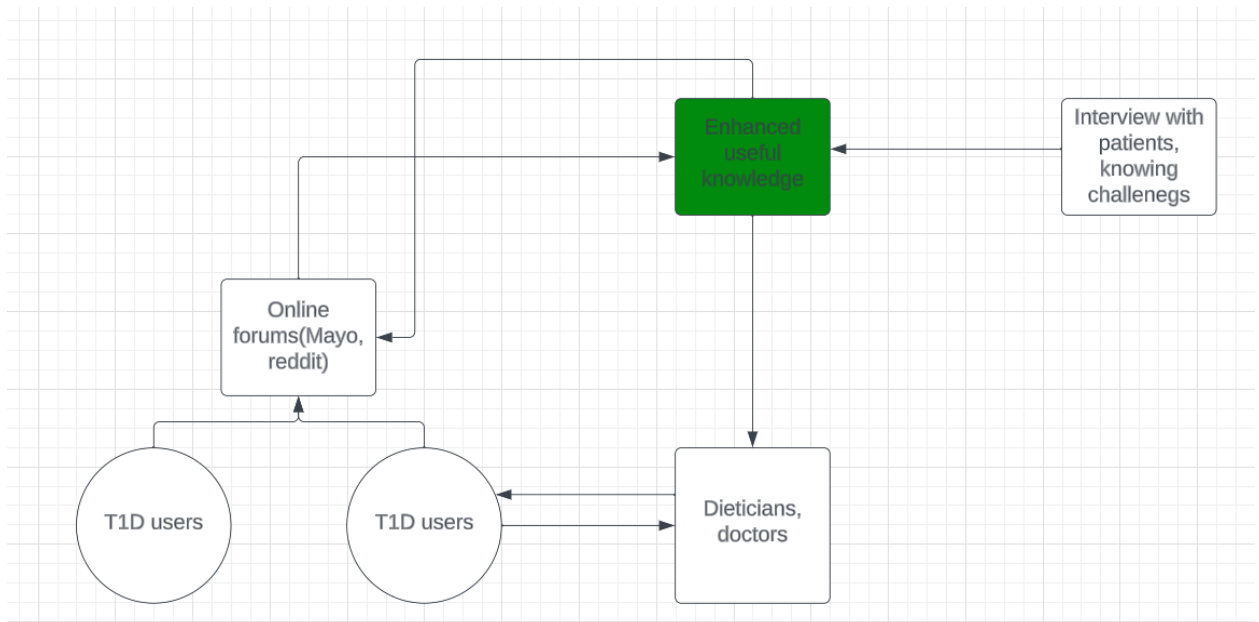
Lead user-
This would be Tidepool loop, Beta-bionics, and other amazing stuff.
Tinkering community(not the same diabetic community): can their knowledge be shared with remote places(countries and states?)
Lead user innovation in India: The tinkering that happens here is indigenous and unique. Can it be improved using lead users from the US?

T1 data literacy-
A lot of data is generated for the T1. Thanks to tidepool. Visualization is being done to understand the sugar level trends, insulin trends, patch changes trends, and infer information.
For example, My pre-lunch bolus(meal insulin) was extremely high in covid(no exercise). This would include Data hunch.

Self ethnography- means writing about something with personal experience(almost scrapped).

2) Social Sites
Before interviewing people and asking them about their experiences, we started looking at social media sites to answer the question, "How do people with t1d debug questions/issues with the devices?"
We looked at sites like PatientsLikeMe, Mayo, Reddit for 2 type-1 diabetic communities, and Twitter.

PatientsLikeMe: It didn't have updated information about t1d.
Mayo: It focused more on diabetes and endocrinology, not type-1 diabetics.
Reddit: Various helpful information was gathered from Reddit, but it was general insight
Twitter: hashtags like #WeAreNotWaiting, #t1d, #diabetes, #dexcom, etc were searched. A handy hashtag, #GBdoc was discovered. It stands for Great Britain with diabetes.
One thing was sure: a lot of data was being generated, particularly on Twitter. See, we looked at many tweets from the relevant hashtags.
After looking at the tweets, some hypotheses were made:
- Tweets with visuals about T1D have claims and proof structure.
- A claim is noted in the text, and proof is in the visuals, and visuals show trends like data.
- The reader requires prior knowledge to understand the 1st and 2nd hypotheses.

3) Evidence Pyramid
Since we saw tweets in the form of some evidence, we decided to study the evidence pyramid and apply it to the diabetic setting.
Evidence pyramids link:
1. Background information and expert opinion: Websites, textbooks, expert opinion on blogs/websites(e.g., doctor about procedure).
2. Case report: Unique cases, but usually detailed reports of symptoms, treatments, etc of an individual patient.
3. Cohort studies: Observational studies

4. Randomized control trials: Asses a drug or treatment to a group of random people. It is known as clinical trials.
5. Critically appraised topics: Short summary of evidence on a topic. Guidelines are used. Gives harms and benefits of clinical and educational questions. It takes too much time. Short life when newer evidence becomes available. 1-2 studies and researchers.
6. Systematic review: Systematic approach to literature to reduce random error and bias. Published in Pubmed. Conducted with transparent and repeatable knowledge while considering all of the published evidence. Not with just review's prior knowledge. Mentions all the studies addressing specific clinical questions in the literature in a database. Allows to take account of a whole range of clinical findings on a particular topic.
7. Meta-analysis: Quantitative methods to summarize systematic reviews.

Evidence Pyramid with respect to diabetes:
1. Background info: Reddit and Twitter information regarding machines.
2. Cohort studies: Regarding a particular food, say artificial sweetener, and how people react to it.

   Or with different foods and see how it increases blood sugar. Say some biscuit vs Oreo.
   Foods that are said to be low/no calories, but they have calories.
3. Randomized controlled trials: (this is done for medicines) Test hypotheses like cinnamon reduces blood sugar or not.

Also, to understand how a community develops their solution, ALS communities were studied in 3 papers. The ALS community is a prominent example of how a community worked together to solve their own issues when no one was listening to them.

1. **Italy paper that showed slowing of ALS:**
   a. Mice were the primary subjects to test. ALS-FRS-R and Norris scales were used. Approved by the Neuromed IRCCS Ethical Committee.
   b. Success in mice prompted researchers to go for humans.
   c. Survival rate was the primary factor, and the secondary factor was ALSFRS-R.
   d. Survival analysis was performed using the Kaplan–Meier curve.
   e. The main effort would have been to analyze the rat and the human population.

2. **Main ALS paper:**
   a. PatientslikeMe matching algorithm used to get the control group.
   b. Even though they failed, there were some things mentioned regarding this. More like advantages:
      i. It was fast.
      ii. World wide access to patients, no bias towards some living near specialist centers.
      iii. Availability of control participants.
      iv. Cost
      v. Patient engagement among themselves.
   c. Patients were reporting their own self-improvement.
   d. Highly motivated to submit data as there is no treatment.
   e. Effort: definitely less as you deal with the public on a platform.
   f. The best thing about this experiment: PLM.

3. **NIH paper:**
   a. Blinded, placebo, something not done in previous papers.
   b. Involved FDA
   c. Patients are lab tested that they have ALS.

4) The study:
The last step was designing a study for a particular experiment: How does artificial sweetener affect the blood sugar level? We created the study and examined at a particular step how much effort is required by the T1D community and how much effort is required by the institutional scientists, considering they have more resources than the T1D community.

Primary Objective: To check if artificial sweeteners increase the blood glucose level or not.

Primary Outcome: Blood glucose level(mg/dL).

Items needed:
1. Artificial sweetener: Primary substance, used to add sweetness to substance without sugar.
2. CGM: Used to monitor sugar levels 24X7.
3. Glucometer: Used to monitor sugar levels at a particular time.

End of study: The period of the whole experiment would be 30 days.Performing the experiment 3 times a week with 1 day gap and 2 day gap(M, W, Sat repeat). So, there are a total of 12 readings.
We divided the efforts into four categories for every stage: knowledge, time, financial resources, and institutional tools and instruments.

1 - knowledge: T1D: need to engage with someone who knows about experimenting, or else educate themselves.

Ins scientists: they can have specific knowledge about the washout period, how long the study would be effective.

2 - time: T1D: need to make time for the experiment. Allot time for this experiment.

Ins scientists: Subjects might only be engaged for this experiment.

3 - financial resources T1D: They need to collaborate with some support group for cheap/free supplies, or else engage with hospitals.
Ins scientists: Supplies won't be an issue.

4 - institutional tools and instruments etc: not relevant

Subject population: Age group 18-45 type-1 diabetic and disease duration > 5 years. People who don't usually consume artificial sweeteners.

4 - institutional tools and instruments etc:
T1D: They would need to expand their circle. Ex: collaborate with the T1D community of other states. Otherwise, they would need to collaborate with the hospital.

Ins scientists: I think they would have a bigger patient network, containing patients with a wide age range and disease age.

Exclusion:
- Pregnant people
- People with high Hba1c(>7.5)
- People with allergies to artificial sweeteners.

1- knowledge and institutional tools:
T1D: Self-assessment is what they usually do. They need to engage with doctors and laboratories to do this stuff.

Ins scientists: They can do sensitivity tests and other tests they think are relevant to perform these.

Procedure:
Step-1) Consume artificial sweetener(one can of Diet Coke (aspartame) or one packet of Splenda (sucralose)) with lunch.

Step-2) For aspartame, consume 1 can of Diet Coke; for sucralose, use one packet with tea/coffee.
1- knowledge: T1D: Need to have this knowledge.

Ins scientists: To have the perfect results, need a particular mixture to consume artificial sweetener(or anything), which can be provided. Again, for this, doctors are required.

2- Financial resources: T1D: They would require money if the product is costly/needs sponsors.

Ins scientists: Money won't be an issue.

Step-3) Take a post lunch that is after 2 hours.

4- institutional tools and instruments etc. T1D: They need to engage with a lab else just do it with CGM.

Ins scientists: For best results, nurses can take out blood for post-meal sugar level.

Step-4) Take a reading after 3 hours as well with a glucometer. (Sometimes carbohydrates take longer to digest fully, so the peak might come at 3 hours rather than the general 2 hours).

Restrictions during the study:
1. Consume habitual food and be in a habitual routine.
2. Avoid extensive exercise as it may change the reading.
3. You can take another 250 ml of caffeine, but not more than that.
4. Alcohol intake to no more than two units of alcohol per day (unit = 10 mL pure alcohol) due to the effect of alcohol on blood glucose.

3- time: T1D: For perfect results, they need to alter their lifestyles for the experiment. (Consume less caffeine, alcohol, etc.)

Ins scientists: The same thing, but patients are likely willing due to incentives.

Conclusion:

We saw a deep insight into the T1D community, which helped us to understand how they function, what issues they face daily, and most importantly, how they create their own knowledge to solve their own issues/ create without the help of institutional scientists.

Work referred:

[Data hunches](#): Used to understand data literacy.
[Thinking in systems:](#) Used to understand how interventions work.
[Study inspiration](#): Used to design the study.