Requirements Specification





DoseBot is an app designed to help TB sufferers adhere to their medication schedules. DoseBot never forgets – so you can.

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6 February 2017	1.0	Final	DigitalMob

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Changes since last version

Sections 4 - 7 completed with references and appendixes added at the end.

Known Omissions

None



Approvals				
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Reviewers Comments

No comments



1. Introduction

1.2. Intended Audience

This proof of concept document has been compiled for the following groups of people.

Team members:

Client, product owner, developers, designers, project managers and marketeers.

Investors and other interested parties:

- 1. Governments public health care
- 2. Pharmaceutical companies
- 3. Private investors data capture
- 4. Medical research institutions data capture
- 5. Health insurers/medical aids reduce outgoing payments for drugs
- 6. World Health Organisation (WHO)
- 7. Medical health care professionals

End users

TB sufferers. It is reported that there were 10.4 million TB sufferers worldwide in 2015 (WHO). The majority of TB patients live across China, India, Indonesia, Nigeria, Pakistan & South Africa. Those 6 countries account for 60% of TB cases worldwide. The ratio of male to female TB sufferers is 2:1, with the majority (65-68%) in the young and reproductive age group and approx $\frac{1}{2}$ in the geriatric age group $\frac{1}{2}$. The figure on childhood TB is approx 1m reported cases in 2015^2 .

² http://www.who.int/mediacentre/factsheets/fs104/en/



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¹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2860414/

1.3. Definitions, Acronyms and Abbreviations

UCD: User Centred Design is a framework of processes (not restricted to interfaces or technologies) in which the needs, wants, and limitations of end users of a product, service or process are given extensive attention at each stage of the design process³.

TB: Tuberculosis, commonly known as TB, is a bacterial infection that can spread through the lymph nodes and bloodstream to any organ in your body. It is most often found in the lungs.

MDR-TB: Multi-drug-resistant tuberculosis (also known as Vank's disease) is defined as a form of TB infection caused by bacteria that are resistant to treatment with at least two of the most powerful first-line anti-TB drugs, Isoniazid (INH) and Rifampicin (RMP).

Adherence: means "to stick firmly." So for people with TB, medication adherence means sticking firmly to a TB regimen—taking TB medicines every day and exactly as prescribed.

Comorbidity: In medicine, comorbidity is the presence of one or more additional diseases or disorders co-occurring with a primary disease or disorder.

DOTS (directly observed treatment, short-course) is the name given to the tuberculosis control strategy recommended by the World Health Organization. According to WHO, "The most cost-effective way to stop the spread of TB in communities with a high incidence is by curing it.

HIV/AIDS: Human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS) is a spectrum of conditions caused by infection with the human immunodeficiency virus (HIV).

PRN: Some medications come with specific instructions for use every day, such as "Take 1 tablet by mouth every 8 hours." ... Medicines that are taken "as needed" are known as "PRN" medicines. "PRN" is a Latin term that stands for "pro re nata," which means "as the thing is needed."

USP: A unique selling proposition (USP, also seen as unique selling point) is a factor that differentiates a product from its competitors, such as the lowest cost, the highest quality or the first-ever product of its kind. A USP could be thought of as "what you have that competitors don't."

Affordance: The affordance of an object gives the user hints about how to use the object.

Mental Models: are conscious or unconscious psychological representations of situations users encounter. These could be hypothetical, real or fictional and lead users to expect certain results and make them behave in certain ways.

Requirements Specification: A document that describes the high level functional requirements of the system to be developed.

³ https://en.wikipedia.org/wiki/User-centered_design



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2. Identifying the Need

2.1. Concept Overview

The greatest risk we face with TB is related to sufferers not sticking to their treatment plan. This can lead to the development of drug resistant TB which adds strain to the system, posing a bigger risk to non-sufferers and greatly reducing the chances of survival. Patients do not sabotage themselves, but when faced with 6 – 30 months of treatment which includes a handful of pills every day, it's easy to forget. Unfortunately, forgetting to take pills can derail treatment, by giving the TB bacteria an opportunity to build resistance against the medication.

DoseBot is a medicine adherence system that empowers and encourages TB sufferers to stick to their treatment. It helps them deal with the psychological and clinical effects of the disease, while providing a simple reminder to take their pills and gives them personal metrics based on their progress.

Doctors or healthcare providers setup the pill schedule, prescribe the medication in a smart dispenser and track patients and their adherence to their treatment plans. They get alerted when a patient misses a dose and can make contact immediately. At the same time the app will start to prompt the patient until they take their medication.

2.2. User Needs

Drug treatment is the only effective treatment for Tuberculosis⁴. The medication regime for a TB patient is lengthy and complex, lasting anywhere from 6-30 months. TB bacteria die very slowly and so a sustained treatment with multiple drugs daily is the only way to completely eradicate TB in the body. Health care providers put patients on a very specific drug regime and unless the patient strictly adheres to this each and every day, their relapse can be fatal. The results of a patient not sticking to this daily medication regime are:

- · TB symptoms worsens.
- · Infection may be harder to treat: drug-resistant TB.
- Other medication may need to be introduced which may not be as effective.
- Patients become contagious again.
- Puts an added weight on the health system.

These points highlight the importance of the patient taking the medication every day for the prescribed time. If successful, the patient will be cured of TB and the goal of ending the global TB epidemic is nearer.

At present the Internationally recommended strategy for TB is DOTS(Directly Observed Treatment, Short course)⁵. DOTS is the direct observation of a patient being treated for

⁵ https://en.wikipedia.org/wiki/DOTS_(Directly_Observed_Treatment,_Short-Course)



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⁴ http://www.tbfacts.org/tb-treatment/

TB by a trained third party. WHO has reported that more than 30 million patients with TB have been treated with its five-element DOTS strategy, resulting in cure rates > 80% and default rates < 10%.

However because direct observation requires strong leadership and a lengthy commitment of human resources, it is not yet universally employed. There is also an argument against this type of direct observation suggesting that it is disrespectful to patients⁷.

Put simply the TB patient's needs for DoseBot, is directly related to their need and desire to 1) cure themselves of TB and 2) to achieve this without constant invasion of a health-care provider, monitoring each and every pill they take for up to 30 months.

DoseBot will act as their assistant on this treatment journey, reminding them what pills to take and when to take them. DoseBot will also send them updates on their progress and offer words of support & motivation. DoseBot will give the patient the confidence to complete this drug treatment journey themselves. But it will also offer the support of their health professional, if and when the need arises.

2.3. Device Affordances

Ideally we want the design and interface to be easy enough for the not so technical person, without boring the more technically advanced. It has to be intuitive with no label or how to use instructions.

The patient's phone will help them identify their medication via a picture of the pill and short description, alert them via a tone or vibration when it's time to take their pills, and provide an intuitive experience using simple buttons, scrolls and the onscreen keyboard when required.

⁷ https://www.ncbi.nlm.nih.gov/pubmed/17943789



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⁶ http://www.who.int/bulletin/volumes/85/5/06-038927/en/

Device Affordances:

Notifications

Onscreen keyboard for text input

Messaging

Raised buttons

Scroll bars

Tabs for navigation.

Device capabilities:

Push notification

Internet connectivity

Storage

Microphone

Sound profile

Calendar

2.4. Competitor Analysis

There are a number of apps similar to DoseBot

- 1. Medisafe https://medisafe.com/
- 2. Dosecast http://www.montunosoftware.com/products/dosecast/about/
- 3. Patient Partner http://www.mycyberdoctor.com/
- 4. MedHelper http://medhelperapp.com/
- 5. My Pillbox http://mypillbox.org/
- 6. Mango Health https://www.mangohealth.com/

Competitors for Analysis

Medisafe: Described as a "virtual pillbox," the app captures the colour and shape of a patient's medications along with their dosages and schedules. It sends the patient push notifications when it's time to take their medication, and notifies a friend or family member if the patient forgets. Medisafe have developed a low-tech version that sends reminders through automated phone calls and SMS messaging for non-smartphone users.

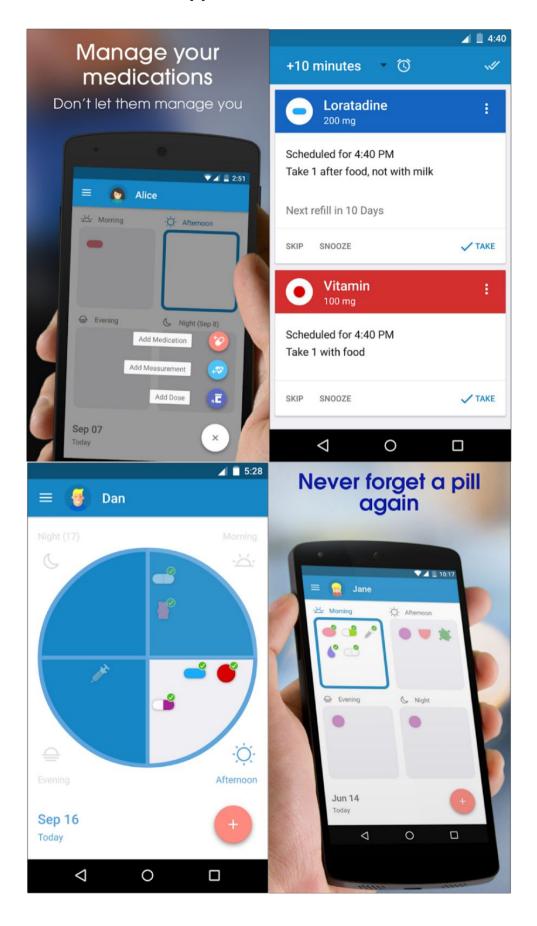
Competitor	Medisafe	
Brief Description	Manages your medications, pills, refills, drug interactions, measurements and doctors' appointments to improve your health. Medisafe is the best pill tracker and planner on the App Store	
Product Features	 Clean and Simple Health App Integration Report Sharing Family Interaction Medtones 	



	 Reminders Refill Reminders PRN Friendly Coupons/ Discounts rewards
Strengths	 Nice easy to use interface Options for alerts and sounds User can customise pill reminder based on day of week Easy to use website Informative help page on website for users with list answers to questions already listed Secure Fingerprint login
Weaknesses	 Version releases appear to come with additional bugs Premium version is costly
Opportunities	 Opportunity for Multi Device Sync Could list a daily health diary on app Opportunity to list drug interaction warnings on app
Threats	 May become known for bugs with version releases so users may move onto another app Major drug manufacturer could bring out their own app New advancements in medicine could mean medicating just once a day
Free/Pay	Free version available plus premium version - Pay
Web/Social Presence	 Nice easy to use and informative website Social Media presence Facebook Twitter Linked-in Instagram Google+
USP	Pharmacists rank Medisafe #1 out of 461 apps they've tested, and MyVCM has recognized Medisafe for HIPAA "leadership and best practices in managing security and compliance."
App Store/ Google Play/ Amazon App store	App Store and Google Play



Screenshots of Medisafe app:





Dosecast: Boasts a range of smart scheduling features for patients. The app adjusts notifications to fit users' bedtimes, provides back-up reminders, and gives users a chance to hit the snooze button on notifications when they're in the middle of something. The frequent traveller never has to worry about missing a dose, since Dosecast tracks any changes in time zone and adjusts scheduling accordingly. The premium edition is perfect for patients taking multiple medications or managing prescriptions for their whole family.

Competitor	Dosecast
Brief Description	Dosecast is an easy-to-use app to help you remember to take your medications, vitamins, or birth control pills on time.
Product Features	 Reliable Notifications Flexible scheduling Customisable dosage amounts and Instructions Postpone-able reminders Smart Scheduling Private and Secure Multi Device Sync Multiple drugs type Dosage history and compliance Quantity tracking refill alert Multi Person Support Doctor and Pharmacist tracking Drug Database Customizable drug photos
Strengths	 Dosecast App adjusts to your changing day enabling you to take your dose early or late Tracks remaining quantities and send refill reminders and logs medication adherence Tracks the time zone you are in, and adjusts the reminders accordingly Enables reminders to be postponed by a custom duration before or after they appear No personally identifiable information is collected
Weaknesses	 Website is poor, content is not engaging and looks dated. Payment required to sync your information App is very cluttered and interface is very difficult to navigate
Opportunities	 Potential to change the look and feel of their website and have it engaging and easy to use Could simplify their app interface



	 Opportunity to offer reward/discounts when patient completes their medication Enable app link to Pharmacy systems
Threats	 May become known for bugs with version releases so users may move onto another app Major drug manufacturer could bring out their own app New advancements in medicine could mean medicating just once a day
Free/Pay	Free, however there are subscriptions for additional features
Web/Social Presence	 Layout of website is poor, everything is on top of each other, bland website No evidence of social Media presence from their website so I had to go into the various mediums and search myself Facebook Twitter Linked-in
USP	Access to a drugs database, patient can simply pick their medication from drug database to pre-populate the drug name, type, amount, strength, and route. Can take a photo of each drug to identify it more easily. With drug photos, you can be sure you're taking the right drug when a dose is due
App Store/ Google Play/ Amazon App store	App Store, Google Play and Amazon App Store



Screenshots of Dosecast App:





Mango Health: Mango Health is a software app that has been created to keep people motivated, build good habits around daily health regimes and to continue to improve their Health. Mango health focuses on the well-being of the user. If the user is successful on their medicine adherence program they can earn points and these points can be used to make donations to their nominated charity or exchanged for a gift card. Mango Health allows users record how their medication made them feel and this can be shared with their Doctors.

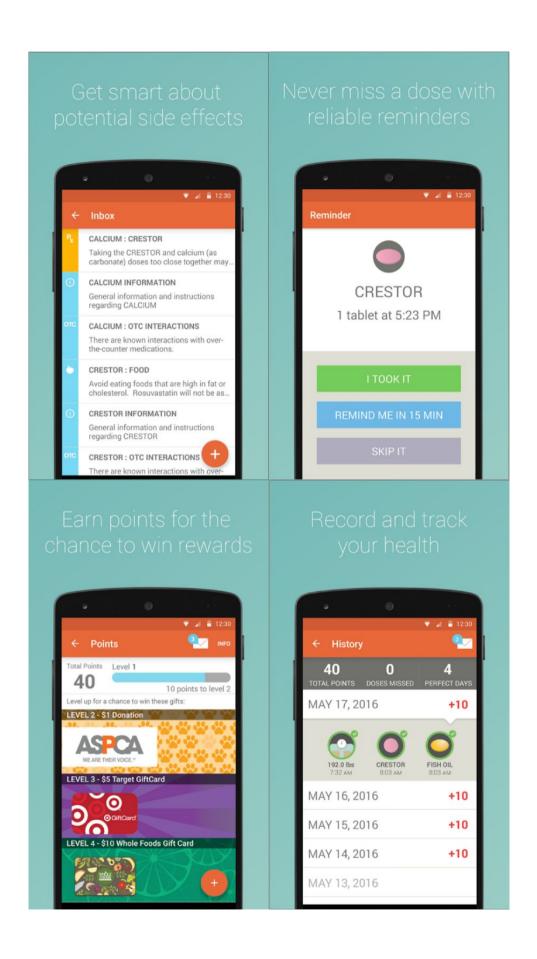
Competitor	Mango Health
Brief Description	Makes managing your medications fun, easy, and rewarding. App feature highlights include: dose reminders, drug interaction info, a health history, and best of all - points and rewards, just for taking your meds!
Product Features	 Reliable medication reminders Drug interaction warnings Points and rewards Daily health diary Timely refill alerts
Strengths	 Easy to use website and App, navigation is quite good. The ethos of the company is well being and they are running this theme throughout the site. Developed by highly skilled personnel who have held positions in healthcare and Google. Offer points are rewards system Staff come from a gaming background so the element of fun and interactiveness is strong Free to download
Weaknesses	 Mango Health app cannot be downloaded in certain jurisdictions e.g. Ireland (their audience and digital presences is primarily in the States). This is good for DoseBot because initially we want to capture the South African audience. Does not link into Pharmacy management information systems so cannot alert pharmacies as to when a patient's medication needs to be restocked.
Opportunities	 Mango Health have some major investors and could easily tap into other geographical regions. Mango Health can easily update their website/app to allow patient engagement. Mango Health could decide to create a complete medicine adherence application for specific illness types. When you sign up for Mango Health they have access to your data so



	they could easily run analytics, and design customised programs for illness they see trending on their app.
Threats	 Staff could leave and bring their knowledge of gaming with them. Investors could move onto the next big thing. Users of the App may move across to more specific medicine adherence apps customised for their specific illness.
Free/Pay	Free
Web/Social Presence	 Simple fun and easy to use website, creates a sense of wellbeing from just going to the site. Social Media Presence Facebook Twitter Linked-in Instagram Google+
USP	Rewards users with real-life rewards
App Store/ Google Play/ Amazon App store	App Store and google Play



Screenshots of Mango Health App:





Competitor summary:

There are combinations of functionality across existing applications that are similar to our product, DoseBot. All of the competitor applications analysed have reliable medication reminders and refill alerts prompts. Two competitors have a points and rewards system and a health diary tracker or integration to a health app (Medisafe and Mango Health).

There is a big market out there for Medicine adherence apps. From completing the competitor analysis we have established that we need to include for our product or perhaps with version releases all of the functionality of our competitors apps and more e.g.

- Report Sharing
- Health App interaction
- Drug Interaction warnings
- Refill reminders and quantity tracking refill alerts
- Customisable drug photos
- Customisable pill reminders and flexible scheduling

Our users will expect all of the competitors functionality combined in order not to move to a competitor's app.

We need to ensure that our interface is easy to use, that the app can be customised as per the patient's needs, and have an informative up to date easy to use website. We need to have excellent technical support and anticipate the user queries in advance so that when they come to our site the answers to their questions are already listed. Our App needs to be secure and we need to be able to motivate the patient to stay with us on their journey by including rewards along the way as they complete their medication adherence program. We need to make sure that the app is fun to use and engaging to the patient.

DoseBot is unique in that it caters solely for TB sufferers, and provides them with the basics that the other apps do. DoseBot also links to the patient's healthcare professional so that they can intervene if the patient does not stick to their medication schedule and try to get them back on track to enable them stay on their programme.

3 Requirements Overview

3.1 Functional Scope

3.1.1 What this concept can do:

The DoseBot smart dispenser and app reduces the burden of treatment imposed on TB sufferers by managing their schedule of medication, reminding them to take their pills and providing encouragement and a sense of progress for what will feel like an endless process with very few signs to indicate that their ongoing treatment is having any effect.

If the patient skips a dose, then the app will prompt them to take their pills. If they ignore these nudges, then an alert will be sent to their healthcare provider.



It allows the prescribing healthcare professional the ability to monitor their patient's adherence to their treatment regimen. When a patient skips a dose, the caregiver is notified via the app and is prompted to make an intervention.

It also provides general information on treatment like contra-indications of the medication and health and nutrition tips. The app will also provide usage and adherence data for the user, their healthcare provider or for 3rd parties needing the anonymized data for research or policy purposes.

3.1.2 What does this concept does not do right now:

This product is specifically for TB patients and MDR-TB patients. It currently does not work with comorbidity cases like HIV/AIDS. In such cases, the medication required will vary because when someone has both HIV and TB, each disease speeds up the progress of the other and requires more rigorous hands-on treatment.

We want to provide a social area for patients to connect with one another for support. An in-app emergency button in case a patient needs to see a human being, linked either to their healthcare provider or nominated contacts. However, these will not be implemented at launch.

3.1.3 What this concept could do in the future:

Expand to other areas of medical care, other disease treatment protocols and even to the lifestyle and wellness market.

The app could also integrate with 3rd party smart pill dispensers, pharmacies or clinic dispensaries to help with stock management and to facilitate prescription renewal. It could also interface with a wearable to provide overlay data on vital signs like heart rate, temperature, blood pressure and oxygenation.

3.2 Initial Specification

DoseBot is a hardware and software suite designed to help TB sufferers adhere to their medication schedules. It consists of one or more smart pill dispensers and an app on the patient's phone. The smart dispenser reports events to the app, such as time opened, how many pills dispensed and current stock levels. The app reminds users to take their medication and initiates a reminder protocol until the dispenser reports that the medication has been dispensed. Failing that, and failing patient response, the app escalates the event to their primary healthcare provider for intervention.

⁸ http://www.tbfacts.org/tb-hiv/



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3.3 Initial Requirements List

Ref	Description
IR-0001	Be able to view in-app medication schedule to monitor progress.
IR-0002	Mobile app will notify user when to take the medication.
IR-0003	Mobile app can measure pill count and actively be aware of consumption events.
IR-0004	Daily messages of support and encouragement overlaid with personal metrics.
IR-0005	Mobile app can notify caregiver when medication has been missed.
IR-0006	Mobile app needs to run on all major platforms (Android, iOS, Windows Mobile).
IR-0007	Be able to setup profile so that the doctor can "assign" a schedule to a patient.



4.4 Validating the Need

4.1 Introduction

We saw a need to assist, monitor and encourage patients to adhere to medication for TB in an aim to eliminate TB and MDR-TB. In order to get a real understanding of what TB patients need & want from DoseBot, we needed to speak directly to former patients about their personal experiences dealing with TB and the challenges they faced adhering to their medication.

We also wanted to speak to experts in this field, so we could understand from their side, where the main problems with medical adherence lay and learn about different TB programmes that countries were undertaking to treat & control TB. While most of the cases of TB are in 3rd world countries, there are patients suffering with TB all around the world. What patients need and want in a 1st world country may be vastly different to what they need and want in a 3rd world country, so we aimed to get an understanding of the different needs & wants between the two, so we could make some informed decisions.

4.2 Interviews

How we recruited interviewees:

As TB is a very sensitive subject we had to be careful about our approach to recruiting former patients for interviews. We started with personal contacts and through this we found two former TB patients willing to be interviewed:

Ann - former TB patient living in Cork, Ireland (see appendix 9.1 for full interview transcript)

Neil - former TB patient living in Dublin, Ireland (see appendix 9.1 for full interview transcript)

During our initial research phase, we had accumulated a list of TB organisations, who we approached via email. We introduced ourselves, gave them a brief overview of DoseBot and explained a little about the research stage we were at. We asked for interviews with medical experts who had first hand experience in dealing with TB patients and any former TB patients who they could put us in contact with. From these calls we secured the following interviews (see appendix for full interview transcripts):

Dr. Gabriel Fitzpatrick⁹ - Chairman of MSF Ireland and Head of Communicable Disease Control at HSE

⁹ https://www.msf.ie/article/dr-gabriel-fitzpatrick-world-tb-day-our-grandparents-used-call-it-consumption



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Thomas Jensen - Physician in the public system in Australia. Has also worked on MSF projects in Africa, as an infectious diseases physician.

Helen Clegg - Communications Manager for TBAlert¹⁰

Arne von Delft - Public Health Medicine Registrar - Western Cape Government Health and University of Cape Town

Zolelwa Sifumba - Final year Medical student University of Cape Town and MDR-TB survivor

Andrea von Delft¹¹ - Assistant Director for Global Health Delivery Online and member of TBProof¹²

We also carried out extensive search on Facebook for TB support groups and made contact through Facebook Messenger, explaining who we were and giving a brief overview of DoseBot. One of the support groups was run by a former patient who agreed to do an interview with us:

Liz - Former TB patient - West Coast of America (see appendix 9.1 for full interview transcript)

How we conducted our interviews:

We contacted about 10 different organisations, help groups and former patients and from them we secured seven good quality interviewees, representing former patients from 1st world countries &, experts with experience in 3rd world countries and including a good mix of gender and age.

Ideally we would have liked to have done some face-to-face interviews with patients but people's locations and the limited time they could give us meant the best approach was either video or phone interviews. We offered both methods as an option to all our interviewees and most declined the video interview and opted for the phone interview.

As a team we agreed on a semi-structured approach to the interviews of the TB patients. We needed to ask some closed ended questions and then agree topics to discuss for the more open-ended questions. We agreed on all questions prior to any interviews taking place. We were conscious of the limited time we had with each person, so the written questions kept us on track and made sure we got relevant quantitative and qualitative data from each interview. No more than one team member was present at each interview. The interviewer talked the interviewees through the script and once the closed ended questions had been completed, they opened up into much less structured interviews. The interviewee used the questions as a guide for the interview but delved much deeper into the open ended questions and we wrote a report after each interview. From this approach we got some great qualitative data from each interview.

¹² http://www.tbproof.org/



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¹⁰ http://www.tbalert.org/

¹¹ https://www.ghdonline.org/users/andrea-von-delft/

The interviews with the experts were far less structured. We had agreed the main points we wanted to ask. They were:

- Expert's own experience with TB patients
- Their opinion on main reasons for problems with adherence in 3rd world countries
- Effective programmes that are working to treat TB
- The role of family and friends in treating TB
- Do they think technology could play a role in treating TB have they seen any examples?
- Do they think an app for medical adherence could take the place of DOTs or aid it?

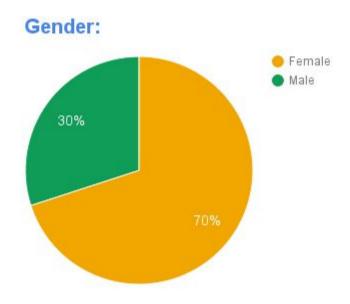
How we reached a larger audience - our survey:

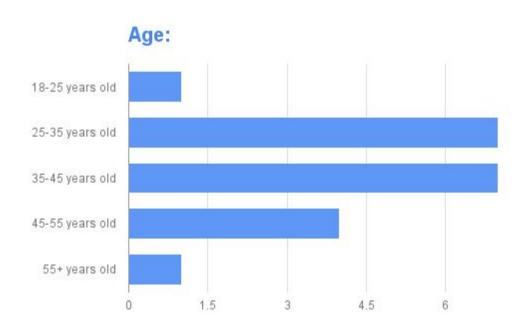
We were contacted by some of the people we had interviewed, saying that they had TB patients that wanted to help us with our research but didn't want to do an interview. So instead of losing the opportunity for this rich data, we decided to turn our questions into a questionnaire and share with as many people as we could. This would act as support data for the interviews we had carried out.

We set up the questionnaire using Google Forms, which was easy to share, easy to use, secure and we were able to build in a consent form. The data was easy to read and all team members were notified when submissions had been made, so we could keep on track of the additional data that was coming in. https://goo.gl/forms/srgcV7LaeKm12NWk1



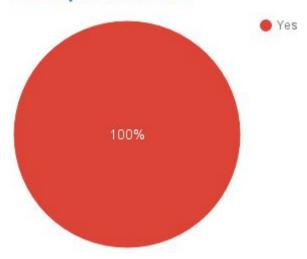
Main quantitative data results from the survey:







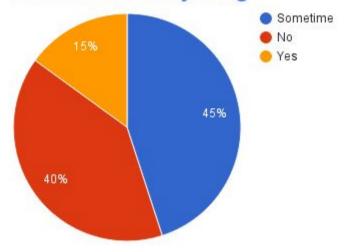
Smartphone users:



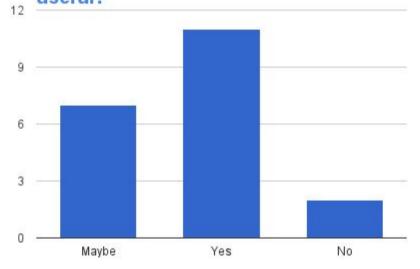
Did you ever forget to take any of your pills? Sometimes Yes No 5 10 15 20



Was information given on nutrition, exercise or healthy living?



Would you have found information on nutrition, exercise and healthy living useful?



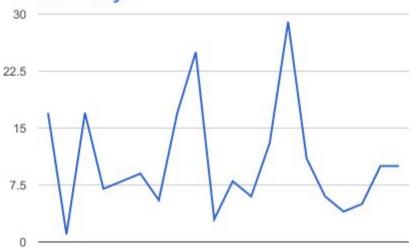


What was the duration of your drug treatment plan?

4.5
3
1.5
0
44 24 12 11 9 6 2

Months

How many tablets did you have to take each day?





Main qualitative findings from the interviews and open ended survey questionnaire:

1.	Patients need motivation and encouragement to help them adhere to their TB medication.
2.	The majority of patients do not forget to take their pills each day, they just don't want to because of the terrible side-effects and the length of time of the treatment.
3.	There is a need for observing/monitoring patients pill taking to ensure they stick to their treatment plan as this has proven successful with TB programmes around the world but the current DOTs programme does not seem to be sustainable given the length of time the treatment can last.
4.	DOTs programmes are there to monitor pill taking but don't offer any other type of support or education. The patient must work around the schedule of the nurse and does not have full control over when and where they can take their daily dose of pills. This proves extremely difficult, for both the health system, in terms of resources and the patient, who might be on medication for anywhere between 6 months to 3 years.
5.	Video Direct Observed Therapy is being tried and tested in countries to replace and/or aid DOTs programmes - https://www.youtube.com/watch?v=uJwjVi5Mt4M
6.	The majority of patients and families are seeking more education and advice around TB and the side effects of the different drugs, so they can help themselves and/or their loved ones through their treatment.
7.	The majority of patients and families want more psychological support to help deal with the length of treatment, the stigma associated with TB and the side-effects of some of the drugs.
8.	The majority of patients found support through contact with other TB patients and or TB help groups.

4.3 Research

Originally DoseBot was an App designed to aid TB patients to adhere to their treatment plan, with both reminders to take their pills and the observation of this by their medical health care professional through the use a smart pill dispenser. We believed that



because of the number of pills that patients had to take, they could easily forget and this was leading to problems with developing various strains of MDR-TB. After research, we have learnt the following:

	LEARNING	UX SOLUTION
1.	The problem is not that people can't remember to take their pills, it's that they don't want to take them because of the amount they have to take and the terrible side effects they experience as a result.	DoseBot needs to offer TB patients and carers a way to empower themselves to take their pills/help loved ones take their medication, through motivation, education and support. A function which allows patients and their families to input their personal motivational messages and get a reminder of them each day to encourage them to take their pills and keep focused on their recovery.
2.	TB patients suffer terrible side effects from all the toxicity of the drugs they are on and are not armed with much information and or advice as to how to deal with these side-effects.	DoseBot needs to offer it's users a full list of all their prescribed medication and details on the side-effects and precautions of each pill. The app also needs to offer the patient advice on ways to manage these side-effects, whether that's through diet, exercise, meditation, supplements or other lifestyle changes.
3.	There's definitely a need to monitor compliance of pill taking but more so from the health system's POV. The patient needs to have control over their treatment plan too and not feel like they have to rotate their lives around the schedule of the clinic or nurses. So how can we answer both needs? Video Direct Observation Therapy is being tried and tested and so far the feedback has been very positive from both a patient and healthcare POV - this is seen as the tech solution or way forward for TB medical	DoseBot needs to offer the patient a less complicated way of being part of a compliance programme, and offer the TB programmes a more realistic and sustainable approach to medical adherence for TB. The app will do this by providing a piece of functionality that will allow the user to video themselves taking their daily pills and securely send this video to their health care provider, so they can ensure daily doses are being taken.



	adherence, for certain types of TB patients (those who are not high dependency).	
4.	Getting family and friends involved is key to successful adherence.	DoseBot can be used by friends and family too and it will educate and inform them about all that their loved ones are going through and tips on how to help and support them. There will be a TIP section on the app that would offer this type of information and support.
5.	A lot of patients feel shame and guilt at having TB and there's no one to talk to about this. There definitely seems to be a need for psychological support for patients but people don't necessarily want to go to help groups in their areas - they want online support, where they can meet real people, going through a similar experiences and can share and support one another.	DoseBot needs to offer it's users a TB support section with listings and links to approved TB support groups, organisations, forums, blogs, where they can go and find support from other patients.
6.	While smartphone ownership is high, smartphone usage might vary from patient to patient.	The design will need to take into account the varying levels of users and reflect a simple, clean design and navigation system.

Interesting sites, blogs & articles that all informed our research findings:

Médecins Sans Frontières (MSF):

http://blogs.msf.org/en/patients/blogs/tb-me

Family support - "But the health lessons they gave us reshaped our thinking and we turned this fear into courage as we were now determined to prove that these drugs really work despite the stigma," - *Linnet Kadzere*

Psychological support - The bad part of the health system in my country is that they don't think psychological support is important. Often we patients need to talk, to share what we feel, but we don't have any access to any mental health services.

• Stop TB:



 http://www.stoptb.org/assets/documents/resources/publications/acsm/TBP atients29x29Reference.pdf

• TBAlert:

http://www.tbalert.org/what-we-do/tb-stories/

• CAP-TB:

 https://www.cap-tb.org/sites/default/files/documents/LanguageofTB.IUATL D.2012.pdf

• TB Alliance:

https://www.tballiance.org/access/understanding-tb-market

• SANTA:

http://www.santa.org.za/coping-with-tb.html

TBProof:

http://www.tbproof.org

Blogs & Support Groups:

- http://tbpatientssupportgroup.blogspot.ie/?view=sidebar+FB+groups
- https://www.facebook.com/tbsupportgroup/

WHO on DOTs:

http://www.who.int/bulletin/volumes/85/5/06-038927/en/

• Video Observed Therapy:

- https://www.ucl.ac.uk/health-informatics/research/impact-in-research/video
 -observed-therapy
- Making California TB Free With Tools Of Today: Smartphone Based Directly Observed Therapy:



https://www.youtube.com/watch?v=uJwjVi5Mt4M

4.4 Other data gathering methods used

We did a huge amount of online research, researching TB patients stories about side-effects, stigmatisation, family involvement and the problems with compliance. We contacted nearly every organization we had researched and we spoke to as many TB patients & medical professionals as we could. To add to our data, we produced a survey



and shared this through the new channels we had created. We choose to focus on open ended and closed questions for our survey. We received 20 completed questionnaires, from people all around the world. We made use of Facebook to ask for assistance with our survey questionnaire.

4.5 Validation Results

The validation process resulted in us not being so focussed on the need to remind the patient to take their medication. The research we carried out suggested that what the user needs is an app that informs, encourages and motivates them to take their medication.

TB patients have to consume a large volume of pills on a daily basis and this can have serious side effects both physically and mentally. Patients want to get better, however the treatment program can in effect cause them to feel worse, so our need is to keep them on track with support and encouragement and offer them an alternative medical adherence programme to the strict and inconvenient DOTS programme, while still receiving supervision from their healthcare professional.

Ref	Description
VR-0001	Mobile app will prompt user to take their daily dose of pills with words of encouragement and motivation.
VR-0002	Mobile app needs to list all drugs that the patient is taking, at any given time & provide up-to-date information on side-effects.
VR-0003	Mobile app offers the user the option to use Video DOT to ensure adherence.
VR-0004	Mobile app needs to offer the patient nutritional and psychological information and advice.
VR-0005	Be able to setup profile so that the doctor can "assign" a schedule to a patient and input their prescribed medication
VR-0006	Mobile app needs to offer the patient information on TB support groups and organisations.



4.6 Critical Success Factors

Ref	Description	Priority
CSF-0001	Fast load-times for app and videos - a server that can deal with high load volumes at any one time	2
CSF-0002	A solid security/privacy system - we are dealing with people's private health matters and so we need to give people peace of mind when using the app & ensure people's data is 100% secure	1
CSF-0003	Fast & attentive customer service function, to deal with any queries, problems/bugs.	4
CSF-0004	Seamless App updates with constant new, accurate & relevant material to keep the user informed, interested and motivated.	5
CSF-0005	Easy to use – a lot of our users will not be tech savvy and need a simple experience in order to realise the full potential of the app.	3



4.7 Personas

Primary Persona - TB Patient			
Profile	 Collette Nyunda 21 year old Student in 3rd level education, studying for a degree in Business Management. Lives in Kimberley with two friends from college. Works part-time in a cafe near her college, where she is a waitress. Has three younger siblings and visits them and her parents every weekend. 		
Likes	 Running Baking Reading Hanging out with friends and family Would love to travel the world one day 		
Attitude	 Independent young women Strong-willed and determined Strong family values Uses technology on a daily basis for communication, entertainment and reminders. 		
Online Behaviour	 Heavy internet user Does a lot of online research for her studies & college projects Snapchat Facebook YouTube Uses online tools to help with her studies. 		
Value Proposition	Would like to be responsible for her medicine and feels DoseBot would assist and allow her keep on track with her TB Medication adherence,		



	while still managing to keep up with her studies and keep herself fit and healthy, both mentally & physically.		
Goals	 Recover from illness & finish her studies, so she can get a good job and start her working life. 		
Scenario	"TODAY" and reads through the list of pills shall she takes the dose for each pill out of her pill glass of water. She enables her camera and pherself taking her list of pills. After she has taken pauses the video and ticks the dose box on they have been taken. Once she's completed ticked each box, the video automatically send provider. She is finished her medication for the	Every morning at 6am, Collette opens DoseBot, clicks on "TODAY" and reads through the list of pills she needs to take. She takes the dose for each pill out of her pill bag and gets a glass of water. She enables her camera and proceeds to video herself taking her list of pills. After she has taken each dose, she pauses the video and ticks the dose box on the App to confirm they have been taken. Once she's completed all the doses and ticked each box, the video automatically sends to her health care provider. She is finished her medication for the day and she can go about her day, knowing that her progress has been reported	

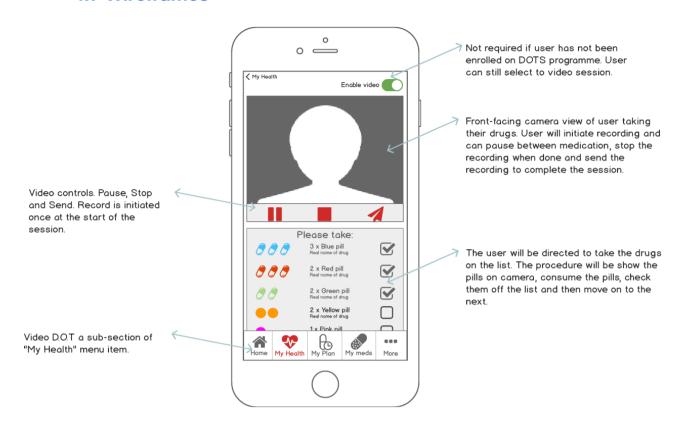
Secondary Persona - Parent of TB Patient			
Profile	 Malaika Mazibuko 38 years old Married Works 6 days a week at local bakery from 6am-1pm She starts her work day early but is home for when the children return home from school. Lives in Mamelodi, Pretoria, with husband and 4 children, ages 4, 6, 9 and 12, Her 9 year old daughter has TB. 		
Likes	SewingCookingBeadingLooking after her family		

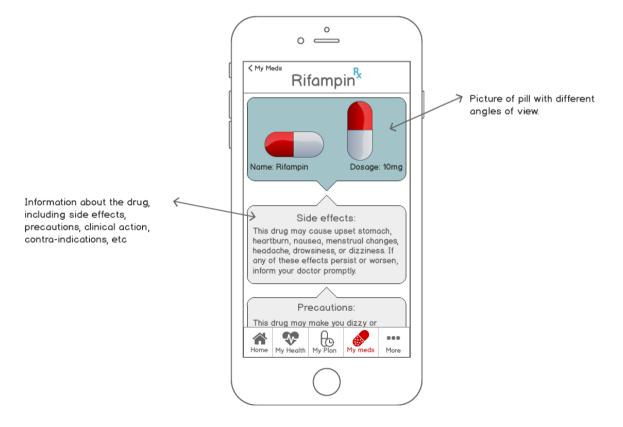


	Going to church	
Attitude	 Optimistic Appreciative of everything she has in her life Family first attitude Hard-working 	
Online Behaviour	 She has become a keen internet user over the last few years, in attempt to keep up with her children and understand how to protect them online. She gets a lot of her baking recipes from cooking blogs Her preferred social network is Facebook, which she uses to keep in touch with her wider group of friends. She is also a member of some FB groups; cooking, church group and recently a TB support group. 	
Value Proposition	 Feels that the app will help her be organised, educated and empowered to deal with her childs TB treatment and help her child through this terrible illness. 	
Goals	Be in control of her child's recovery from TB.	
Scenario	Malaikas daughter has taken her daily drugs before her breakfast today and is complaining of terrible pains in her stomach and doesn't want to eat any breakfast. Malaika is worried and so she opens DoseBot and goes to My Pills and reads up on the side effects of the drugs her daughter is on. She sees that one of the drugs gives terrible stomach cramps if eaten on an empty stomach. It recommends drinking cooled boiled water and eating small amounts of boiled white rice. It says to avoid dairy as this might aggravate the symptoms. Malaika is relieved and decides to follow these instructions and see if things improve. If not, she will go to her TB Support page and contact a local health care provider to ask for assistance.	



4.7 Wireframes







5. Assumptions, Issues and Risks

5.1 Introduction

Our team have made assumptions regarding DoseBot before we have had an opportunity to make detailed business and technical analysis, we have documented the assumptions so that everyone has the same understanding. We have listed our dependencies so that we will be able to catch problems early and track them through to resolution. We need to be aware of the following language barriers, the nature & sensitivities around medical adherences, the nature of TB and the variety of markets we would need to enter into.

5.2 Assumptions

Ref	Description
0001	It will be assumed that the user/patient owns a smartphone.
0002	It is assumed that the app will work with and without an internet connection. If the patient is required to use Video DOT, then videos will be cached on device and uploaded when connection is available.
0003	It will be assumed that user/patient can read English.
0004	Its is assumed that the user is undergoing professional treatment for TB or has a relative undergoing professional treatment for TB.
0005	Is it assumed that the user/patient will have all the correct notifications turned on and will have set up the desired settings in their account, in order to fully experience all that DoseBot has to offer.



5.3 Constraints

Ref	Description
0001	Finding a consistent look and feel for the app across multiple host platforms, each with it's own design language.
0002	Slow mobile network speeds that may cause problems for uploading Video DOT files.
0003	Host operating system quirks - Android and iOS ¹³
0004	Screen sizes vary per phone build.

5.4 Issues

Ref	Description
0001	Data protection of sensitive medical data.
0002	Server or service down time.
0003	Potential errors in updates due to phone platform build or operating system conflicts.
0004	Service disruption in politically unstable countries, or in countries that control the flow of information to their citizens.

5.5 Risks

Ref	Description
0001	Lifestyle recommendations have to be verified by a trained health care provider. If not, then this would be a big risk causing potential problems/issues to the patient's health.
0002	Changes in local laws brings risk, due to the sensitive nature of medical information.

 $^{^{13} \ \}underline{\text{http://www.androidauthority.com/developing-for-android-vs-ios-697304/}}$



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0003	Upload function could malfunction and cause delays in information about the patient's adherence, which could throw their whole adherence programme off schedule.
0004	Uploaded videos could be used in a criminal inquiry if part of an investigation where user overdosed due to medical negligence.
0005	Delays to update of medication schedules from doctor to patient via the app could cause treatment or adherence issues.

5.6 Dependencies

Ref	Description
0001	Mobile data services like 3G,4G, LTE for Video DOT uploads and GPRS for telemetry based app functions (schedule updates, adherence, etc)
0002	Operating systems build, version number and part backwards compatibility when building native apps. Note: This risk could be reduced if we use something like PhoneGAP ¹⁴ to build and deploy to host platforms.
0003	Mobile phone battery life above 10 percent for Video DOT uploads.
0004	The uptime of our infrastructure - Database servers, web services and 3rd party services (see section 6).

¹⁴ http://phonegap.com/



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6. System Requirements

6.1 Overview

From a backend service perspective, DoseBot will require a application and database servers with adaptive load balancing. To more effectively utilise resources and manage cost, we would use something flexible like Amazon Web Services (AWS) so that in times of high demand, the servers could automatically provision more processing power and bandwidth to handle the load and equally adapt downwards in periods of low usage. We would also require a storage service for the Video DOTs uploads archive.

From a user-facing app perspective, we would require the user's smartphone to have a data connection, either wifi or 3G/LTE. This would be a dependant requirement, in other words the DoseBot app will still work, caching data on the device until a connection becomes available.

We would also require location services so that we could help the user find TB support groups or events nearby. If the user disables location services, then we will provide a search function with results displayed on a map.

The user's device will also be required to record video for the compliance/adherence functions within the app, namely Video DOTs.

Additionally we would make use of 3rd party services for messaging and maps.

6.2 Out of Scope

The backend production environment will require additional expertise to set up and continued management and monitoring moving forward.

Equally, our security and encryption setup will require further development. See section 6.5 below.

The provision of an API for partner reporting also requires further scrutiny, and will not be available until a full understanding is obtained. See section 6.8 Report requirements below.



6.3 Objectives

The following table outlines the functional objectives (not project objectives) of this specification.

Ref	Description	Priority
DO-0001	Remind users to take their medication	2
DO-0002	Educate users about their medication specifically and TB generally	3
DO-0003	Provide social support to users	4
DO-0004	Report user/patient adherence via Video DOTs or if not on Video DOTs, then basic adherence data.	1

DO = Delivery Objectives

6.4 Minimum Viable Product

Ref	Description	Priority
MFS-0001	Medication schedule reminders with the built-in ability to participate in a DOTs programme that is flexible (Video DOTs)	1
MFS-0002	Education around TB and their specific medication.	2
MFS-0003	Provide social support to users	3

MFS = Minimum Feature set required as a Minimum Viable Product (MVP) release



6.5 Security and Privacy requirements

Security

This is a complex issue, with many variables and approaches. At a bare minimum, we will require secure end-to-end encryption using the Secure Sockets Layer (SSL). This will ensure that user data is secured in transit and not susceptible to snooping on public or private networks.

In a typical SSL usage scenario, we will have a server configured with a certificate containing a public key as well as a matching private key.

- 1. The patient's phone will perform a handshake with the server.
- 2. The server then proves it has the private key by signing its certificate with the public key.

Privacy¹⁵

We will include settings that give a patient control over what data we collect about them, by providing an opt-out for generic data collection (Google Analytics, logon attempts, location data, etc). Adherence data however, especially if the patient is on Video DOTS, cannot be disabled¹⁶.

We will tell patients what we're doing by including a notice setting out how we will use their data, making sure that the notice is accessible and in a language that they can understand. We will adopt a 'surprise minimisation' approach so that we can reasonably argue that individuals would not be surprised by the data we collect on them in a given context.

We will tell individuals about data sharing with 3rd parties and will conform to any rules that require us to obtain a patient's consent before sharing their data i.e. for WHO research on TB.

We will also adopt an 'implied consent' approach to our in app and website cookie collection.

¹⁸ http://privacylawblog.fieldfisher.com/2013/cookie-consent-update-implied-consent-now-widespread



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¹⁵ http://www.wallatlaw.com/privacy/pointers-for-designing-apps-to-avoid-privacy-liability/

¹⁶ Some patients will be required to be on a V DOTs programme, meaning this feature can't be disabled.

¹⁷ http://www.nature.com/articles/srep16575

6.6 Audit requirements

DoseBot will generate information that third parties will need to look at and track the usage of the users of the App. Including (but not limited to) TB patients, healthcare providers, customer support and partners.

TB patients

Patients or users of the app could allow 3rd parties to view elements of their treatment data. These 3rd parties could be family members, TB support groups or other DoseBot users. For example, a patient could enable a setting that allows their Video DOTs session to be copied to selected family and/or friends, so that the patient can "harvest" support and encouragement from them.

Healthcare providers

This group of people would be able to see adherence data and Video DOTs sessions for their patients, as well as contextual information around the data. For example, A patient is adhering to their schedule, but for the last week they have been feeling poorly. Maybe that has to do with a drug, or maybe that has to do with the level of support the patient is receiving. Bottom line is that we would aim to provide a holistic view of the patient's wellbeing to their healthcare provider.

Customer support

Customer support will have access to the 'plumbing' of the system in order to handle support calls around things like login issues to settings and usage questions. This group of people will not have access to sensitive patient specific health information, but rather a systems view of the mechanisms and their interactions. For example, if a user can't login, customer support could reset their password.

Partners

Partners would typically be 3rd party organisations conducting research around TB, side effects of prescribed drugs or more generally, medication adherence. The data we provide to them would be sanitised and anonymous and this could be a source of income for us.



Audit conditions

- Number of Allowable unsuccessful logon attempts. A patient will be allowed 4
 attempts at a login before an action gets triggered. Actions could include a time
 based lock on the account, an intervention from customer support or the lost
 password dialog appears and the user is verified and allowed to change their
 password.
- Minimum Password Length and complexity. We require a mix of alphanumeric characters and a minimum length of 8 characters.
- Password Expiration. Patients will be encouraged to change their password regularly, and forced to change their password in the event of a security breach.
- Password reuse ability. Patients will not be allowed to reuse a password that they
 have used within the last 18 months.

Localisation requirements

US English will be the seed language for the user interfaces, however user can customise app for their preferred language¹⁹.

6.7 Accessibility requirements

General requirements

There will be a contact us section within the app and a link to the FAQ on the DoseBot website. Context specific help will also be enabled at first run, so that we can give the patient the best possible chance of getting to grips with the app from the outset.

Screen layout

As a general rule, we will limit the number of buttons and/or options per screen. The buttons will be big and sufficiently separated to reduce the chance of false selections. We will ensure that colour is not the only way of distinguishing between elements so that people with colorblindness can identify the important elements. This will also require sufficient contrast between text and background. Magnification of text and images, to an extent that makes sense for the device, will be allowed. The app will also operate in landscape orientation, which some users may prefer. It will be possible to use the app in either landscape or portrait orientation.

¹⁹ http://apple.co/2l3C1D8



'^s <u>ht</u>

Operating Issues to be considered

If the patient presses the wrong button, then they can easily get back to where they were and try again via the 'back' option in the upper left corner of the app. The label of this button would be the name of the previous screen. For example if the patient ends up on the Video DOTs screen, then the 'back' label for them would be "My Health" see wireframe in section 4.7.

A delete button can be dangerous - press it by mistake and the item has gone. We will provide the patient with a delete confirmation function. This could be disabled in the settings for power users. Nothing worse than an annoying "Are you sure" dialog slowing you down when you know exactly what you're doing.

Typing on a touchscreen or a small keyboard can be difficult, so we will minimise the need for typing by using elements such as list choosers, spin choosers and pre-fill options.

6.8 Report requirements

Reporting would largely be automated and triggered via patient driven events within the app. Reporting would be broken down according to section 6.6 Audit Requirements:

TB patient reporting

Patients will be able to see all the data related to themselves and their treatment from within the app. They will have a view of their schedule with past events colour-coded for quick reference, as described in section 7.3.7 My Plan FM 3. i.e. Green for all pills taken, orange for some pills taken and red for skipped doses.

Patients can view any appointments they have to attend at the clinic for blood tests or check-ups and can keep a record of their attendance history, which they will have full access to.

Healthcare provider reporting

Healthcare providers will have access to an online dashboard with a global summary view of all their patients and the ability to drill down to individual patient reports. Metrics for adherence, mood and Video DOTs will be reported on. Alerts around non-adherence will be surfaced in the global view to enable quick action. These reports will be automated, but not necessarily real-time since they are dependant on the patient and their devices having access to wifi or network capabilities and could require additional processing and formatting for the dashboard view.



Customer support reporting

Real-time global usage data would be the primary reporting requirement here. How many logins, how much time spent within the app, any features not being used across the userbase, service outages and security related issues.

Partner reporting

We believe that this would be via the provision of a limited API for always up to date data. The API would be limited in the sense that we would need to supply anonymised patient information and we wouldn't allow partners access to operational data like app usage or anything else other than data that can be used for specifically defined use cases. This would need further exploration.

6.9 Monitoring requirements

Infrastructure

The optimal performance of the DoseBot ecosystem will be crucial to its success. Monitoring backend systems will be crucial in avoiding downtime, but also will inform strategies for scaling and maximising performance over time.

Customer support

We need a team that will monitor and manage user interactions with our company via a multitude of communication channels. We would need to keep a handle on live support requests, emails to support, the DoseBot Twitter feed and our own support forums on the website. We would also have to monitor 3rd party forums where we're mentioned, so that we can provide the best possible experience for ourselves, but mostly for the users of our app.

Policy environment

Data protection laws change, or new requirements are introduced. Equally, sentiment around user privacy shifts. This will always be the case. We need to make sure we continually keep an eye out for policy changes, both at a governmental/regional level and at an online professional association level. For example, do we subscribe to the Safe Harbour²⁰ privacy principles, which is backed by US law, but has also become a generally accepted online requirement within some professional bodies.

²⁰ http://bit.ly/1qzgluE



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7. Requirements Definition

7.1 High Level overview

Provision of an app DoseBot which is designed to help TB suffers adhere to their medication schedules. The App will act as an adherence & reminder service, to prompt patients to take their prescribed medication and allow the patient to keep track of their daily drug intake and/or comply with their DOTS program by providing Video uploading functionality from within the app. The App will provide support and encouragement during their treatment process. DoseBot will provide information on their prescribed drugs and provide health and nutritional tips to deal with the associated side-effects of the harsh and long treatment plan.

7.2 Functional Modules

Settings / Support / Health / Medication / Help

Ref	Name	Description
FM-0001	Settings	Patient login credentials to DoseBot, adjust settings on phone for app to fully work - camera, notifications, location with privacy and security settings
		COMPLEXITY = L
FM-0002	My Health	Takes patient to Video DOTs Screen and lists what medication they need to take that day.
		Gives user tips and advice on nutrition, exercise and healthy living.
		Reports can be viewed or emailed at any time.
		Tracks late and missed doses.
		Family support messages
		COMPLEXITY = M
FM-0003	My Plan	Shows patient their full treatment plan in calendar format.
		Information on type of TB and treatment required.
		COMPLEXITY = M



FM-0004	My Meds	Displays a photo of each drug in order to identify it more easily.
		Gives patient information on their prescribed medication, precautions and associated side-effects.
		Tips on how to take medication.
		Warnings on what not to consume while taking medication.
		List allergies associated in drugs within the prescribed medication and allows patient to input their known allergies.
		COMPLEXITY = L
FM-0005	Support	COMPLEXITY = L Lists Patient's medical health care professionals contact details.
FM-0005	Support	Lists Patient's medical health care professionals
FM-0005	Support	Lists Patient's medical health care professionals contact details. Lists local hospitals/doctors/emergency contact
FM-0005	Support	Lists Patient's medical health care professionals contact details. Lists local hospitals/doctors/emergency contact details for Patient.



7.3 Functional Module Breakdown

7.3.1 Settings FM1 - Functionality

A more detailed listing of these requirements is provided below:

FM-0001 Settings

_		
Ref	Description	CrossR
		ef.
FR-1.010	Functional requirement and objective	IR-0007
	Patient registers LOGIN credentials with DoseBot	
	Behaviour	
	 Registration: Patient enters his/her name Patient enters his/her Medical ID Patient enters his/her email address Patient enters his/her mobile phone number Patient can opt to upload profile picture. LOGIN: Prompt for username and password combination. Forgot username/password option 	
FR-1.020	Functional requirement and objective	IR-0007
	Patient can control their ACCOUNT SETTINGS, so they can personalise their App and allow them to fully experience all the benefits of DoseBot.	
	Behaviour	
	 Patient can control privacy to enable 3rd parties to see all data, some data (certain areas of the app, like medication side effects) or no data at all. Patient ticks the chosen privacy setting to activate. 	



	 Security - gives the user information on security measure taken to ensure safe use of App and shared information. Delete or edit my profile - option to delete all information or edit existing information. Location - patient can choose to have locations on, and receive information about local TB support groups and activities in their area. Camera - enable App to access camera to use for Video DOTs. Notifications - patient can set up daily reminders 	
	for certain times each day, when they want to take their medication and any vitamins, supplements they are taking.	
FR-1.030	Functional requirement and objective	IR-0002
	Patients can control their NOTIFICATIONS.	
	Behaviour	
	 Notifications - patient can set up daily reminders for certain times each day, when they want to take their medication and any vitamins, supplements they are taking. Patients can see all notifications available Patients can choose how they would like to be notified - email or mobile. Patients can activate sound to receive audio alerts/notifications Show Preview of mail or message Reset Notification Settings 	
FR-1.040	Functional requirement and objective	IR-0005
	Assign Family Member and/or Caregiver access to App information and send/receive data.	
	Behaviour	
	 Patient enters his/her next of kin email and contact number 	



	 Patient enters his/her medical health care professionals full name, clinic and contact email All this info is entered into CAREGIVERS section of SETTINGS 	
	Functional requirement and objective	IR-000
FR-1.050	Patients can choose if they would like to receive progress reports from their medical health care professional and how often, so they can keep on track of their recovery.	4
	Behaviour	
	 Patients go to REPORT section in SETTINGS Patient can tick RECEIVE REPORT and if ticked they will be asked to input Medical Health Care provider email, if not already inputted in CAREGIVERS section above. Setting options enable the patient to request either weekly or monthly health reports from medical health care provider. 	
FR-1.060	Functional requirement and objective	IR-000
	Patients will be able to invite loved ones, to submit messages of love and support to motivate and encourage the patient, on their road to recovery. Behaviour:	4
	Bellaviour	
	 Patient goes to SUPPORT MESSAGES section in SETTINGS. Patient registers emails or mobile number of their loved ones. Patient can choose to allow text only messages, or allow any form of messaging - audio, picture and or video messages. An invite is sent to the entered emails/mobile numbers. They are asked to reply with a support message for the patient. Default setting allows this group to submit messages of support at anytime. 	
	Patient can also choose a setting which sends a reminder email to this group every week, fortnight	



or month, asking them to submit new messages	
of support.	
 Or patient can choose certain people to send a 	
reminder to and choose how often.	
 Patient can choose group from contacts to 	

receive Video DOTs submissions.

7.3.2 Settings FM1 – asset Requirements

Ref	Description	CrossRef.
AR-1.010	Template & DoseBot artwork/branding for login area of the App	FR-1.010
AR-1.020	Artwork for icons to show each of the options under;	FR-1.020
	account settings, notifications, caregiver settings, report settings & support settings.	FR-1.030
		FR-1.040
		FR-1.050
		FR-1.060

7.3.3 Settings FM1 – complexity

Functional Module 1 has a low complexity rating, as it only involves the patient inputting data in email or number format and choosing settings. The only issue we see is the language barrier. We have made the assumption that all patients will speak and/or read English and so all instructions and information on security will be given in English. We also assume that all users will be real patients or caregivers of real patients, who are under the care of a medical professional. There is also issues surrounding privacy and security, with patients inputting personal data and that of family members.



7.3.4 My Health FM2 - Functionality

FM-0002 My Health

A more detailed listing of these requirements is provided below:

Ref	Description	CrossRef.
FR-2.010	Functional requirement and objective	IR-0003
	Allow patient to video themselves taking their prescribed daily pills and submit the video to their medical centre and optional nominated contacts for drug supervision programmes.	
	Behaviour	
	 Patient goes to TODAY tab. Camera enabled is default setting. Front-facing camera view of patient taking their drugs. Patient will initiate recording and can pause between medication, stop the recording when done and send the recording to their medical health care professional to complete the session. Pop-up instructions will help the patient navigate through this functionality. 	
FR-2.020	Functional requirement and objective	IR-0003
	Allow patient to view a list of all their medication to be taken that day and what they must capture on video.	
	Behaviour	
	 In the TODAY tab and below the video option, the patient is presented with a list of all prescribed pills for that day. Physical representation of the pill - colour, size, name, etc The relevant daily dose is marked beside each pill. Pop-up instructions will help the patient navigate through this functionality. 	



FR-2.030	Functional requirement and objective	IR-0005
	Allows patient to confirm when prescribed medication has been taken for each day.	
	Behaviour	
	 In the TODAY tab and beside each daily dose of pills is a tick box. Patient must tick each box when this dose has been taken and recorded on video. Once all boxes have been ticked, the video can be sent. This adherence information is saved in their calendar, updated to show the status of their complete daily dose of medication. Pop-up instructions will help the patient navigate through this functionality. 	
FR-2.040	Functional requirement and objective	IR-0001
	Patient can also just tick the boxes against each pill dose, without needing to film it, if they are not on a adherence programme but just want to keep track of their pill intake for themselves.	
	Behaviour	
	 Patient swipes tab on top of TODAY screen, to disable the camera functionality for VDOTS. 	
	 Patient ticks each box against the relevant pill, when they have taken the dose. 	
	 They can save this information at any stage, which updates their calendars. Their daily dose status is reflected in their calendar. Pop-up instructions will help the patient navigate through this functionality. 	
FR-2.050	Functional requirement and objective	IR-0004
	Patient can access relevant and updated information around nutrition, exercise and mental health, in an aim to educate and support themselves in dealing with the side effects or precautions of their drugs, the length of	



Beha	aviour	
	Patient clicks on the Wellbeing Tab. This will provide information on three areas - Nutrition Exercise Mental Health Information and advice in each area will be fed to the patient in the form of text and video content, all curated by a medical health care professional.	
FR-2.060 Fund	ctional requirement and objective	IR-0004
of n	ent can view text and/or listen to audio messages notivation from their loved ones to encourage and p them focused on getting better and sticking to r treatment plan.	
Beha	aviour	
•	the CAREGIVERS SETTINGS (REF FR-1.060).	
FR-2.070 Fund	ctional requirement and objective	IR-0004
them	ents can access a journal in the App which allows not on to input personal information on a daily basis keep track of how they are feeling.	
Beha	Behaviour:	
	Under the Mental Health tab, patients will have access to a journal. They can click on this journal and it will default to open on that days date. They can also choose a calendar view, which allows them to choose which day they want to access. Once the patient is on their desired day, they	



emoji scale to communicate their mood for that day - Happy/Sad/Sick/OK etc.
 Underneath this there will be an area for writing.
Patient clicks on the SAVE button at the top of
the screen.
 Patient also has the option to share it with their
loved ones or health care provider by clicking
on the SHARE button at the top of the screen.
 If they share, their contact list appears (names
from CAREGIVERS & SUPPORT MESSAGES
SECTIONS) and they can choose who they
would like to email it to. Or they have the option
to input a new email to send to.

7.3.5 My Health FM2 – Asset Requirements

Ref	Description	CrossRef.
AR-2.010	Video template for VDOTS and artwork for pop up instructions for user.	FR-2.010
AR-2.020	Daily dose adherence template and art work with accurate images and descriptions of the pills they will need to consume.	FR-2.020
AR-2.030	Video content around nutrition and lifestyle advice and support. Audio will be needed for this too and possibly music, if a playlist is offered for meditation or other mental health exercises. Content will also be needed here, for written information and advice from certified practitioners.	FR-2.040
AR-2.040	Art work to display the support messages and audio and video template, if some messages were sent as audio/video messages rather than text.	FR-2.050
AR-2.050	Templates for reports, so that all the relevant information is requested and displayed in an easy to digest format.	FR-2.060
AR-2.060	Journal template.	FR-2.070



7.3.6 My Health FM2 – complexity

Functional Module 2 is rated at a M (Medium) complexity mainly because of the Video DOTs functionality. Using the camera and taking the pills at the same time, may be complex for some people, especially those who are not so text savvy and may not be familiar with using a camera. It will take the patient a few attempts at the Video DOTs process before it becomes second nature to them.

There's also the issue of no, or slow network connection and the option of caching their video on the device and uploading when connection is available. For a lot of patients, this will be frustrating and will also take some understanding of what's needed here, and why. The pop up icons on DoseBot will help the patient navigate through this functionality with as much ease as possible and instruct what to do.

The patient journal will raise issues and risk around security and privacy of data. The rest of this functional module will be the patient receiving information they've requested and reading, listening and or watching it. The issues around this is the lack of internet connection and the delay in receiving up-to-date data or the slow load times for video and audio content. There are also a lot of assets required for this section and the need for the content to be medically verified. So the issues and risks here are; slow and or no internet connection and medically certified content, both of which are listed in Section 5 in more detail.

7.3.7 My Plan FM 3 - Functionality

FM-0003 My Plan

A more detailed listing of these requirements is provided below:

Ref	Description	CrossRef.
FR-3.010	Functional requirement and objective	IR-0001
	Patient and users are able to view their medication schedules, as set up by themselves or their medical health care professional, so they can be on track with medication adherence. This is produced and visible in the "my plan" tab using a simplified calendar view Behaviour	



	 User clicks on "My plan" and can view the calendar first. Calendar has dates and times for medication intake User can click on the date and view more info on the day's medication intake and additional days ahead View can be changed to day, week or month view 	
FR-3.020	Functional requirement and objective	IR-0001
	Patient can enable updates to calendar, via the SETTINGS, allowing the status of VDOTS/DAILY PILL TAKING to be reflected in the calendar.	
	Behaviour	
	 Once the VDOTS/Daily Dose page has been completed, it will update the calendar. The calendars turns to GREEN for all pills taken ORANGE for some pills taken. RED if no pills have been taken that day. This information can be shared with their medical health care professional or family member depending on patient's preference in SETTINGS. 	
FR-3.030	Functional requirement and objective	IR-0001
	Patients can view any appointments they have to attend at the clinic for blood test, check ups etc and keep a record of their attendance history.	
	Behaviour	
	 Patient can input these dates themselves or allow their Medical Health Care professional to add them. The appointments will show up in the calendar and once attend, the patient can click ATTENDED in calendar and this appointment will turn to GREEN. 	



FR-3.040	If the patient does not click ATTENDED, the appointment will turn RED and can be reported to their medical health care professional. Functional requirement and objective Patient and users are able to view information on the type of TB they are infected with. The objective of the information is to create awareness and educate the user and or patient.	IR-0004
	Behaviour	
	 Within the My plan tab users and patients can click on a tab that has information on their current TB type and what the cause and effect of it is. 	
	 The information is displayed in text format with some images. The users can scroll up and down to read information. 	
FR-3.050	Functional requirement and objective	IR-0004
	Patient can view up-to-date reports on their treatment progress, as supplied by their medical health care professional.	
	Behaviour	
	 The reports are requested by the patient through SETTINGS in the App. These reports are received in a template format in a REPORTS tab in My Plan. Reports are automatically saved for the patient to call up and review at any time. Patient has the option to delete any of the reports, should they wish. 	



7.3.8 My Plan FM3 – asset Requirements

What artwork, content, music, templates, video, audio might be required to support the functionality:

Ref	Description	CrossRef.
AR-3.010	Calendar template	FR-3.010
AR-3.020	Artwork and colour palette for inputs and updates to calendar.	FR-3.020
AR-3.030	Content in the form of text and images to accompany the information on types of TB.	FR-x.040

7.3.9 My Plan FM3 - complexity

The complexity around the My Plan functional module and calendar use can be rated as (M) medium. This is because not everyone may have used a calender app. The calendar colour coding maybe of medium complexity for those who are colour blind. On first use the app has a guided walkthrough that will assist the user in understanding the basic usage of the app thus reducing complexity.

The TB Info associated with the secondary tab within the My plan section features scrolling up and down. The guided walkthrough will also prompt the user to do this on their own. Finally, the reports tab, will be information that the patient can read without any need for complex interaction. The reports will be a template form and set up so they are easy to understand. The doctors/medical health care professional will fill out and submit, so nothing complex will be needed from the patient other than the ability to understand the information in the reports.

7.3.10 My Meds FM 4 - Functionality

FM-0004 My Meds

A more detailed listing of these requirements is provided below:

Ref	Description	CrossRef.
FR-4.010	Patient has access to a list of their up-to-date prescribed medication.	IR-0007
	Behavior	



	 Patient clicks on My Pills, a list of prescribed medication appears with name, picture and side effects associated. The information will be displayed in text format with exact images of the pills for easy identification. The user is able to scroll up and down to read the information on the pill. 	
FR-4.020	Patient can view the dosage, strength per drug and allergies related to the medication. Behavior	IR-0001
	 Patient clicks on the image of the pill prompted. A full description of the drug is displayed. Directions on how it should be taken (with or without food). Frequency of the pill (daily, weekly or monthly) A diagnosis for taking that particular drug will also be displayed. 	
FR-4.030	Patient has the ability to input other medication, other than what has been prescribed for TB, should the patient be on multiple medications or taking vitamins, supplements etc.	IR-0007
	Behavior	
	 Patient can list other drugs and pills that they are taking. Edit and update on the My Meds option should the drugs change. 	
FR-4.040	Shows a record of pill count as it depletes and notifies patients and health care provider on the available amount until the next refill.	IR-0003
	Behavior.	
	 Pill count will record levels and availability when notification and alerts are active and 	



	 VDOT submitted, as confirmation that the pill was taken by the patient. Patient will receive visual and audible notification for all medication dose. Records medication taken in ratio and dose and enable dosage tracking by the health care provider and caregiver. 	
FR-4.050	Patient can list side effects per drug, the data collected can then be used by pharmaceutical companies and stakeholder. • Patient select the pill, and a drop down menu which will allow input to select preloaded side effect per drug and also note new and unfamiliar side effects. • Data can be shared anonymously with other patients as a guide on what to look out for when taking a particular drug and tips on how	
	to relieve.	

7.3.11 My Meds FM4– asset Requirements

What artwork, content, music, templates, video, audio might be required to support the functionality:

Ref	Description	CrossRef.
AR-4.010	Template to input and edit prescribed medication	FR-4.030
AR-4.020	Content in the form of text and images for easy drug identification.	FR-4.030
AR-4.030	Calendar for dates of dosage intake.	FR-4.040

7.3.12 My Meds FM4 – complexity

The complexity around My Meds is rated Low complexity as it requires lesser interaction by the patient. Most data will be readily made available for the patient as a display in a drop down selection model without a need for much input.



7.3.13 Support FM 5 - Functionality

FM-0005 Support

A more detailed listing of these requirements is provided below:

Ref	Description	CrossRef.
ED 5 040		150004
FR-5.010	Functional requirement and objective	IR0004
	Patient has access to a support directory.	
	Behaviour	
	 Patient goes to My TB Support and is provided with a list of local hospital/doctor's/emergency contact details based on devices geolocation. Default setting is Location On. 	
FR-5.020	Functional requirement and objective	IR0006
	Patient can access a technical support area for DoseBot.	
	Behaviour	
	 Link to how DoseBot works, for example: Getting Started Your Progress How often content is added to the DoseBot library How does the notifications caregiver feature works Top Known issues Current issues IOS/Android/Windows updates Troubleshooting tips Facility to email or live chat with DoseBot support with technical query from within the app. 	
FR-5.030	Functional requirements and objective	IR0004
	Patient will have access to a listing of online TB support groups and organisations.	



	Behaviour	
	 Provides a lists/links of approved online TB support groups and organisations. 	
FR-5.040	Functional requirements and objective	IR0004
	Area for families/caregivers to get support.	
	Behaviour	
	 Tips for families caring for a loved one who is undergoing a treatment plan. Behaviour/mood patterns that families should be aware of due to side effects of certain combinations of medications. 	

7.3.14 Support FM5- asset Requirements

What artwork, content, music, templates, video, audio might be required to support the functionality:

Ref	Description	CrossRef.
AR-5.010	DoseBot artwork/branding for background of all support areas	FR-5.010 - FR-5.040
AR-5.020	Written content for support directories and technical support area	FR-5.011 - FR-5.040
AR-5.030	Email and or live chat template for technical support	FR-5.020

7.3.15 Support FM5 – complexity

The complexity of Functional Module 5 is rated as L (Low). This area does not require much interaction from the patient, other than clicking on recommended links, reading information and posting questions for technical/customer support. The issues/risks are making sure all the suggested links are relevant and certified and the family support tab has updated, relevant and certified advice and information.

The risk around the geo-location would be low or no internet connection and an inability to pick up location and recommend local directories. The same applies for the online



technical and customer support - with low or no internet connection, this could lead to frustration and delays in resolving issues.

8. References

Footnotes have been placed throughout the document and can be found at the bottom of each page (if applicable).

Additional references:

- WHO on DOTS: http://www.who.int/bulletin/volumes/85/5/06-038927/en/
- BLOGS & Facebook groups:

http://tbpatientssupportgroup.blogspot.ie/?view=sidebar FB groups

https://www.facebook.com/TBAlert/

https://www.facebook.com/StopTBPartnership/

https://www.facebook.com/tbsupportgroup/

https://www.facebook.com/Somali-TB-Support-Group-633653943483126/

https://www.facebook.com/ControlAndPreventionOfTuberculosis/

https://www.facebook.com/stoptbcampaign/

https://www.facebook.com/TBAllianceCE/

https://www.facebook.com/ForTBFreeIndia/

- SANTA: http://www.santa.org.za/
- User research http://blogs.msf.org/en/patients/blogs/tb-me



9. Appendix

9.1 Interview reports

Interview 1: 19/1/17

Method: Phone interview

Interviewer: Babs Chaney

Interviewee: Ann Long

Age: 65

Interviewees location: Cork, Ireland

Main Findings:

- 63 years old
- 9 months drug treatment
- 17 tablets per day
- Weekly drug box to house pills for each day
- Woke early to take pills alarm on phone
- Never missed a day taking pills very organised individual
- Weekly contact with clinic, & monthly contact with specialist

Ann contracted TB when she was 63 years old. Symptoms started in the October and she was give three rounds of antibiotics before she was finally sent to a specialist and given a chest x-ray. Her specialist was Dr. Terry O'Connor from the Mercy University Hospital, Cork

X-rays revealed she had TB and she was diagnosed with Active TB in the February. She went through a series of tests, including HIV to rule out any other illnesses related to TB.

Her drug treatment plan was 9 months and she started off with a prescription for 17 tablets per day. Drugs to be taken on an empty stomach and all at the same time.

She had a weekly drug box, with 7 compartments and each week she filled each box with required drugs for that day. She set her alarm each morning for about 5am, woke, took her 17 tablets and went back asleep.

She preferred to take them this way, as she wanted to sleep some of the drugs off that may cause upset stomach, before she woke to start her day.

She was also recommended to take Folic Acid and Vit B by her doctor. She took these later in the day and had no method of remembering to take these, other than relying on memory & routine.

Her liver functions were not good on the first round of drugs, so her specialist changed one of her drugs to Streptomycin, which she had a reaction to.

Her side affects to this drug were similar to vertigo and she later found out, through a brain scan, that it caused damage to her inner ears and left her with limited ability to drive and walk unaided.

She saw her specialist once a month for the full 9 months of treatment - she would have an X-ray and he would give her an update on her progress.



She would get a blood test every week at her local clinic.

The only information she was given on nutrition & healthy living while undergoing TB treatment, was the Folic Acid & Vit B intake.

Ann had a great support network of family and friends, who helped her through her illness and all that came with her.

She considers herself a very organised, strong-willed & focused person and had no problem sticking to her daily drug prescription.

She has suffered from Cancer, Septicemia and has had a hip replacement, so her life experience played a big role in her acceptance, management and recovery of TB.

Interview 2: 19/1/17

Method: Phone interview

Interviewer: Babs Chaney

Interviewee: Neil

Age: 35-45

Interviewees location: Dublin, Ireland

Main Findings:

- 35-45 year old age bracket
- 6 months drug treatment
- 18-20 tablets per day
- Took pills out at the start of each and took throughout the day with no specific schedule
- Never forgot to take pills, as he knew clearly the consequences of not taking them
- Knew what pills to take daily, based on the label on each of the boxes
- Contact with his doctor every few weeks at the start

Neil caught TB while living and studying in Paris, France, when he was 27 years old. He was put on 2 rounds of antibiotics for what they thought was a chest infection, before they diagnosed him with TB.

He had to spend the first three weeks of his treatment in France, due to the contagious nature of TB at the early stages. The language barrier proved difficult in fully understanding his illness and the extent of the treatment he would have to undergo.

He saw a specialist when he returned to Ireland and from here he understood everything that lay ahead for him and the importance of taking his pills each day. His treatment plan was about 5-6 months.

At the beginning of the treatment, he remembers being on about 18-20 tablets per day. This gradually decreased as he progressed through his treatment.

He had a very loose schedule for taking his tablets each day. When he woke, he would set aside all the pills he needed to take for that day, by reading the label on each pill box and taking out the prescribed daily amount. He would then leave these pills out and take them at intervals throughout the day.



He never forgot to take his pills but as the months went by he definitely became more relaxed about it and his schedule slipped a little. He agreed that some type of alert on his phone may have helped him with his schedule.

He saw his medical health care professional every few weeks at the start but as he progressed, it became less frequent. He felt that he didn't really need the support of his medical health care professional and would have opted to see him/her less often if he could have,

He wasn't given any information on nutrition, healthy living or exercise but said he wouldn't have taken any notice of it, if he was given it. He was a 27 year old guy and he just wanted to take the pills and be cured and then return to his normal life. He wasn't interested in changing his lifestyle to make the journey a little easier.

He received reports from his doctor in the form of reviews of his x-ray's and he remembers not being very interested in them or really understanding what the doctor was talking about. He just wanted to know he was getting better and wasn't interested in any other information.

He was never offered any psychological support but says he wouldn't have been interested if any had been offered, as he didn't have any psychological issues during or after the treatment.

He was not given any information about TB support groups etc but again he wouldn't have been interested in joining or talking to any other patients. He just wanted to keep to himself and get better.

For Neil, the worst part of having TB was feeling weak and fatigued all the time, especially at the start and the quantity of pills he had to take. He wishes they could find a way to minimise the pills you have to take by combining some of them. He also suffered bad stomach cramps and nausea as a side-effect of some of the pills.

Interview 3: 20/1/17

Method: Phone interview

Interviewer: Babs Chaney

Interviewee: Dr. Gabriel Fitzpatrick

Profession: President of MSF Ireland & Head of Communicable Disease Control at HSE.

Interviewees location: Dublin, Ireland

Main Findings:

- Main difficulty with compliance is length of treatment & side-effects.
- Best to target app at family of patients & educate and update them on progress and educate them along the way.
- VOT Video Observed Therapy may assist with adherence.
- Pansensitive TB cases are decreasing
- MDR-TB cases are increasing because people are not adhering to their medication plans.
- Number and types of drugs vary for MDR-TB patient.

Dr. Gabriel Fitzpatrick has extensive knowledge & experience working with TB patients and their families. He has spent time working with TB programmes all around the world, including Chad, Swaziland & Zimbabwe.

In Chad, he followed a childhood malnutrition programme, for children suffering with TB. The team were in direct contact with each child and their family, for the duration of the child's treatment and they had huge success rates. The reason why the cure rates were so high, was because of the constant connection between



the clinic/programme and the family. Each month the family had to attend the clinic to collect their month supply of drugs. It was noted if someone didn't attend and immediately followed up. One girl who lived 16 miles from the clinic, could not attend one month because of bad road conditions, so the team had to travel to her to deliver the drugs. It took 2 Landrovers & 8 staff to get to her - they got stuck twice along the way and had to be rescued. They eventually made it to her with her drugs, but the cost to deliver them was not sustainable.

In his opinion the main reason people lapse on their drug taking is due to the length of the treatment and the nasty side-effects associated with some of the drugs. There is also a big education job to be done in some of the poorer affected areas, to inform and remind people of the importance of sticking rigidly to their treatment plan. He also feels they need to be motivated because of the length of time - they get fed up with it all and feel like just giving up, so constant monitoring and encouragement are needed.

Dr. Fitzpatrick also identified a high volume of smartphone usage in these areas.

During his time in Swaziland, he worked at a hospital that was set-up specifically, to deal with MDR-TB. Their way of dealing with patient adherence was mostly through drug observational therapy and also involving the family. These are all close-knit communities and so support from family and friends was key in success rates. They had field workers, educating and encouraging family and friends in ways they could assist in the patient's treatment plan - eg. contagious periods, importance of taking the tablets, side-effects and what to do/who to contact.

He mentioned VDOT's and suggested this might help with monitoring people who can't always make it to the clinic and to cut out high labour costs associated with the DOTs programme. He suggests the target audience for our app, should be a family member, rather than the TB patient themselves, who are sometimes too ill or disillusioned to care about taking their pills -

https://www.ucl.ac.uk/health-informatics/research/impact-in-research/video-observed-therapy

He also suggested we focus on MDRTB patients, as the rates of this type of TB are increasing, while Pan-sensitive TB (reacting to all standard TB drugs) are decreasing.

Dr. Fitzpatrick also commented on the different types of treatment for the various types of TB. For pansensitive TB, which is where their is no evidence of the patient having been in a country with reports of MDR-TB, the patient will be given a standard treatment plan, which is 4 drugs per day for 6 months. If there's any drug-resistant evidence, then the patient will be subjected to an avalanche of different drugs. Side-effects also occur, which mean more drugs are added to treat these.

His next programme will be in March when he travels to Checkistan, Uzbekistan & Kyrgyzstan to monitor a large programme dealing with MDR-TB. His aim is to talk to staff on the ground and understand what tools they are using for medical adherence and their success rates.

Interview 4: 20/1/17

Method: Skype video interview

Interviewer: Babs Chaney

Interviewee: Liz

Age: 27 years old

Interviewees location: West Coast of America



Main Findings:

- 27 years old
- 11 months drug treatment
- 6-7 tablets per day
- Caught TB in Kenya
- On the DOTs programme so daily visits from a health nurse to observe pill taking
- Felt the DOTs programme was clinic & cold and just focused on pill taking
- No other support offered for dealing with the psychological difficulties that patients go through
- Set up a TB support group to offer support and education to patients around the world
- Would love a more holistic approach to treating TB

Liz is a 27 year old woman who lives on the West Coast of America and suffered from TB when she was 23 years old. She caught TB while working in Kenya. She was diagnosed with Pulmonary TB and had to spend a further 1.5 months in Kenya before she could fly home to the US because of the contagious nature of the disease at the early stages. She rented a little house and stayed pretty much isolated for the 1.5 months.

While in Kenya, she would go to the clinic every 2-3 weeks to pick up her drugs. She was on about 6-7 tablets a day at the start of her treatment. In Kenya, they gave her pre-packed roles with her tablets for each week, so it was easy to keep on track of what you had to take each day.

When she returned to the US, she was put on the DOTs programme, which is mandatory in the US for anyone suffering with TB. The DOTs programme in the US is very a very strict compliance programme and as they hadn't witnessed Liz taking the medication for the first 1.5 months in Kenya, they wanted her to start the treatment all over again. So her 9 month drug treatment plan because nearly 11 months by the end of it.

The DOTs staff are trained nurses, so they were able to give Liz a detailed overview of her treatment plan and information on the side-effects of some of the drugs she was on. They came to her most days to observe her take and swallow each pill. They would also take blood tests each week. On the days they couldn't attend and on weekends, they left her a little tablet bag for each day and she would take the pills herself.

She refers to the DOTs programme as being clinic and cold. It is in place to cure the patients of TB, not to treat them and support them. She also acknowledges that they are very short staffed and so time with each patient is limited, so they just get through what they need to. The nurse she dealt with, had a number of other patients to see each day, in her county.

She did feel the observation was good in that it 'kept her honest' and she took the pills on days she might otherwise not want to. It wasn't so much that she would have forgotten to take the pills, it was more how they made her feel once she took them. She would feel fine before she took the drugs but as soon as she took them, she would experience stomach cramps, nausea, fatigue and just a general unwell feeling. There was days she just couldn't bring herself to take them and so the DOTs nurses would allow her some 'days off'. She could officially take up to 13 days off her treatment plan, without causing any problems to her recovery. She says that if she hadn't been on the DOTs programme she probably would have taken a lot more of these 'days off' and her treatment would have gone on for a lot longer.

We spoke about VOT (video observation therapy) and how that could aid the DOTs programme by eliminating the need for the nurses to physically visit each patient, instead they would receive a video of the patient taking the tables each day. They could therefore use their time to call to the patients and offer them more psychological help and support.

Liz wanted to be very involved in her treatment and feel she had some element of control left, so she constantly asked for updates on her bloods and her progress, which she got from the DOTs nurses. She also saw a pulmonary specialist every few months (about 3 months or so) and she remembers him just being concerned with her liver functions. She did not receive much update of support from him.



Liz believes in alternative medicine and so she saw her own doctor during her treatment, who recommended she take some probiotics to aid with the harshness of the drugs on her system. She feels they really helped her and she remembered that they also recommended probiotics to her in Kenya. The DOTs nurses never gave any nutritional info or support.

She was never offered any type of psychological help and she really felt she needed it - she needed to hear that other people were going through the same thing and feel supported, rather than suffering in silence. There's a lot of stigma around TB, especially in 1st world countries and she was made feel like a burden on the health system & society. She also felt guilt for having put her family and friends at risk of catching TB. She searched for TB support groups online but couldn't find anything, so she decided to set up her own TB patient support group on Facebook. It is called https://www.facebook.com/tbsupportgroup/

She started connecting with other TB patients and parents/family of TB patients from all around the world. Everyone wanted to share their experience and get support from each other and she has built up a great community of people who all support and educate each other. She is still running the page today. She feels very passionate about offering support to TB patients and their families. She says the system just wants to control the problem through compliance but they need to understand what the patients are going through and help treat them by offering support, the focus can't just be on the pill taking. She says a lot of the patients in her support group feel totally unsupported and some of them suffer with depression because they are overwhelmed with feelings of guilt and shame at having TB and no one to talk to about them.

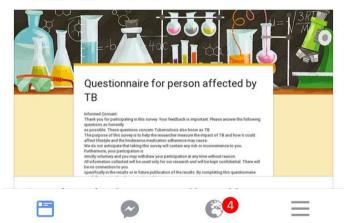
Liz would love if there was a more holistic approach to treating and curing TB.





Hi friends! I hope you are all doing well! Please reach out if you are looking for help and support, you can send a message to me via the page at anytime! This is a link for a questionnaire from a caring team of people who are trying to create at an app to help with treatment compliance and support. I talked with one of their members today and am very hopeful that this app and all the research that has gone into it is a great step in the right direction for supportive TB treatment that doesn't just look at pill compliance but also patient support! If you have time please fill out the questionnaire, it is private.

https://goo.gl/forms/srqcV7LaeKm12NWk1





Interview 5: 25/1/17

Method: Phone interview

Interviewer: Busisiwe Nyembe

Interviewee: Zolelwa Sifumba

Age: 25-35

Interviewees location: Cape Town South Africa

Occupation: Final Year Med Student University of Cape Town.

Main Findings:

- 25-35 year old
- 24 months drug treatment
- 21 tablets and injections daily for the first 6 months.
- Focused on pill taking as she was just starting her Degree in Medicine.

Findings.

Zolelwa contracted MDR TB and was on treatment between 2012-2014. "You don't forget to take your pills, you will definitely remember, you just don't want to take them" she says. Nobody tells you about the side effects and explains the technicalities and what to expect while you're on treatment and that is the toughest part.

Being a medical student, I knew I had to read up on it and educate my family as the clinic only provides you pamphlets with basic information.

She opted to take her pills at night when going to bed, because taking them in the morning would mean she would be sick all day. Her program was to visit the clinic daily for her dose, but couldn't because of school. With the help from TBProof personnel and a letter from the University of Cape Town she was allowed to collect for the month in advance after 6 months, as she still had to go into the clinic daily for injections.

She says that she probably wouldn't have finished her treatment if it weren't for the guys at TBProof," you need to have support all around, yes, your parents are there, but they don't know what you are going through and just how bad the side effects can get". Most clinics in East London have counselling facilities, but people don't attend because of the stigma around TB. So it's up to you as an individual to find a group of people with the same goal and belong. She mentions that the support group she was part of helped her through her treatment, seeing people of different ages and races, she could relate to. People that were going through the same thing as her.

She feels that technology/app would aid the DOTS program. The interaction, inspirational messages and encouragement. A feature that allows you to put in your goal and reason why you take the medication, as hers was to finish her Degree and become a Doctor, she would look at the sticky note on the mirror and she knew why she needed to take her pills.

Interview 6: 21/1/17



Method: Phone interview

Interviewer: Busisiwe Nyembe

Interviewee: Andrea von Delft

Age: 25-35

Interviewees location: Cape Town South Africa

Occupation: Medical Doctor.

Findings.

Because Andrea and her husband Nils are both medical doctors, they knew of the precautionary measures they needed to take. They decided on a strict infection policy until his culture came back negative. Nils was moved to an outside room and they had dinner outside, even in the cold and wet Cape Town winter.

Andrea prepared all of the meals and did the shopping and cleaning around the house, she was responsible for his treatment by arranging different pills in different patterns to a make it easier. "I would leave him notes under his pillow to encourage him and we would pray together daily" she says.

Coping with the side effects was the hardest part and Nils slept a lot, so all the household responsibilities fell upon Andrea, including financial matters. Nils's persona changed and he became fuzzy and forgetful to a point where Andrea says it irritate her, but she couldn't explain to him. Everything revolves around the patient, when they have to take the drugs, when is their next culture due, what were the results, is he/she eating and exercising enough.

A lot of changes had to be made in their social lives, they didn't spend time with friends in the first 8 weeks, while he was still considered "infectious" and even after they still saw friends less and didn't do much activities together as before, because he was always tired and slept.

Andrea thinks that technology should be utilized in preventing and treating TB. Skype calls, because of the isolation factor. "I think we need to move away from DOT police-ing and "adherence" and rather move towards a platform where patients are encouraged, informed, supported and empowered. It should change their perception of being a victim of TB to a fighter, who has support from their community. I think to make family and friends of the patient also knowledgeable will help them get through the treatment. Making them part of a TB survivor community will be great. Giving them a platform where they can share their stories so that others can benefit can also be great. We need to evolve our thinking from the biomedical approach (take tablets under supervision = get cured) and acknowledge the psycho-social issues and leverage for our patients." She says.

Interview 7: 26/1/17

Method: Phone interview

Interviewer: Babs Chaney

Interviewee: Helen Clegg

Profession: Communications Manager, TBAlert UK



Interviewees location: Brighton, UK.

Findings:

Helene works as the Communications Manager for TBAlert in the UK. TBAlert focus on issues like creating awareness of TB, helping communities & organisations in highly affected areas and supporting them through their treatment. TBAlert offers help and support in the following countries - UK, India, Zimbabwe, Malawi and Zambia. Her experience was mostly behind the scenes with TB awareness & support and they organisation had previously been looking into an App for medical adherence, so we spoke to her around what role she feels technology could play in help treat TB.

Helen feels there is definitely a role for technology to play in the treatment of TB. She agrees that the reason patient don't always take their prescribed medication is because of the toxicity of the drugs and the associated side-effects, rather than simply forgetting to take them due to the number of time and the length of the treatment plans. She also says that after about 2 weeks of treatment, the TB patient may start to feel alot better and not feel like they need to continue to take the drugs. Helen says there's a big education role to play here, in an aim to educate patient and families about the risks of developing MDR-TB if they do not adhere to their medication. She feels this could be done through the App because with such diverse markets, it is difficult to offer educational communications through all channels. The App would be a point of reference for the patient and their families and empower them to learn more about their illness and take more control of their recovery.

Helen also spoke about the type of TB patient that an App like DoesBot may not be suitable for and that is for those with more chaotic lifestyles - drug addicts, HIV-patients, homeless people and those with poor literacy. For these type of TB patients, the DOTS programme is still the only effective method of treatment, as they need constant monitoring on a one to one basis.

Helen spoke about the importance of including family, friends and communities in the treatment of TB patients, both to reduce the stigma associated with TB, to educate them as to how to deal with side-effects and to teach them how to offer support to the patient during the difficult and lengthy treatment plan.

She spoke about the need for more psychological support, be that through expert advice or just encouraging patients to express their feelings to their family, friends, local medical worker etc. They need a place to talk openingly about how they are feeling, the good days and the bad, so they can learn to talk care of their mental health. A very important aspect to recovery is finding strength, focus and determination to succeed and beat the illness and this can only be done with a healthy mind.

Lastly, Helen spoke about the insights that the App might offer pharmaceuticals in relation to their drugs and the side-effects and this could be an avenue for funding.

Interview 8: 26/1/17

Method: Phone interview

Interviewer: Babs Chaney

Interviewee: Thomas Jensen

Profession: Physician in the public system in Australia. Has also worked on MSF projects in Africa, as an infectious diseases physician.



Interviewees location: Sydney, Australia.

Findings:

Dr. T Jensen has worked with TB programmes in the public system in Australia and as an infectious diseases physician on several projects in Africa, where he worked with Medecins sans Frontieres (MSF/Doctors without borders). Quite different contexts, but a lot of similarities in the way DOTS is organised, including the mandatory observation of taking the tablets. TB treatment is long, especially for MDRTB, and from his experience the outcome is often closely linked to the relationship between the patient and staff. There are often side effects from the drugs, that need to be accepted and tolerated by the patient and it is key to have good support in that process.

Thomas believes that the problems with compliance are mainly caused by intolerable side effects. Other factors are disruption of supply and cost, but that depends a lot on the country and context. The increasing MDR incidence is closely related to the HIV pandemic as well as collapsing health systems leading to interruption of TB treatment.

He believe that patients could benefit greatly from programmes that don't just focus on compliance but that offer the patient additional support around lifestyle and mental health.

Thomas has seen examples of patient using tech, such as HIV, where a lot of patients use reminders on their phones for pill taking. He hasn't seen any TB programmes which encourage or use tech for medical adherence but feels there is definitely a role for it to play in aiding DOTS or similar programmes.

He has worked in a lot of different DOTS programmes and says they are all very different. It really depends on the individual clinic and the staff, as to how much other support they can offer the patient. He believes that a more supportive approach to compliance is vital. Patients often have side effects that they need a lot of support to accept/tolerate because there are no other options (or the available alternative medications are less effective).

He hasn't not seen Video DOTS in use but thinks it could have a role, but mainly for patients in the later stages of their treatment - for example after a couple of months where side effects are better dealt with and the patient has settled into a routine with the treatment and are well enough to manage on their own.



9.2 DoseBot privacy policy

Sections:

- 1. Collecting and Using Your Information
- 2. Collecting and Using Your Personal Information and Health
- 3. Automatic Data Collection
- 4. App
- 5. Cookies
- 6. Disabling the app

The Privacy Policy applies to the use of the DoseBot mobile device application.

INFORMATION COLLECTION AND USE

DoseBot respects your right to privacy.

The use of the App requires user registration. This information is subject to applicable data protection laws and requires user consent. If a patient chooses to register with us they will be asked to provide Personal Information and may be asked to input personal health information. such as the medications you take, the date of your prescription, the number of refills you have made, how often you take your medication, the frequency you would like us to send you reminders to take your medication, whether you take your medication, your doctor's name ("Health Information"). We will send you reminders to take your medications in accordance with this information.

Collecting and Using Your Information

Collecting and Using Your Personal Information and Health Information (Actively Provided Information)

Whenever a user submits information via our App, they consent to the collection and processing of their Health Information and geo-location data and other personal information they provide to us, and the use of their data for marketing purposes, all in accordance with this Privacy Policy. DoseBot respects your right to privacy. Please read this Privacy Policy for more information about collection, storage, use, processing, combination, deletion and disclosure of your Personal Information.

"Personal Information" means information that can be directly associated with a specific person (and includes Health Information). When you register, or update your information through our App, we collect Personal Information including your:

- first and last name,
- e-mail address,
- year of birth,
- gender,



geographic location.

If you are a healthcare provider, during registration you will be asked to provide information regarding your professional qualifications as well as other Personal Information.

If you do not agree to the terms of this Privacy Policy, including with respect to (a) the collection and processing of Health Information (as defined below), (b)our cookies policy, please do not click "START NOW" or "Sign up" and do not use the Application.

We have the highest regard for your privacy and personal information and realize that the success of our service depends on the trust that users have in the way we handle their personal information. This policy sets out our commitments and explains the rights that you have with respect to your personal information.

During registration to use the App you will be required to input other Personal Information with respect to your health, such as the medications you take, the date of your prescription, the number of refills you have made, how often you take your medication, the frequency you would like us to send you reminders to take your medication, whether you take your medication, your doctor's name and the name of your pharmacy ("Health Information"). We will send you reminders to take your medications in accordance with this information.

If you are a healthcare provider using the Application to invite individuals under your supervision to use the Application, you agree not to include any Personal Information about you or your professional qualifications in the text of these invitations. We may also use your Personal Information in order to provide you with personalized third party content or links to third party sites that might interest you, as part of the feed on the Application. We provide this third party content and/or links to third party sites for information purposes only and are not liable for such content or sites.

While we take great care to keep your Personal Information confidential and secure, when you share your health or medication information with others or provide feedback regarding health matters, medications and otherwise, including by means of social media sites, or when you participate in a forum on the Application, any information disclosed that may be automatically made public, and such information will not be considered Personal Information by us. You should exercise caution when disclosing any information (including Personal Information) in such ways, as you do not know who will access or use such information and for what purposes. Your Personal Information will not be combined with other information and will not be used for other purposes, except as explained in this policy. Please note that we are not subject to medical secrecy obligations.

We may also use the Personal Information (1) to identify your account for purposes of providing you with customer services and to respond to your requests, (2) to provide you the specific services you select (including the requested reminders), (3) to help diagnose



problems with our servers, to make the Application more useful, for other internal purposes or to customize the Application and personalize its content for you; and (4) to send you texts, emails or other communications regarding general adherence information, Application maintenance, updates, or changes to this Privacy Policy or any other relevant agreements. Please note that we reserve the right to send you such service related communications without offering you the opportunity to opt out of receiving them unless you cancel your account.

Automatic Data Collection

Site: We collect information about your use of the Site (IP address, type of computing or mobile device you use, language of your operating system, the Internet browser you are using, geo-location and use of the Site) through the use of various technologies, such as cookies, web beacons and navigational data collection (log files, server logs, clickstream). For more information on our cookies policy, please see below.

App: When you download, and install our App onto a mobile device, we assign a random number to your App installation. We use this random number in a manner similar to the user of cookies. Because the random number is assigned to your installation of the App itself, it cannot be removed through the settings of your App or your device. If you do not want us to use the random number for the purposes for which we use cookies, please do not install our App.

The App may automatically collect certain information about you when you use the App, such as the type of computing or mobile device you use, your device's IP address and/or unique device ID, your device's operating system, the language of your operating system and the Internet browser you are using. We may use third party service providers to collect such information, in order to assist us with the following: pseudonymised installation tracking, social media recommendations, anonymized crash tracking, anonymized behavior tracking and testing (including in real time) and anonymized A/B testing. We collect such information in order to facilitate use and ensure technical functioning of the App, dynamically generate and deliver targeted content, statistically monitor usage of the App, and improve the overall quality of our users' experiences.

Data collected automatically on the Site or App may be used, for example, to help diagnose problems with our servers, to make DoseBot more useful, to customize DoseBot and personalize its content for you.

The App might access a list of installed apps on your device. This is done only to ensure proper quality of service, as some apps might interfere with the App functionality, such as blocking notifications. Information about installed apps is not transmitted and not shared with anyone.

Cookies



A cookie is a small piece of text that is sent to a visitor's browser. The browser provides this piece of text to the device of the originating visitor when this visitor returns. We use cookies to help personalize your DoseBot experience. Most Web browsers automatically accept cookies, but allow you to modify security settings so that you can approve or reject cookies on a case-by-case basis or reject all cookies. You can configure your web browser to remove cookies by following the directions provided in your Internet browser's "help" section.

SECURITY

We will take reasonable steps to protect Personal Information as you transmit it to us and to protect such information from loss, misuse and unauthorized access, disclosure, alteration or destruction. However, you should keep in mind that no Internet transmission is ever completely secure or error-free.

We will use a tool called "Google Analytics" to collect information about the use of the Application. Google Analytics collects information such as how often users visit the Application, what pages they visit when they do so, and what other sites they used prior to coming to the Application. Google Analytics collects only the IP address assigned to you on the date you use the Application, as well as information regarding your operating system, language and information regarding your use of the Application, rather than your name or other identifying information. We do not combine the information collected through the use of Google Analytics with Personal Information. We use the information we get from Google Analytics only to improve the Application. Google's ability to use and share information collected by Google Analytics about your use of the Application is restricted by the Google Analytics Terms of Use located at http://www.google.com/analytics/terms/us.html and the Google Privacy Policy located at http://www.google.com/policies/privacy/.

DISABLING THE SERVICE, ACCESS, CORRECTIONS AND DELETION

At any time, you can stop the collection of your information by uninstalling the App and refraining from using the Site. You may also request that your Personal Information be deleted from our active databases. We cannot restore information that we have deleted. You are responsible for backing up the data that you store on the Application. We may retain any data in non-identified form, subject to applicable law.

Privacy policy updated February 2017



9.3 Evidence of teamwork

Initial logo and tagline brainstorm:



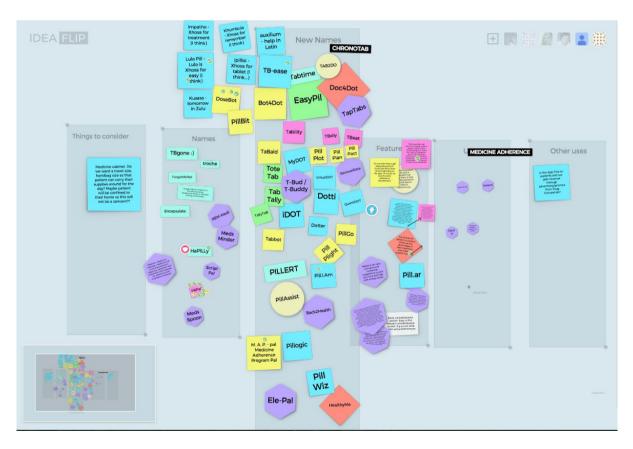


Roadblock! - Brainstorm for name change: from PillPal to DoseBot

When we conducted the first brainstorm around the name, no one on the team Googled the name "PillPal". We were all very excited about having thought of such a great name! However, if we had Googled, we would have quickly realised that not only was the name taken, but the products named "PillPal" did very similar things to what we were thinking about.

It felt like a death punch. Would we have to start again? Do any of the other names work? It feels like we're cheating now that we know there's something like this out there. Not only out there, but also with the same name. On the positive side, it was quite affirming to realise that there was a company making a go at this.

A rather low-key stand-up meeting ended on a high when we decided on the name DoseBot. It was such a good pivot for us, that it's hard to even remember why we liked "PillPal" to begin with. We aren't developing a copy of an existing product, we're developing our product and we believe in it wholeheartedly.





Task boards - team workflow in Trello:

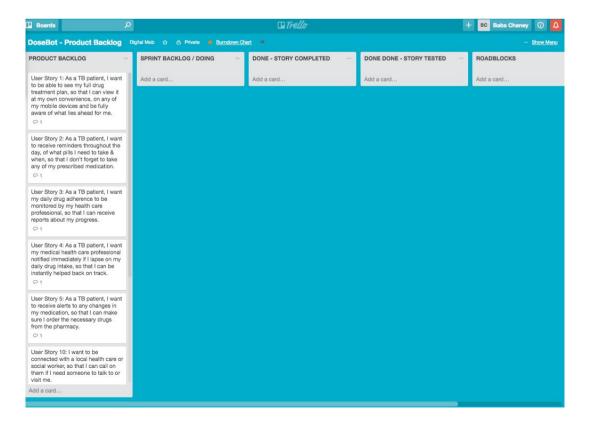
For our initial task board, we set up a simple board with 4 swimlanes:

- Todo list this contained all items on the POC that needed to be done for assessment 1
- Doing this swimlane is for tasks we agreed to do for the week's sprint. They were assigned to a team member.
- Done this was set up for tasks that the team agreed had been completed & needed no further work

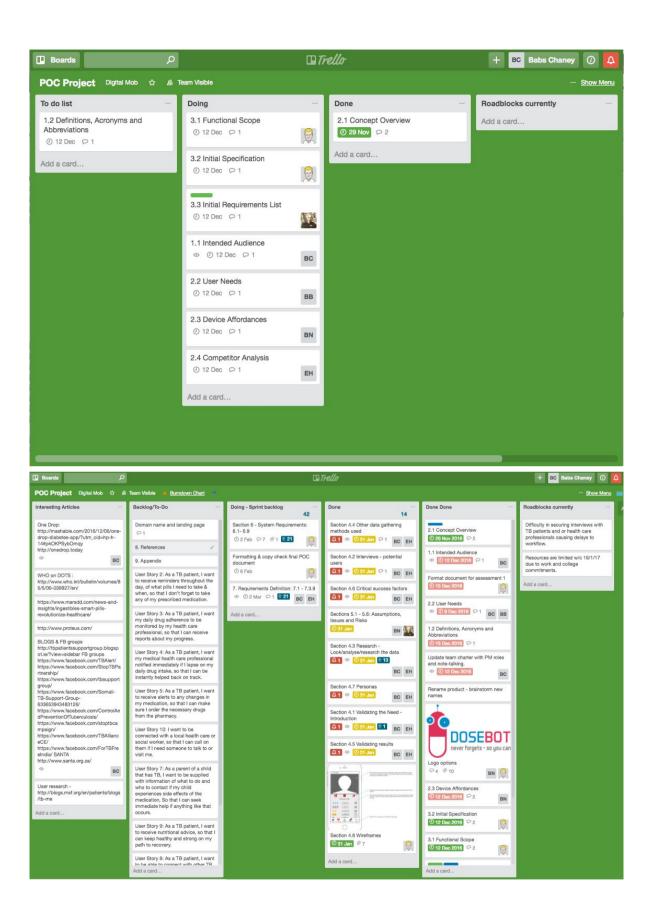
Roadblocks - this was to highlight any potentials issues we had to deal with that week. Once we moved through different topics on the course and became more familiar with Trello, we decided to rename and add in some more swimlanes. To the left (first swimlane) we had an "Interesting Articles" swimlane, which is where team members were encouraged to put sites, FB pages, articles, etc relating to our POC product.

We then renamed our to-do list as our product backlog, as this would be our PB if we were in development stage. Our DOING lane, became our sprint backlog. We then separated out DONE & DONE DONE because we found that some tasks in the sprint were DONE but needed further review and sign off by team members.

When the team felt they needed more time to approve the task, then it went into DONE. Once it was reviewed and approved, then it moved into DONE DONE. This way we could keep track of things that still need final team approval. We found this system worked very well for our team and allowed everyone complete clarity on what was completely done and what was still left to complete.

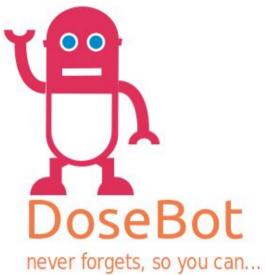








DoseBot logo design - the iterations:

























Final logo:







