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Study of needs for data gathering of migraine patients to monitor their disorder

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Abstract (Italian)

Dalla letteratura e da una serie di conversazioni con pazienti emicranici emerge chiaramente la necessità di avere una traccia fedele delle crisi e dei comportamenti del paziente e di sensibilizzare e coinvolgere le cure primarie nella gestione dei propri pazienti emicranici affinché possano affrontare e seguire loro in un corretto percorso di cura. Nelle conversazioni i pazienti aggiungono il desiderio di migliorare il rapporto umano con gli Specialisti dei Centri.

Questo studio sviluppa una proposta di Sistema Informativo che soddisfi i requisiti emersi. La procedura e il Sistema Informativo qui proposti consistono in un'Applicazione Web che implementa la maggior parte delle funzionalità utili a Medico di Base, Specialista e Paziente più una App Mobile dedicata esclusivamente alla registrazione del Diario Emicrania; l'applicazione mobile può funzionare off-line e viene fornita una funzione di sincronizzazione per allineare i due database. Dalle verifiche effettuate, la soluzione proposta in questo studio, sembra offrire una soluzione realistica in grado di: coinvolgere il Medico di Base nel processo di cura del paziente, aiutare il paziente a tenere il proprio diario nel tempo e semplificare la comunicazione tra Specialista e paziente, aiutando per stabilire una migliore relazione umana tra paziente e clinici. Tuttavia, l'effettiva attuazione di una procedura come quella proposta incontra ostacoli importanti: non ci sono abbastanza medici di base in Italia per garantire la necessaria attenzione ai pazienti "atipici"; ogni Medico di Base utilizza uno dei tanti sistemi informativi per la gestione dello studio medico disponibili sul mercato e replicare parte delle informazioni in un nuovo sistema dedicato ad una specifica patologia sarebbe considerato uno spiacevole lavoro aggiuntivo.

Thesis Summary (Italian)

L'emicrania non è un sintomo ma è una malattia neurologica che colpisce principalmente le donne e rappresenta la terza patologia più frequente e la seconda più invalidante dell'umanità secondo l'Organizzazione Mondiale della Sanità (OMS). La caratteristica tipica dell'emicrania è quella di convertire in dolore stimoli non dolorosi come stress, cambiamenti ormonali femminili, cambiamenti climatici, ritmi sonno-veglia irregolari, digiuno, ecc. In Italia lo studio IRON, finalizzato alla creazione del Registro nazionale dell'emicrania cronica, mostra come il 48,5% dei soggetti abbia eseguito esami diagnostici impropri o inutili e l'80% di queste procedure sia grave in termini economici sul Servizio Sanitario Nazionale. Impressionanti anche i dati sulla consultazione degli Specialisti da parte dell'emicrania cronica: pur trattandosi di una malattia cronica, solo il 52,6% ne ha consultato uno nella propria vita, rivolgendosi a Specialisti non idonei nel 19,6% dei casi, e chi pensava di sentire uno Specialista l'opinione si è rivolta mediamente a 7 diversi Specialisti, dimostrando ancora una volta il loro girovagare alla ricerca di novità e cure. L'emicrania nasce dall'impatto di fattori esterni / stile di vita su una base biologica predisponente. Ogni trattamento farmacologico deve quindi essere sempre associato all'adozione di un miglioramento delle abitudini e alla rimozione dei trigger evitabili (Barbanti, Malorni, & Tarricone, Impatto socio - economico dell'emicrania in Italia, 2018).

È quindi evidente la necessità da un lato di avere una traccia fedele delle crisi e dei comportamenti del paziente e dall'altro di sensibilizzare e coinvolgere la medicina di base nella gestione dei propri pazienti che soffrono di emicrania affinché possano indirizzarli e seguirli nel un corretto percorso di cura.

Durante lo stage a tempo pieno che sto attualmente frequentando presso “Your Business Partner” (YBP), società di consulenza strategica, innovazione e leadership (Your Business Partner, 2020), sono stata coinvolta in prima persona in un progetto di consulenza sponsorizzato dal l'azienda farmaceutica Lundbeck (Lundbeck , 2020) che sta lanciando un nuovo trattamento di profilassi per l'emicrania cronica. All'interno di questo progetto, abbiamo effettuato conversazioni con chi soffre di emicrania, medici di medicina generale e specialisti dei centri per la cefalea. Le interviste confermano le esigenze sopra espresse e aggiungono il desiderio del paziente di migliorare il rapporto umano con gli Specialisti dei Centri, troppo spesso concentrato solo sugli aspetti clinici del disturbo; un'analisi completa dell'esito delle interviste e dei punti chiave emersi fanno parte di questo lavoro. Questo studio è stato fatto per capire se, utilizzando la tecnologia, è possibile rendere più efficace e fluido il rapporto tra il Paziente emicranico e tutti i clinici che se ne prendono cura così da entrare in empatia con il tempo della visita. Diverse applicazioni disponibili sul mercato supportano la registrazione del diario dell'emicrania e alcune offrono anche un sito web per condividere i risultati con gli Specialisti. L'esame di alcune di queste applicazioni mostra che esse affrontano solo in parte i punti chiave emersi dalle interviste: manca il coinvolgimento del Medico di Medicina Generale e le applicazioni generalmente privilegiano la completezza dei dati raccolti rispetto alla facilità d'uso per il paziente. Inoltre, le interviste mostrano che pochi pazienti utilizzano applicazioni digitali e spesso le abbandonano.

Ho quindi elaborato una proposta di Sistema Informativo che soddisfi i requisiti emersi. La procedura e il Sistema Informativo qui proposti consistono in un'Applicazione Web che implementa la maggior parte delle funzionalità utili a MMG, Specialista e Paziente più una Applicazione Mobile dedicata esclusivamente alla registrazione del Diario dell'Emicrania; l'applicazione mobile può funzionare off-line e si prevede una funzione di sincronizzazione per allineare i due database. Le caratteristiche necessarie a garantire la riservatezza dei dati gestiti sono previste e descritte in questo documento. Questo studio descrive brevemente le funzioni della Web Application e la sua architettura, mentre include una descrizione precisa del Database, che ho ritenuto necessaria per la comprensione del sistema. Per l'App mobile è stato descritto il Database ed è stato realizzato anche un prototipo dettagliato dell'Interfaccia Utente. Per facilità di descrizione, il nome convenzionale M-Migraine viene utilizzato per identificare il sistema. La logica generale di M-Migraine è stata discussa con alcuni clinici, che hanno dato parere positivo sulla soluzione e la procedura che si propone di attuare. Il prototipo dell'interfaccia è stato invece testato con alcuni pazienti affetti da emicrania: i risultati dei test sono stati positivi e sono state apportate alcune modifiche in base alle osservazioni dei pazienti. Alcuni dei commenti, come l'integrazione di Migraine Diary con Google Calendar, sono riportati come idee per ricerche future.

Dalle verifiche effettuate, la soluzione proposta in questo studio, basata su componenti web condivise da tutti gli attori coinvolti nel processo e una semplice applicazione mobile per la gestione del diario dell'emicrania, sembra offrire una soluzione realistica in grado di: coinvolgere il medico di base nella processo di cura del paziente, aiutando il paziente a tenere il proprio diario nel tempo e semplificando la comunicazione tra Specialista e paziente, contribuendo a stabilire un miglior rapporto umano tra paziente e clinico. Tuttavia, l'effettiva attuazione di una procedura come quella proposta incontra ostacoli importanti: non ci sono abbastanza medici di base in Italia per garantire la necessaria attenzione ai pazienti "atipici"; ogni MMG utilizza uno dei tanti sistemi informativi per la gestione dello studio medico disponibili sul mercato e replicare parte delle informazioni in un nuovo sistema dedicato ad una specifica patologia sarebbe considerato uno spiacevole lavoro aggiuntivo.

Abstract (English)

From the literature and from a series of conversations with migraine patients it is clear the need to have a faithful trace of the patient's crises and behaviors and to raise awareness and involve primary care in the management of their migraine patients so that they can address and follow them in a correct path of care. From the conversations the patients add the desire to improve the human relationship with the Specialists of the Centers.

This study develops a proposal for an Information System satisfying the emerged requirements. The procedure and the Information System proposed here consists of a Web Application implementing most of the functions useful to GP, Specialist and Patients plus a Mobile App exclusively dedicated to the recording of the Migraine Diary; the mobile application can operate off-line and a synchronization function is provided to align the two databases. From the verifications made, the solution proposed in this study, seems to offer a realistic solution capable of: involving the GP in the patient care process, helping the patient to keep his/her diary over time and simplifying communication between Specialist and patient, helping to establish a better human relationship between patient and clinicians. However, the effective implementation of a procedure such as the one proposed comes up against important obstacles: there are not enough GPs in Italy to guarantee the necessary attention to "atypical" patients; each GP uses one of the many information systems for the management of the medical office available on the market and replicating part of the information in a new system dedicated to a specific pathology would be considered an unpleasant additional work.

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First of all, I thank my Supervisors, Professor Franca Garzotto and Professor Susana Muñoz Hernández, who promptly helped me in the development of this thesis.

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A special thanks to all the patients I interviewed to check the prototype and to the doctors who had the patience to discuss with me the ideas and the structure of the procedure proposed in the thesis.

Finally, my gratitude goes to the many Internet sites that I have consulted to understand the world of migraine, to the Figma application that I used to make the prototype and to the dbdiagram.io application that I used to describe the Databases.

1 Introduction

During the full-time internship that I am currently attending at “Your Business Partner” (YBP), a strategy, innovation and leadership consultancy company (Your Business Partner, 2020), I have been involved first-hand in a consultancy project sponsored by the pharmaceutical company Lundbeck (Lundbeck , 2020) which is launching a new prophylaxis treatment for chronic migraine (based on a medicine named Vyepti®). The project aims at understanding and mapping the journey of the Patient affected by migraine in Italy as well as understanding how to catch the Patients at early stages of the disease before the chronicization, that is highly linked to the overuse and addiction of Patients to symptomatic drugs, and offer effective treatments.

Together with my YBP teammates, I carried out conversations with migraine sufferers, General Practitioners and clinicians of specialized Centres, named in Italy “Centri Cefalee”, to understand the situation as-is in this country. From these conversations has emerged that the quality of the relationship between clinicians and Patients is fundamental for the success of any therapy: as of today, it is too often reduced to the pure clinical sphere and the human-to-human aspect is not cherished enough. As it will be explained later, this does have an impact on the chronicization of the disease as the Patient is less likely to stay with the Specialist and follow the treatment plan correctly. The Annex 1 is the signed permission from YBP to use some of the project data in this study. Any data used is anonymized.

Even though I personally have some relatives affected by migraine, I didn’t know much about the disorder. I realized through my readings and the researches carried out with the consultancy company how disabling the disease is and how much it is underestimated.

“Migraine affects 11% of the general population worldwide, with a prevalence of 18% in women and 9% in men in Italy. It is estimated that 6 363 000 Italians suffer from current migraine. Migraine leads to severe disability with negative effects on quality of life and an obvious impact on direct and indirect social costs and work productivity. (S, 2009)”

As reported from the World Health Organization, “In the Global Burden of Disease Study, updated in 2013, migraine on its own was found to be the sixth highest cause worldwide of years lost due to disability (YLD). Headache disorders collectively were third highest” (WHO, 2016)

It should also be noticed that in most case the Specialist in treating headaches (neurologist) will likely diagnose migraines based on medical history, symptoms, and a physical and neurological examination of the Patient and only in rare circumstances when the condition of the sufferer is unusual, complex or suddenly becomes severe, tests to rule out other causes for the pain (Mayo Clinic, 2011). It is then essential to collect as much information as possible about the anamnesis of the Patient, including the co-morbidity and a detailed diary of the migraine attacks.

After having understood how much migraine affects the daily life of the sufferers and the diffusion of it, I decided that I wanted to give a contribution. Initially I had the idea of creating an application that the Patient could use to track their attacks; after further exploring the state of the art, I realized that such applications are already on the market (Jewell, 2020). But all of them lack in:

- Helping or supporting the human relationship between the involved parts.

- Including the General Practitioner in the information flow, concentrating on the Specialist-to-Patient.
- Being simple enough to invite the Patient to continue collecting the diary in time.

1.1 Migraine

Headache disorders affect a vast part of the population: within the last year about half of the adult population have had a headache. Such diffusion makes headache disorders one of the most common nervous system disorders (World Health Organization, 2016). Headache disorders are characterized by recurrent cephalalgia divided into two categories: primary and secondary headaches. The primary ones are a disorder by themselves, caused by independent mechanisms; the most common primary headaches are migraine, tension-type headache and cluster headache (ICHD-3, 2019). The secondary ones instead are a consequence of other conditions of which the most common is medication-overuse.

As previously mentioned, among the most common primary headache disorders there is migraine (or severe Cephalalgia), characterized by recurrent cephalalgias of various intensity. Migraine attacks last from 4 up to 72 hours with a variety of symptoms. Other than the one-sided thumbling headache that gives the name to the disease (from Greek hēmikrania, from hēmi- "half" + kranion "skull" (Online Etymology Dictionary, 2020)), other symptoms of the attacks are visual disturbances, nausea, vomiting, dizziness, extreme sensitivity to sound, light, touch and smell, and tingling or numbness in the extremities or face (Migraine Research Foundation, 2020). A widely spread type of migraine is the migraine with aura in which attacks are preceded by a sight disturbance in the form of blind spots and flashes of light, the so-called aura, which usually lasts less than an hour.

Migraine affects 1 billion people worldwide (Migraine Research Foundation, 2020), making it the 3rd most prevalent illness in the world behind dental caries and tension-type headache (The Migraine Trust, 2020). Migraine affects 12% of the population with higher diffusion among women than men (3:1). The disorder is most common between the ages of 18 and 44, but can develop also in younger children and in menopausal women. 90% of sufferers have relatives with the same condition, making migraine a familiar condition, even though it has not been identified yet a clear pattern of inheritance (U.S. National library of medicine, 2020).

As a consequence of the severity, frequency, and unpredictability of the condition, it is not unusual for the affected people to also suffer from depression, anxiety, and sleep disturbances. Not being able to predict when an attack may arrive, makes for the migraine Patient impossible to plan activities as well as fear of when the headache may strike next time. Dr. Richard Lipton during the interview “Understanding the Economic Burden of Migraine: Q&A with Dr. Richard Lipton” carried out by the American Migraine Foundation in 2017 affirmed that “People with migraine might live with the ‘what if’ question—what if I get an attack today and can’t do what I need to do? What if I get an attack today and my boss doesn’t understand? What if I get an attack today and my child is ill and needs me?” emphasizing how migraine reflects also on the social lives of the sufferers. (Lipton, Understanding the Economic Burden of Migraine: Q&A with Dr. Richard Lipton, 2017)

Despite the severity of the disorder, migraine is often underestimated by the sufferers and by the General Practitioners. The majority of subjects affected by the disorder do not investigate their condition and do not seek medical care for it. The underestimation of the disorder causes the diagnosis to not arrive, as for about half of the migraine sufferers, or to arrive very late: the average time between the first symptoms and the diagnosis is 7 years (Vaccaro, 2020). Sufferers are highly impacted by the delayed diagnosis as episodic migraine may turn chronic due to medication overuse (Migraine Research Foundation, 2020). The Medication-overuse headache (MOH) is a major health problem all over the world, considering the potential secondary effects of chronic drug overuse on different organ systems (e.g., kidney, liver) (Grazzi & Andrasik, 2006)

Migraine comes in a spectrum, from mild to chronic. It is defined as chronic when the sufferer counts 15 headaches per month with at least 8 attacks with migraine characteristics (American Migrane Foundation, 2020). Chronic migraine affects 1% of the population, 85% of which are women (Migraine Research Foundation, 2020). Most people under-estimate the disease and don't fully realize how disabling the condition is: migraine disorder classifies 6th among the most disabling diseases in the world as 90% of sufferers cannot function properly while having the attack, making the sufferer impaired for days at end. About 20% of chronic migraine affected people are disabled and the possibility of disability greatly increases in case of comorbidity.

Lastly, an overlook of the economic impact of such a severe and common condition is needed. The economic burden of migraine is due both to direct and indirect costs. With "direct costs" it is meant all the costs that are due to the treatment of the disease itself: Specialist medical visits as well as other doctor appointments, pharmaceutical treatments, eventual hospitalizations, diagnostic tests and general exams all fall under the category of primary costs. In the United States, where the majority of costs are sustained directly by the Patient and not by the state, it has been estimated that the annual direct cost of migraine is $9.2 billion. (Agosti, 2018)

Indirect costs are all the expenses or lost revenue caused by migraine not relative to the treatment of the condition. Reduced productivity and work loss are part of the indirect costs. It is estimated that in Europe, out of the annual cost per capita of 1177€, 93% is due to indirect cost. (Agosti, 2018) It is important to highlight that the issue of absenteeism is not the only indirect cost source: presenteeism is very important. With presenteeism it is intended the work hours attended while ill. In a study where productivity loss due to different conditions were being compared, it was shown that migraine related presenteeism costs were the highest: 89% of costs related to migraine are due to presenteeism.

1.1.1 An overview of Migraine symptoms and treatment

A simple and useful overview of the migraine disorder may be found in the *webmd.com* website (Ratini, 2020). The following information is derived by this source. Well-structured description of the disorder, symptoms, therapies may be found in the article MIGRAINE - A COMPREHENSIVE REVIEW (Ravisankar, Hundia, & Sindhura¸others, 2015). The following describes shortly the migraine disease, to better clarify the context where the proposed System should operate and the data that will be collected.

- Migraine is a strong headache.
- The symptoms vary and mostly happen in stages:

    - **Prodromes**: hours or days before the headache, most people experiment something unusual, like being sensitive to light, sound, or smell, feeling fatigued, food cravings or lack of appetite, mood changes, other unusual feelings.
    - **Aura**: some time before the attack, behavioral disorders generated by the nervous system. These symptoms last generally less than 1 hour and include vision disorders (lights, black dots, decreased vision), difficulties in speaking clearly, and others.
    - **Attack**: A migraine headache often begins as a dull ache and grows into throbbing pain. It usually gets worse during physical activity. The pain can move from one side of the head to the other, can be in the front of the head, or can feel like it's affecting the entire head. Nausea and vomiting very often accompany a migraine attack. The headache last mostly less than 4 hours, but there are worst cases, lasting for days. The frequency of the attacks varies: mostly 2 to 4 events per month are reported.
    - **Postdrome**: up to one day after the attack, the Patient may feel unusual conditions: tired or euphoric, hungry or without appetite etc.
- Migraine causes are yet unknown: researches are in progress to find changes in brain or in genes. “Current thinking is that a migraine likely starts when overactive nerve cells send out signals that trigger your trigeminal nerve, which gives sensation to your head and face. This cues your body to release chemicals like serotonin and calcitonin gene-related peptide (CGRP). CGRP makes blood vessels in the lining of your brain swell. Then, neurotransmitters cause inflammation and pain”. Studies show that some genetic inheritance may exist.
- Most common migraine triggers are: hormone changes (women), stress, foods, skipping meals, changes in weather, strong smells, loud noises, flashing lights, medications (for comorbidities), Caffeine, Physical activity, Tobacco, Alcohol, Changes in sleep pattern.
- Nowadays there is no cure for migraine, but several drugs can treat or prevent the attacks. Medications used to fight migraines fall into two broad categories (Mayo Clinic, 2011):
    - Pain-relieving medications: these types of drugs are taken during migraine attacks and are designed to stop symptoms.
        - Pain relief: Over-the-counter (OTC) drugs mainly based on acetaminophen, aspirin, caffeine, and ibuprofen
        - Triptans Ergotamine and other strictly doctor prescribed drugs depending on the Patient sensitivity.
    - Preventive medications: If other treatments don’t work, the headaches are severe, or the Patient has four or more migraine days a month, the doctor may suggest these. The sufferer takes them regularly to make their headaches less severe or frequent; next chapter contains more information on the medicines normally used.
- Home remedies ease migraine symptoms: resting in a dark and quiet room, ice pack on forehead, drinking plenty of water, tea or similar.

The following schema shows the “Alberta Guideline” used in Canada to help the General Practitioner in assessing the headache case for adult Patients (Becker, Findlay, Moga, & others, 2015).

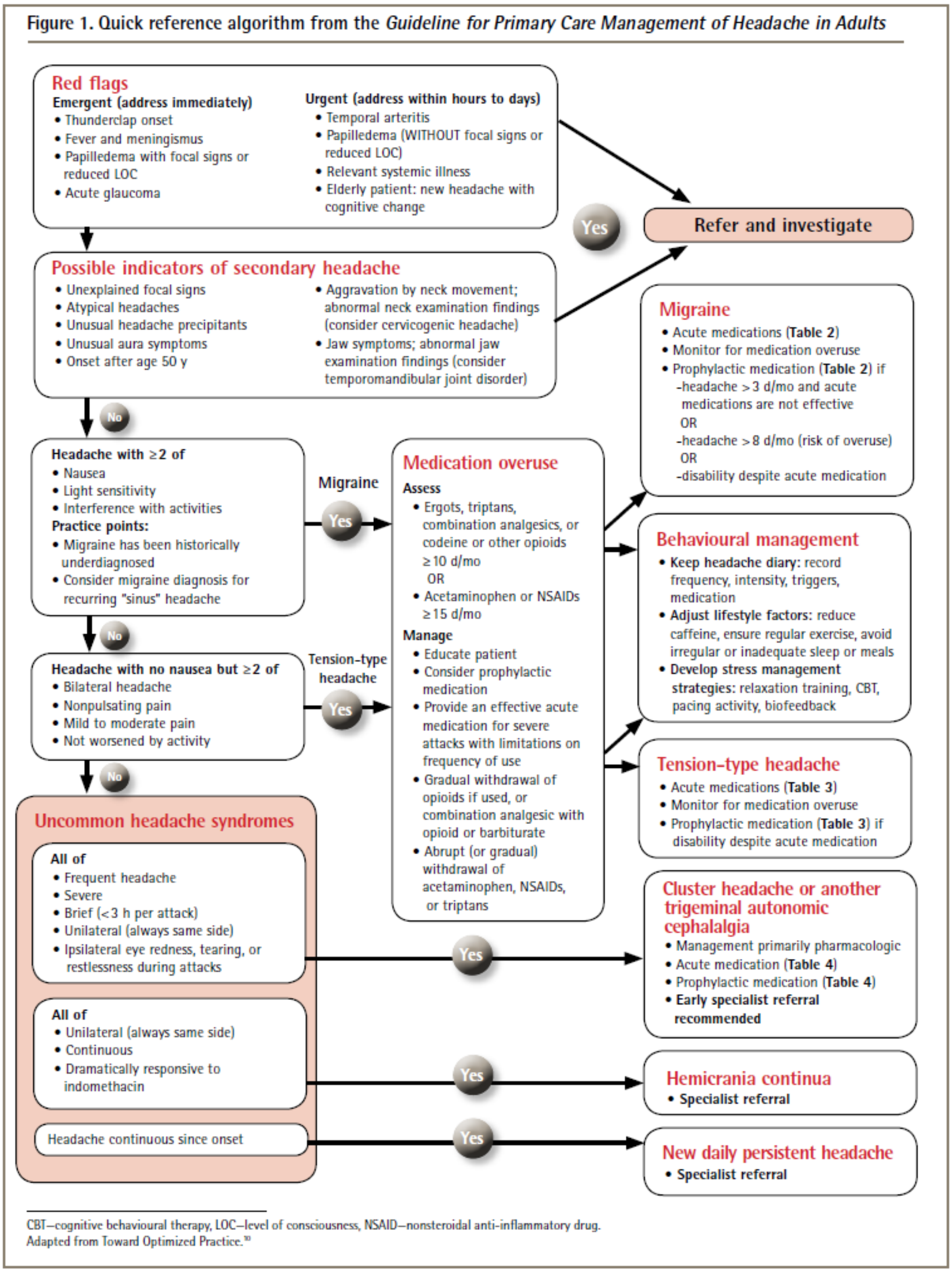

Figure 1.1: The Canadian suggested diagnosis flow for the GP

1.1.2 Frequently named Drugs for Migraine treatment

For ease of reading, I list here some drug classes and active principles used in the therapies of Migraine, that will be mentioned in this study. Definition taken from Wikipedia.

Pain killers: drugs taken to relieve symptoms. E.g.:

Paracetamol: also known as acetaminophen, is a medication used to treat fever and mild to moderate pain.

Ibuprofen: is a medication in the nonsteroidal anti-inflammatory drug (NSAID) class that is used for treating pain, fever, and inflammation.

Antidepressant: are medications used to treat major depressive disorder, some anxiety disorders, some chronic pain conditions, and to help manage some addictions.

Anti-epileptics: are a diverse group of pharmacological agents used in the treatment of epileptic seizures. Anticonvulsants are also increasingly being used in the treatment of bipolar disorder and borderline personality disorder, since many seem to act as mood stabilizers, and for the treatment of neuropathic pain.

ARB: angiotensin receptor blockers are a group of pharmaceuticals that bind to and inhibit the angiotensin II receptor type 1 (AT1) and thereby block the arteriolar contraction and sodium retention effects of renin–angiotensin system. Their main uses are in the treatment of hypertension (high blood pressure), diabetic nephropathy (kidney damage due to diabetes) and congestive heart failure.

FANS: (Italian acronym for NSAIDs, Nonsteroidal anti-inflammatory drugs) are members of a drug class that reduces pain, decreases fever, prevents blood clots, and in higher doses, decreases inflammation. Side effects depend on the specific drug but largely include an increased risk of gastrointestinal ulcers and bleeds, heart attack, and kidney disease. The term nonsteroidal distinguishes these drugs from steroids, which while having a similar eicosanoid-depressing, anti-inflammatory action, have a broad range of other effects. First used in 1960, the term served to distance these medications from steroids, which were particularly stigmatized at the time due to the connotations with anabolic steroid abuse.

> **Indomethacin:** is a nonsteroidal anti-inflammatory drug (NSAID) commonly used as a prescription medication to reduce fever, pain, etc. In Italy, the medicine named Difmetre, containing Indomethacin, Caffein, and Prochlorperazine is commonly used as a strong symptomatic treatment of migraine especially when accompanied by nausea.
>
> **Aspirin**: also known as acetylsalicylic acid (ASA), is a medication used to reduce pain, fever, or inflammation. Specific inflammatory conditions which aspirin is used to treat include Kawasaki disease, pericarditis, and rheumatic fever.

Beta Blockers: are a class of medications that are predominantly used to manage abnormal heart rhythms, and to protect the heart from a second heart attack (myocardial infarction) after a first heart attack (secondary prevention). They are also widely used to treat high blood pressure (hypertension). Beta-blockers reduce blood vessel dilation, which is known to contribute to migraine. Reduce nervous system electrical activity. Beta-blockers make the nervous system less excitable. They also suppress waves of electric currents that are thought to be a factor in migraine aura.

Ca Blockers: Calcium channel blockers (CCB), calcium channel antagonists or calcium antagonists are a group of medications that disrupt the movement of calcium (Ca2+) through calcium channels. Calcium channel blockers are used as antihypertensive drugs, i.e., as medications to decrease blood pressure in Patients with hypertension. CCBs are particularly effective against large vessel stiffness, one of the common causes of elevated systolic blood pressure in elderly Patients. Calcium channel blockers are also frequently used to alter heart rate (especially from atrial fibrillation), to prevent peripheral and cerebral vasospasm, and to reduce chest pain caused by angina pectoris.

Triptans: are a family of tryptamine-based drugs used as abortive medication in the treatment of migraines and cluster headaches. This drug class was first introduced in the 1990s. While effective at treating individual headaches, they do not provide preventive treatment and are not considered a cure. They are not effective for the treatment of tension–type headache, except in persons who also experience migraines. Triptans do not relieve other kinds of pain.

Botulin: Botulinum toxin (BoNT) is a neurotoxic protein produced by the bacterium Clostridium botulinum and related species. It prevents the release of the neurotransmitter acetylcholine from axon endings at the neuromuscular junction, thus causing flaccid paralysis. The toxin causes the disease botulism. The toxin is also used commercially for medical and cosmetic purposes. In 2010, the FDA approved intramuscular botulinum toxin injections for prophylactic treatment of chronic migraine headache.

Monoclonal Antibodies: CGRP migraine treatment is a new type of treatment used to prevent and treat migraine pain. The medication blocks a protein called Calcitonin Gene-Related Peptide (CGRP). CGRP may cause inflammation and pain in the nervous system of people who have migraine attacks.

1.1.3 Migraine in Italy

Migraine affects 11.6% of the Italian population: 15.8% of Italian women and 5% of men suffer from the disorder. Chronic migraine is more frequent in the older population, with 42.2% of sufferers being 55 to 65 years of age, with prevalence of occurrence in women. In average, the first symptoms occur at age 22, but can also occur in teenagers and younger children. Also, in the case of early onset, prior to 18 years of age, women are more affected than men: (42,1%, against 26%). (Berti, 2019)

It is important to highlight that despite the severity of the condition, overall, only 30% of sufferers takes advantage of the specialized Centre, called Centri Cefalee. In particular, the people that go to the Centers are 50.4% of chronic sufferers and 35% of women. In particular, only 14.5% consider the Centro Cefalee as their main point of reference for the disease. More than 55% of the sufferers have as main reference a Specialist, a neurologist operating through the public health service (SSN, Servizio Sanitario Nazionale) or privately. The 25% of migraine Patients instead, have as main interlocutor their General Practitioner. (Berti, 2019)

The economic burden in Italy is very high. Migraine costs the country 20 billion euros each year, 93% of which is due to indirect costs. (Barbanti, Malorni, & Tarricone, Impatto socio -economico dell'emicrania in Italia, 2018) As demonstrated in the “International Burden of Migraine Study” conducted in 5 countries among which Italy, direct costs for a non-chronic Patient in the country amount to € 828,52 per year (€ 425.60 spent on pharmaceutical treatment) and to € 2.648,12 for chronic Patients (€ 1.279,92 spent on pharmaceutical treatment). (Barbanti, Emicrania, storia di un personaggio in cerca d'autore, 2021)

Last but not least, Migraine in public opinion is mostly not perceived as a real disease, but as a minor disorder, just a matter of a couple of analgesics. Sometimes the attack is considered as a classical excuse not to do something unwelcome. Then creating a wrong approach to the migraine possible cares, often not consulting any Doctor at all, exaggerating in symptomatic treatment, worsening the situation.

1.1.4 The Migraine Registries

In many countries a database concerning the anamnesis of migraine sufferers is organized and maintained in Databases allowing the Clinicians to study changes in headache patterns, health care resource utilization, diagnostic and management strategies, development of co-morbidities and responses to therapies.

In the case of American Registry for Migraine Research (ARMR)[1] "the registry has multiple components: The first component is an online platform in which participants fill out a baseline and follow-up questionnaires and clinicians enter the participants' headache diagnoses. There is also an ARMR headache diary mobile app in which participants share daily information about their migraine attacks, their level of function and their treatment, if any. The third component is a blood sample, which is processed and stored in the ARMR biobank and will be used for genetic analyses. Brain imaging data are collected in the ARMR Neuroimaging Repository, and electronic health record data are pulled and confidentially entered into a centralized ARMR database." (American Migraine Foundation, 2018)

In Italy, as from my searches, there are open projects aimed to the creation of National Migraine Registry, but no Standard Database is published yet or at least I did not find any publishing references. The projects are:

- I-GRANE, promoted by Centro Ricerche San Raffaele;
- RICe, by SISC (Società per lo Studio delle Cefalee);
- IRON, by Centro Cefalee of University of Bologna.

2 Definitions and Acronyms

This chapter lists the actors involved in the Migraine care process and some other terms used in this document that need some explanation. The Chapter "Involved Actors and Key Terms" contains further details on the most relevant terms used.

General Practitioner (GP): "is a medical doctor who treats acute and chronic illnesses and provides preventive care and health education to Patients" (Wikipedia). Named in Italy "Medico di Base".

Centro Cefalee: (plural Centri Cefalee) Italian equivalent of Headache Centre. Centre specialized for the treatment of headache disorders, among which migraine.

SSN: Servizio Sanitario Nazionale, the Italian National Healthcare Service

CUP (Centro Unico di Prenotazione): The IT based reservation system of the Italian National Healthcare Service.

LEA: The essential levels of assistance (LEA) are the performances and services that the National Health Service (SSN) is required to provide to all citizens, free of charge or upon payment of a participation fee (ticket), with the public resources collected through the general taxation.

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[1] The ARMR project has been suspended May 6, 2020 due to lack of funding (American Migraine Foundation, 2020)

Codice Fiscale: The Italian tax code is a code that is used to uniquely identify physical persons and other subjects other than physical persons in their relations with the entities and public administrations of the Italian State. For natural persons it consists of 16 alphanumeric characters. (Wikipedia)

FDA: USA Federal Drug Administration

Patient: the person suffering from migraine headaches.

Clinician: someone, such as a doctor, who has qualifications in an area of very skilled health work.

Specialist: in this context the Clinician specialized in Headache diseases, normally a Neurologist, working in a "Centro Cefalee" or other Clinical Structures.

Migraine Registry: A national database collecting data about Patient attacks, therapies, comorbidities, clinical information, etc. Basic asset for the researchers in the field.

Migraine Diary: The paper or digital journal of migraine attacks and other relevant events that the migraine sufferer should constantly maintain to help the Clinician in driving the therapy.

MOH: Medication-overuse headache.

Patient Journey: The path they take while facing an illness: an approach that highlights all the moments of the personal care experience of the individual and of the figures that revolve around him. What this proposed system wants to support in the migraine case.

Your Business Partner (YBP): The consulting firm managing the Lundbeck migraine consultancy project.

Lundbeck: The Pharmaceutical company committing the YBP consultancy project.

Novartis: Novartis International AG is a Swiss multinational company operating in the pharmaceutical sector. Second largest pharmaceutical multinational in the world by turnover after Pfizer.

SISC: Società Italiana per lo Studio delle Cefalee (Italian Association for headache study).

3 Statement of the Problem

A significant number of applications designed to record the Migraine Diary are available on the market (Jewell, 2020). But what I examined is mainly dedicated to the data recording from the Patient side, giving small attention to the relationship Clinic – Patient and offering an interface that appears heavy to use for a Patient suffering of bad and frequent diseases: the applications taken into consideration seem to favor the completeness of the data over the ease of use for the Patient, which facilitates its continuous use over time.

Then the psychological support offered by the Specialist of Centro Cefalee, very relevant for the Patient, nowadays is often insufficient because of the lack of time of the Specialists. As a result, the Patient judgement on the Centri is sometimes poor and distances the Patient from attending the treatment (as from YBP conversations with Patients).

Then the problems approached in this study are:

- How to include the General Practitioner in the information flow, now concentrated on the Specialist-to-Patient.
- How to improve the Human relationship between Patient and Specialist.
- How to help the Patient to maintain over time a simple and sufficiently detailed diary of his life with migraine that facilitates the work of the Specialists who treat him.
- How to contribute to the data gathering at national level to support the growth of an Italian National Registry.

4 Purpose of the Study

This study is based on state-of-the-art analysis of:

- The migraine Patient journey,
- The applications available for collecting diaries,
- The research carried out with YBP commissioned by Lundbeck.

The outcome of the study is:

- A system proposal (Procedure, Requirements, Data required to support the process, and an overall description of a possible IT support system) that involves physician, Specialist, Patient in different ways.
- The implementation of the prototype of the smartphone application supporting the Patient's diary recording.

5 Method of this Study

1. As explained in the introduction, the question to be answered with this study arose from my participation in the Lundbeck consultancy project during the full-time internship at Your Business Partner (YBP). In a nutshell, the question is:

   Using technology, is it possible to make the relationship between the migraine Patient and all the clinicians who take care of them more effective and fluid so as to empathize with the time of the visit?

2. Information on the actual state of the doctor - Patient relationship is obtained primarily from the conversations carried out in the project by myself and colleagues with doctors and Patients. Conversation logs have to be processed identifying classes of Patients (personas), their needs, as well as the strengths and the areas for improvement in the relationship with clinicians.
3. In the meantime, search and study of the bibliography necessary to better understand migraine, the current state of medicine on the subject, the health organization that treats these Patients in Italy, the data necessary for Specialists to propose the correct therapy. I extend the study to the collateral elements, not strictly clinical, of the doctor-Patient relationship that can improve the Patient's confidence in the results of the therapy: the empathic relationship between Patient and doctor.
4. From the above, I set the goals and the requirements to be satisfied by an IT system supporting the process.
5. I prepared a summary of the procedure and look for some doctors to whom to submit the identified requirements for further validation.
6. Then I searched the net to understand the state of the art of the applications available today to manage this specific process. I select

the most used and appreciated products and make a deeper analysis on them.

7. Consolidating the requirements, considering the info coming from the product available, I defined a general design of the proposed system.
8. I designed the required database to support the system.
9. Afterwards, I develop the user interface prototype and validate it with Patients.
10. A review of the prototype based on the feedback received by Patients is finally done.

6 Involved Actors and Key Terms

This chapter lists the actors involved in the Migraine care process and some other terms used in this document that need further explanation.

General Practitioner (GP): "is a medical doctor who treats acute and chronic illnesses and provides preventive care and health education to Patients" (Wikipedia). Named in Italy "Medico di Base", he is the medical doctor that should know at best the overall situation of the Patient and be most frequently in touch with them. The migraine sufferer, because of the perception of its own disorder, does not ask for their support and on the other side the competence of the GP on the subject is not deep enough to offer proper support.

In Italy the citizen refers to one and only one General Practitioner; the citizen can choose to change doctor at any time without giving reasons for the revocation. As from the site of the Italian Ministry of Health, "Every citizen enrolled in the National Health Service (SSN) has the right to a General Practitioner (or family doctor). Every citizen registered with the SSN has the right to a General Practitioner, called "medico di base" or "medico di famiglia". The family doctor is the professional who knows our state of health well and, when the need arises, guides us throughout the therapeutic path within the structures of the SSN, allowing us to access all the services and services included in the Levels of essential assistance (LEA)" (Ministero della salute, 2019).

Centro Cefalee: (plural Centri Cefalee) Italian equivalent of Headache Centre. Centre specialized for the treatment of headache disorders, among which migraine. It is the organization that should identify and supply the proper therapy for the Patient and drive him to a better quality of life. Centro Cefalee is normally included in the Neurology departments of major hospitals, but the availability seems insufficient: for instance, in the metropolitan area of Torino (2,26 million people) only one public Centro Cefalee is available. In all Italy the "Società Italiana per lo Studio delle Cefalee (SISC)" reports 85 "Centro Cefalee".

Patient: the person suffering from migraine headaches.

Clinician: someone, such as a doctor, who has qualifications in an area of very skilled health work.

Specialist: in this context the Clinician specialized in Headache diseases, normally a Neurologist, working in a "Centro Cefalee" or other Clinical Structures. As from my research about the organization of the care levels for primary Headache in Italy, the support is normally organized in 3 levels, sometimes in 4, depending on the Region organization[2]:

LEVEL 1: "Medico di Base" (General Practitioner) or pediatrician
LEVEL 2: Neurologist
LEVEL 3: Centro Cefalee
LEVEL 4: Research Center for Headache. (New, dedicated to complex treatments)

In the following the term Specialist will be used to address the Clinician of any of the level 2-4 that is in charge of the Patient.

Migraine Registry: A national database collecting data about Patient attacks, therapies, comorbidities, clinical information, etc. Basic asset for the researchers in the field.

Migraine Diary: The paper or electronic journal of migraine attacks and other relevant events that the migraine sufferer should constantly maintain to help the Clinician in driving the therapy.

Patient Journey: The path he takes while facing an illness: an approach that highlights all the moments of the personal care experience of the individual and of the figures that revolve around him. What this proposed system wants to support in the migraine case.

CUP (Centro Unico di Prenotazione): The IT based reservation system of the Italian National Healthcare Service. The reservation to any of the Level 2-4 is through this system and any reservation is based on a prescription issued by the "Medico di Base".

Your Business Partner (YBP): The consulting firm managing the Lundbeck migraine consultancy project. "Founded in 2008 by Maria Rosaria Natale Ph.D., who is an entrepreneur, a philosopher and an innovation consultant. Today, the company has expanded its horizons, working on projects of strategy, collaboration and innovation around the world to bring change within companies. Your Business Partner started as a firm working on leadership management to help companies grow, develop their people and improve constantly over time." (Your Business Partner, 2020)

Lundbeck: The Pharmaceutical company committing the consultancy project. It is a Danish international pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of pharmaceuticals across the world. The company's products are targeted at brain diseases, including depression, schizophrenia, Alzheimer's disease, Parkinson's disease and migraine (Wikipedia). The company is launching in Italy a new product named Vyepti, a preventive drug proven to significantly reduce the monthly migraine days of the sufferer.

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[2] In Italy the Regions have direct responsibility for the implementation of the government and the expenditure for achieving the health objectives of the country. The Regions have exclusive competence in the regulation and organization of services and activities intended for the protection of health and the financing criteria of local health authorities and hospitals.

7 Process for the Identification of the Requirements

In the following chapters I am reporting the activities done to gather and consolidate the requirements of the System. The steps have been:

- Collection and review of literature available on the subject.
- Examination of some of the existing Migraine Diary applications.
- Together with the project team, Interviewing of Patients, Specialists and GPs within the YBP – Lundbeck project; study of the results and identification of patterns from the data collected.
- Identification of key points and work out of requirements for the new System.
- Discussion of the results with some Patient and Doctors.

7.1 Literature Review

My first need was understanding the Migraine disorder and the overall state of the art in Italy.

The classical book “Migraine” by Oliver Sacks (Sacks, 1992) in the Italian edition has been my first reading about the subject. The author, as in all his writings, alongside a precise description of a large number of cases, highlights the importance of the human relationship between the Patient and the doctor: “*On a deeper level, however, it is necessary to know the "economy" of a life, the physiological and psychological "needs" of an individual. And this cannot be ascertained quickly or casually: it requires a relationship between the doctor and the Patient and, on the part of the latter, an introspection on the connections between his way of life and his migraines, an introspection that cannot be achieved suddenly.*”

The book “Emicrania, storia di un personaggio in cerca d'autore” (Barbanti, Emicrania, storia di un personaggio in cerca d'autore, 2021) is a more recent review about the disease and the available therapies today. The book “Emicrania: una malattia di genere Impatto socio-economico in Italia” (Barbanti, Malorni, & Tarricone, Impatto socio -economico dell'emicrania in Italia, 2018) from “ISS, Istituto Superiore di Sanità” offers a rich review about the Migraine in Italy and the impact on the society.

7.1.1 Migraine and Patient Journey

The above-mentioned book (Barbanti, Emicrania, storia di un personaggio in cerca d'autore, 2021) is also a useful source about the Migraine Patient Journey.

“Patient Journey is the path he takes while facing an illness. In fact, even the treatment has a departure, encounters, crucial moments with discoveries and obstacles, and a point of arrival: as in a real journey, the Patient experiences all these moments. The scenario in which this journey takes place is that of modern healthcare, a complex system based on a dense network of relationships and services that employ numerous professionals, grouped by membership, and different models of care. Health services are structured in organizational areas that have a certain level of autonomy and sometimes this involves a management of care that is specialized, and that sometimes loses sight of the overall picture. The traditional approach to personal care is to work with the individual department, without considering the entire care process. Working on the Patient journey instead means having a privileged vision of the management of the disease, structuring all the phases of the Patient's journey to understand which are the critical areas so as to redesign his path, in order to improve the quality and efficiency of care. The Patient's gaze is essential to understand the Patient journey in its entirety: they are the protagonists who manage the disease on a daily basis, moving between the different moments of care and meeting multiple professionals.” (Fatebenefratelli, 2019)

A pragmatic description of disease and of the process is also given in the Mayo Clinic[3] document (Mayo Clinic, 2011) where an effective summary is given. Mayo clinic holds an important research team on pain and headache carrying out relevant studies on the subject (Mayo Clinic Neurology, 2021).

Headache classification is well explained in the World Health Organization site (WHO, 2016).

An explanation of prophylaxis drugs and impact on Patients may be found in the “Prophylaxis of migraine: general principles and Patient acceptance” Article (D’Amico & Tepper, 2008).

These are just a subset of the many articles that may be found about migraine on the Internet, especially on *Academia.edu* and *ReserchGate.net* websites.

7.1.2 Existing Diary Tools and Applications

In my overview of the state of the art of the electronic migraine diaries available I noticed how complex they are and how the focus is for the vast majority limited to the gathering of technical medical data ignoring the “human factors” of the Patient. This causes the person to progressively use the application less and less, losing its effectiveness. Indeed, the primary function of the tracker is to log:

- frequency and intensity of attacks
- symptomatic drugs assumed
- connection with side events

helping the Specialist to evaluate how they evolve in time also related to the therapy adopted.

Other information may be useful for the Clinician to build a full picture of the situation when the attacks occur, to find out patterns and understand possible individual triggers of the attacks:

- Weather condition (pressure mainly)
- Sleeping time and continuity
- Blood pressure and rhythm
- Traveling
- Walking / running / physical exercises
- Food (unusual events)
- ………………

Recording all of these requires hospitalization and is clearly hard to record in daily life for a long time. Otherwise, standard technology available on

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[3] “Mayo Clinic is one of the largest not-for-profit, academic health systems in the U.S., with $14 billion in annual revenues and 65,000 employees. With a focus on caring for patients with serious, complex illnesses, Mayo Clinic operates in five states and cares for more than one million people a year, from all 50 states and nearly 140 countries. Mayo Clinic is ranked #1 in the nation by U.S. News and World Report”. (Mayo Clinic, 2021)

smartphones and wearable devices may help in this field. The Migraine Buddy application examined partially implements some of these functionalities.

Many apps are available on Android and Apple smartphones supporting the Electronic Migraine Diary (Jewell, 2020). Out of these many applications, the "Migraine Buddy" app appears to be considered the best (from some reviewer) and definitely the most used: I installed it on my Smartphone and made a careful analysis.

Interesting to notice, there are studies about reasons for non-compliance with headache diaries. In an article from Universitade de Lisboa comes out a 34% of Patients examined as non-compliant; the number of cases examined is about 100 (Borbinha & Martins, 2021). Main reasons for non-compliance: I did not remember to register; I did not have time; I consider the calendar irrelevant.

As usual, different sites give different scores to the apps. The Doctorpedia site lists as the best product the Migraine Coach app, that is not available in Italy, therefore outside the scope of this study. It should also be considered that Migraine Buddy counts more installations than the others.

The following picture shows the Doctorpedia evaluation summary (Doctorpedia, 2020)

Doctorpedia

Migraine App Overall Ratings

Rank	App Name		Effectiveness	Functionality	Design	User-friendliness / Ease of use	Credibility	Score	Total Score
1	Migraine Coach	Doctor	8	7	7	8	8	38	80
		Patient	9	7	9	9	8	42	
2	N1-Headache	Doctor	8	8	8	8	9	41	76
		Patient	7	7	6	7	8	35	
3	Relax Lite	Doctor	8	7	6	8	6	35	72
		Patient	8	8	7	7	7	37	
4	iHeadache	Doctor	7	7	5	7	9	35	70
		Patient	6	6	7	8	8	35	
5	Migraine Buddy	Doctor	6	7	6	8	8	35	69
		Patient	7	6	6	7	8	34	
6	Symple	Doctor	7	6	7	8	7	35	67
		Patient	7	4	7	7	7	32	
7	Ouchie	Doctor	6	4	5	5	6	26	64
		Patient	8	10	6	6	8	38	

Figure 7.1: The Doctorpedia Migraine app ratings

Legenda:

- The Effectiveness category evaluates the effectiveness of the app; how well it does what it's advertised to do.
- The Functionality category evaluates the functions of the app; how many features it offers to the user.
- The Design category evaluates the app's design; how visually pleasing it is to the user.
- The User-friendliness / Ease of use category evaluates how easy the app is to use; if it's comprehensible or difficult to navigate.
- The Credibility category evaluates the credibility of the app's content; do its features have any scientific basis?
- And finally, the Total Score category rates the app based on the combined rating of all the other categories.

The examined applications seem to be standalone app on the smartphone, and the communication with the Clinicians is based on the production of reports required by the Patient. The lack of a central database collecting all the information simplifies the Privacy problem but does not allow the Specialist and the General Practitioner to check real time the progress of the Patient, the compliance to the diary and so on.

7.1.3 Existing National Registries in Italy and Other Countries

Migraine Registries are collections of clinical data, but not only, for study purposes. I could not find on the Internet any open access to registries or to their content, while documentation is available.

In Italy I found mentions of 3 registry projects: IRON, RICe, and I-GRAINE.

IRON project: in progress at the University of Bologna, at the Centro Cefalee of the DIBIDEM department (Università di Bologna, 2020) is also mentioned in the ISS study on Headache impact in Italy (Barbanti, et al., 2018).

RICe project: was created by SISC (Società Italiana per lo Studio delle Cefalee) and launched April 1st 2019 (SISC, 2020).

I-GRANE project: was created by the Centro San Raffaele, AIC and others and launched in 2014 (San Raffaele, 2014), then the project is again named in 2018 (Barbanti, Fofi, Cevoli, & others, 2018).

In general, the data regarding such registries are very few and scattered. It is not clearly declared the set of data collected, the reason for many different projects, and I did not find any guideline to collect a standard set of data from any Centro Cefalee as expected.

More information is found on American equivalents, such as the American Registry for Migraine Research (ARMR). “ARMR is a multicentric study and the data gathered are clinical data, electronic health record (EHR) data, blood samples, and brain imaging data from individuals with migraine or other headache types” (Schwedt, Digre, Tepper, & others, 2020).

7.1.4 Standard Questionnaires

Many examples of migraine diaries are available either in paper and electronic form. Some standard questionnaires are also available and validated by specific studies in different countries. The goal of all these questionnaires is to give a kind of a measure of the disease. Instead, I’m using these to define essential data to be collected by the System proposed in this study.

ID-Migraine: This questionnaire was originally proposed in an article from dr. R. Lipton to identify Migraine in Headache sufferers. He concluded: “The three-item ID-Migraine migraine screener was found to be a valid and reliable screening instrument for migraine headaches. Its ease of use and operating characteristics suggest that it could significantly improve migraine recognition in primary care.” (Lipton, Dodick, Sadowsky, & others, 2003).

The questions of the ID-Migraine questionnaire are the following (Rapoport & Bibal, 2004):

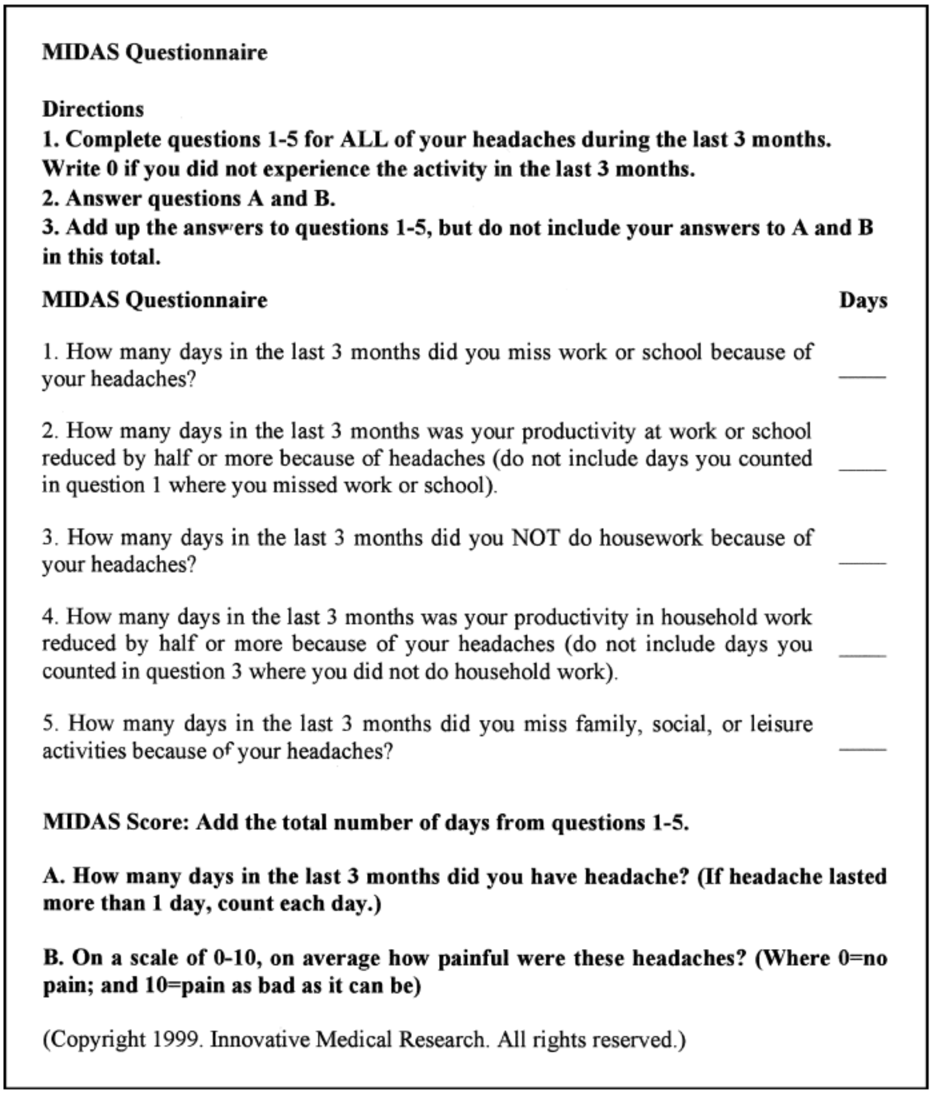
During the last 3 months, did you have the following with your headaches:	
1- You felt nauseated or sick to your stomach	( ) Yes ( ) No
2- Light bothered you (a lot more that when you don't have headache)	( ) Yes ( ) No
3- Your headaches limited your ability to work, study or do what you needed to do for at least one day.	( ) Yes ( ) No

Rapoport adds the following questions in his analysis:

1. Pain is worse on just one side?
2. Pain is pounding, pulsing, or throbbing?
3. Pain is moderate or severe?
4. Pain is made worse by activities such as walking or climbing stairs?
5. You feel nauseated or sick to your stomach?
6. You see spots, stars, zig-zags, lines or grey areas for several minutes or more before or during your headaches (aura symptoms)?
7. Light bothers you (a lot more than when you don't have headaches)?
8. Sound bothers you (a lot more than when you don't have headaches)?
9. Functional impairment due to headache in last 3 months?

The ID-Migraine has been validated for Italy: "In conclusion, preliminary observations on 60% of the sample we planned to examine showed the Italian version of the ID-Migraine as a valid and reliable tool for screening of migraine in Italian headache Patients. If confirmed in the total sample, these results would warrant further validation of the ID-Migraine screener in PCP. This indeed would establish the Italian ID-Migraine as a simple and effective tool to increase recognition of migraineurs also in an Italian population, giving these Patients the chance of more specific and effective treatment." (Brighina, Salemi, Fierro, & Gasparro, 2005)

The MIDAS questionnaire was originally created to identify chronic migraine situations. "The MIDAS questionnaire captures information on disability in terms of missed days of paid work (or school), housework (chores), and nonwork time. All questions are asked about either days of missed activity or days where productivity was reduced by at least half. If productivity is decreased to 50% or less, the day is considered missed. The MIDAS score is derived as the sum of missed days due to a headache from paid work, housework, and nonwork activities, and days at paid work and in housework where productivity was reduced by at least half (sum of responses to questions 1 through 5).". (HeadHache.org MIDAS, 2018; Bigal, Ropoport, Lipton, & Tepper, 2003)



MIDAS Questionnaire

Directions
1. Complete questions 1-5 for ALL of your headaches during the last 3 months.
Write 0 if you did not experience the activity in the last 3 months.
2. Answer questions A and B.
3. Add up the answers to questions 1-5, but do not include your answers to A and B in this total.

MIDAS Questionnaire **Days**

1. How many days in the last 3 months did you miss work or school because of your headaches? ____

2. How many days in the last 3 months was your productivity at work or school reduced by half or more because of headaches (do not include days you counted in question 1 where you missed work or school). ____

3. How many days in the last 3 months did you NOT do housework because of your headaches? ____

4. How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches (do not include days you counted in question 3 where you did not do household work). ____

5. How many days in the last 3 months did you miss family, social, or leisure activities because of your headaches? ____

MIDAS Score: Add the total number of days from questions 1-5.

A. How many days in the last 3 months did you have headache? (If headache lasted more than 1 day, count each day.)

B. On a scale of 0-10, on average how painful were these headaches? (Where 0=no pain; and 10=pain as bad as it can be)

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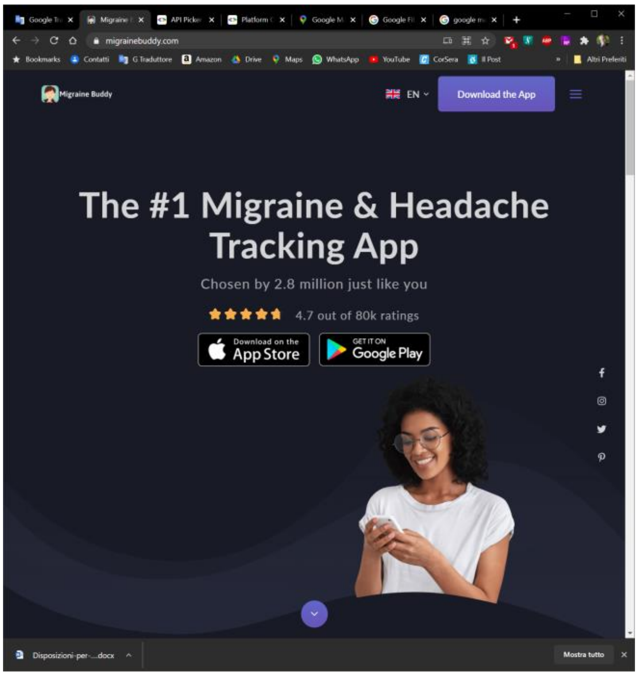
MIDAS questionnaire from (Bigal, Ropoport, Lipton, & Tepper, 2003)

7.2 **Analysis of some Migraine Tracker Application**

7.2.1 Migraine Buddy App

The following description is based on information collected from the *https://migrainebuddy.com/* website and executing the app installed on my own smartphone.



The #1 Migraine & Headache Tracking App

Chosen by 2.8 million just like you

4.7 out of 80k ratings

Figure 7.2: The Migraine Buddy site

The App is widely used (2.8 million of downloads declared at May, 2021), available on Android and iOS, Multilingual.

A registration is required to use the App.

The interface appears to be friendly but the huge amount of information that can be collected requires to go through many forms. The setting allows the user to select the screen that the user wants to fill.

The app is well designed and reasonably friendly. Most of the comments of the users are positive. However, there are also some criticisms:

- Not so easy to use when the Patient is under an attack.
- All the info required is surely useful to help the clinician in driving the therapy, but the effort required to fulfil the forms may discourage the Patient in long term utilization.
- The report produced are not usable for personal analysis (not usable in another app like spreadsheet)
- Some users dislike the high number of notifications sent by the app.
- The mandatory registration opens the door to a lot of spam (but the app is free, and money should come back somehow). Data is also stored on a provider server for security reasons. Healint (the company managing the site) declares that maximum privacy is granted anyway.

7.2.2 Migraine Coach App

As at the beginning of May 2021 the app is not available in Italy on the Android platform. Information in the following come from the author company site *https://migrainecoach.io/home.*

The info available is then not much.

From the site of the product owner the app appears to be simple to use and quite concise.

Eventually not enough information is available to make a meaningful opinion. From what I can see, the metaphor of several bars in the same screen seems effective to reduce the effort in entering data.

7.2.3 N1-Headhache App

This App is available in Italy and I installed it on my smartphone.

The Google Play store reports less than 5000 installations (as of May 2021).

The app requires a registration. Differently from the previous two, this one requires a set of information about the user at registration time. Remarkable is the request of data about drugs assumed for comorbidities and for headache itself.

The application is real time updating data on a central server and offers powerful capabilities of analysis studying connection between Factors (triggers) and Migraine attacks.

The interface to record data about the attack is instead extremely detailed. Many screens, each one relevant to a single fact and many data required makes the all recording long and tedious. Something that will be abandoned soon also if the info collected are probably the dream of the clinicians.

It extends the simple diary capabilities offering some kind of self-care support, as well as support for clinicians.

7.2.4 The NoEmi Web application

NoEmi is a new internet-based application created by Novartis and Paginemediche srl. It is available for free on the Paginemediche.it website (paginemediche, 2020). Noemi has been presented at the SISC virtual congress 2020 (SISC, 2020).

The application is offering a nice interface on a PC or on a tablet, while no smartphone app is available at the time being.

NoEmi offers many functions, starting from a registration of the Sanitary Booklet recording the basic information about the health of the Patient, typically the info that the GP records on their own system while here the Patient is required to make the recording and the update in time.

All the data are maintained historically: new versions may be added not overlapping the previous, so that a track of changes is available.

The information collected include:

- Basic personal info (weight, height, etc.)
- Lifestyle
- Clinical measures (blood pressure, blood glucose value, etc.)
- Comorbidities anamnesis
- Headache anamnesis, creating an “Identity Card” of the Patient’s headache
- MIDAS questionnaire

The lack of the smartphone component makes the all application not user friendly at all for the Patient: they should have access to a PC or a tablet connected to the internet and this is not so widely available in this country. Instead, the advantage is the complete availability of the data to the Specialists.

Nowadays the site suggests to the Patient to use Migraine Buddy as a smartphone application if desired, meaning a double entry of the data on the two applications or renouncing the availability of the diary information on the NoEmi Database.

7.3 The YBP Consultancy Project

During my internship at YBP I took part on the Lundbeck Consultancy project, which is wider than the needs of this study.

During the full-time internship that I am currently attending at "Your Business Partner" (YBP), a strategy, innovation and leadership consultancy company (Your Business Partner, 2020), I have been involved first-hand in a consultancy project sponsored by the pharmaceutical company Lundbeck (Lundbeck , 2020) which is launching a new prophylaxis treatment for chronic migraine (based on a medicine named Vyepti®). The project aims at understanding and mapping the journey of the Patient affected by migraine in Italy as well as understanding how to catch the Patients at early stages of the disease before the chronicization, that is highly linked to the overuse and addiction of Patients to symptomatic drugs, and offer effective treatments.

Together with my YBP teammates, I carried out conversations with migraine sufferers, General Practitioners and clinicians of specialized centers, named in Italy "Centri Cefalee", to understand the situation as-is in this country. From these conversations has emerged that the quality of the relationship between clinicians and Patients is fundamental for the success of any therapy: as of today, it is too often reduced to the pure clinical sphere and the human-to-human aspect is not cherished enough. As it will be explained later, this does have an impact on the chronicization of the disease as the Patient is less likely to stay with the Specialist and follow the treatment plan correctly.

I used conversations and personas created by YBP to identify the needs of the migraine Patients and consequently design the solution proposed.

7.3.1.1 Anthropological Conversations

The goal of the anthropological conversations is to identify the unarticulated and unmet needs of the interviewees, in this case Patients with chronic migraine. To achieve this purpose, a standard interview is not satisfactory. More space is left to the interviewed Patient that decides what information to give following their own pace and granularity. After the Patient narrates its story, in this case their life with the condition, the interviewer guides the conversation towards the points that the Patient has not touched yet. The process allows the gathering of data that the interviewer does not know they need. The downside of the approach is that Patients may not answer certain questions because the flow of the conversation is variable.

7.3.2 Results of the YBP research used in this study

7.3.2.1 Conversations

Conversations with Patients, General Practitioners and clinicians of Centri Cefalee have been carried out by the Your Business Partner team of which I'm part of. The Centri Cefalee involved in the study are: Policlinico di Bari, I.R.C.C.S. San Raffaele Pisana (Roma), A.O. Sant'Andrea (Roma), I.R.C.C.S. Istituto Neurologico Carlo Besta (Milano), Fondazione Mondino - Istituto Neurologico Nazionale I.R.C.C.S. (Pavia). The Patients and the GPs to be interviewed have been pointed out by the Centri Cefalee involved in the study.

Each Patient has been interviewed individually and so happened for the General Practitioners. The meetings with the clinicians of the Centers instead, have been carried out collectively: each session involved the whole team of clinicians of the Centro Cefalee (neurologists, nurses and others).

The conversations have been structured following the YBP approach, leaving the decision of the topics to be treated to the interviewees themselves and using a 360 ° approach. Eventually some final questions are added to deepen important topics that may have been overlooked or touched on superficially.

1. Each conversation lasts 40 minutes to 2 hours and is followed by at least two YBP consultants (I participated in several conversations).
2. Detailed notes (named Transcripts) are kept during the conversation.
3. Then the Transcripts are reviewed and discussed by the consultants and the list of key issues emerged is produced to summarize the results of the conversation. The structure of Key issues has been defined and the transcript is analyzed and each key issue is identified and filled in in a structured report.
4. The YBP study uses mainly a qualitative approach to group and classify the cases in a set of archetypes named Personas, then used to qualify the real needs of the Patients. We analyzed qualitatively the raw data gathered. We clustered the information obtained and developed some personas (fictional characters used to represent Patient types). We also created an empathy map (Gibbons, 2018) to better understand the feelings shared among the Patients. From the conversations with the General Practitioners, insightful information came out regarding their knowledge and relationship with the disease and the Specialists, but due to the limited number of interviews, no formal analysis has been done yet.
5. For the purpose of this study, I have reorganized the key points in an anonymized matrix (one case per line, one Key point per column and assigned keywords to the answer to allow some quantitative analysis on the results of the interview). The Patients' conversations considered in this task are 38. They all come from Patients of the Centers, so they are all experiencing bad and often long paths looking for improvement in their life.
6. The project carried out by YBP involves more conversations and is still in progress. The data used for the purpose of this study is a snapshot of the state of the art at the end of April 2021: only 38 have been analyzed. The sample is sufficient to draw a realistic picture of the real needs of the migraine sufferers.

7.3.2.2 Results from the conversations

Using the coded classification, I made some study on the data of the sample.

7.3.2.2.1 An Overview of the sample

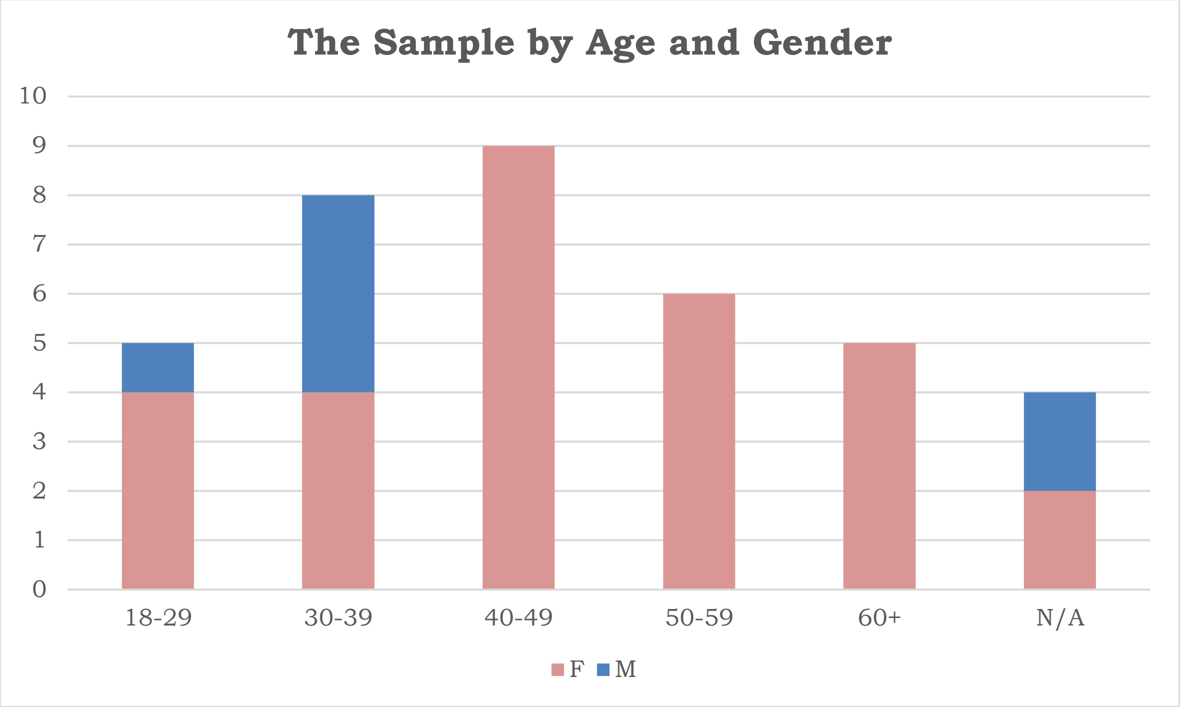


Figure 7.3: Gender and Age in the Sample

From this chart we may see that the Migraine is homogeneously distributed on the ages. As from (Barbanti, et al., 2018) we see that the disorder is more evident in women, but in this sample the ratio is accentuated.

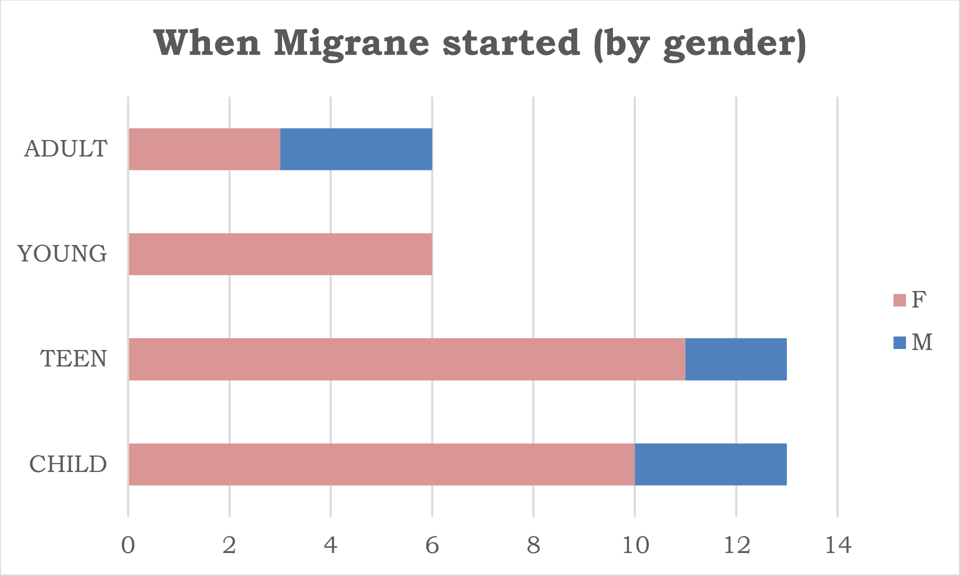


Figure 7.4: Migraine starting in the sample

This chart shows that most of the subjects started to suffer from headaches in their youth or worse childhood.

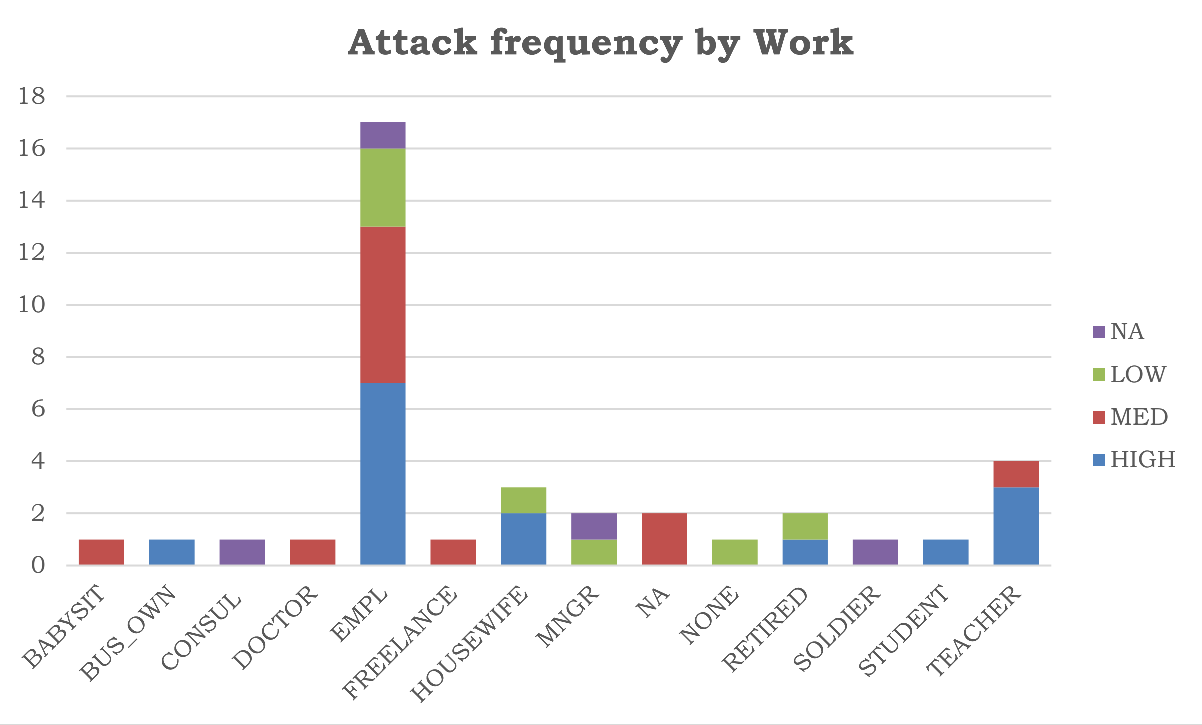


Figure 7.5: Attack frequency by work

In this chart we see the type of work done by the people in the sample and the frequency of attacks (before the current Therapy). No special relationship appears or at least the sample is too small.

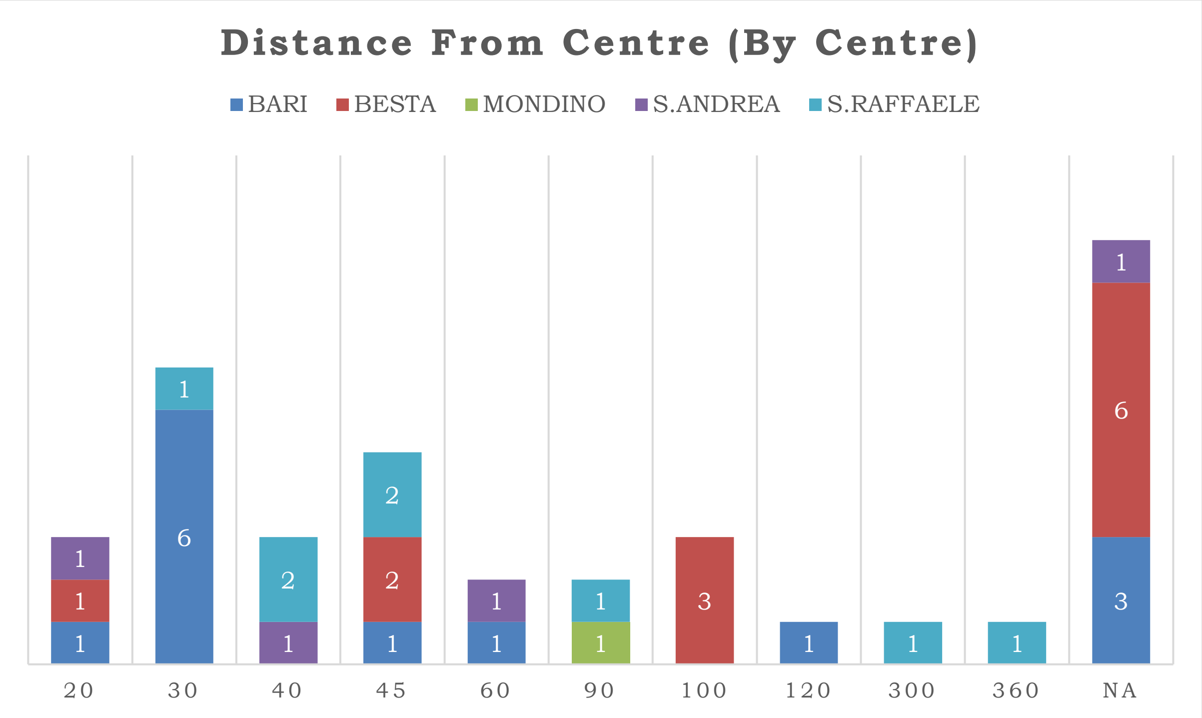


Figure 7.6: Traveling time to the Centre

This chart shows the distance (in minutes of traveling) that each Patient spends to reach the Centre assisting him. This is somehow measuring the intensity of the need for the cure.

7.3.2.2.2 Triggers

Looking at the Migraine triggers, the event or conditions that the Patients recognize as frequently causing a migraine attack, we find the distribution shown in the next chart:

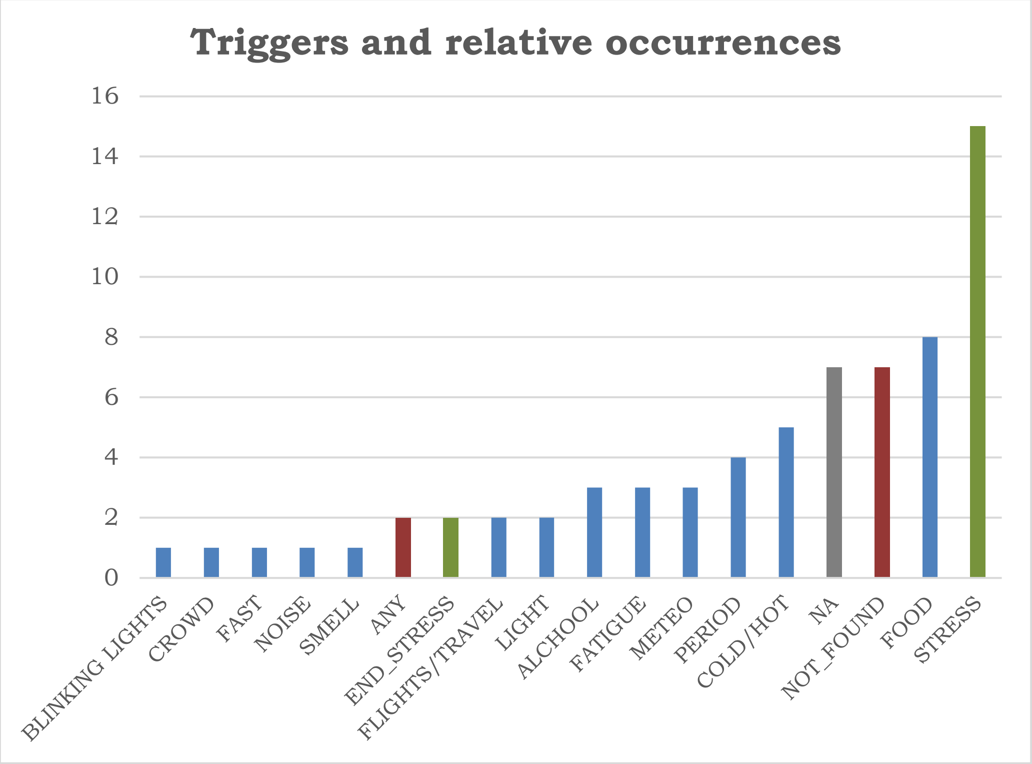


Figure 7.7: Migraine Triggers

The orange bars highlight that Stress (including many different conditions that alter the quiet of the Patient) is by far the most common trigger for migraine attack. It is also relevant to notice that many Patients (red bars) are not able to identify any specific trigger.

7.3.2.2.3 Relationship with the General Practitioner (GP)

The status of the relationship between the Patient and the General practitioner in the cure of Migraine is relevant for this study. The analysis of the sample confirms that in most cases it is unsatisfactory.

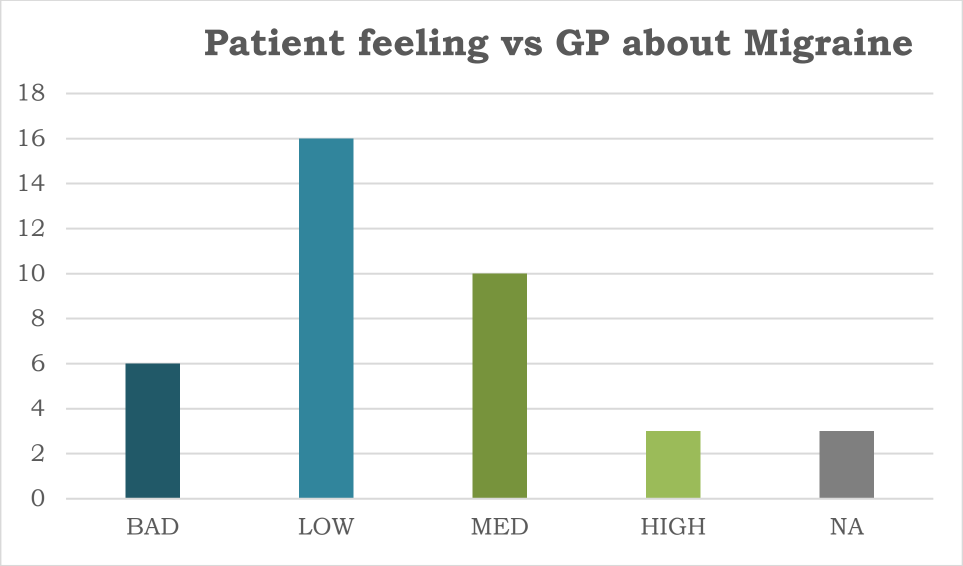


Figure 7.8: Patient feeling vs GP about Migraine

Patient feeling vs GP about Migraine	VALUE	CASE #
GP does not help at all	BAD	6
Minimum support from GP	LOW	16
Some Support from GP	MED	10
GP helps and addresses the Patient	HIGH	3
Patient does not answer	NA	3
	TOTAL	**38**
	Valid Answers	**35**

Relationship level	CASE #	Ratio to valid answers	*Ratio to total*
Negative Relationship	22	63%	*58%*
Acceptable or good	13	37%	*34%*
Do not Answer	3		*8%*
TOTAL considered	**35**		***38***

The above chart and tables show the results: eventually, about 2 Patients out of 3 did not find a valid help in the GP.

7.3.2.2.4 The relationship with the Centro Cefalee
The question is about the feeling of the Patient vs the Specialists of the Centre where they are currently treated.

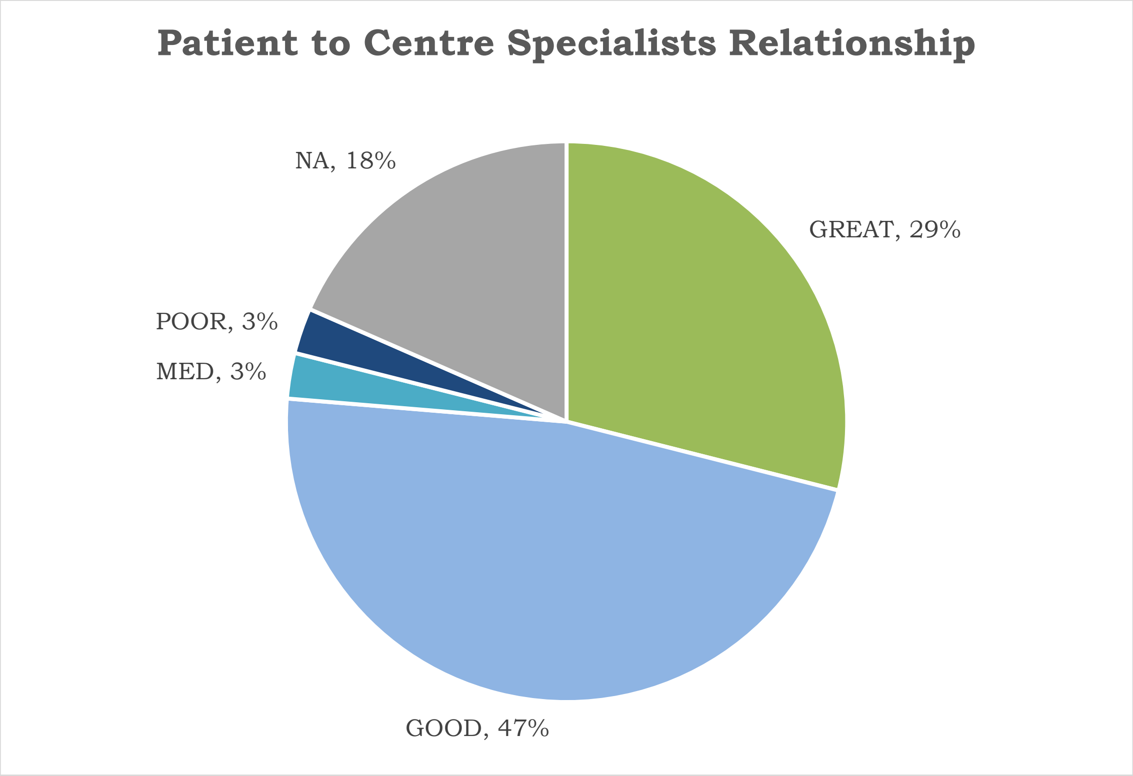


Figure 7.9: Patient feeling vs Centre Specialist

The Specialists of the Centre appear mostly appreciated and trusted. Obviously, the competence on Migraine is much higher than the GP, but also the attention and the availability of the Doctors appears to be good.

7.3.2.2.5 The path of the Patient to the Centre

This key point appears interesting to evaluate the help that the Patients have got in the search of a valid cure.

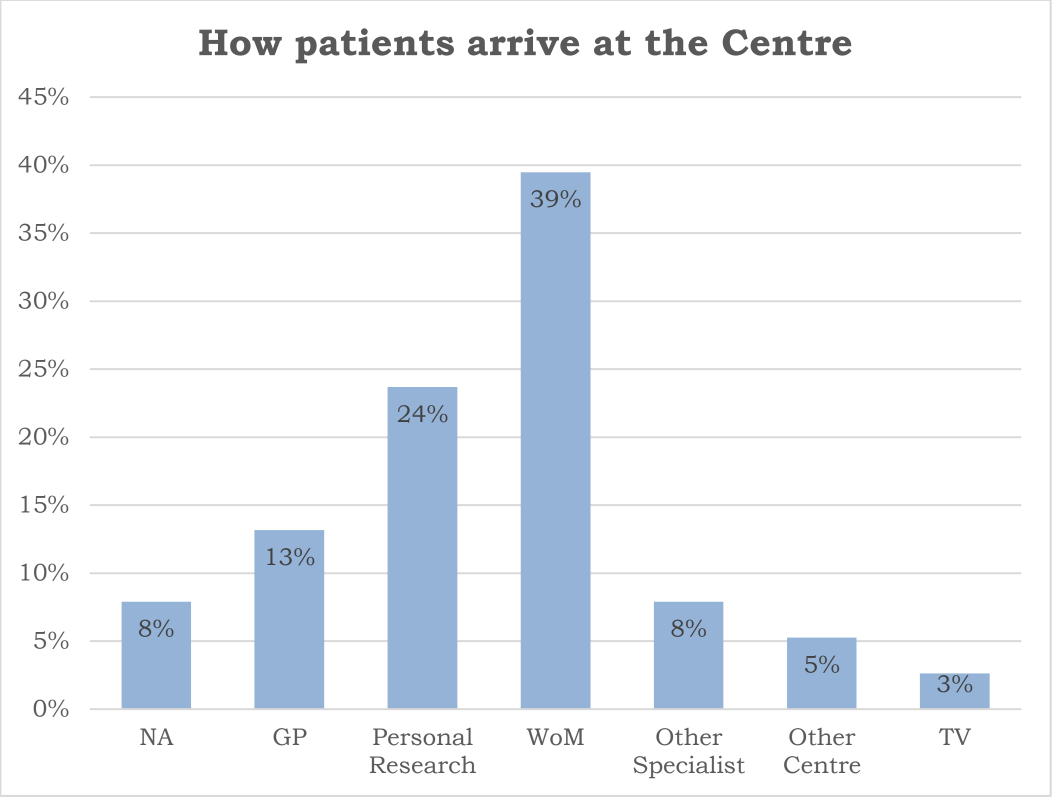


Figure 7.10: The Patient's journey to identify the Center where he is now being treated

Out of this sample, only 13% have been addressed to a specialized Centre, while the vast majority was driven by word of mouth or by personal research. This confirms the ineffective support of the GPs to the migraine Patients.

7.3.2.2.6 How Patients use migraine diaries

Considering what the Patients interviewed declared about their current utilization of diaries, we may see that most of them use a paper support and a relevant percentage does not keep any diary at all. The orange quote declares to look for a better way to keep the diary

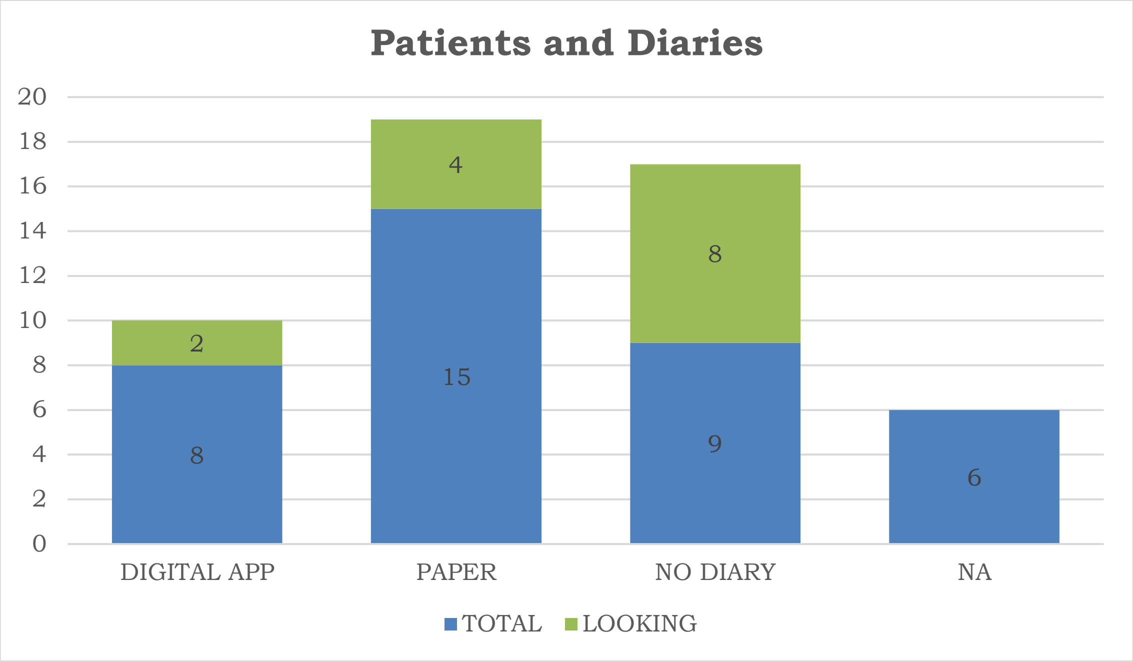


Figure 7.11: How Patients keep diaries

This analysis confirms that there is a real need for an application simple and effective that helps the Patients to keep track of their migraine events.

7.3.2.2.7 Potential users for a new App

Still about the relationship between Patients and diaries, I made another classification of the responses reported in the following table:

Patient Usage of Diary	**Value**	**# of Occurrences**	**% Occurrences**	**Potential Interest (0 - 1)**	**Possible Users**
Use an App, but feel too complex	APP_COMPLEX	2	5,3%	1	2
Use Migraine Buddy	APP_MB	2	5,3%	0	0
Use Patch_AI	APP_PATCH_AI	1	2,6%	0	0
Use other App	APP_UNDEF	2	5,3%	0	0
Use App supplied by the Centre	CENTRE_TOOL	1	2,6%	0	0
Do not Answer	NA	6	15,8%	0	0
Do not keep Diary	NONE	1	2,6%	1	1
Keep a diary on paper or on Excel	PAPER	11	28,9%	1	11
Made on paper, but now stopped	PAPER_ABANDONED	4	10,5%	1	4
Search for a simpler App	SIMPLE_APP	2	5,3%	1	2
Wish a simple App	WISH_APP	6	15,8%	1	6
	TOTAL	38	100,0%		26
	Percentage of Patient estimated interested in a Smartphone simple APP for diary				**68%**

Concluding that from my sample, 68% of the Patients are potentially interested in a new digital diary application.

7.4 **What is emerging**

7.4.1 Key points from the research

The key points emerged from the conversations carried out together with YBP and the study of the literature about Italian migraine Patients and General Practitioners are the following:

KEY1. The Patient needs to be recognized as a sufferer of a condition today too often underestimated, and wants to be followed closely by the clinician.

KEY2. The selection of the Specialist is highly influenced by the human characteristics of the clinician: the Patient is more likely to be more confident in the treatments and stay longer in a Centro Cefalee if they have a good human relationship with the Specialist.

KEY3. The exchange of information between General Practitioner and Specialist occurs for the great majority through the Patient, increasing the probability of loss or alteration of information.

KEY4. The General Practitioner is not always involved first-hand in the Patient's search for the Headache Centre as the GP is not as informed on the disease or because the Patient prefers to do their search solo.

KEY5. It is important to consider the Patient at 360°, therefore involving all comorbidities, daily routine and habits, psychological aspects and so on.

KEY6. Patients use a lot of symptomatic drugs in order to live their day-by-day life. This causes an addiction to the medications reducing their effect, causing the Patient to become drug resistant.

8 Identified Goals and Requirements

8.1 **Goals**

Here follows a list of the main goals derived from the previous key points that the proposed system aims at satisfying.

The system aims at:

GOAL1. Each Actor in the system should be unequivocally identified.
GOAL2. The Patient should feel followed and understood by the Specialist and General Practitioner.
GOAL3. Privacy regulations must be respected protecting the data entered by the Patient. All these data are sensitive.
GOAL4. The General Practitioner should be involved in the migraine clinical care of the Patient as they know the Patient clinically and personally more deeply and broadly than the Specialist.
GOAL5. The Headache diary is the primary output: The Patient should be able to fill the "headache tracker" quickly and with ease, prioritizing these aspects to the completeness of data gathered.

GOAL6. The Specialist should also focus his/her attention to the non-strictly clinical sphere of the Patient emphasizing the empathic and psychological relationship.

GOAL7. The Actors should collect data not only strictly related to the headache disorder to allow for a 360° assessment of the Patient (comorbidities, food habits, sleep pattern, physical activity, hydration, stress factors, blood pressure, cardiac pulse).

GOAL8. The Specialist and the General Practitioner should be kept updated on the number of symptomatic drugs taken by the Patient and their effect.

GOAL9. All Actors should be able to use the interface.

8.2 **Requirements**

When a requirement satisfies more than one goal, it is repeated.

GOAL1. Each Actor in the system should be unequivocally identified.

REQT01 The system must allow Specialists and General Practitioners to register creating an account that identifies them unequivocally (associating their role to their Codice Fiscale).

REQT02 The system must allow the General Practitioner to register their Patients creating an account that identifies them unequivocally using their Codice Fiscale as username and a temporary password.

REQT03 The common database uses as primary key the Codice Fiscale + Role of each Actor which is unique.

REQT04 The system must allow the Actors to access and modify the Patient data only after logging into the system and only if allowed by the Patient.

GOAL2. The Patient should feel followed and understood by the Specialist and General Practitioner.

REQT09 The system must allow the General Practitioner (associated) to create the Patient profile entering:

- a. Comorbidities
- b. Allergies
- c. Medicines prescribed for comorbidities
- d. Medicines (symptomatic) prescribed or suggested for Headache
- e. Any other relevant clinical info
- f. Additional comments and notes

REQT07 The system must allow the General Practitioner and the Specialist to analyze the information recorded by the Patients associated whenever needed.

GOAL3. Privacy regulations must be respected protecting the data entered by the Patient. All these data are sensitive.

REQT21 The system forces the Patient to change password on the first login.

REQT04 The system must allow the Actors to access and modify the Patient data only after logging into the system and only if allowed by the Patient.

REQT05 The system must allow the Patient to specify who (Specialist and General Practitioner) will be allowed to access its own data. The General Practitioner and the Specialist accept the Patient allowance of access. The allowed GP and Specialist may be changed in time by the Patient.

REQT06 The system allows the General Practitioner and the Specialist to access the data only of the Patients they are treating, therefore allowed by the Patient as in REQT05.

REQT08 The system must anonymize the data for any statistical use

GOAL4. The General Practitioner should be involved in the migraine clinical care of the Patient as they know the Patient clinically and personally more deeply and broadly than the Specialist.

REQT09 The system must allow the General Practitioner (associated) to create the Patient profile entering:

a. the "Codice Fiscale" of its General Practitioner (Medico di famiglia)[4]
b. Comorbidities
c. Allergies
d. Medicines prescribed for comorbidities
e. Medicines (symptomatic) prescribed or suggested for Headache
f. Any other relevant clinical info
g. Additional comments and notes

REQT10 The system allows the Patient to complete its own profile including:

a. minimal personal data
b. the Specialist "Codice Fiscale", when known.
c. Migraine triggers he considers relevant.
d. Changes in their life that the Patient wants to inform the clinicians. Relevant events in working life, house management, and private life that may act as strong triggers, but that the Patient may consider as belonging to a very private sphere.

REQT11 The system must allow the Specialist to integrate the Patient profile adding:

a. Preventive treatments prescribed
b. Detox program applied if any
c. Symptomatic treatment prescribed
d. Frequency of visits suggested
e. Additional comments and notes

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[4] This data can be found in any Prescription

REQT12 Because the clinical info may change in time, the system must allow the General Practitioner to record the changes. The history of changes will be stored. The changes (specially changes in treatments for comorbidities) may act as triggers of Migraine attacks or influence the pattern.

GOAL5. The Headache diary is the primary output: The Patient should be able to fill the "headache tracker" quickly and with ease, prioritizing these aspects to the completeness of data gathered.

REQT13 The Headache Tracker feature provided to the Patient must allow for the creation of headache models to quicken the overall process of data insertion. The headache model contains:

a. Type of pain
b. Localization of headache
c. Movement impact
d. Symptoms during the attack

REQT14 The Headache Tracker feature requires a minimal amount of mandatory data to enter.

a. Start and End time (start and end may lay in different days)
b. Model of headache (either choose among existent or create new one)
c. Intensity of the attack
d. Symptomatic medical treatment applied (what and how much)
e. Triggers
f. Attack and period relationship (women only)

REQT15 Optional info to be collected for each attack are:

a. Other relieve actions taken
b. Impact of the attack on daily normal activities
c. Where the Patient was located when attack started
d. Other comments (timed along the attack)

GOAL6. The Specialist should maximize the time that can be devoted to the non-strictly clinical sphere of the Patient emphasizing the empathic and psychological relationship.

REQT07 The system must allow the General Practitioner and the Specialist to analyze the information recorded by the Patients associated whenever needed.

REQT18 The system must be able to create a specific report that can be downloaded to show the Patient situation from different perspective:

a. The reports will include the dated information added by the Patient, General Practitioner and the Specialist in the Patient profile
b. List of the events for the Patient, showing complete data for each attack ordered by date (changes in therapy, Visits, Attacks with all recorded data)
c. Calendar view selecting the type of events to be shown

GOAL7. The Actors should collect data not only strictly related to the headache disorder to allow for a 360° assessment of the Patient (comorbidities, food habits, sleep pattern, physical activity, hydration, stress factors, blood pressure, cardiac pulse).

REQT16 Other optional info, useful for the anamnesis, may only be connected when automatic data sampling applies. A manual input from the Patient would not be used.

a. Weather info in the location of the attack
b. Running, Walking, Biking in the 24 hours before the attack
c. Traveling in the 24 hours before the attack
d. Blood pressure changes before and during the attack
e. Sleeping situation before the attack

REQT17 (optional) The diary updates a specific Google Calendar of the Patient, so that the disease information integrates with life information.

GOAL8. The Specialist and the General Practitioner should be kept updated on the number of symptomatic drugs taken by the Patient and their effect.

REQT18 The system must be able to create specific reports that can be downloaded to show the Patient situation from different perspective:

d. The reports will include the dated information added by the Patient, General Practitioner and the Specialist in the Patient profile
e. List of the events for the Patient, showing complete data for each attack ordered by date (changes in therapy, Visits, Attacks with all recorded data)
f. Calendar view selecting the type of events to be shown

REQT19 (Nice to have) AI analysis of the data to find possible triggers for the attacks and others.

GOAL9. All Actors should be able to use the interface.

REQT20 The system interface should be compliant with the WCAG 2.1 standard so as to be accessible for everyone.

REQT22 The web application must be designed and built in such a way as to be comfortably used using a Personal Computer or Tablet: in particular the functions dedicated to the Patient.

8.3 **Assumptions, Dependencies and Constraints**

8.3.1 Assumptions

ASPT1 It is assumed that the Codice Fiscale is unique for each individual and that it is entered correctly when the new user profile is created.

ASPT2 Each Patient can be assigned only to one General Practitioner at a time.

ASPT3 Each Patient can be assigned to more than one Specialist.

ASPT4 The system database is safe and resistant to failures.

ASPT5 The data entered by the General Practitioner and Specialist are correct and true to reality.

8.3.2 Dependencies

DEP1 The Patient must have been profiled by the General practitioner in order to be able to use the application.

DEP2 Doctors can access Patient data only after the Patient has authorized access.

8.3.3 Constraints

CONST1 In the following system proposal I assume to use features available in the Google ecosystem (Mobile).

CONST2 The Patient diary recording function is provided in the form of an application for mobile devices as it is the tool most often brought around by the Italian population. The application should also work off-line. Some additional functions useful to the Patient but of occasional use are instead provided within the Web application. So, the Patient seldom needs access to the Web Application.

9 Feedbacks from Doctors and Patients

These feedbacks report the comments made by doctors of various specializations that I had the opportunity to contact directly and who kindly lent themselves to think about the general description of this work. The conversation with the doctors was based on a document in Italian describing the M-Migraine proposal that I sent them before the interview.

9.1 A Neurologist

I was not able to talk directly with the neurologist as she was very busy in the clinic, though she has been kind enough to send me feedback on the project via email.

In the email she said that the work seems complete to her eyes and well rounded, considering the most significant characteristics of the disorder itself, and that the proposed system seems satisfying the main issues related to taking charge of the migraine Patient.

9.2 An Anesthetist and Acupuncturist

With a past as an anesthetist in the pediatric resuscitation department, after retiring from the hospitals about 30 years ago, he got involved in alternative medicine and into acupuncture and hypnosis. The feedback of this doctor is particularly insightful as many migraine Patients turn to alternative medicine at some point in their journey to search for a treatment.

While I was presenting the need that arose from the interviews involving more the General Practitioner, the doctor highlighted how it is important to weigh the opinion of the Patient carefully, as often they asperse the GP as not informed even if that is not the case. Moreover, he underlined how today Patients have free access to the internet and therefore to all the good and bad information about the disease. The Patient is therefore an expert on the pathology and often goes to the Specialist with already well clear in mind what therapy they want the Specialist to prescribe to them. This affects the Patient-doctor relationship as the expectations are high and often unmet as the idea that the Patient has about the therapy may be wrong or not agreed upon by the Specialist. The Patient-doctor relationship is strongly based on Trust, and if this is not present, “no therapy will work to a non-trusting Patient”.

Later in the conversation I explained how the system and in particular the sharing of information would allow the Specialist to know in advance the general picture of the Patient and therefore able them to spend more time investigating the personal sphere of the Patient. The doctor expressed interest in the topic and he said that “in med school they don’t teach us to consider the person as such, but only as an ill individual”. He also underlined many times how “the Patient does need to be listened to and also to be treated effectively: the cure though, depends on many factors as medicine is not an exact science”.

Lastly, another important consideration made by the doctors is how important is for the Patient to understand WHY they are ill, not just cure the symptoms and how relevant it is to listed to the body as a sickness is a “malessere” (Italian for illness, uneasiness), in English “bad-being”, and therefore understanding what took the wrong path and caused the illness.

9.3 A Dermatologist

Even if not directly involved in the journey of the migraine Patient, the opinion of a certified doctor has been useful as he is directly involved in the Servizio

Sanitario Nazionale and has a clear view and expertise of the national health care system.

I explained to him the system described in this paper and the process that led to it. The doctor was particularly interested in the involvement of the General Practitioner. He said that the idea of involving the GP more in the migraine Patient journey is interesting and indeed would bring a lot of benefits as it allows for a more general view of the Patient. Though, he pointed out how this involvement can be successful or not depending on GP to GP and their willingness to be part of the process.

9.4 A Gastroenterologist

As for the dermatologist, the opinion of the Gastroenterologist results useful due to the first-hand involvement in the Italian public healthcare system.

The certified doctor found particularly insightful the general picture of the Patient and their needs. He found also very interesting the involvement of the General Practitioner that would boost the vision at 360° of the Patients. Lastly, he commented how in the system proposed the participation of the Specialist would positively be “less aseptic”.

9.5 A Chronic Patient

61 years old, sufferer of daily migraine since he was in his early 20s, this man kindly gave me his opinion on the system proposed:

“Personally, I would not use it as much because I do not like using the smartphone, and because after 40 years of suffering I do know my condition well. On the other hand, younger people or in general people that just started suffering from migraine and need to explore their disorder more, would find the system incredibly useful in my opinion. I don’t have anything left to learn, I went to dozens of doctors, though the younger Patient could learn a whole lot from the data gathered by the application and more broadly by the system.

At the beginning, when you first explained the system to me, I did not understand why the GP should have been involved in the system, I never involved mine. Now, after you clarified the concept of comorbidities and the 360° view of the Patient for the Specialist, I find it very valuable and interesting.

Something I would suggest you do is to gather information also about food supplements because nobody ever asks me about those but personally, I think they are one of the things that make the difference. In general, in my life with the disorder I found foods have a big influence, so I would like to gather more data about this sphere”.

10 The Proposed Solution

10.1 Method of work

I developed this study following the philosophy of "Human Centered design", which I met and used in my internship in YBP and the steps of the Design Thinking method.

Human Centered design is defined by the design company IDEO as a creative approach to problem solving with a particular focus on the people involved.

“It’s a process that starts with the people you’re designing with and ends with new solutions that are purpose-built to suit their needs. Human-centered design is about cultivating deep empathy with the people you’re designing with;

generating ideas; building a bunch of prototypes; sharing what you've made together; and eventually, putting your innovative new solution out in the world." (IDEO, 2020)

IDEO is the company that invented the term "Design Thinking". Tim Brown, executive chair of IDEO, defines design thinking as a "human-centered approach to innovation that draws from the designer's toolkit to integrate the needs of people, the possibilities of technology, and the requirements for business success." (IDEO, 2020)

Hasso-Plattner Institute of Design (Standford) proposes a model of design thinking that sees the process divided in 5 consecutive steps (Interaction Design Foundation, 2020):

1. **Empathize**: the aim is to gain empathic understanding of the tackled problem. The aim of this phase is to eliminate any assumption or bias that the designer may have toward the area of interest. Specifically in the case of this study, the area I wanted to explore and investigate deeply is the migraine world of which I did not know enough about. To better understand the involved stakeholders, interviews to sufferers of the disorder, General Practitioners, and clinicians of the Centri Cefalee have been carried out.
2. **Define**: in this phase the information gathered from the Empathize stage are analyzed in order to define the core problem. Regarding this paper, the core problem identified is the lack of information flow between the involved stakeholders (Patients, General Practitioners and Specialists of the Centri Cefalee).
3. **Ideate**: during this phase, the most diverse ideas are put down on paper by the design team. Many techniques are available, such as SCRAMPER and Brainstorm. It is important in this phase to have a diverging portion at the beginning, and a converging one afterwards.
4. **Prototype**: in this phase the ideas are created in a scaled down and inexpensive way. In the case of this study, wireframes and mock-ups of the Patient smartphone application have been created.
5. **Test**: the outcome of the prototyping phase is tested, and refinements are done following the testing results. For this study, tests have been carried out on migraine Patients.

It is important to highlight the non-linear nature of the design thinking process. It is a flexible process, and more stages can also be carried out in parallel by different members of the design team and can be repeated iteratively.

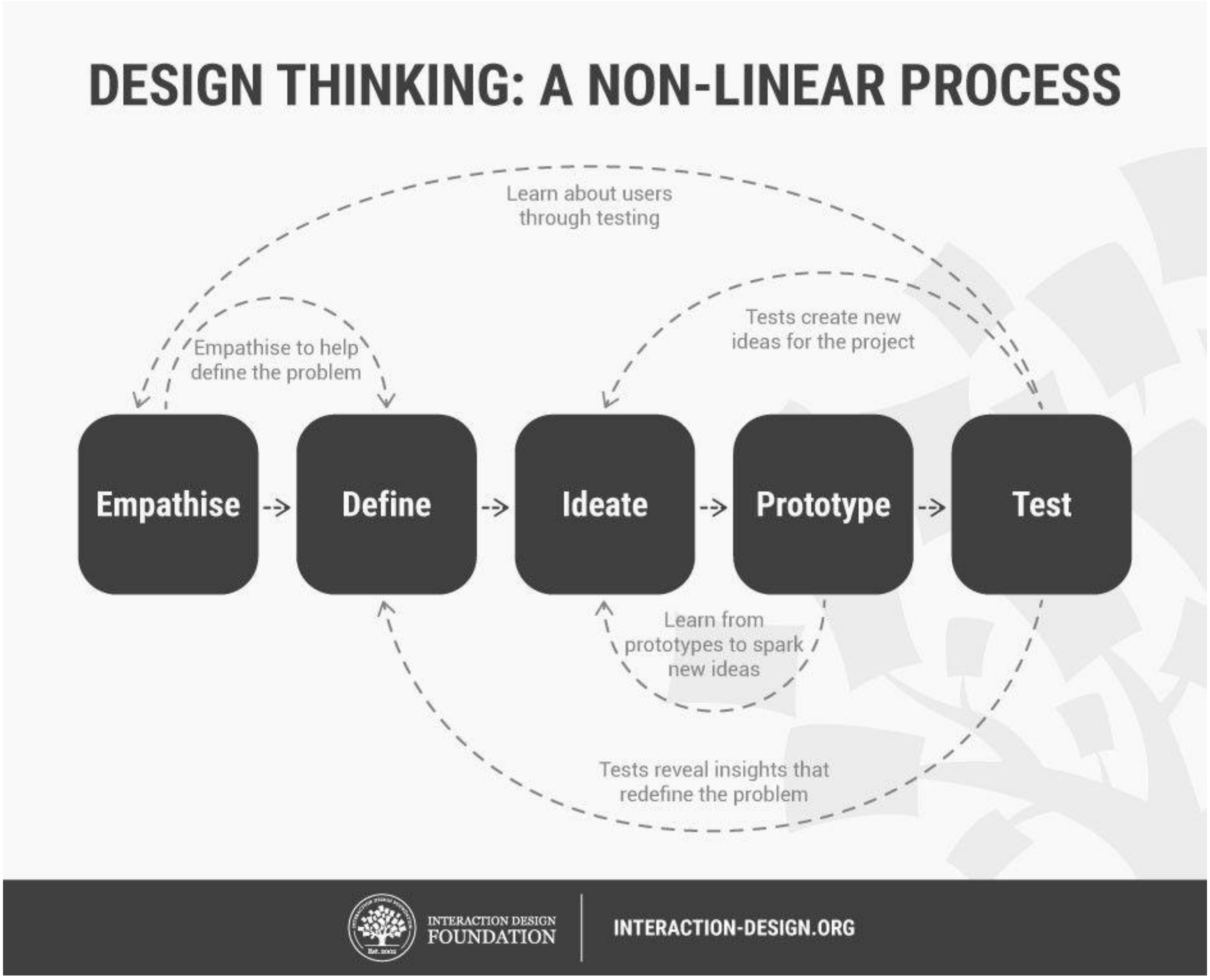

Figure 10.1: The Design thinking Process (Interaction Design foundation)

10.2 The System

I remind the reader the main goal of the System:

- Involve the General Practitioner in the migraine treatment process.
- Minimize the Patient's effort in recording the diary, so that they continue to use it over time.
- Promote a more empathic relationship within Doctors and Patient.

The procedure and the Information system proposed here implement features to address these goals:

- The registration of the Patient should be done by General Practitioner, improving their involvement in the cure.
- It is mostly a web application. The Specialist and the General Practitioner always have a web terminal available in their office.
- The Diary recording tool is very simple to use. To keep the Diary tool as simple as possible, I decided to implement some functions useful to the Patient on the web application.
- The diary tool may be executed also when the device is off line, to maximize availability to the Patient.

For ease of description, the conventional name **M-Migraine** is used below to identify the system.

10.2.1 Patient Journey in the System

In this chapter I explain the basic flow of experiences of a Patient in the system proposed.

The following chapter (use cases) shows some different scenarios in the process. Here I describe the basic flow. It is assumed that the doctor is informed about the general approach to migraine treatment, otherwise they would also ignore the existence of the application. Some initial form of publicity and dissemination of information relating to migraine treatment is therefore necessary for the process outlined here to be realistic.

1. The Patient talks with their GP about their troubles with migraine. It may happen in a visit relevant to other morbidity of the Patient or in a dedicated visit. The meeting with the GP relating to migraine could be preceded by a different sequence of events: the Patient may have followed a different path (as evidenced by the analysis of the interviews) to decide to go to a Headache Centre. In any case, access to the center using the SSN requires the issuing of a request by the GP, which must therefore be consulted.
2. The doctor suggests that the Patient begin to collect his or her migraine life experience in an orderly manner and suggests using the system. This will allow the Patient to meet the Specialist having more precise information, considering that the waiting list is usually quite long, so an average waiting time of two months should be expected, as found in the YBP conversations.
3. The GP instructs the Patient about the Patient Smartphone Application and makes the application set up:
4. The General Practitioner enters the clinical history of the Patient on the system through their Web Interface.
5. The General Practitioner enters the daily habits of the Patient together with them via the Web Interface.
6. The General Practitioner gives the credentials for the Application login to the Patient.
7. The Patient makes a first login to check that everything is fine[5].
8. Now the Patient may start using the App to journal its migraine experience. The Patient may now change their access credentials.
9. The Patient uses the application every time an attack comes and finishes and whenever a relevant event should be logged.
10. When the recording occurs after the end of the attack all data may be recorded together. When only the Start is recorded, then at the next connection the App reminds to enter the end and to complete the other data. Every 24 hours a notification reminds the Patient to complete the attack in case it ends.

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[5] See the Limitation chapter about General Practitioners in Italy

11. The Patient has the option of creating attack models to quicken the recording of next events.
12. A number of standard information (type of pain, drugs, triggers) are pre-recorded in the system, but the user may add its own cases.
13. The Patient goes to the Centro Cefalee for the first visit. The Patient may print the summary report to have all data available also when the Centre has not access to the application. It is assumed here that the Special is accessing the application.
14. Through their web interface, the Specialist consults the clinical data and the Patient habits inserted by the General Practitioner as well as the attack occurrences and other data entered by the Patient.
15. During the visit, because the objective data have been already shared, the Specialist has more time to dedicate to the personal sphere of the Patient and other subjective information that the Patient may want to share allowing for a more holistic visit.
16. The Specialist enters clinical details in the Patient profile through their web interface, like changes in the Therapy.
17. The Patient continues using the application frequently entering their data regarding attacks and significant events.
18. In case of changes in the trends of frequency, intensity, duration of attacks or increased usage of symptomatic drugs, General Practitioner and Specialist get notified[6].
19. The Patient is notified in case of positive and negative changes in the trends.
20. Reports can be downloaded from the Patient mobile application as well as from the web interfaces of GP and Specialist.

10.2.2 Use Case Scenarios

The scheme adopted to represent the Use Cases is taken from the Usability.gov site (U.S. General Services Administration Technology Transformation Services, 2021).

10.2.2.1 UC01: The Patient consults their GP for help with their headache

Section	#	Action	M-Migraine Function
Description	UC01	The Patient consults their GP for help with their headache	
Actors		Patient; General Practitioner (GP)	

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[6] Notification should be generated by the Web application component.

Pre-conditions		The GP is a M-Migraine user	
		The Patient uses an Android Mobile and has access to a Browser via PC or Mobile	
Post-conditions		The Patient Account is active in M-Migraine, the new account is associated to the GP, and most of the sanitary booklet is filled in. The Patient is ready to start using M-Migraine.	
Normal Flow	1	The Patient explains his headache situation to the GP	
	2	The GP makes their own hypothesis (e.g., see Figure 1) and consider whether to refer the Patient to a Specialist.	
	3	However, the GP proposes to the Patient to start keeping a diary of his attacks, then to use M-Migraine.	
	4	The Patient agrees, the GP creates a new account for the Patient in M-Migraine	Register a new Patient to the system, assigning credentials
	5	The GP passes temporary login credentials to the Patient.	
	6	The GP records in M-Migraine the Sanitary Booklet, as complete as possible.	Record Sanitary Booklet
	7	Create/update Headache assessment card	Maintain Headache assessment card
	8	If step 2 suggests addressing the Patient to a Specialist (Centro Cefalee) then the GP gives the Patient the information necessary for booking.	
	9	The case is complete.	
Variations			

Description		Visit after the first one relating to headache.	
	v1.1	The GP inquiries about the evolution of the disorder	
	v1.2	The GP checks if the Patient is recording the Diary	Query Patient calendar
	v1.3	GP and Patient discuss the evolution and go to step 6	
Alternative flows			

10.2.2.2 UC02: The Patient starts using the M-Migraine system

Section	**#**	**Action**	**M-Migraine Function**
Description	UC02	The Patient starts using the M-Migraine system	
Actors		Patient	
Pre-conditions		The GP registered the Patient to M-Migraine	
		The Patients has initial credentials	
Post-conditions		The Patient is ready to use the M-Migraine diary recorder.	
Normal Flow	1	Using the receipts from the GP, the Patient connects to the M-Migraine web application and changes his or her temporary password.	Change password
	2	The user accepts privacy conditions	Set privacy acceptance flag on the user
	3	The Patient allows the GP to access their data	Allow Specialist and/or GP to access its own data

	4	The Patient fills in the MIDAS questionnaire (optional)	MIDAS questionnaire
	5	The Patient downloads the M-Migraine diary app on their Mobile device.	
	6	The Patient opens M-Migraine on the mobile device and logs in using the new credentials	Mobile: Login
	7	The case is complete.	
Variations			
Description			
Alternative flows			

10.2.2.3 UC03: The Patient records the start of an attack

Section	**#**	**Action**	**M-Migraine Function**
Description	UC03	The Patient records the start of an attack	
Actors		Patient	
Pre-conditions		The Patients have installed and activated the M-Migraine app on their smartphone.	
		No internet connection is required	
Post-conditions		The start of a new attack is recorded locally on the app	
Normal Flow	1	The Patient realizes that a new Headache attack is starting and decides to log the fact on M-Migraine app.	
	2	The Patient opens the app	Hello, Patient
	3	Record the start of the attack	Record attack
	4	The Patient leaves the app.	

	5	The case is complete. The detailed description of the flow may be found in the Application Flow chapter.	
Variations			
Description		The Patient logged out from the app.	
	v1.2	The Patient open the app and los in entering credentials	Let's start
	v1.3	proceed to 3	
Alternative flows			

10.2.2.4 UC04: The Patient records the end of an attack

Section	**#**	**Action**	**M-Migraine Function**
Description	UC04	The Patient records the end of an attack	
Actors		Patient	
Pre-conditions		The Patients have installed and activated the M-Migraine app on their smartphone.	
		No internet connection is required	
		The Patient has recorded the start of an attack and has not yet completed it	
Post-conditions		The attack info is completed and saved in the local permanent storage.	
		New Attack models, pain types, drugs, symptoms, and triggers may be created and made available for next Attack recording for this (and only this) Patient.	

Normal Flow	1	The attack is over, and the Patient decides to record when it is finished and the details of what happened.	
	2	The Patient opens the app	Ongoing attack!
	3	The Patient records the time of the end (or now) of the attack	Record the end of the attack
	4	The Patient selects the Attack model (within the existing set)	Select your headache model
	5	Completes the other Attack info	Attack Details Intensity, Pain Type, Drugs, Triggers, Period (women only)
	6	The Patient checks the summary of the data entered	Overview of your attack
	7	The case is complete. The detailed description of the flow may be found in the Application Flow chapter.	Hello page
Variations			
Description		The Patient logged out from the app.	
	v1.2	The Patient open the app and logs in entering credentials	Let's start
		proceed to 3	
Description		None of the recorded models fits the current attack.	
	v2.4	The Patient tap "New"	Define the new Headache / where does it hurt?
	v2.4_1	Patient selects the pain location	Define the new Headache / does movement make it worse?
	v2.4_2	Patient selects impact of movement	Define the new Headache / What symptom…
	v2.4_3	Patient select the symptoms experienced	Save as new headache model

	v2.4_4	Patients confirm the decision to save as a new model	Save as new headache model / Give a name…
	v2.4_5	Patient enters the name for the new model	Attack Details
		Proceed to 5	
Description		None of the recorded Triggers fit this case. (a similar procedure applies for each of the characteristics of the attack, see details in the Application flow chapter)	
	v3.5_1	The Patient taps "new trigger"	Add new trigger
	v3.5_2	The Patient enters the name of the new trigger. Selecting the "save as new trigger" tag will make the new one available for future reuse.	Attack details
		Proceed to the next 5 (Period in this case)	
Alternative flows			

10.2.2.5 UC05: The Patient records an attack after it is over

Section	**#**	**Action**	**M-Migraine Function**
Description	UC05	The Patient records an attack after it is over	
Actors		Patient	
Pre-conditions		The Patients have installed and activated the M-Migraine app on their smartphone.	
		No internet connection is required	
		There is no initiated and unfinished attack in the system	

Post-conditions		The attack info is completed and saved in the local permanent storage.	
		New Attack models, pain types, drugs, symptoms, and triggers may be created and made available for next Attack recording for this (and only this) Patient.	
Normal Flow		An attack occurred in the past, it is over, and the Patient decides to log it now.	
	1	The Patient opens the app	Hello page
	2	The Patient taps the Record attack button	When did the attack start?
	3	The Patient taps the Set date and time button	Set date and time of the beginning…
	4	The Patient selects the date and the time when the attack started	Did the attack end?
	5	The Patient taps "yes, set date and time" of the end of attack Button	Set date and time of the end of the attack
	6	The user selects the date and the time of the end of the attack	Attack details
	7	The case continues as case 4 (recording the end of the attack)	
Variations			
Description		All the variations of user case 4 apply	
Alternative flows			

10.2.2.6 UC06: The Patient records a party where he assumed too much alcohol

Section	**#**	**Action**	**M-Migraine Function**

Description	UC06	The Patient records a party where he assumed too much alcohol	
Actors		Patient	
Pre-conditions		The Patients have installed and activated the M-Migraine app on their smartphone.	
		No internet connection is required	
Post-conditions		The personal event info is completed and saved in the local permanent storage.	
Normal Flow		On Saturday evening the Patient attended a party and drank a little more than usual: he fears that this could trigger an attack and decides to record the event in the diary.	
	1	The Patient open the app	Hello page
	2	The Patient taps the personal event button	Personal Event
	3	The Patient taps the date and time button	Set date and time of the personal event
	4	The Patient selects the date and the time of the party, then taps Next	Title of the event
	5	The Patient enters the title, selects the category, enter some additional notes (maybe too many drinks) and taps the "save in calendar" button	Hello page
	6	The case is complete	
Variations			
Alternative flows			

10.2.2.7 UC07: The Patient books a visit to the new Specialist

Section	**#**	**Action**	**M-Migraine Function**
Description	UC07	The Patient books a visit to the new Specialist	
Actors		Patient; Specialist	
Pre-conditions		The Patient is a registered user of M-Migraine	
Post-conditions		The Patient is registered as being treated by the Specialist; the appointment is registered by the Specialist.	
Normal Flow			
	1	The Patient calls the Doctor to fix an appointment.	
	2	The Specialist accepts the new Patient and register the new Patient in M-Migraine	Accept new Patient or register new Patient
	3	The Patient allows the doctor to access their data	Allow Specialist and/or GP to access its own data
	4	The Specialist records the new appointment	Record/change new appointment
	5	The case is complete	
Variations			
Description		The Specialist is not a registered user of M-Migraine	
	v1.2	No registration on the System by the Specialist	

	v1.3	The Patient may record the appointment	Personal Event
		Proceed to 5	
Alternative flows			

10.2.2.8 UC08: The Patient prepares the visit to the Specialist

Section	#	Action	M-Migraine Function
Description	UC08	The Patient prepares the visit to the Specialist	
Actors		Patient	
Pre-conditions		The Patient is a registered user of M-Migraine	
		Internet available, Mobile connected	
Post-conditions		The Patient has collected all the useful information to make the next visit with the Specialist profitable. The Specialist has the information in advance.	
Normal Flow		The Specialist is registered in M-Migraine	
	1	The Patient checks the completeness of the registrations on the Diary and completes the missing data.	Mobile Diary Calendar
	2	The Patient synchronize the data stored on the mobile and the web	Mobile Diary Sync
	3	Optionally, the Patient checks the validity of Midas and updates if necessary.	Web app MIDAS
	4	The Patient prints a report of the current month. Just in case, the Specialist has full visibility of the Patient data.	Web App Report

	5	The case is complete	
Variations			
Description		The Specialist is not a registered user of M-Migraine	
	v1.3	The Patient prints the report to have it available at the visit. Optionally the report and additional info may be sent via e-mail to the doctor to offer early availability of info.	Web App Report
	v1.4	The case is complete	
Alternative flows			

10.2.2.9 UC09: The visit to the Specialist

Section	**#**	**Action**	**M-Migraine Function**
Description	UC08	The visit to the Specialist	
Actors		Patient; Specialist	
Pre-conditions		The Patient is a registered user of M-Migraine	
		The Patient has prepared the visit as described in Use Case 8	
Post-conditions		The medical examination at the Specialist is completed effectively, the Doctor has a good history of the Patient and all the information necessary to devote time to the human aspects of the relationship with the Patient.	
Normal Flow		The Specialist is registered in M-Migraine	
	1	The Specialist reads on M-Migraine the status of the Patient, including the Diary, the	Query functions of the M-Migraine web

		Midas, the evolution in time of the Patient condition etc.	application. (Patient Calendar, Sanitary booklet etc.
	2	After or during the visit, the Specialist update the Therapy applied	Therapy update
	3	The Specialist updates other info about the Patient	Diagnosis card update, Headache assessment card, other
	4	The case is complete	
Variations			
Description		The Specialist is not a registered user of M-Migraine	
	v1.1	The Patient gives to the Doctor the Report he/she has prepared and other documentation available. The report offers a concise view of the Patient's "life with headache" and will still help the physician in assessing the Patient's disorder.	
		The M-Migraine is not involved anymore in the visit.	
	v1.4	The case is complete	
Alternative flows			

10.2.3 The System Architecture

The proposed System will support the following features:

- A Web Application Database containing all the application data and accessible by all the users, limited to their authorizations. The database structure is described in the following chapters. The access will be limited to the data relevant to the user by role and by content:
    - The Patient may access only their own data and to the functions specific to their role. The Patient is the only role allowed to change the Diary data.
    - A General Practitioner may access the data of all Patients he/she is treating and to the functions specific to their role.

    - A Specialist may access the data of all Patients he/she is treating and to the functions specific to their role.
- A Web Application running on servers under control of an Application Server (e.g., Jboss, Apache Tomcat). This component will support:
    - The part used by the Patient to support any required function but the recording of Attacks and Personal Events.
    - The part used by General Practitioner, accessing the system via Browser.
    - The part used by the Specialists, accessing the system via Browser.
    - The part supporting the Storage of data required by the Patient Smartphone application.
    - The reporting features.
- A Mobile application dedicated to the Patient (the prototype of the user interface is part of this study). These components may run off-line but require connection when the data collected need to be consolidated on the application database. The Mobile app will only support the recording of Attacks and Personal Events. Any other function available to the Patient will be done through the web application.

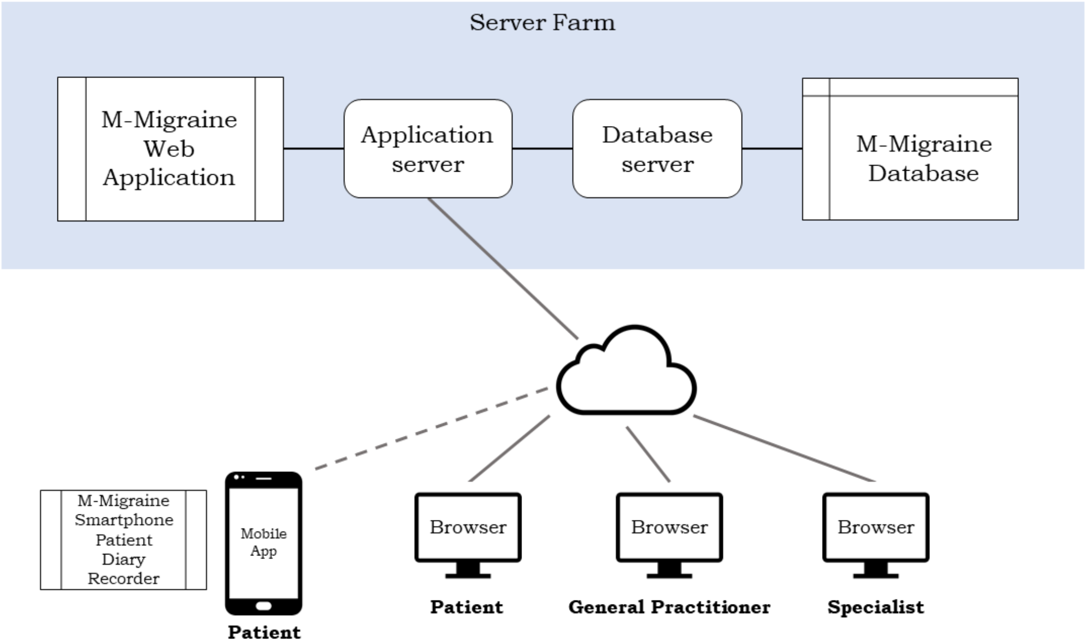

Figure 10.2 The System main components

To define the data to be gathered by the system, the web application NoEmi and the mobile app Migraine Buddy have been taken as the starting point, and extended with the information learned from literature and interviews.

10.2.3.1 Notes about the Synchronization process

The synchronization will consider each single record (replace the full record, not single fields) and select the version based on the timestamp of the last update of the record. Most of the data should be updated on one side only, but I suggest implementing a bi-directional sync, selecting the newest record on each table. This study does not include an analysis of the process, and the Web application database does not include the required timestamp columns[7]. The Timestamp columns have been included only on the Smartphone app DB as a reminder for possible further development.

The main flow of the sync is shown in the next table:

Mobile DB	Sync versus	Web application DB
	⇐	Patient Master Data
Reference Tables	⇔	
	⇐	MIDAS
Headache Models	⇒	
Personal Events	⇒	

The very first synchronization required by the Mobile will actually download from the server to the mobile all the data relevant to the user connected.

10.2.3.2 Security and Privacy

The information contained in this database is to be considered "sensitive data". Then the access to the data should be limited and granted.

The security on the Web Application should be based on 3 principles:

1. Any user may access the system only when registered.
2. Any registered user has one and only one role assigned. When the same user has more than one role, (e.g., Patient and General practitioner) will register two different users, each one with its own role. The roles are:
   - Application Administrator
   - Patient
   - General Practitioner
   - Specialist
3. The accessibility to data is driven by the role and by the data themselves.
   - The role defines the functions that the user may use (menu)
   - The records that each function may access for the user requiring the access are limited by the ownership of each record itself: actually, each information is relevant to one specific Patient, and the database contains all data necessary to identify the ownership of each record.
     - The Patient has access only to its own data.
     - The GP has access to the data relevant to its own Patients.
     - The Specialist has access to the data relevant to its own Patients.

The Application Administrator role has full access to functions and data.

The Mobile App will:

- Require a login to the application that is available only when the mobile is on line: the validation of the credentials is executed on the server. The only role accepted is Patient.
- The Mobile device will accept one single user.
- The Mobile App database contains data relevant to one single Patient.

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[7] The last sync timestamp may be added to the Patient table.

- The App is available to the user without any additional access validation until the user logs out explicitly: this is to minimize the diary recording effort.

About the privacy of the Patient's data will be granted by:

- Each role allows the storage and maintenance of their own data on the system (privacyAllowed flag on the Subject table)
- The acceptance of the Specialist is done only by the Patient themselves.
- The Patient explicitly allows the Specialist and the GP to access their data (privacyAllowed flag on Patient_GP and Patient_Specialist tables).

10.2.4 The Web Application

The detailed analysis of the web application is not part of this study. I describe here the overall architecture of the components. I instead made a deeper study of the database necessary to support the process.

10.2.4.1 The Web Application Functions

This chapter lists the main features that should be available on the web application. The list of functions below shows only the basic functions: it has the sole purpose of better illustrating the functions expected from the system as a whole.

- Application Administration
  - Manage Lost Credentials
  - Check Patient devices Synchro
  - Query and report access log
  - Report overall Patient – GP – Specialist relationship
  - Manage common reference tables
- Patient functions to register and maintain:
  - MIDAS questionnaire
  - Sanitary booklet[8] (date driven[9]):
    - Life style: weight, height, usual sleeping hours, usual alcohol, coffee, sport, food habits, smoking, etc.
    - Clinical measures: heartbeat rate, blood pressure, Analysis results (attachments),
    - Clinical anamnesis: comorbidities, allergies, surgeries, drugs assumed, etc.
  - Query Headache Assessment card[10]
  - Calendar including:
    - Attacks and Personal events (query and upload attachments),
    - Visits[11] appointment
  - Change / add / cancel new Specialist
  - Allow Specialist and/or GP to access its own data
  - Change password
  - Set privacy acceptance flag on the user
- General Practitioner functions

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[8] Sanitary booklet should be maintained by GP, but can be maintained also by the patient and the Specialist.

[9] History of values should be maintained

[10] The Headache Assessment card is the collection of information and symptoms that allow the Specialist to formulate the current diagnosis.

[11] Visits when not recorded by the doctors

    - Register a new Patient to the system, assigning credentials
    - Sanitary booklet (date driven):
        - Life style: weight, height, usual sleeping hours, usual alcohol, coffee, sport, food habits, smoking, etc.
        - Clinical measures: heartbeat rate, blood pressure, Analysis results (attachments), etc.
        - Clinical anamnesis: comorbidities, allergies, surgeries, drugs assumed, etc.
    - Maintain Headache assessment card
    - Visit new appointment
    - Visit report (when relevant changes to the sanitary booklet)
    - Cancel Patient association to GP (myself)
    - Accept new registered Patient
    - Query Patient calendar
    - Query[12] Patient sanitary booklet and Headache Assessment Card
    - Query My Patients list
    - Set privacy acceptance flag on the user
- Specialist functions
    - Set privacy acceptance flag on the user
    - Accept new Patient or register new Patient
    - Cancel accepted Patient
    - Record/change new appointment
    - Record new visit
        - Therapy update
        - Diagnosis card update
        - Attach clinical analysis reports
        - Update Headache Assessment Card
    - Query Patient calendar
    - Query Patient sanitary booklet and Headache Assessment Card

10.2.4.2 The Web Application Database

This chapter describes the database designed to support the complete M-Migraine Web Application. The ER diagram of this database can be found in Annex 3 at the end of this document.

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[12] All queries will consider validity dates of the records. Report returned is by default calculated at today's date, but a specific date may always be required.

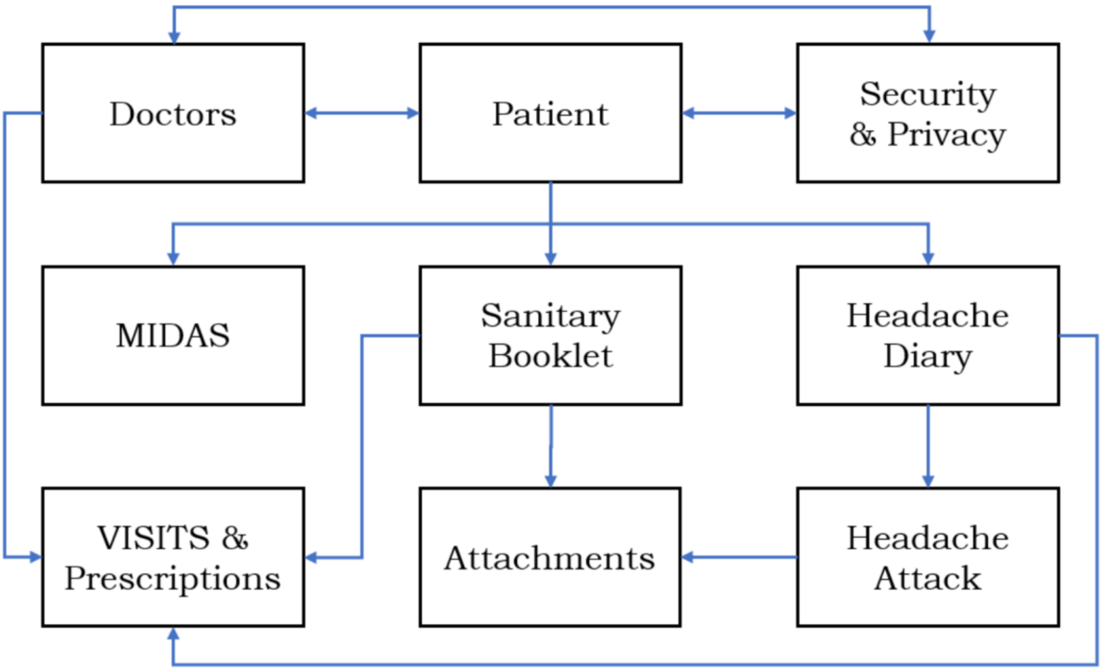


Figure 10.3: Web Application Database main logical entities

All the actors involved (Patient, Doctors) are identified by the Codice Fiscale, a standard unique identifier for any citizen and for foreigner's resident in Italy.

Most of the data maintained here are managed by validity date: most of the medical treatments, personal clinical data like weight or blood pressure, as well as Doctors taking care of the Patient may change in time. I am using here the start and end validity date on each record[13]. This standard technique allows a much more efficient navigation in the data, never requiring search for the max value of the date.

Some reference tables (e.g., Symptoms) may include entries valid for general use and specific values added by Patients for their own use. These last records will contain the patientId code in the specific column. The valid set of records for the user will then include the records having the patientId column null or equal to the currently executing patientId. Notice that the limited size of these tables will limit the impact of the OR condition on performance.

The above picture summarizes the content of the data managed by the application:

Patient: the main subject, all the data recorded are relevant to him. Some basic attributes are maintained here: the data in this block do not require a validity date.

Doctors: Information about the General Practitioner and the Specialists who treat the Patient.

---

[13] When recording a new value for a record, the end date of the previous is updated to the start date – 1 of the new record and the end date of the current date is set to a fictitious 31/12/2300 (or the max allowed by the DB engine)

Security & Privacy: The connections between Patient and doctors, granting privacy along the time.

Sanitary Booklet: The information of the Patient History and current clinical status relevant to the headache disorder. All data are subject to validity date.

MIDAS: the Midas questionnaire (impact of headache disorder on working and social life) filled in by the Patient. Several questionnaires may be filled in time.

Headache Diary: The journal of events relevant to the headache disorder for the Patient. Mainly the disorder attacks.

Headache Attack: The data collected by the Patient about each attack.

Visit & Prescriptions: The visits from the doctors, and the changes in the therapy.

Attachments: Any file may be attached to the booklet of the Patient (as results of clinical examinations and other documents)

A subset of this database will be made available on the Mobile component to allow the recording of the diary without a connection to the web application. This will include only the tables required to record the attack, the personal events and to add new entries in some reference tables (e.g., drugs, triggers).

The design and the document are made using the *dbdiagram.io* (Holistics, 2021) free on-line application.

10.2.5 The Mobile Diary Recorder

The Mobile App has been designed keeping well in mind that:

- It will be used by suffering persons; they may be under a headache attack.
- The user has a very indirect return in recording the data (the Specialist will hopefully improve their diagnosis and cure) so they will continue to use the application only if it makes the least effort.

Therefore:

- The functions available are limited to the minimum required to record attacks and personal events.
- The data required are the minimal compromise between the data needed by the clinician and the recording effort by the Patient.
- The attack model function is implemented to still reduce the data to record for an attack when similar symptoms are recurring.
- The look and feel of the interface are very simple and dark, to make it easy to use and non-invasive.

The application requires an internet connection only to login and to synchronize with the server. Any other function is available also when the Mobile device is off-line.

10.2.5.1 The Mobile Diary Recorder Functions

The mobile Diary recorder include the following functions:

- Log in
- Log Attack including:
  - Recording of a new attack model

    - Adding specific personal entries in Drugs, Triggers, Pain types, Symptoms.
- Log personal event
- Show Calendar with Attacks and Personal events
- Synchronize data with server
- Download report

The application flow shows all functions in details.

10.2.5.2 The Mobile Diary App Database

The App used by the Patient to log their Migraine Diary needs a permanent storage to keep the entered data at least until next synchronization with the Web Application.

I describe here a relational model: considering the small size of the database, the actual implementation may use relational DBMS like SQLlite or Json files depending on the implementation preferences.

The ER diagram of this database can be found in Annex 4 at the end of this document.

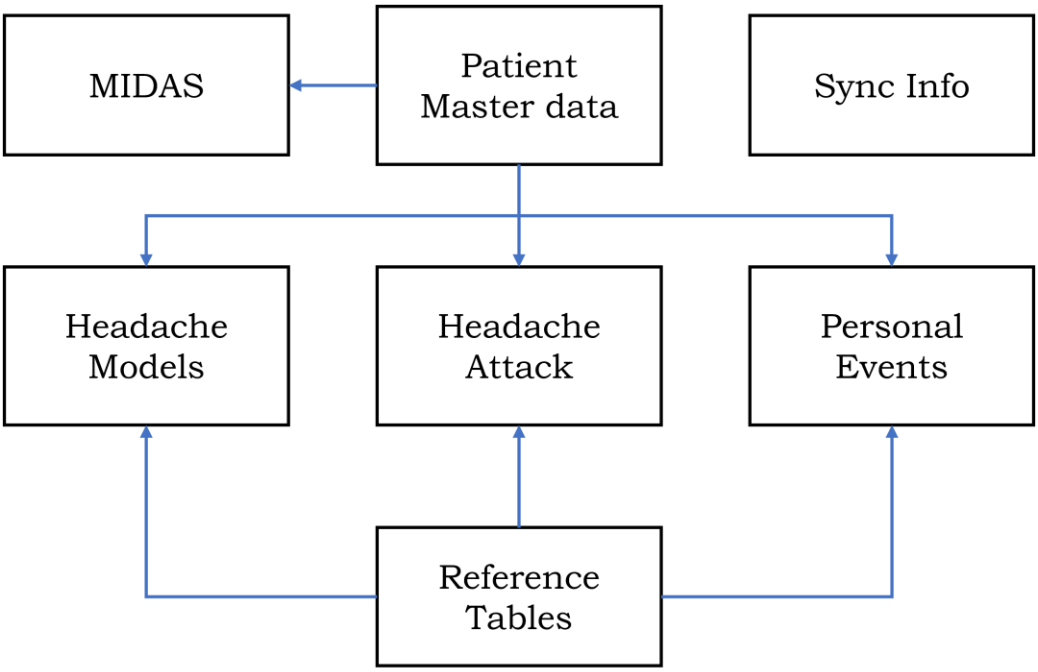


Figure 10.4: The Smartphone App main logical entities

Patient master data: The basic info about the Patient and as a snapshot from the web application at last synchronization. It will include codes and descriptions for current General Practitioner, Specialist, Diagnosis and other info useful to offer a reasonably complete view of the Patient status also when off-line through the report (see the relevant chapter).

MIDAS: The latest Midas questionnaire filled in by the Patient via the Web application. It is necessary to produce the Report.

Sync info: The data required to administer the synchronization process with the Web Application.

Headache Attack: The info about the single attack.

Headache Models: The attack models saved by the Patient.

Personal Events: The personal events recorded by the user.

Reference Tables: drugs, triggers, type of events and other.

As for the Web Application, the design and the document are made using the dbdiagram.io (Holistics, 2021) free on-line application.

10.2.5.3 High Fidelity Prototype

The prototype has been developed using the on-line design tool Figma (Figma, 2020). It is a vector graphics editor and prototyping tool which is primarily web-based, with additional offline features enabled by desktop applications for macOS and Windows.

The Italian prototype used for usability testing can be accessed and navigated through the link

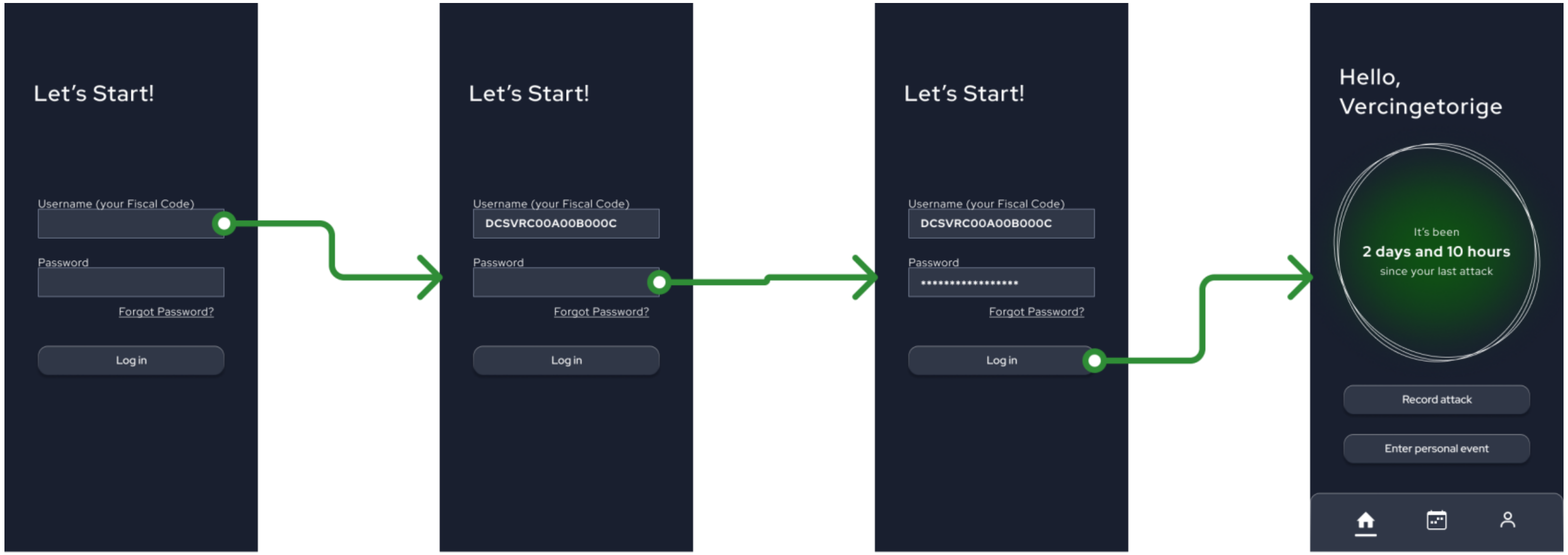
https://www.figma.com/proto/bGhk8Uvv1ATPLBwxr9qL4e/ITA-Mazzi-Tesi?node-id=307%3A157&scaling=scale-down&page-id=307%3A31

The English version, the one described in the following chapters, can be found at:

https://www.figma.com/proto/WVG6ei3p6l3vP7CQPd2W9S/ENG-Mazzi---Tesi?node-id=307%3A157&scaling=scale-down&page-id=307%3A31

10.2.5.4 Application Flow

10.2.5.4.1 Login



The Patient is required to log-in to the App. This should be done only if the user disconnects themselves.

To successfully login, the user must enter the credentials given to them by their GP: Codice Fiscale and a temporary password, that it will be changed by the Patient after the first login.

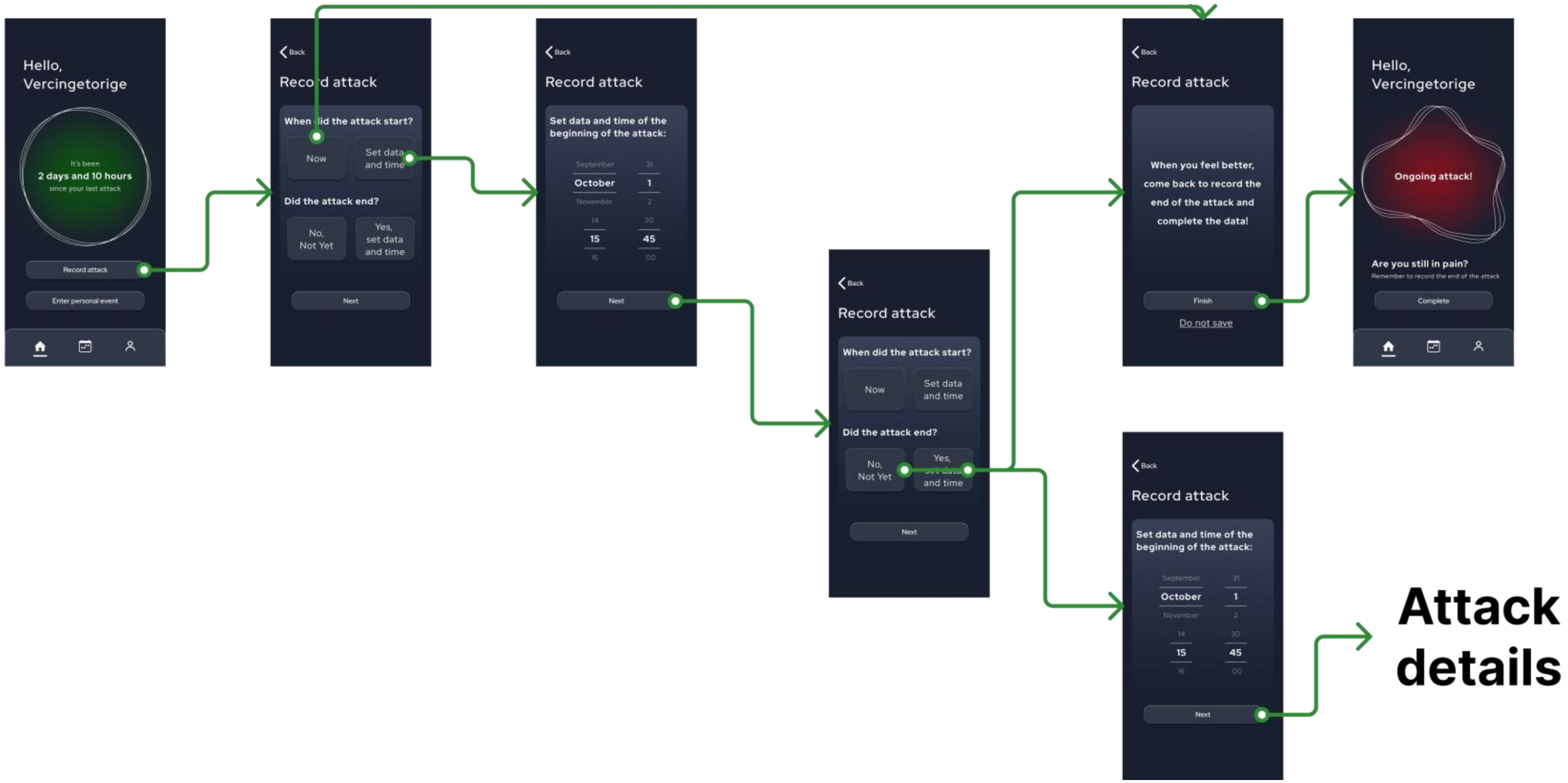
“Forgot password?” Allows to get a new temporary password when the password is forgotten by the user.

At a successful login or restarting the App, the app is ready to record a new attack or a personal event.

When the previous attack is still open, the App requires first to complete the previous attack info (see Complete Attack).

The central button of the navbar in the lower part of the home page moves to the My Calendar page (see Calendar), and the left button instead takes the Patient to their profile data overview.

10.2.5.4.2 Record Attack

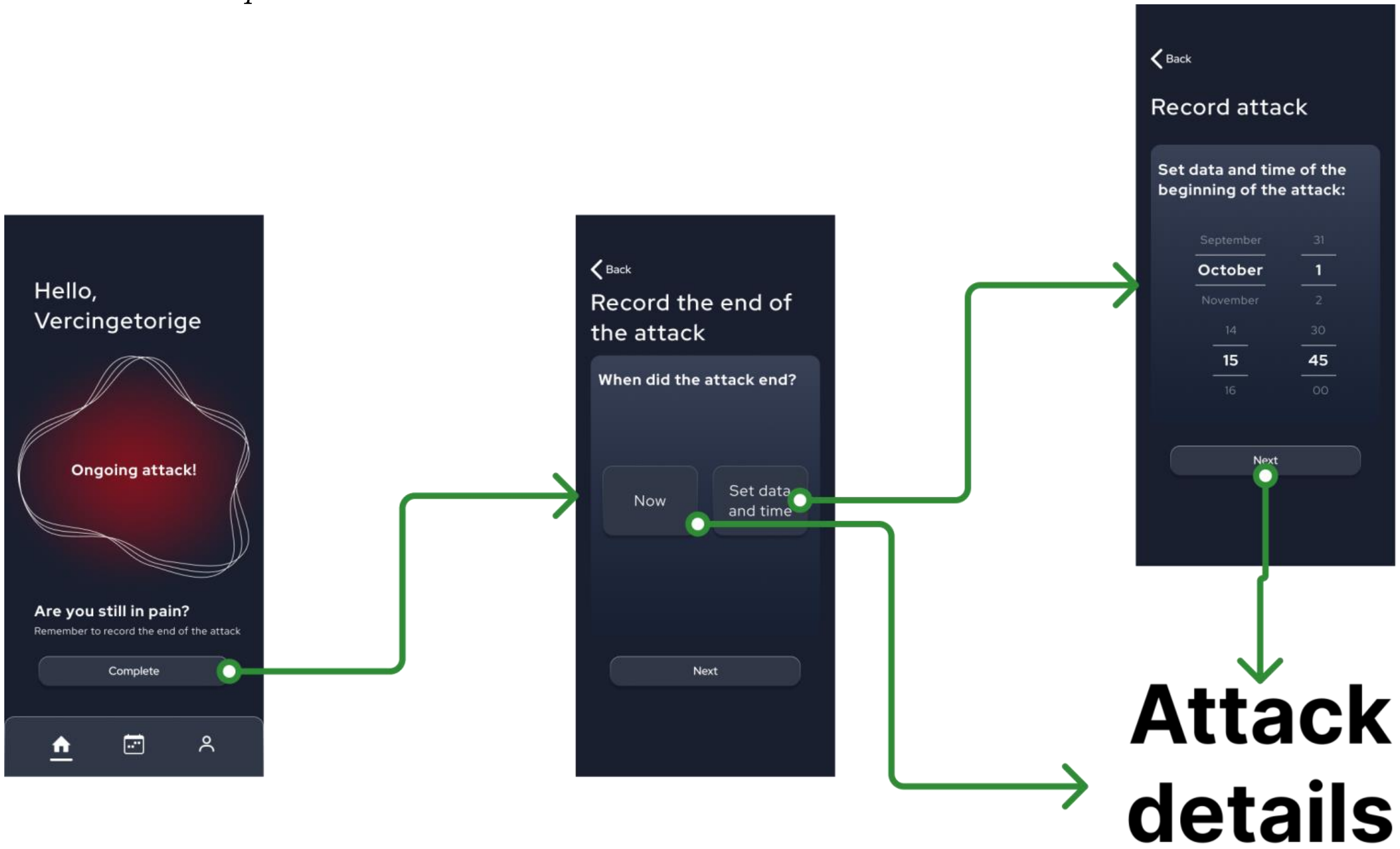


To record an attack:

1. press on the button in Home called “Record Attack”.
2. Select date and time of the beginning of the attack or if it just started and the moment of the end of the attack.

3. If the attack is just started or not yet finished, the screen “When you will feel better come back to record the end of the attack and complete the data!” will appear. After pressing on “Finish” the “Ongoing Attack” version of the Home screen will appear.
4. If the attack is over, the user will be taken to the “Attack details” flow (see Attack Details).
5. “Do not save” allows the user to delete the instance.

10.2.5.4.3 Complete Attack



To complete an ongoing attack, press on the “Complete” button.

The user is then asked to enter the moment of the end of the attack, and then taken to the “Attack details” flow.

10.2.5.4.4 Attack Details

Your attack:
Start: Oct. 1, 15:45
End: Oct. 1, 21:00
Model: My usual migraine
Type of pain: Throbbing
Where: R back of head
Worse with movement: Yes
Symptoms: Nausea, Vomit
Intensity: Moderate
Drugs: Advil (1)
Triggers: Blinking lights
Period: Yes

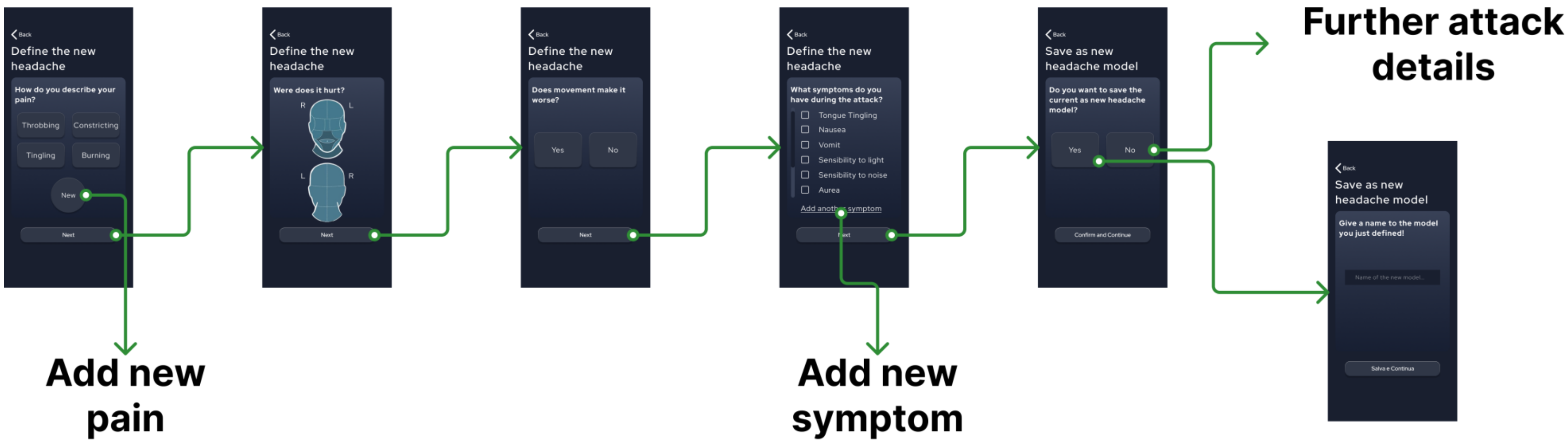
The user defines all the characteristics of the attack.

1. Select the model of the attack, if already defined, otherwise, define the new model (see “Define New Model”).
2. Select the intensity of the attack.
3. State whether they assumed any drug.
4. If so, the type of drug assumed, and the quantity is asked.
5. Select the triggers of the attack, if known (otherwise the “I don’t know” flag is to be selected)
6. State whether the user is currently on their period or not. This screen will be skipped in case of male users.

When none of the elements is fitting the current case, a new one may be added via the dedicated screen. In this case the feature is available for Drugs and triggers

When the selection is complete, a form summarizes all the data entered. Confirm returns to the home page. “Do not Save” allows the user to delete the instance just created.

10.2.5.4.5 Define New Model



The model concept allows the user to record the basic features of their attacks to make faster the recording of recurring cases.

The model includes:

1. Type of pain
2. Prevalent location of pain
3. How the pain relates with motion
4. The symptoms experienced during the attack.

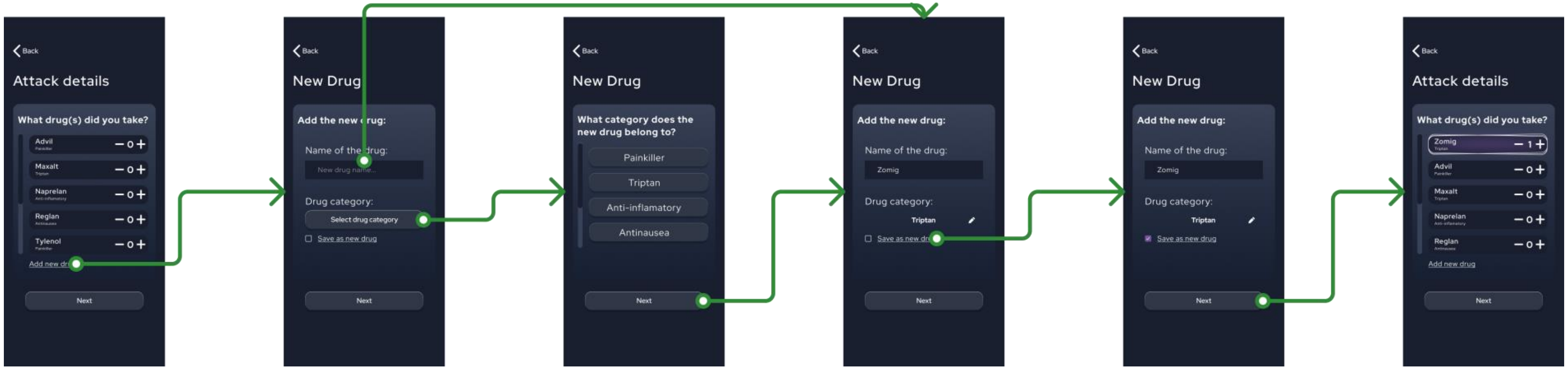
This information is to be selected in the subsequent screens reported above.

When none of the predefined (by the system or by the user) case fit the need, a new occurrence may be created: this feature is available for Type of Pains and Symptoms. Tapping “add a new one” moves to the screen dedicated to the feature.

When completing the selections, the Save Model screen allows the user to assign a name to the model and save it for reuse. If the new model is not saved, the data will be associated only to this specific attack.

After the definition of the model, the user is taken back to the main flow of “Attack details” definition.

10.2.5.4.6 Add New Drug



If the drug assumed is not present among the options, a new one can be added. To do so, the used taps on “Add new drug”.

The user can then write the commercial name of the drug and select the category that the drug belongs to among some predefined options. If it does not fit in any group, “Other” can be selected (not shown in the reported screen).

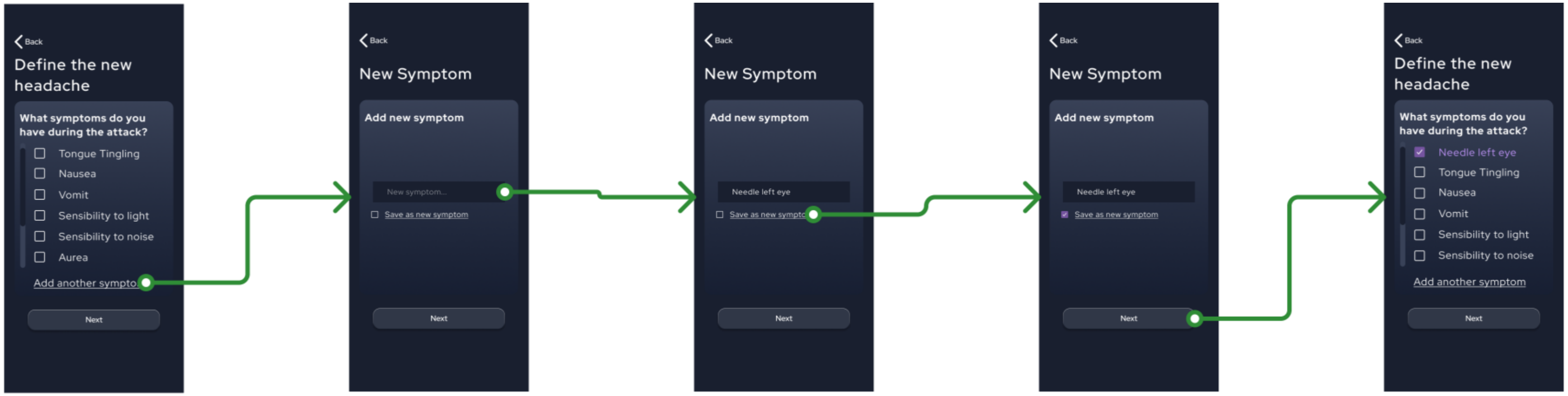
Flagging the field “save as new drug”, the user saves the entered drug, and it will be seen also in the next records. Otherwise, the drug will be saved only for the current instance.

10.2.5.4.7 Add New Trigger

When a Trigger is not found in the list, this section allows the Patient to record a new one.

The new Trigger inserted will appear in the selection list if the “save as new trigger” flag is turned on. Otherwise, it will be recorded only within this event.

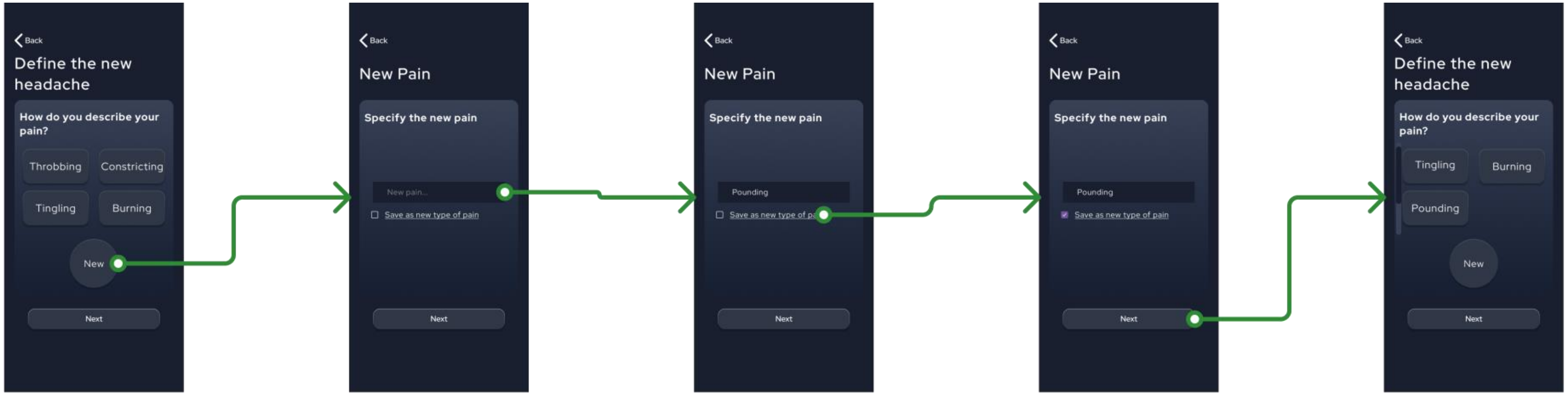
10.2.5.4.8 Add New Symptom



When a Symptom is not found in the list, this section allows the Patient to record a new one.

The new Symptom inserted will appear in the selection list if the “save as new symptom” flag is turned on. Otherwise, it will be recorded only within this event.

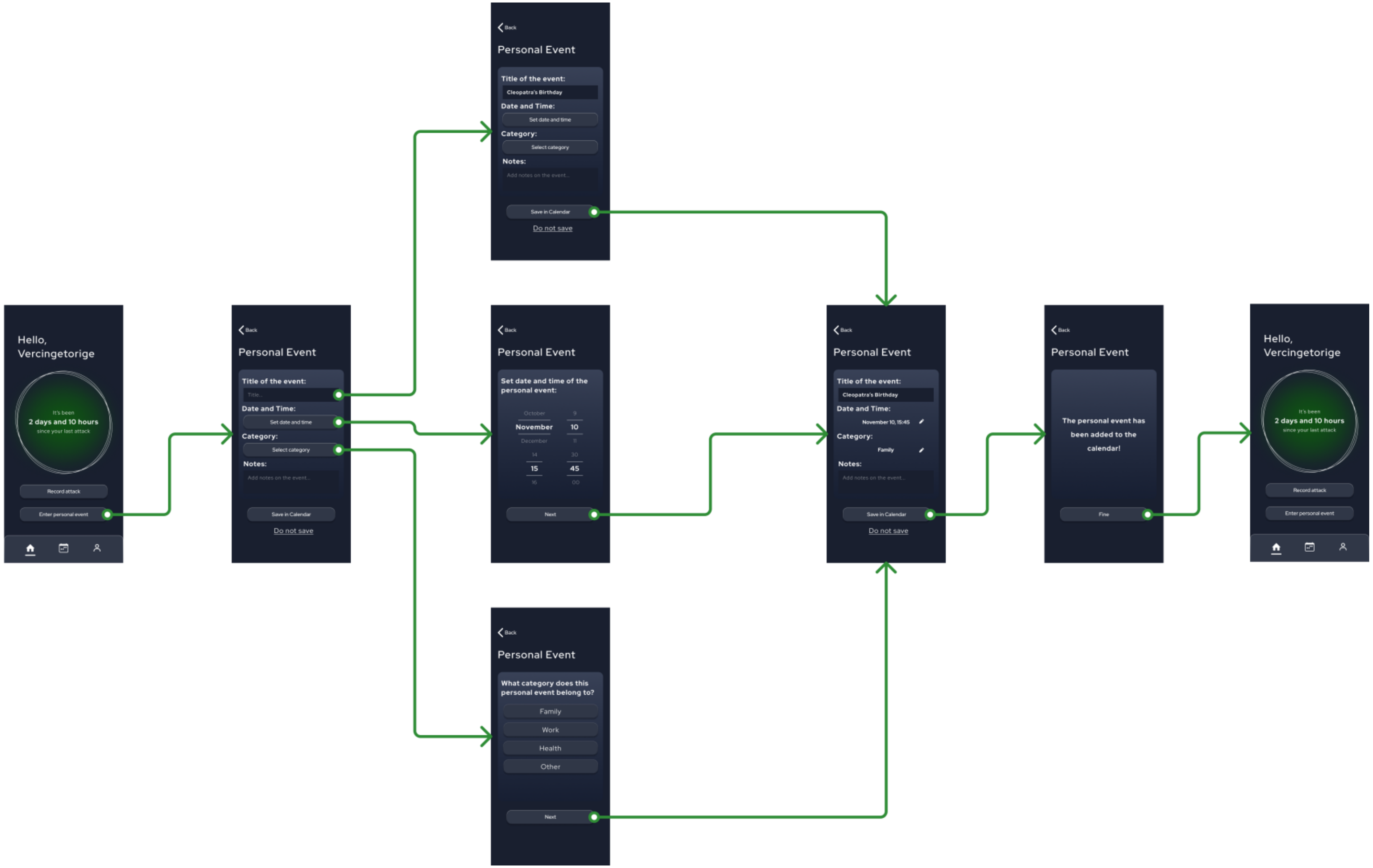
10.2.5.4.9 Add new Pain



When a Type of pain is not found in the list, this section allows the Patient to record a new one.

The new Type of pain inserted will appear in the selection list if the “save as new type of pain” flag is turned on. Otherwise, it will be recorded only within this event.

10.2.5.4.10 New Personal Event



Hello, Vercingetorige

It's been 2 days and 10 hours since your last attack

Title of the event: Cleopatra's Birthday

Set date and time of the personal event:

What category does this personal event belong to?

Title of the event: Cleopatra's Birthday

Date and Time: November 10, 15:45

Category: Family

The personal event has been added to the calendar!

The Personal Event section allows the Patient to record personal occurrences that they consider useful to be reported to the doctor because of their possible influence in the migraine history.

Tapping the Record Personal Event button in the home page moves to the Add Personal Event screen, where the Patient will type the title, the description, and call the dedicated screens to record:

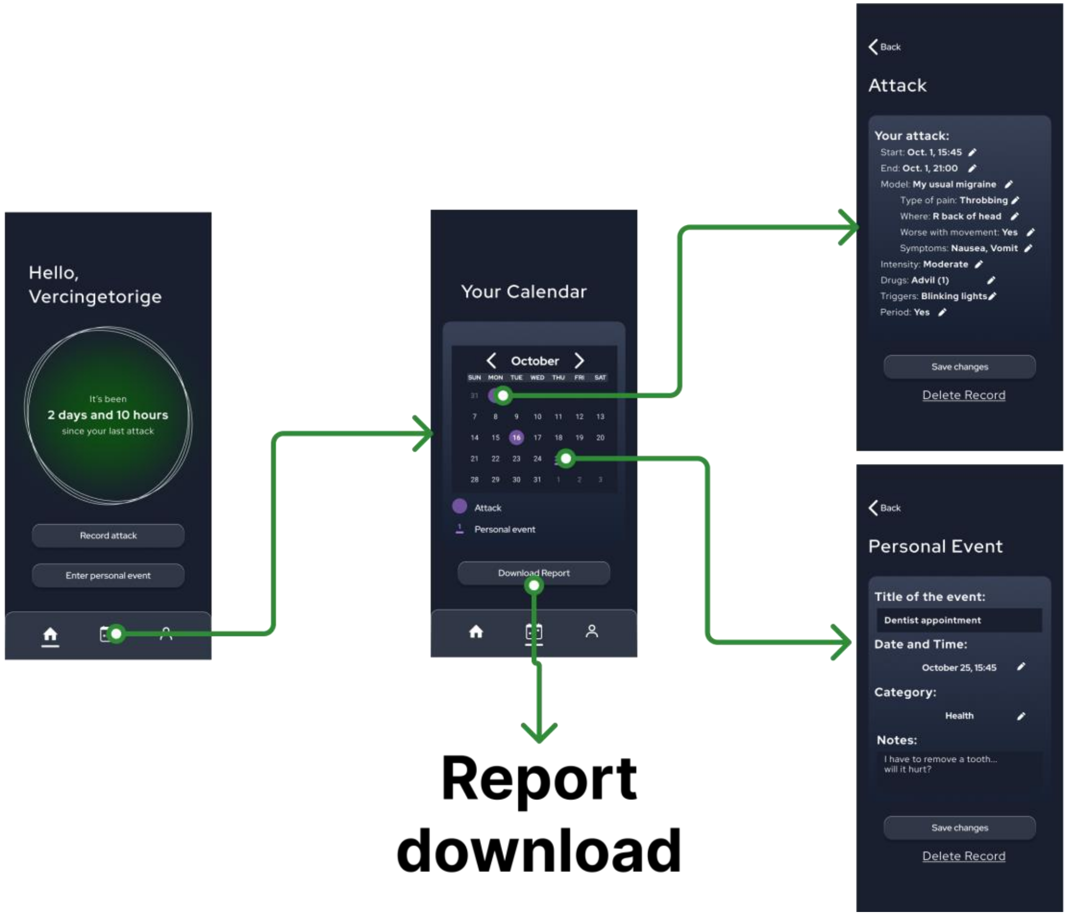
1. Date and time
2. Category (Family, Work, Health, Other)

Tapping the save button cause the data to be recorded and moves to the "Event is saved" screen.

The “Do not save” button does not record the data and returns to the home page.

The End Button on the "event is saved" returns to the home page.

10.2.5.4.11 Calendar



Back

Attack

Your attack:
Start: **Oct. 1, 15:45**
End: **Oct. 1, 21:00**
Model: **My usual migraine**
Type of pain: **Throbbing**
Where: **R back of head**
Worse with movement: **Yes**
Symptoms: **Nausea, Vomit**
Intensity: **Moderate**
Drugs: **Advil (1)**
Triggers: **Blinking lights**
Period: **Yes**

Back

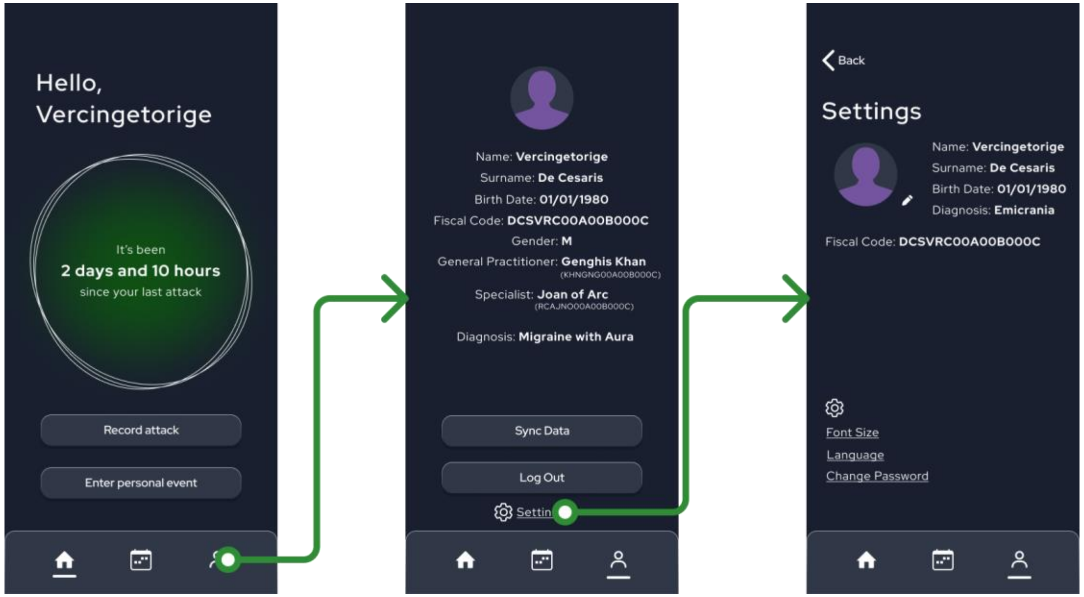
Personal Event

Title of the event: Dentist appointment
Date and Time: October 25, 15:45
Category: Health
Notes: I have to remove a tooth... will it hurt?

The My Calendar page has multiple goals:

1. Giving an overall view of the occurrences of the month
2. See the details recorded on a date, selecting the date itself. From the overview of the attack and the one of the personal events, it is possible to modify them and to delete them with the “Delete Record” button.
3. Download the report (see in the thesis document) summarizing the info recorded in the selected month (using the button Download Report).

10.2.5.4.12 User Profile and Settings



Hello,
Vercingetorige

It's been
2 days and 10 hours
since your last attack

Name: **Vercingetorige**
Surname: **De Cesaris**
Birth Date: **01/01/1980**
Fiscal Code: **DCSVRC00A00B000C**
Gender: **M**
General Practitioner: **Genghis Khan** (KHNGNG00A00B000C)
Specialist: **Joan of Arc** (RCAJNO00A00B000C)
Diagnosis: **Migraine with Aura**

Name: **Vercingetorige**
Surname: **De Cesaris**
Birth Date: **01/01/1980**
Diagnosis: **Emicrania**
Fiscal Code: **DCSVRC00A00B000C**

From the Home page, tapping the Account button (underlined in the picture) the app displays the basic data of Patient.

1. The “Sync Data” button, available only when the Smartphone is online, allows the synchronization of the data stored in this device and the Web application database.
2. The logout button disconnects the user.
3. Tapping the setting button access the Settings page, where basing set up of the Application may be changed (Font size, Language, password)

10.2.5.5 Test Process and Test Results

The usability testing of the high-fidelity prototype of M-Migraine aims at understanding the usability of the interface with particular focus on the SUS and UEQ questionnaire. In the following sections the reader may find a description of the testing process adopted and the results obtained with consequent analysis.

10.2.5.5.1 Dates, places, and roles

Due to the restrictions imposed by the COVID-19 pandemic, the testing had been carried out remotely on the platform Google Meet.

Test	Date	Time	Platform	Comments
1	19.05.2021	20.00	Google Meet	High frequency Migraine Patient
2	18.05.2021	19.45	Google Meet	Chronic Migraine Patient
3	21.05 2021	14.30	Google Meet	High Frequency Migraine Patient
4	21.05.2021	17.00	Google Meet	Chronic Migraine Patient
5	23.05.2021	15.00	Google Meet	Sporadic Migraine Patient
6	23.05.2021	18.00	Google Meet	Sporadic Migraine Patient

The tests have been performed in Italian, in the Italian version of the high-fidelity prototype, of which I report here the link: **https://www.figma.com/proto/bGhk8Uvv1ATPLBwxr9qL4e/ITA-Mazzi-Tesi?node-id=307%3A157&scaling=scale-down&page-id=307%3A31**. The facilitator explains step by step the task to be carried out by the interviewed subject, and then proceeds in asking the questions from the questionnaires.

10.2.5.5.2 Participants

6 tests have been carried out, with a total of 6 subjects. Each test involves one subject at a time to assure the authenticity of performance.

The prototype to be tested is the Patient interface, the M-Migraine Migraine Diary, that allows Patients to record migraine attacks and personal events through a smartphone application that is part of a larger system of data gathering. It is targeted toward users of 15 to 65 years of age.

To carry out the test, the subject needs a personal computer with a camera and microphone and must be able to interact with it. Camera and microphone are needed to allow the facilitator and the observer to interact with the tested subject.

Participants	6 subjects have been interviewed remotely due to the restrictions imposed by the COVID-19 pandemic in Italy.
Recruiting	The participant must be a migraine sufferer. In this way, other than the usability of the stand-alone application, the participant can express their opinion about the possibility of including the application in their daily life and other opinions strictly related to their condition.

10.2.5.5.3 Sequence

Welcome text:

Good morning, I am <facilitator_name> and this is <observer_name>. I am currently writing a Master thesis concerning a system that aims at improving the empathic relationship between doctors and Patients, targeting the flow of information between the General Practitioner and the Specialists taking care of the Patient and lastly to ease the process of recording of attacks for Patients on their device.

I am <facilitator_name> and I'm going to walk you through the whole session. Your feedback is important, so please make your comments and express your though process out loud. There are no right or wrong answers, so feel free to give any type of feedback, as it would be of great help for the future development of the prototype.

The session will last about 60 minutes. I will start by asking you about some personal information such as age, employment, and habits. Remember that all data gathered will be anonymous. After the gathering of personal data, we will proceed with the test of the application: you will share your screen and perform determined tasks. If you have any questions, feel free to ask at any point. After the tasks will be completed, I will ask you some other questions regarding the activity just performed and how you felt while doing it.

Do you have any questions for me?
We can start.

Process:

1. Welcome Text
2. Personal Information
3. Ask participants to perform the tasks and gather feedback and results.
4. SUS questionnaire, UEQ questionnaire, general feedback.

NOTE: more information about the system that the application is part from have been given along the test session when asked by the participants.

10.2.5.5.4 The Usability Testing Results

For the usability testing of the M-Migraine application prototype, I selected 6 users within the target age range of the application (15 to 65) all suffering from migraine to some extent. The migraine Patients that took part of the tests are 6:

4 females and 2 males of age between 22 and 61, uniformly spread as frequency of attacks as shown in the following graphs.

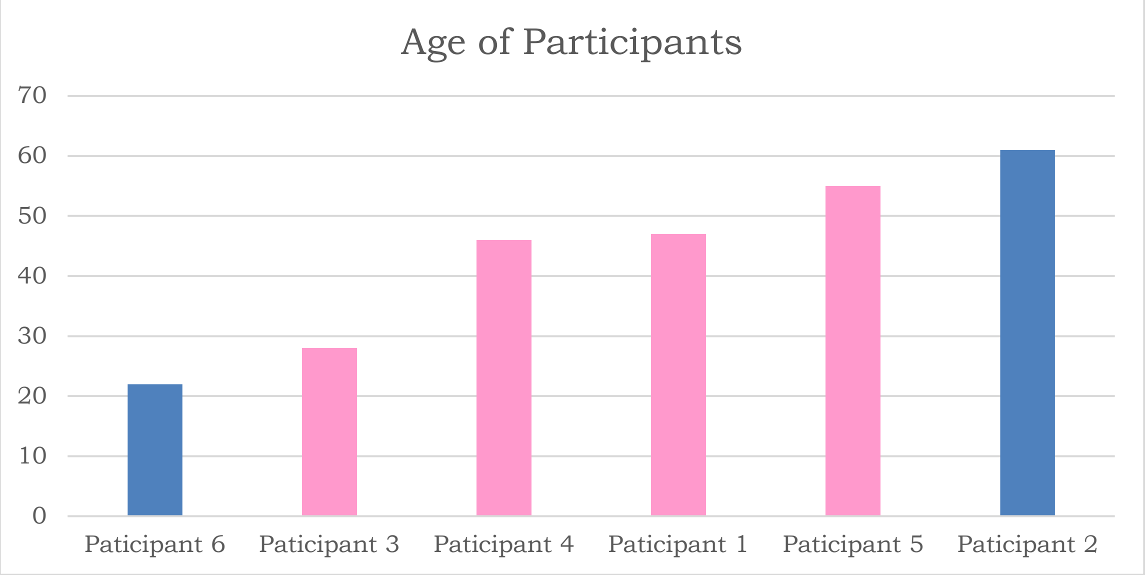


Figure 10.5 Bar graph showing the age of each participant. The gender is color coded: pink for Female and blue for Male.

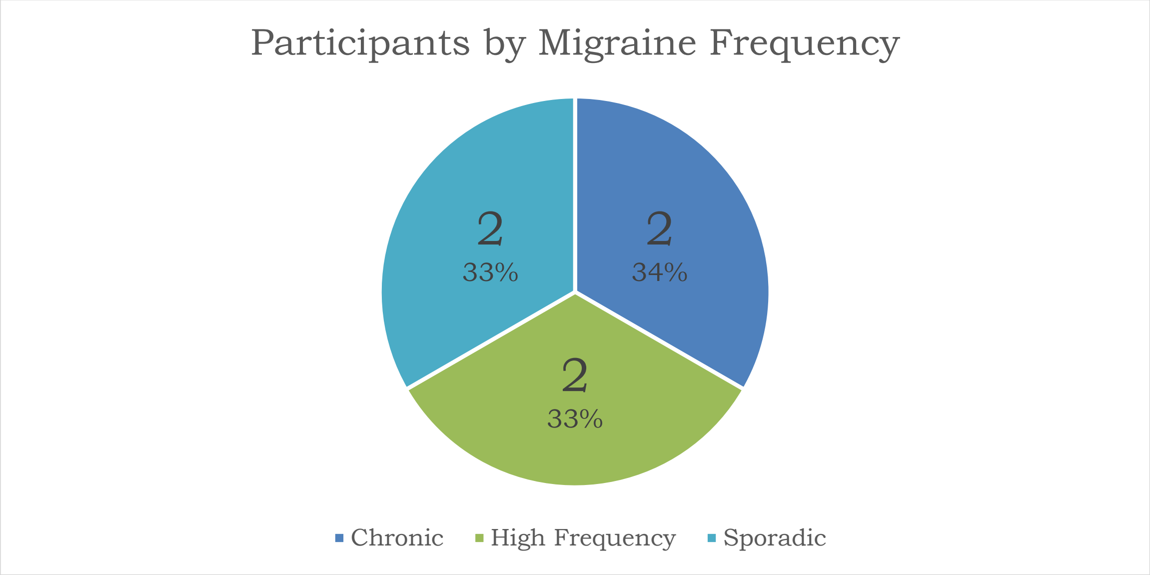


Figure 10.6 Test participants by their migraine frequency. The disorder is considered chronic if there are more than 8 occurrences per month.

The test procedure included 5 tasks to be performed by the participant. The benchmark values, called in the graphs “Theoretical values” of each task for number of actions and time needed to complete the task, are reported in the following table.

Theoretical value	**Task 1**	**Task 2**	**Task 3**	**Task 4**	**Task 5**	**TOTAL**
Time (s)	6	19	73	20	13	131
# Actions	3	6	34	9	6	58

Figure 10.7 Benchmark values for each task included in the test.

Here follows the results obtained in terms of number of actions performed to complete each task by each participant, and in terms of the time taken to successfully complete the tasks.

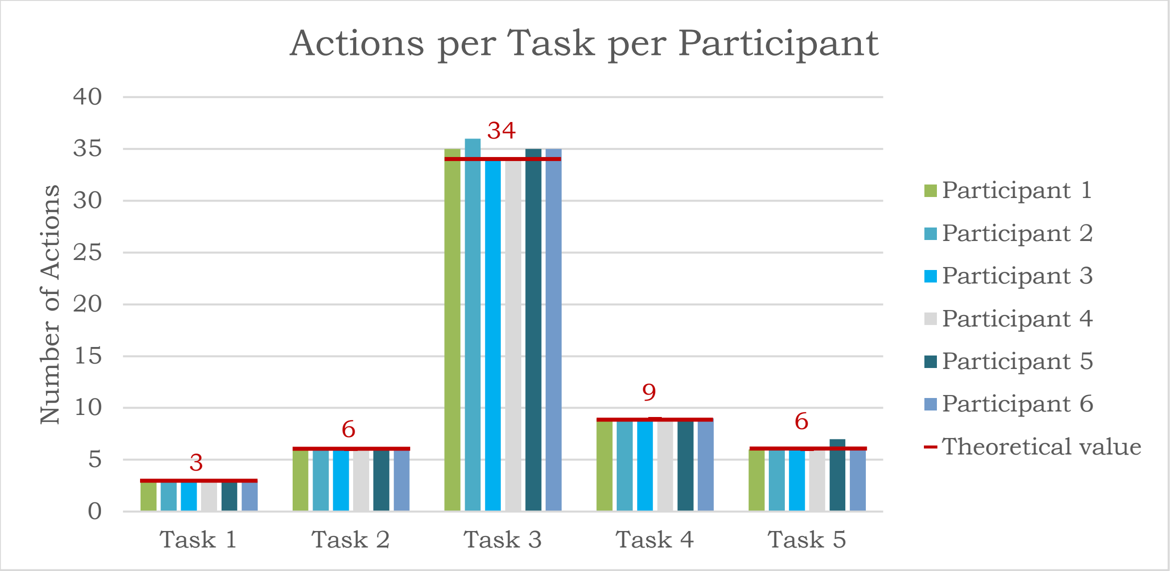


Figure 10.8 Number of actions performed by each participant to complete the tasks.

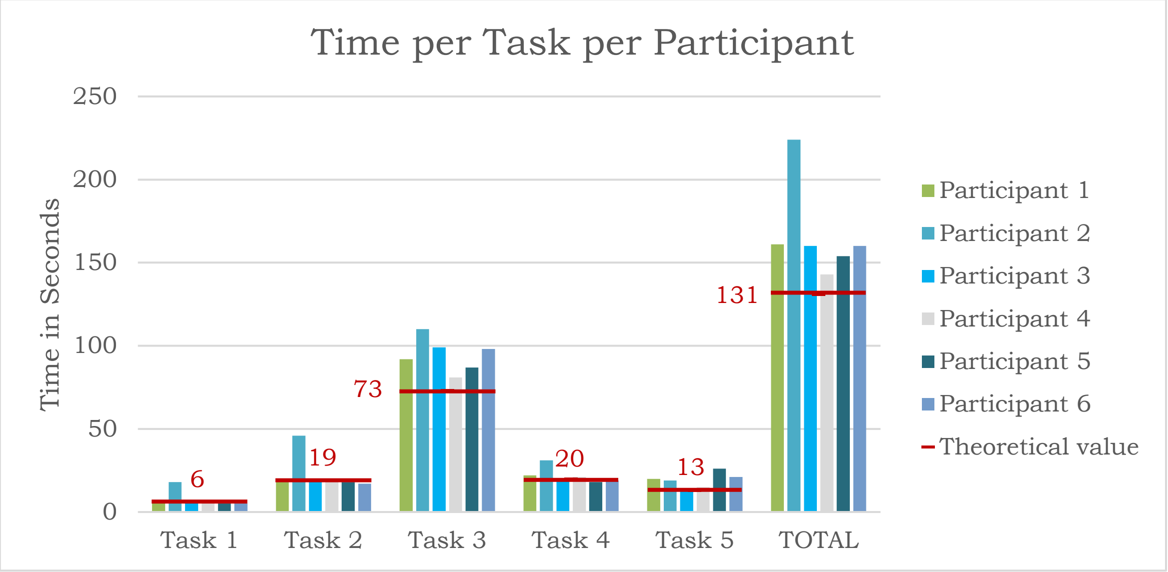


Figure 10.9 Time taken by each participant to complete the tasks.

It is worth pointing out that all tasks have been carried out successfully by all participants and no major mistakes have been done.

The number of actions has always been similar enough to the benchmark values.

More variances have been found in terms of the time taken to perform the tasks. This is partially because to correctly time the performance, the stopwatch has been paused from time to time to provide the explanation of the tasks when asked by the participant. The further details provided were not only about the task itself but also about the more general system, as it was a topic that aroused particular interest in the tested subjects.

10.2.5.5.5 System Usability Scale (SUS)

The System Usability Scale (SUS) provides a “quick and dirty” tool for measuring the usability performance. It was originally created by John Brooke in 1986 and it allows for the evaluation of products and service either hardware or software.

The benefits of such scale are the ease of administration of the questionnaire, the reliability it provides even if applied to a small sample, and the validity as it effectively differentiates among usable and non-so usable systems.

The SUS questionnaire consists of 10 items that the user rates from 1 to 5 (See figure below), where 1 is “Strongly disagree” and 5 corresponds to “Strongly agree”. Each of the 10 questions has a weight of 10 points for a total of 100 points. Even if the scale is 0-100, the SUS score is not a percentage, and a result is considered as above average if it is over 68. The graph below represents how the percentile translates in SUS score and letter grades. In particular, to get an A, the SUS score should be over 80.3 and anything below 51 corresponds to an F.

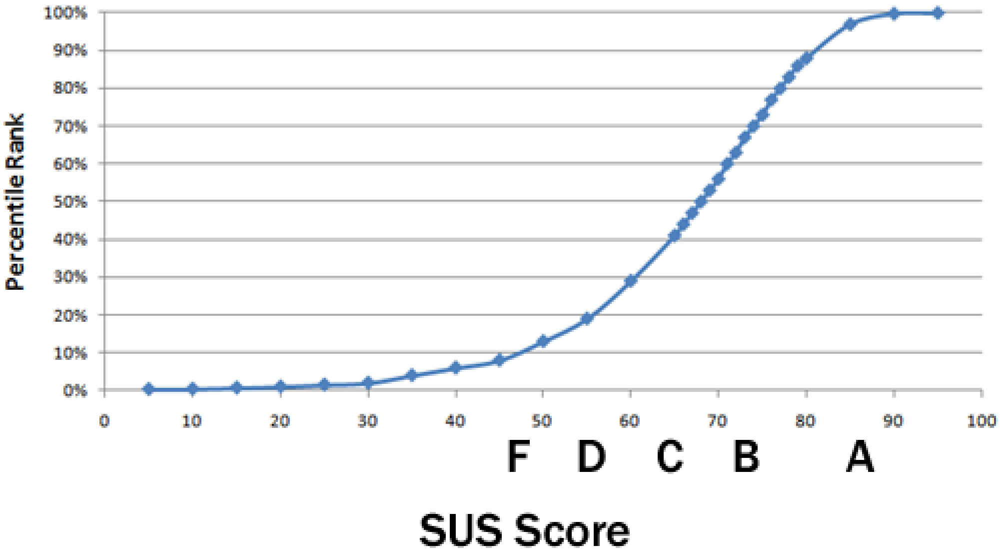


Figure 10.10 SUS Questionnaire Score vs percentile rank and A-D scale

Here are the instructions for Scoring the System Usability (Sauro, 2016):

- For odd items: subtract one from the user response.
- For even-numbered items: subtract the user responses from 5.
- This scales all values from 0 to 4 (with four being the most positive response).
- Add up the converted responses for each user and multiply that total by 2.5. This converts the range of possible values from 0 to 100 instead of from 0 to 40.

Results of the SUS Questionnaire

The overall SUS Score has been calculated as the average of the SUS score given by each participant. The table below summarizes these results showing the partial scores and the overall average. Moreover, the Standard Deviation has been calculated to have an idea of how much the results are spread out. The results are promising as all participants scored the prototype above the 81.3 boundary, therefore grading the prototype ‘A’ in a A-D system, and the standard deviation is relatively small.

Participant	SUS Score (max 100)	Grade
Participant 01	95	A
Participant 02	90	A
Participant 03	95	A
Participant 04	97.5	A
Participant 05	92.5	A
Participant 06	95	A
Average SUS Score	**94.17**	**A**
Standard Deviation	**2.58**	

The table reported below shows how participants answered to each question of the questionnaire.

Question #	"Strongly Disagree"	"Disagree"	"Neutral"	"Agree"	"Strongly Agree"
1	1	0	1	1	3
2	5	1	0	0	0
3	0	0	0	0	6
4	6	0	0	0	0
5	0	0	0	2	4
6	6	0	0	0	0
7	0	0	0	2	4
8	5	1	0	0	0
9	0	0	0	1	5
10	6	0	0	0	0

The results are promising as the answers are skewed to the left for the even sentences and the odd ones instead see the answers concentrated on the right side of the table. Indeed, it is important to remember that the even questions are the ones with a negative connotation, such as question 4 "I think that I would need the support of a technical person to be able to use this system".

10.2.5.5.6 UEQ Questionnaire

The UEQ questionnaire was originally created in Germany in 2005. It consists of a set of 26 items with the following structure:

Attractive ○ ○ ○ ○ ○ ○ ○ Unattractive

As stated in the official website, "the scales of the questionnaire cover a comprehensive impression of user experience. Both classical usability aspects (efficiency, perspicuity, dependability) and user experience aspects (originality, stimulation) are measured." (Hinderks, Schrepp, & Thomaschewski, 2018)

The six dimensions measured are:

- Attractiveness: Overall impression of the product. Do users like or dislike it?
- Perspicuity: is it easy to get familiar with the product and to learn how to use it?
- Efficiency: Can users solve their tasks without unnecessary effort? Does it react fast?
- Dependability: does the user feel in control of the interaction? Is it secure and predictable?

- Stimulation: is it exciting and motivating to use the product? Is it fun to use?
- Novelty: is the design of the product creative? Does it catch the interest of the user?

Attractiveness is a pure valence dimension, while the others are divided into two categories: pragmatic qualities and hedonic qualities. Pragmatic Quality is now the user can accomplish the goal, while Hedonic Quality refers to how the system is perceived by the user.

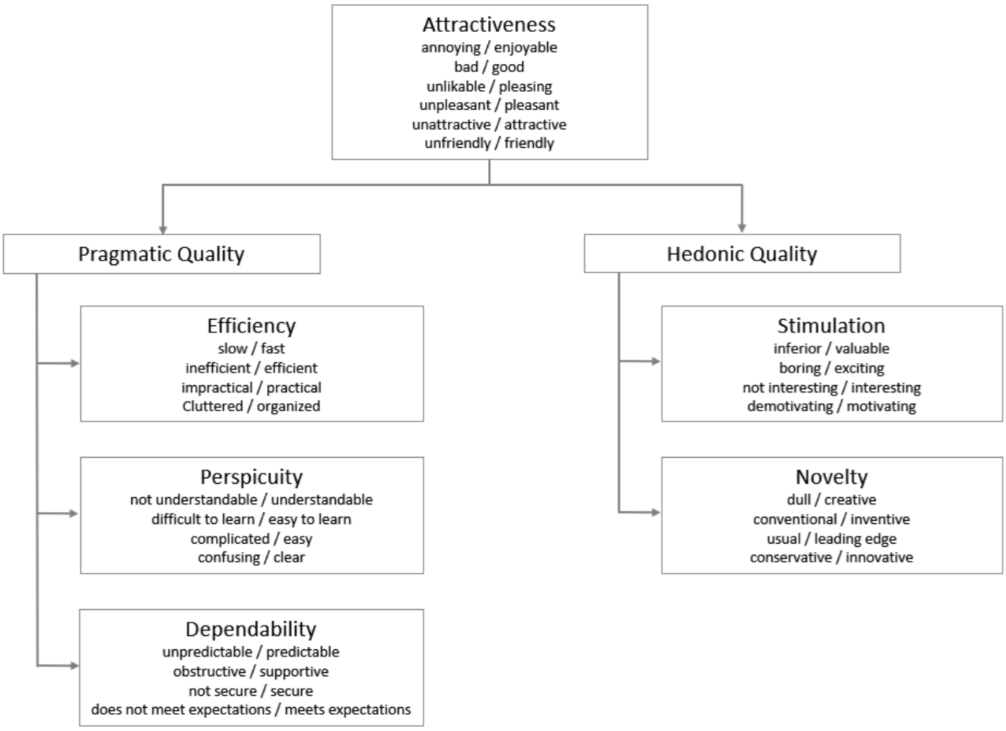


Figure 10.11: The UEQ questionnaire

The UEQ questionnaire is often used to compare two products, usually the existing version with the re-designed one or to test if a product has sufficient user experience. In this paper the UEQ is used for the latter.

Results of the UEQ Questionnaire

The analysis reported in this section have been carried out using the spreadsheet available for download on the official website **https://www.ueq-online.org/.**

The standard interpretation of the scale means that values are considered neutral if between -0.8 and +0.8, positive if > 0.8 and negative if <-0.8.

The following graph shows the results obtained from the 6 tests performed on the prototype of the Patient mobile application for each of the 6 dimensions.

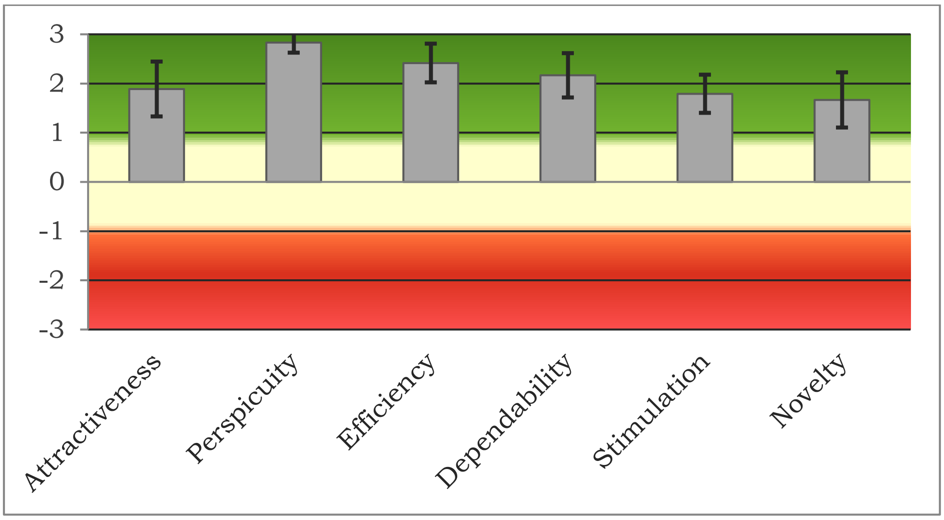


Figure 10.12 Bar graph representing the average score for each dimension.

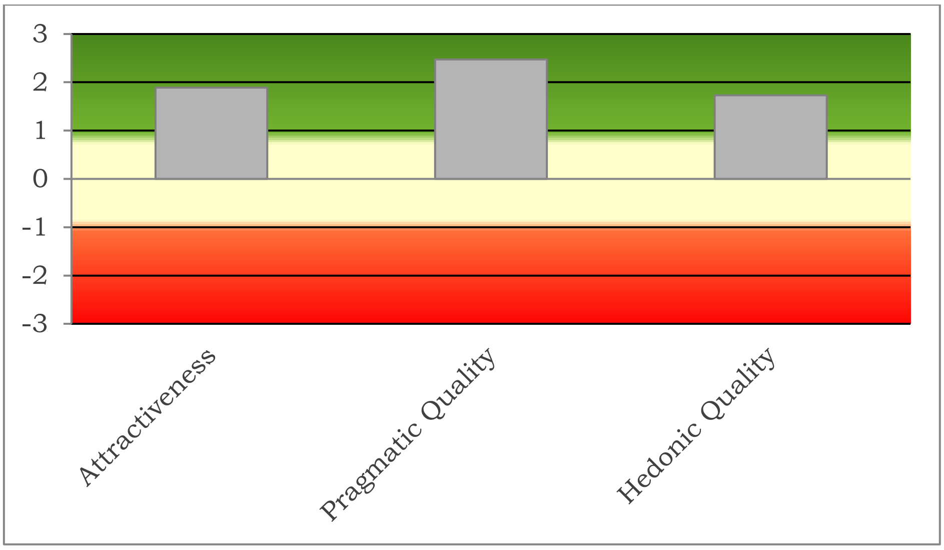


Figure 10.13 Results obtained by category.

The overall results are positive as all dimensions are over the 0.8 threshold.

Here follows a more detailed view of the results obtained. The horizontal bar graph indeed shows the mean obtained for each factor.

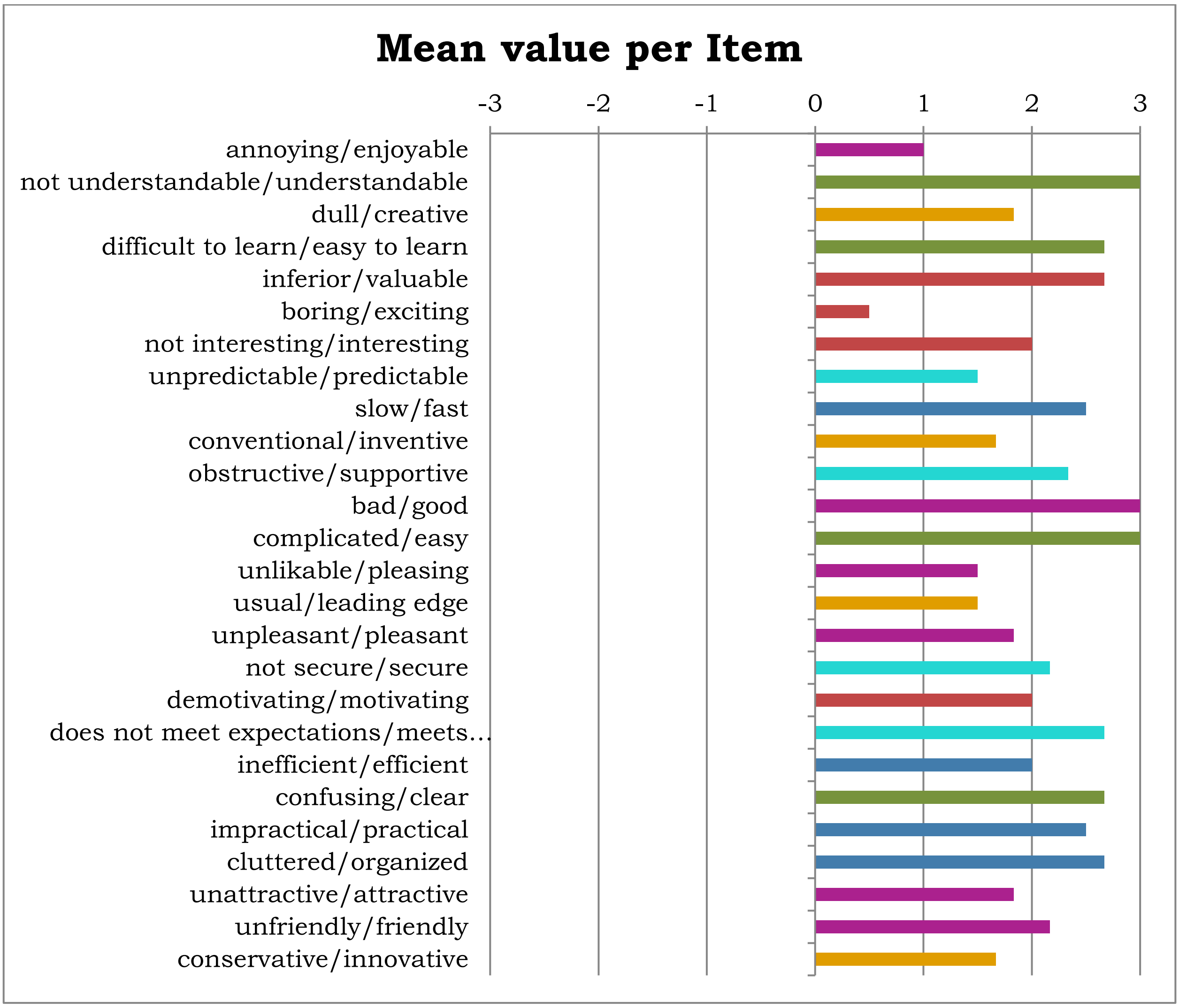


Figure 10.14 mean score of each of the 26 factors

Notice how the lowest mean is the item boring/exciting. This is because some individuals associated the diary application to the migraine event itself and commented how hard it is to see something related to their pain as exciting.

A plotted benchmark against other samples follows. It can be noticed how all dimensions lay in the "Excellent" portion of the graph.

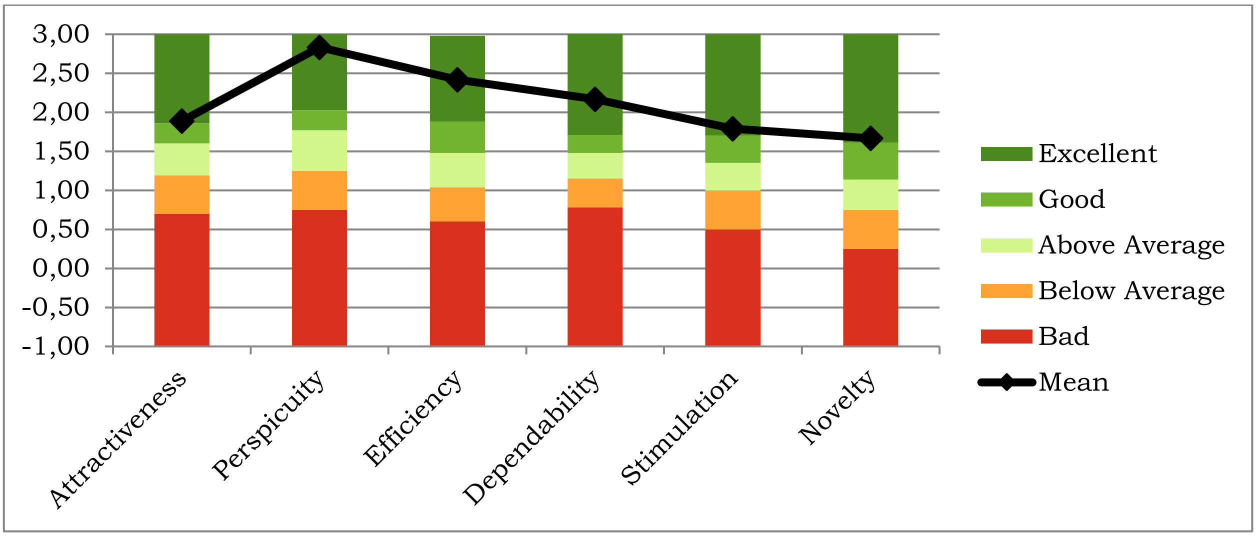


Figure 10.15 Plotted benchmark against other examples

Even though the results are promising, it is important to consider the reduced dimension of the sample, only 6 tests. The prototype can be therefore considered as a good starting point, but to have a more exhaustive result, further testing is needed.

The confidence intervals of the 6 parameters are reported in the table here below.

Confidence intervals (p=0.05) per scale						
Scale	Mean	Std. Dev.	N	Confidence	Confidence interval	
Attractiveness	1.889	0.697	6	0.557	1.332	2.446
Perspicuity	2.833	0.258	6	0.207	2.627	3.040
Efficiency	2.417	0.492	6	0.393	2.023	2.810
Dependability	2.167	0.563	6	0.450	1.716	2.617
Stimulation	1.792	0.485	6	0.388	1.403	2.180
Novelty	1.667	0.701	6	0.561	1.106	2.228

All the attributes have a standard deviation lower than 1, meaning that the distribution of the ratings in all categories is consistent and not sparse.

In conclusion, the prototype was overall well perceived but increasing the number of valuations is needed to have a clearer picture of the User Experience.

10.2.5.5.7 Test Results Discussion and the Changes Made to the Prototype

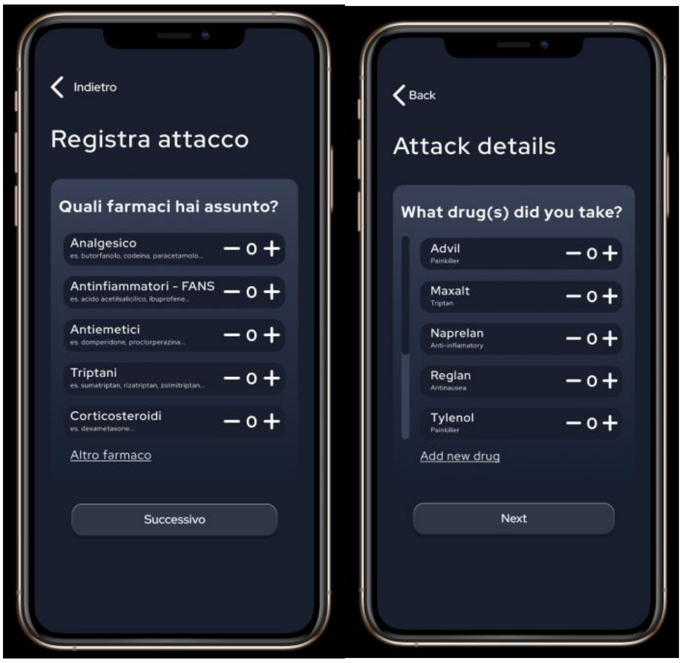
In general, the results are promising as all tasks have been performed successfully and the UEQ and SUS questionnaire results are positive. Even if the size of the sample considered is limited, its variety in age, gender and frequency of migraine, allows for a good first round of results.

The system in its entirety has been well perceived as it has been the prototype of the M-Migraine application. The main comments of the interviewed subjects are:

- The application is easy to use and complete in the amount and type of data gathered.
- The type of application is formal. A more friendly app would encourage me more in using it daily.

- When entering the amount of drug taken, there should be the option of selecting the “half dose”.
- The application does not ask anything about my nutrition habits, though in my case it has a very strong impact on my migraine.
- There should be an option for entering the supplements taken, as for me they are key for the improvement of the condition.
- The application asks to enter the category of the drug assumed, though I think it would be easier for me to enter the name of the drug rather than its category.

After this first round of testing, I decided to make some changes following the feedback of the tested subjects to the English version of the prototype itself. In particular, the form for the drugs assumed has been changed, as shown in the following figure. In the latest version, the highlighted name is the commercial name of the drug and not the category. Moreover, in the latest version, the “+” for the drug intake allows the user to increase the dosage 0.5 at a time.



Even though one subject mentioned how they would have preferred a more friendly language, I am not planning on changing it as a more formal language is preferable given the diversity of target users (ranging from 15 to 65 years of age).

As for the food intake diary, even if it would be an interesting integration, it is thought as a possible future development where more study should be put in. As for the current state of the art of the system, such integration would make the application more cumbersome and demanding for the user.

Other changes to be performed before proceeding with the second round of usability testing, are:

- Add a final section in the “Log attack” flow for letting the user enter any other notes about the attack.
- Include the possibility of recording food supplements intake.

10.2.6 Report

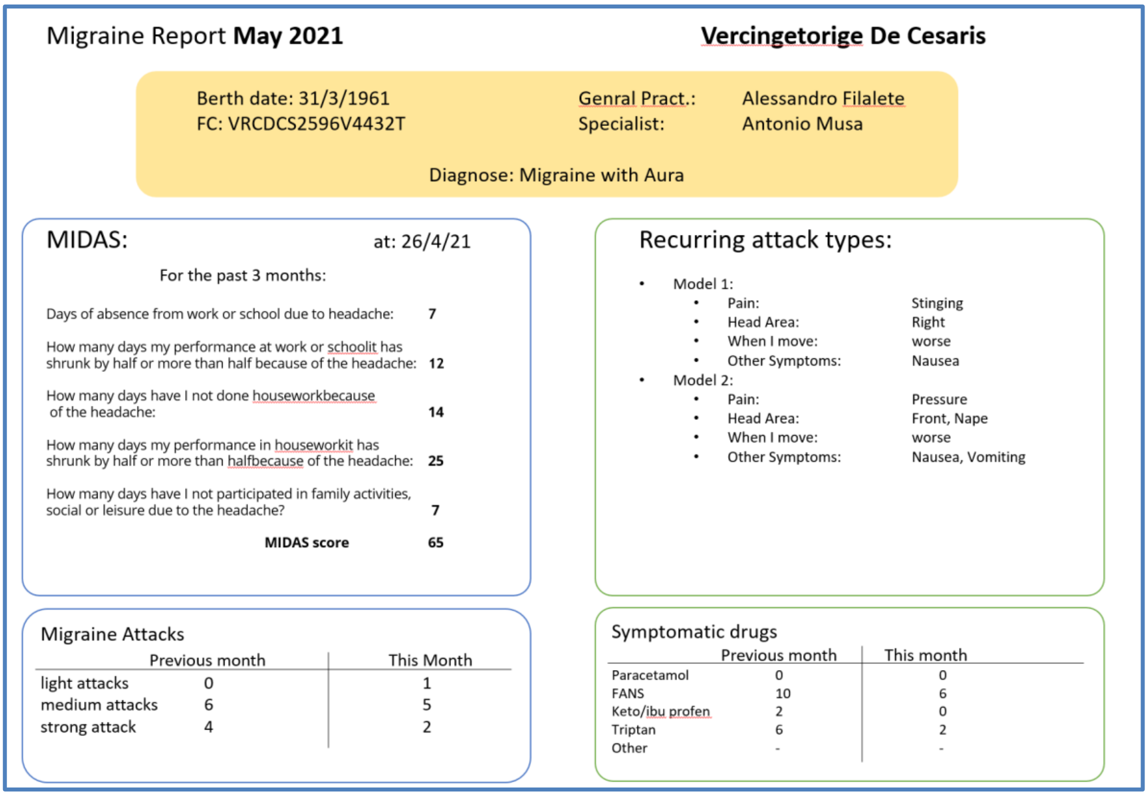
The report I'm proposing here is a monthly snapshot of the Patient status. The goal is offering an easy-to-read synthesis to the doctor. It does not include the info that should be registered by the Doctor, like the therapy currently applied, and contains only the data recorded by the Patient in the last period.

The goal is to minimize the time required to the doctor to analyze the data, allowing more time to informal communication with the Patient.

The report can be obtained both from the Web Application and from the Mobile Diary recorder. Thus, the report can be produced and presented to a clinician even in out of the ordinary situations. To this end, some data is reported on the mobile device by the synchronization process (Midas).

The first page includes the basic personal data of the Patient and the data that synthetizes the Migraine anamnesis of the Patient:

- The Latest version of the Midas questionnaire filled in by the Patient showing the impact of the disease on the social life
- The Attack models that the Patient has recorded, to highlight what type of attack occurs more frequently
- A summary of the attack occurrences in the previous month compared to this month
- The symptomatic drugs assumed last month compared to this month



Migraine Report **May 2021** **Vercingetorige De Cesaris**

Berth date: 31/3/1961
FC: VRCDCS2596V4432T
Genral Pract.: Alessandro Filalete
Specialist: Antonio Musa

Diagnose: Migraine with Aura

MIDAS: at: 26/4/21

For the past 3 months:

Days of absence from work or school due to headache:	**7**
How many days my performance at work or schoolit has shrunk by half or more than half because of the headache:	**12**
How many days have I not done houseworkbecause of the headache:	**14**
How many days my performance in houseworkit has shrunk by half or more than halfbecause of the headache:	**25**
How many days have I not participated in family activities, social or leisure due to the headache?	**7**
MIDAS score	**65**

Recurring attack types:

- Model 1:
  - Pain: Stinging
  - Head Area: Right
  - When I move: worse
  - Other Symptoms: Nausea
- Model 2:
  - Pain: Pressure
  - Head Area: Front, Nape
  - When I move: worse
  - Other Symptoms: Nausea, Vomiting

Migraine Attacks

	Previous month	This Month
light attacks	0	1
medium attacks	6	5
strong attack	4	2

Symptomatic drugs

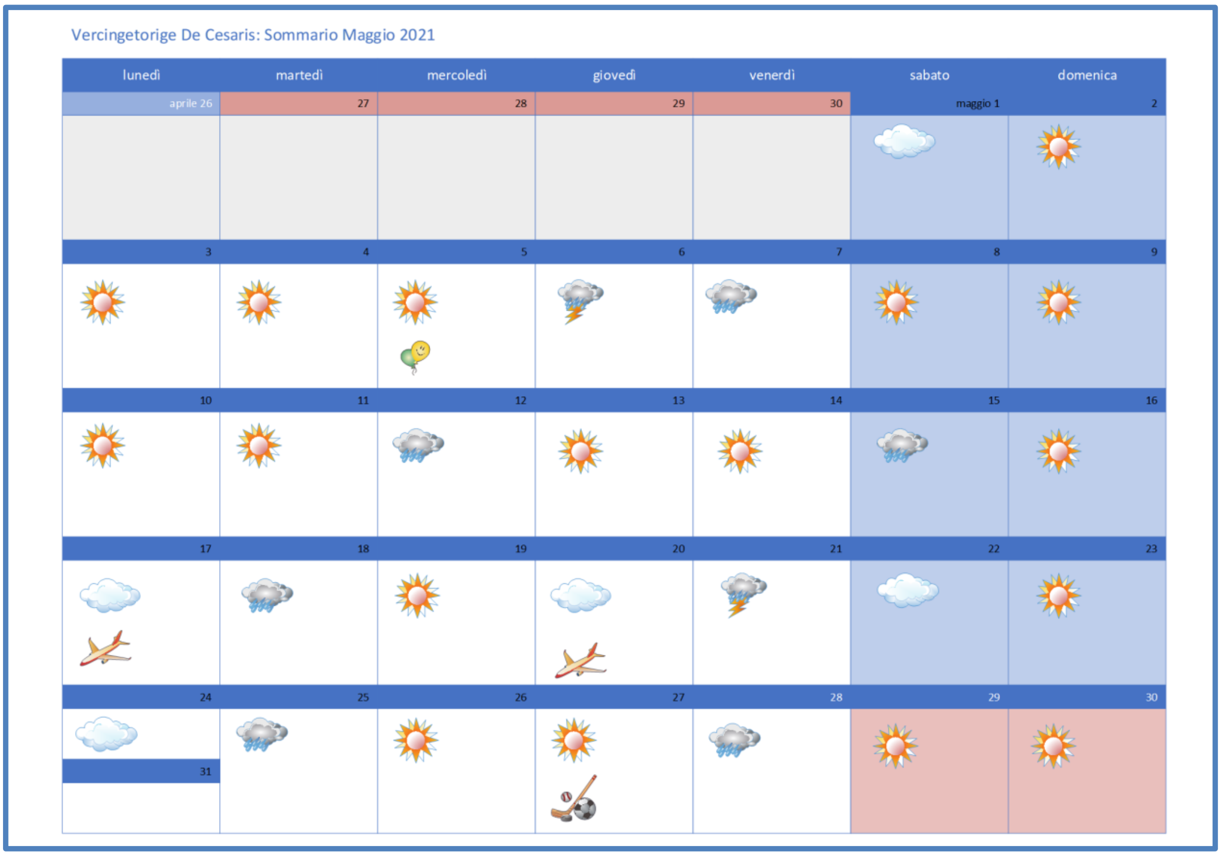
	Previous month	This month
Paracetamol	0	0
FANS	10	6
Keto/ibu profen	2	0
Triptan	6	2
Other	-	-

Figure 10.16: Report page 1

The second page shows at a glance what happened in the month. The layout is a monthly calendar and icons show what relevant events happened every day.

The legenda of the icons follows:

☀	No attack today
☁	An attack of low intensity
🌧	An attack of medium intensity
⛈	An attack of heavy intensity
🎈	A relevant family event
✈	A flight
⚽	Relevant physical activity
📅	Especially heavy work activity
🍝	Extraordinary food intake or fast

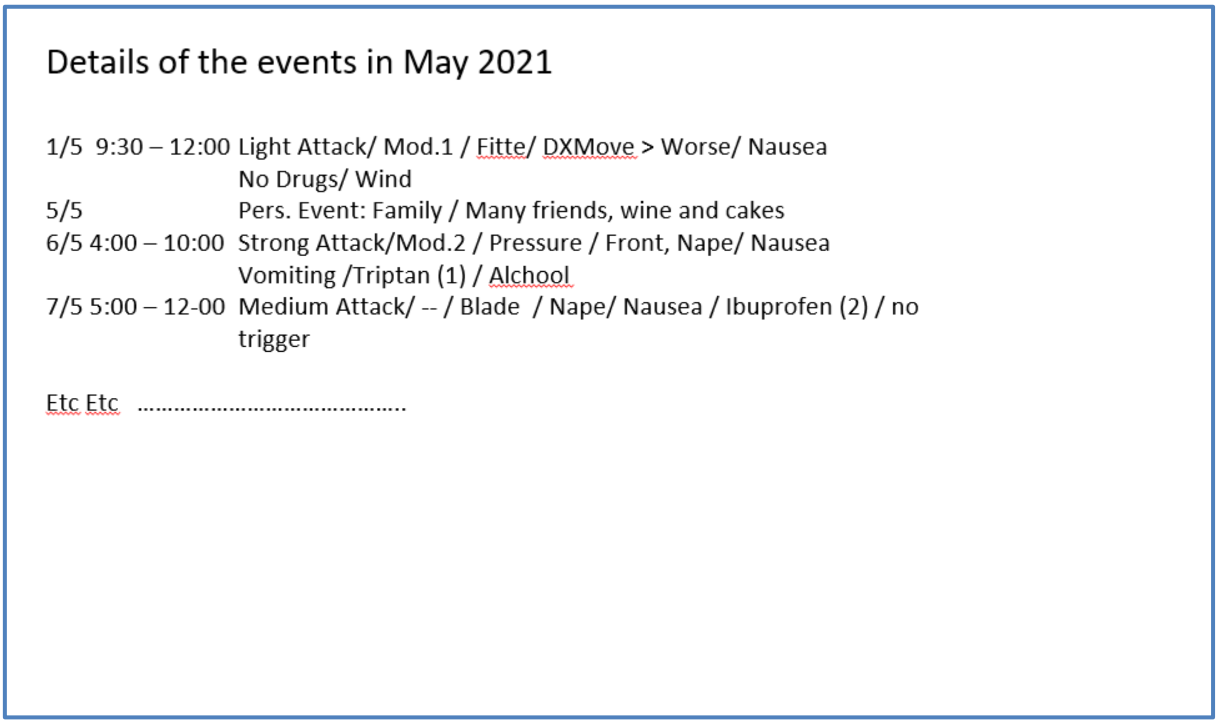


Vercingetorige De Cesaris: Sommario Maggio 2021

lunedì	martedì	mercoledì	giovedì	venerdì	sabato	domenica
aprile 26	27	28	29	30	maggio 1 ☁	2 ☀
3 ☀	4 ☀	5 ☀ 🎈	6 ⛈	7 🌧	8 ☀	9 ☀
10 ☀	11 ☀	12 🌧	13 ☀	14 ☀	15 🌧	16 ☀
17 ☁ ✈	18 🌧	19 ☀	20 ☁ ✈	21 ⛈	22 ☁	23 ☀
24 ☁ 31	25 🌧	26 ☀	27 ☀ ⚽	28 🌧	29 ☀	30 ☀

Figure 10.17: Report page 2

The third page shows the details relevant to each Icon, ordered by date. Short form is used for any info, to allow the all facts to be contained in a single page to ease the connection between page 2 and the details in page 3.



Details of the events in May 2021

1/5 9:30 – 12:00 Light Attack/ Mod.1 / Fitte/ DXMove > Worse/ Nausea
No Drugs/ Wind
5/5 Pers. Event: Family / Many friends, wine and cakes
6/5 4:00 – 10:00 Strong Attack/Mod.2 / Pressure / Front, Nape/ Nausea
Vomiting /Triptan (1) / Alchool
7/5 5:00 – 12-00 Medium Attack/ -- / Blade / Nape/ Nausea / Ibuprofen (2) / no
trigger

Etc Etc ……………………………………

Figure 10.18: Report page 3

11 Accessibility

Today, over 1 billion people live with some form of disability and this number is quickly increasing because of the ageing of population and increase of chronic health conditions. Moreover, almost everyone will or has experienced some form of disability at some point of their life. Disabilities can be permanent or temporary, such as a broken arm, and can affect how people interact with devices. For this reason, developing an accessible interface and system is important. (World Health Organization, 2020)

The European Standardization Organizations – CEN, CENELEC and ETSI – have published the new European Standard on accessibility requirements for Information and Communication Technologies (ICT) products and services: EN 301 549 (ETSI, 2021).

It is intended in particular for use by public authorities and other public sector bodies during procurement, to ensure that websites, software, digital devices are more accessible – so they may be used by persons with a wide range of abilities (ETSI, 2014).

The proposed system is thought to be implemented at national level in public health services, therefore it must be compliant to the accessibility requirements of Italian government. From the Direttiva UE 2016/2102 con il Decreto legislativo n. 106 of August 10th, 2018, that updated the existing Legge 4/2004, the websites and mobile applications of public administrations of the States part of UE should improve the accessibility. In particular, the compliance with WCAG 2.1 of websites and mobile applications is required. (AGID, 2020) The standard is also included in the European Standard EN 301 549, in particular in the sections regarding Web (Section 9) and Software (Section 11) of the document.

Even though it is not part of this paper, the web applications for the General Practitioner, the Specialist and the Patient will be developed in compliance with the WCAG 2.1 requirements, at least to level AA, preferably also compliant to the level AAA.

For the Patient mobile application instead, a deeper analysis about compliance with WCAG 2.1 can be found in Annex 2 (W3C, 2019) .

The prototype has been developed keeping in mind the WCAG 2.1 constraints where applicable (therefore mainly for language used, contrast and size of elements).

The application is tough to be developed in Android and iOS. To make it compliant with accessibility requirements, in particular Section 11.5 of the document EN 301 549 "Interoperability with assistive technology", accessible components will be used: buttons, checkboxes being the main ones.

The compliance with assistive technologies is key to allow all users to be able to access and effectively use the application. Examples of assistive technologies are screen readers (TalkBack, Voiceover) and directional controllers (trackball, keyboard). For this purpose, it is important to describe each component so that the assistive technology can effectively translate for the user the screen elements. This can be achieved in Android with the contentDescription attribute and in iOS with accessibilityLabel.

In the prototype of M-Migraine the design choices have been made with the concept of accessibility in mind.

1. Dark background and white text.

High contrast was chosen to allow low vision users to be able to use the application. At the same time, the dark background has been a choice driven by the migraine condition: as emerged from the interviews and the literature review, one of the most common symptoms during the migraine attack is sensibility to light. Darker background is more suitable for such symptoms (Kim, Erickson, & Lambert, 2019). Though recent studies (Bullock, 2020) are debunking this belief, therefore the possibility of choosing "light-mode" for the application may be a future development.

2. Form as successive screens and not a continuous form.

Putting information in subsequent screens lets the user focus on fewer information at a time, therefore requiring a lower concentration level. This is preferable if we think that the Patient may be entering the information right after a debilitating migraine attack. Moreover, this allows the application to be more suitable for users with learning impairments such as dyslexia or ADHD.

3. Presence of "Next" or "Confirm" button.

Being in successive screens and not as a scrollable form, the screens to enter the attack details or other choices in the app, all have a confirm button. This is to lower the probability that the user selects options by mistake and allow them to fix their choices on the go.

4. White border appears when the item is selected.

This choice allows one to well distinguish the selected item among the others. The purple cloud further identifies the selected item. This choice still makes the contrast ratio higher than 4.5, though for compliance to WCAG 2.1 level AAA, this design choice may be changed.

5. Color change in the selected checkbox option and filled checkbox.

Also in this case, the choices had been done having accessibility in mind. The color change of the text allows it to be different from the other unselected options. For similar reasons, the checkbox has been designed as filled when selected and empty when unselected.

6. Usage of simple, standard symbols

The home button, calendar page, profile page, settings, edit symbols are all standard to avoid misunderstanding from the user.

In conclusion, design choices have been made according to accessibility constraints, though further work is needed to develop an application and more in general a system compliant to accessibility guidelines.

12 How the System Satisfies the Goals

Recalling the objectives identified in chapter xx, we see if and how the system described satisfies them. With "Satisfy", it is intended that the proposal describes a solution for the related requirements.

GOAL1. *Each Actor in the system should be unequivocally identified.*
The usage of Codice Fiscale and Role associated to a unique ID grant the goal.

GOAL2. *The Patient should feel followed and understood by the Specialist and General Practitioner.*
Requirements 07 and 09 are satisfied fully. The system indeed allows the Specialist and GP to access data previous a visit.

GOAL3. *Privacy regulations must be respected protecting the data entered by the Patient. All these data are sensitive.*
Requirements 21, 04, 05, 06 have been fully satisfied. For further details, see chapter "Security and Privacy".

GOAL4. *The General Practitioner should be involved in the migraine clinical care of the Patient as they know the Patient clinically and personally more deeply and broadly than the Specialist.*
The goal is satisfied by involving directly the General Practitioner in the System, allowing the Specialist to access to the data in advance. Requirements 09, 10, 11, 12 are satisfied.

GOAL5. *The Headache diary is the primary output: The Patient should be able to fill the "headache tracker" quickly and with ease, prioritizing these aspects to the completeness of data gathered.*
The description of the Patient Diary Recorder application explains thoroughly this point (see section "The Mobile Diary Recorder"). Requirements 13, 14, 15 are satisfied.

GOAL6. *The Specialist should also focus his/her attention to the non-strictly clinical sphere of the Patient emphasizing the empathic and psychological relationship.*

Requirements 07 and 18 are satisfied. Consulting data in advance, allows the Specialist to focus more on the human relation with the Patient during the visit time.

GOAL7. *The Actors should collect data not only strictly related to the headache disorder to allow for a 360° assessment of the Patient (comorbidities, food habits, sleep pattern, physical activity, hydration, stress factors, blood pressure, cardiac pulse).*
The manual collection of such information is included in the web component of the solution, though the Requirements 16 and 17 are not fully satisfied by the system proposed. The section “Options for Future Research” describe possibilities to cover these points.

GOAL8. *The Specialist and the General Practitioner should be kept updated on the number of symptomatic drugs taken by the Patient and their effect.*
The system gathers information about drug intake of the Patient. Additional AI analysis and reports may be considered for future extensions. Requirements 18 is partially satisfied, while requirement 19 is not covered here.

GOAL9. *All Actors should be able to use the interface.*
Requirement 22 is satisfied. For requirement 20, details about the state of the art of the accessibility of the proposed system and the planned future developments are found in the chapter “Accessibility”.

13 Options for Future Research

The study could be extended to analyze better relevant features emerging from what has been done here and from specific suggestions from the Patients interviewed to validate the prototype.

13.1 Integration in Google calendar

The younger Patients interviewed, using heavily the Mobile features, suggest to study an integration of the Migraine Diary with Google Calendar. The requirement is to extend the recording of an event in Google Calendar to access the collection of migraine attacks and migraine personal events. The integration should be studied both in terms of ergonomics and technical feasibility.

13.2 Gathering of data collected by the mobile devices

A detailed reconstruction of the overall scenario in which the Patient's migraine attacks originate and develop cannot be based solely on the information recorded manually by the Patient: the registration work is excessive and certainly leads to an abandonment of the application.

The current mobile and/or wearable devices automatically collect a lot of data about us and our lifestyle.

- Physical activity, heartbeat rate, sleeping quality and other are collected by most of the wearable devices

- Travels and visits to shops and restaurants, as well as the location when an event occurs are collected by Google Maps (and others).
- Weather conditions at the location and at the time may be obtained by public Weather services.

Understanding what is available and how (including credentials required and privacy issues) to access this info may be a very interesting area of study. Integrating these data in the diary will create a complete scenario without any additional effort for the Patient.

Some examples follow.

There is no need for a real-time connection: data may be collected asynchronously, just before producing reports or on a scheduled timing. Then the proposal is to use standard existing applications on the smartphone, I consider here Google Fit, and develop within the System Patient app the software required to collect data from Google fit and integrate with data collected by the app itself by time and date (GOOGLE, 2020).

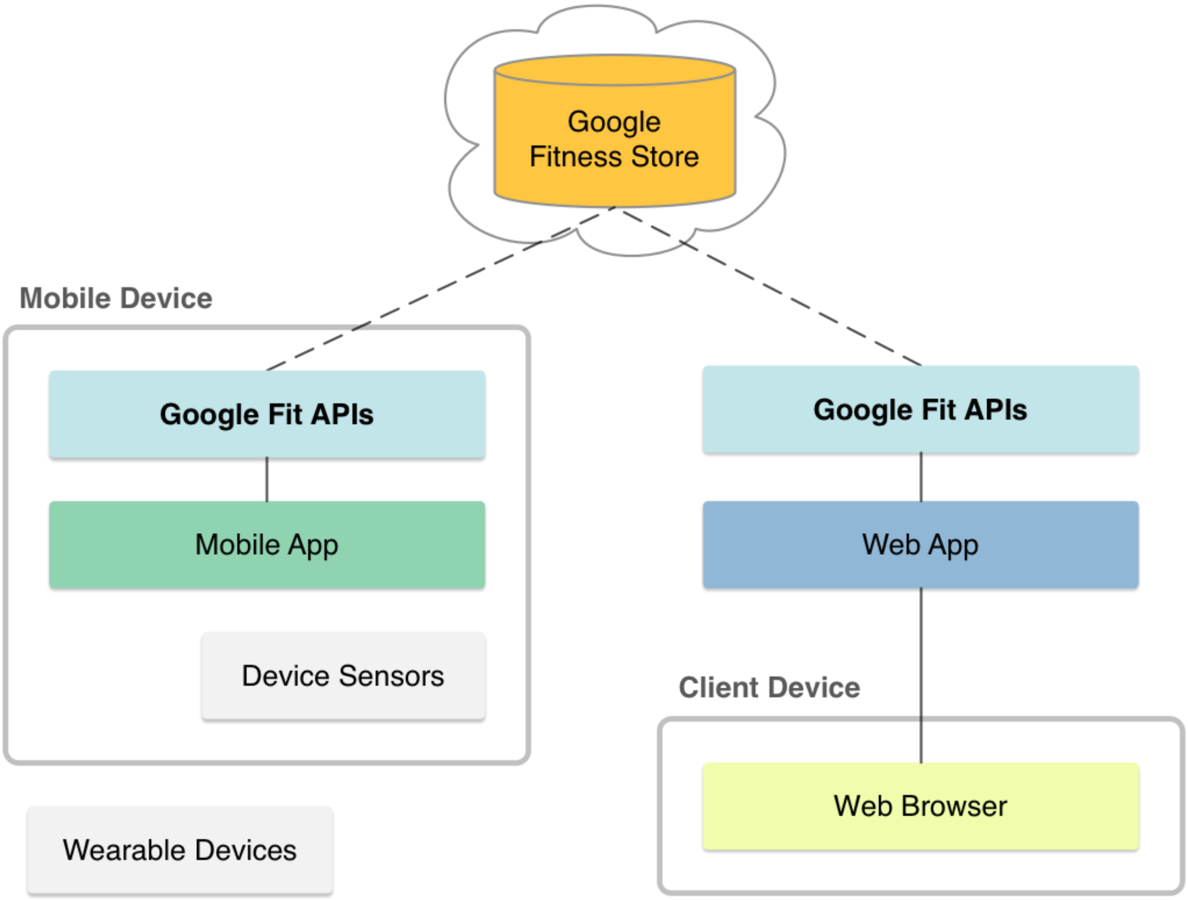


Figure 13.1 The Google Fit Platform

The Google Fit platform is designed to allow new applications to load data into the "Fitness Store" from their own application collecting data from the existing and future sensors. Nowadays, much valuable information is collected by Smartwatches and new sensors will become available in the future. The platform is also taking care of the security and privacy.

The data that can be collected today from Google fit when the user is using an appropriate smartwatch could be:

- Sleeping pattern history
- Blood pressure
- Heartbeat rate
- Walking steps and other activity (e.g., biking)
- Cardio score (a measure of effectivity of the activity of the day)

12–18 aprile

145 pt

Totalizzi Punti cardio quando svolgi attività più intense, come le camminate veloci. Aumenta il ritmo per accumulare più punti.

Lunedì 12 aprile
30 Punti cardio

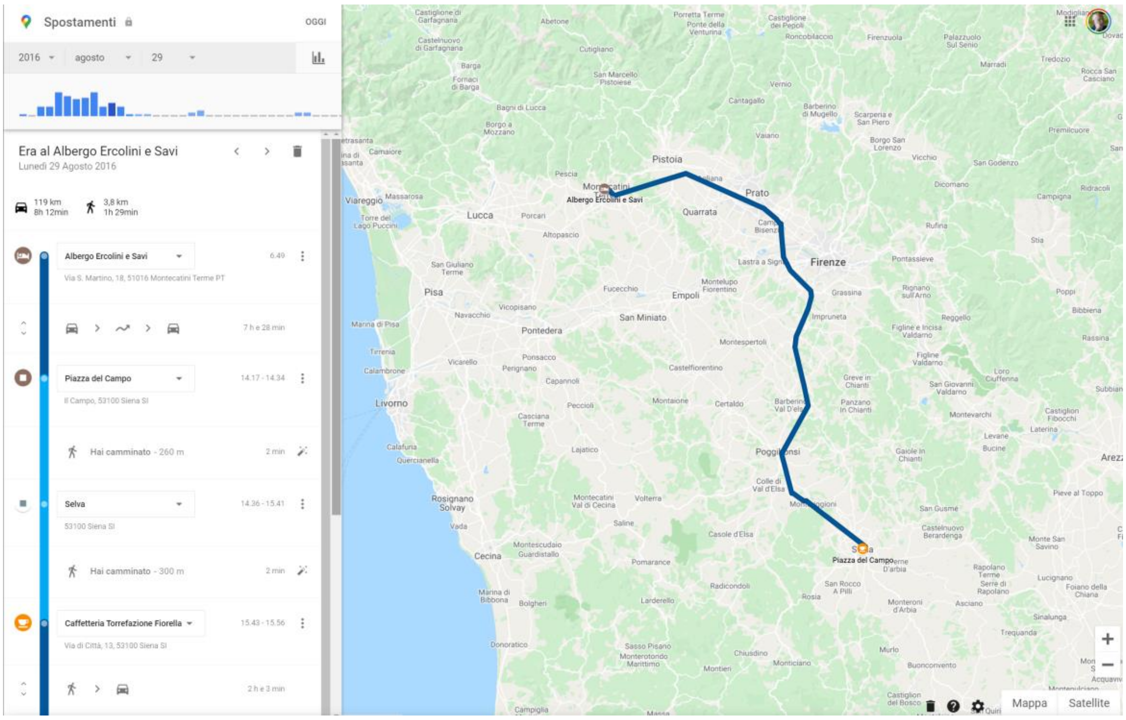
Martedì 13 aprile
6 Punti cardio

Mercoledì 14 aprile
52 Punti cardio

Figure 13.2: A google fit form

With similar procedures, from other applications other data may be collected. For the following types of data, I made no check about availability of API to access the data, while the data are collected:

- Trips (where, when, how long, how) (Google Maps)



Spostamenti

OGGI

2016 agosto 29

Era al Albergo Ercolini e Savi

Lunedì 29 Agosto 2016

119 km
8h 12min

3,8 km
1h 29min

Albergo Ercolini e Savi 6.49

Via S. Martino, 18, 51016 Montecatini Terme PT

7 h e 28 min

Piazza del Campo 14.17 - 14.34

Il Campo, 53100 Siena SI

Hai camminato - 260 m 2 min

Selva 14.36 - 15.41

53100 Siena SI

Hai camminato - 300 m 2 min

Caffetteria Torrefazione Fiorella 15.43 - 15.56

Via di Città, 13, 53100 Siena SI

2 h e 3 min

Figure 13.3: From Google Maps

- Weather condition by location and date (i.e., **https://www.meteoblue.com/**, https://www.ilmeteo.it/)

Che tempo faceva a Siena il 16 Agosto 2016 - Archivio Meteo Siena

Regione: Toscana
Provincia: Siena (SI)
Comune/Località: Siena
Cerca

Anno: 2016 Mese: Agosto Giorno: 16

Dati registrati dalla stazione meteo di Firenze Peretola.

16 Agosto 2016	Dati rilevati
Temperatura media	26 °C
Temperatura minima	18 °C
Temperatura massima	34 °C
Punto di rugiada	15 °C
Umidità media	53 %
Umidità minima	20 %
Umidità massima	88 %
Visibilità media	29 km
Velocità del vento media	11 km/h
Velocità massima del vento	24 km/h
Raffica	-
Pressione media sul livello del mare	1016 mb
Pressione media	-
Pioggia	-
Fenomeni	Nessuno
Condizione Meteo	Sereno

I valori di colore rosso hanno una bassa attendibilità.
Link veloci: Italia > Toscana > Siena (SI) > Siena

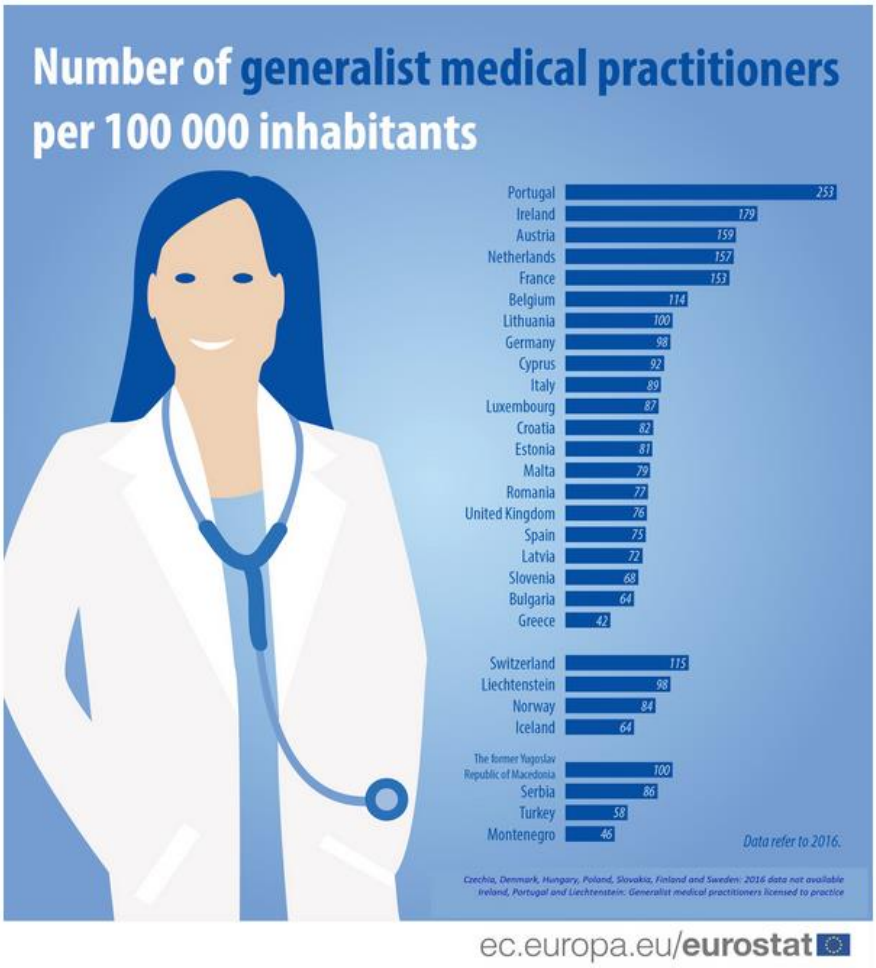
Province della regione Toscana

Figure 13.4: Weather condition in a past date

14 Limitations

14.1 **Availability of General Practitioners**

The procedure proposed in this study assigns a significant role to the GP (medico di base o di famiglia). This is a relevant issue because of the low number and the age of GPs in Italy. The data from Eurostat show that in Italy we have 89 Medici di Base per 100.000 inhabitants and that 54% of them are older than 55 years. These facts limit the dedicated time-per-Patient and the familiarity with computer-based procedures.



14.2 **GP application overlap**

Many GPs are using a dedicated application to manage their Patients. This records the medical history of the Patients; many different applications are available on the market: e.g.: (DoctorMANAGER, 2018), (Gipo.it, 2021), (medinformatica, 2020). Recording of data on a special system dedicated to migraine Patients may generate the need for double entry of some data.

14.3 **Sponsorship**

Implementation of the procedure in the real world requires a strong sponsorship by the involved authority (either public or private). Involving several actors, they should all adhere to the project.

14.4 **Familiarity of Patients with technology**

The reviews of the prototype with Patients shows signs of difficulty in using the technology by older Patients.

15 Conclusions

From the study of the bibliography that I did to understand the world of migraines, I want to highlight some elements that seem relevant to me:

- Migraine is considered by researchers throughout the world to be a serious disease, extremely widespread and with a very heavy social and economic impact. Scientific research is intensely dedicated to this pathology and new therapies have been discovered and applied in recent decades. However, no specific tests have yet been identified to diagnose the disorder.
- Knowledge of the disease is generally insufficient on the part of General Practitioners: university training on the subject is poor and summary (Barbanti, Emicrania, storia di un personaggio in cerca d'autore, 2021).
- The social perception of the disorder is not that of a real disease: it is often interpreted as an excuse to avoid some tasks. Thus, the Patient often hides or minimizes their illness in order not to be socially marginalized.
- Lacking clear guidance and support from primary care, the Patient is informed and addressed based on word of mouth and Internet based research. This leads to inevitable waste of time and public and private money.
- The identification of the correct therapy requires an analysis of the Patient's situation at 360°: comorbidities, lifestyle, and the evolution of the migraine crises. Trust in the doctor and the human relationship with them are very important.
- Lastly, we note the lack of a single national migraine registry in Italy despite the various projects launched to implement it. The relevance for the research of this database is high but it seems not sufficient to create a unified effort on the part of the actors involved.

These elements were promptly confirmed by the conversations done during the internship at YBP. It is particularly evident:

- The low participation of the General Practitioner in the Patient's journey
- The importance of word of mouth in choosing the Specialist
- The importance of the human relationship with the Specialist which improves the trust in the applied therapy and continuity of care
- The Patient's lack of willingness to collect the migraine diary over time.

I refer to this last point to report the considerations that emerged from the analysis of some market applications dedicated to collecting the medical history of Patients suffering from migraine. The two applications that I found of greatest interest are: “Migraine Buddy”, a standalone application on Mobile, which collects a large amount of information but requires a considerable effort from the Patient (the only actor entering data); NoEmi, a recent web application that involves the Specialist in the process and manages a database rich in information. NoEmi does not offer a smartphone version, which makes it difficult to use for a large number of Patients. Both are valid applications and have inspired the solution described in this study.

From the verifications made, the solution proposed in this study, based on web components shared by all the actors involved in the process and a simple mobile application for managing the migraine diary, seems to offer a realistic solution that meets the needs highlighted in this research:

- Primarily involve the General Practitioner in the migraine Patient care process. The complete absence of the doctor who best knows the Patient in the current situation was highlighted in the conversations of the YBP consultancy project but above all by the doctors who kindly participated in the verification process. The participation of the GP in the Patient's journey is important both for the effectiveness of the process (referral to Specialists) and for the psychological support of the Patient (trust in the doctor who knows me).
- Helping the Patient to maintain the migraine diary with a minimum effort so that it is not soon abandoned is important to provide the Specialist with a complete view of the crises and collateral events that may have triggered it. On this point too, the feedback of the doctors I consulted highlight the importance of the Patient's overall knowledge in setting up a correct therapy.
- The active contribution of the GP to the Patient's care path and the availability of a good migraine diary allows the Specialist to have a broader view of the Patient's situation, helping to establish a better human relationship between Patient and clinicians.

However, the effective implementation of a procedure such as the one proposed comes up against important obstacles:

- There are not enough GPs in Italy to guarantee the necessary attention to "atypical" Patients;
- Each GP uses one of the many information systems for the management of the medical office available on the market and replicating part of the information in a new system dedicated to a specific pathology would be considered an unpleasant additional work.

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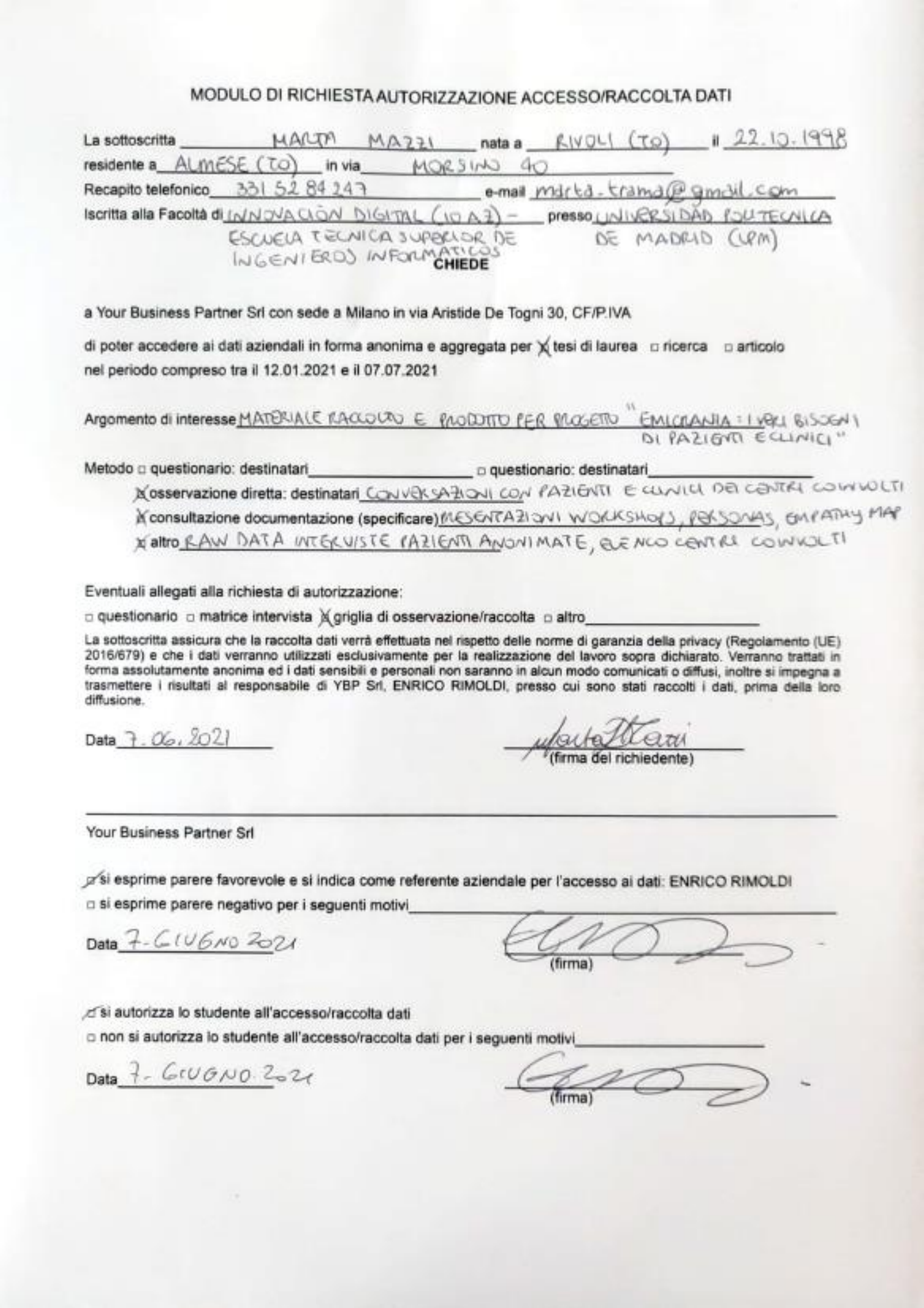
17 ANNEX 1: YBP Data Use Permission



MODULO DI RICHIESTA AUTORIZZAZIONE ACCESSO/RACCOLTA DATI

La sottoscritta MARTA MAZZI nata a RIVOLI (TO) il 22.10.1998
residente a ALMESE (TO) in via MORSINO 40
Recapito telefonico 331 52 84 247 e-mail marta.trama@gmail.com
Iscritta alla Facoltà di INNOVACIÓN DIGITAL (10AZ) - ESCUELA TECNICA SUPERIOR DE INGENIEROS INFORMATICOS presso UNIVERSIDAD POLITECNICA DE MADRID (UPM)

CHIEDE

a Your Business Partner Srl con sede a Milano in via Aristide De Togni 30, CF/P.IVA

di poter accedere ai dati aziendali in forma anonima e aggregata per ☒ tesi di laurea ☐ ricerca ☐ articolo
nel periodo compreso tra il 12.01.2021 e il 07.07.2021

Argomento di interesse MATERIALE RACCOLTO E PRODOTTO PER PROGETTO "EMICRANIA: I VERI BISOGNI DI PAZIENTI E CLINICI"

Metodo ☐ questionario: destinatari ☐ questionario: destinatari
☒ osservazione diretta: destinatari CONVERSAZIONI CON PAZIENTI E CLINICI DEI CENTRI COINVOLTI
☒ consultazione documentazione (specificare) PRESENTAZIONI WORKSHOPS, PERSONAS, EMPATHY MAP
☒ altro RAW DATA INTERVISTE PAZIENTI ANONIMATE, ELENCO CENTRI COINVOLTI

Eventuali allegati alla richiesta di autorizzazione:
☐ questionario ☐ matrice intervista ☒ griglia di osservazione/raccolta ☐ altro

La sottoscritta assicura che la raccolta dati verrà effettuata nel rispetto delle norme di garanzia della privacy (Regolamento (UE) 2016/679) e che i dati verranno utilizzati esclusivamente per la realizzazione del lavoro sopra dichiarato. Verranno trattati in forma assolutamente anonima ed i dati sensibili e personali non saranno in alcun modo comunicati o diffusi, inoltre si impegna a trasmettere i risultati al responsabile di YBP Srl, ENRICO RIMOLDI, presso cui sono stati raccolti i dati, prima della loro diffusione.

Data 7.06.2021

Marta Mazzi
(firma del richiedente)

Your Business Partner Srl

☑ si esprime parere favorevole e si indica come referente aziendale per l'accesso ai dati: ENRICO RIMOLDI
☐ si esprime parere negativo per i seguenti motivi

Data 7-GIUGNO 2021

(firma)

☑ si autorizza lo studente all'accesso/raccolta dati
☐ non si autorizza lo studente all'accesso/raccolta dati per i seguenti motivi

Data 7-GIUGNO 2021

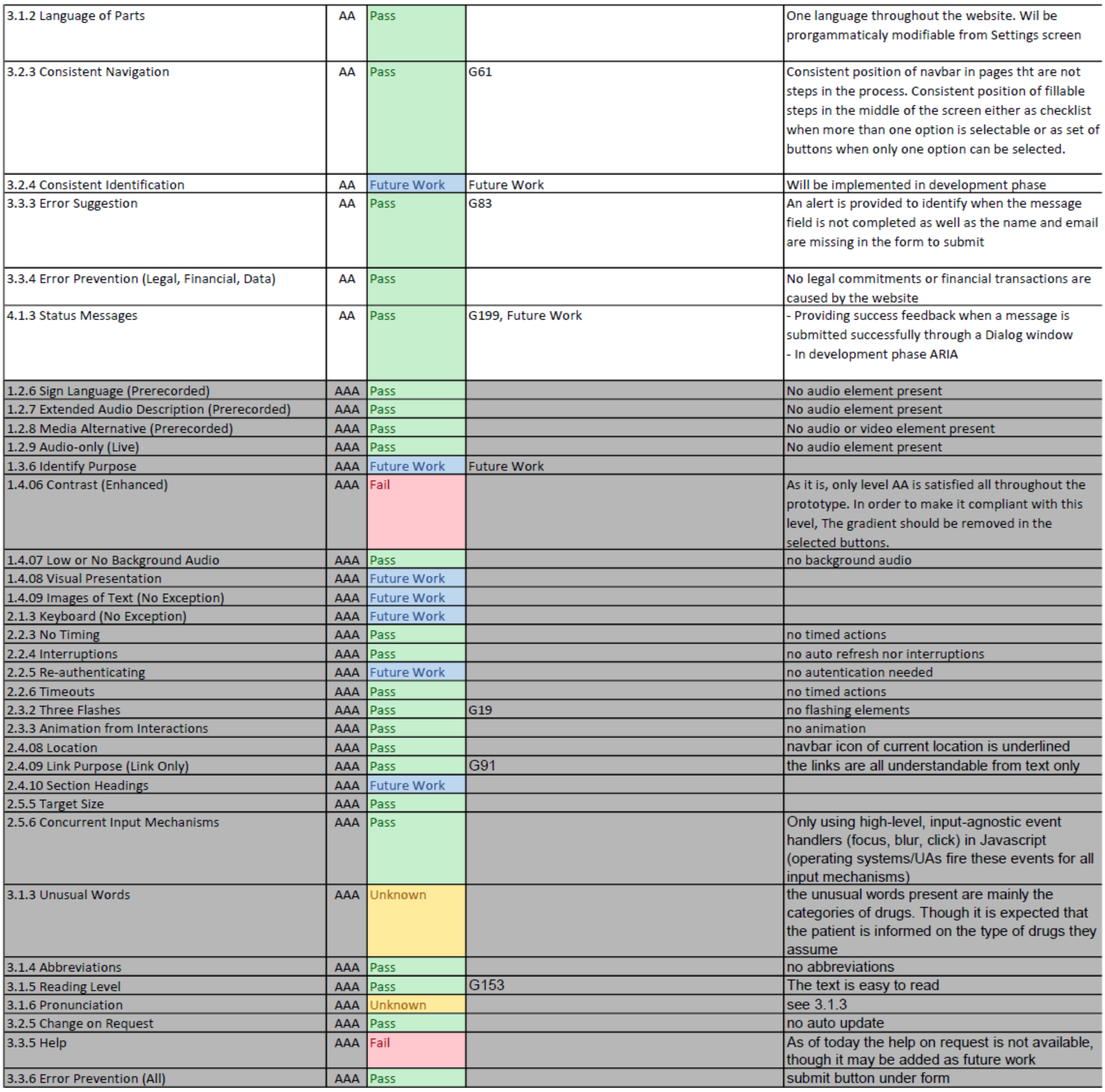
(firma)

18 ANNEX 2: WCAG 2.1 Checklist

WCAG 2.1 Checklist

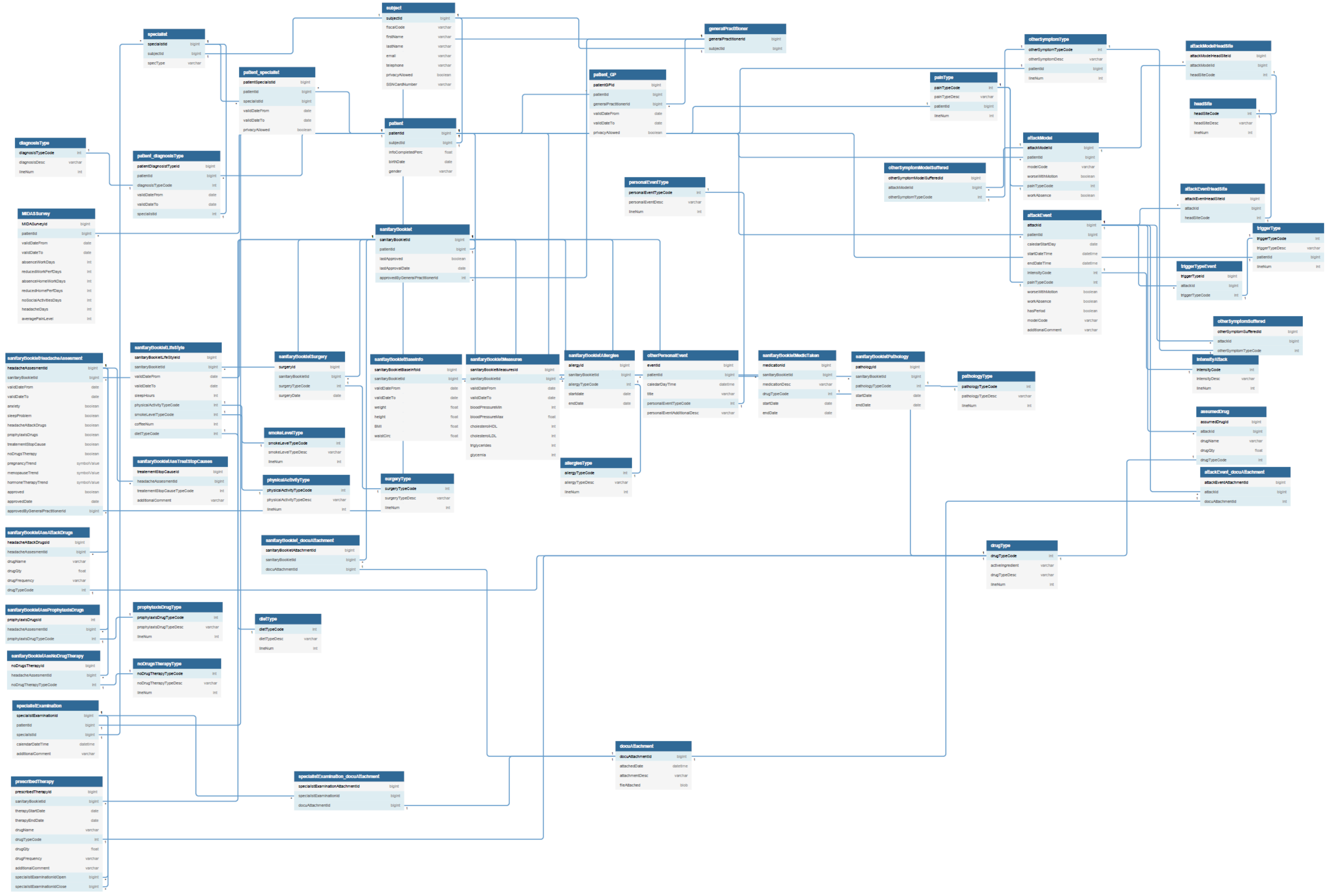
Web site: ENG M-Migraine Prototype
valuators' names: Marta Mazzi
Comment: The techniques used are the ones found in the "how to meet the WCAG" (Quick Reference) website, https://www.w3.org/WAI/WCAG21/quickref/

			If the success criterion passes, write down the	Write your own comments to justify your decision
Success criteria	**Level**	**Value**	**Techniques & Failures**	**Comments**
1.1.1 Non text content	A	Future Work	Future Work	The images will have text alternative (in particular head sections in the "where does it hurt?" screens)
1.2.1 Audio-only and Video-only (Prerecorded)	A	Pass		No pre-recorded audio or video
1.2.2 Captions (Prerecorded)	A	Pass		No pre-recorded audio or video
1.2.3 Audio Description or Media Alternative (Prerecorded)	A	Pass		No pre-recorded audio or video
1.3.1 Info and Relationships	A	Future Work		
1.3.2 Meaningful Sequence	A	Future Work	Future Work	The elements will be developed as to be focusable in logical order
1.3.3 Sensory Characteristics	A	Future Work	Future Work	The parts of the head in the "where does it hurt?" screens will be implemented with alternative text available
1.4.1 Use of Color	A	Pass	G181	not only color, but also border style changes when selecting an option
1.4.2 Audio Control	A	Pass		No audio file
2.1.1 Keyboard	A	Future Work	Future work	In the development phase, all action will be possible from keyboard attached to the mobile device.
2.1.2 No Keyboard Trap	A	Future Work	Future Work	No keyboard traps will be present
2.1.4 Character Key Shortcuts	A	Pass		due to the limited type of interactions, no shortcuts are planned to be made available specifically for the application
2.2.1 Timing Adjustable	A	Pass		No time-limited actions
2.2.2 Pause, Stop, Hide	A	Pass		No time-limited actions
2.3.1 Three Flashes or Below Threshold	A	Pass		No areas flashes in any 1-second period
2.4.1 Bypass Blocks	A	Future Work	Future work	Link to go to main content at very top, visible only when focused, will be made available when browsing screens with keyboard device
2.4.2 Page Titled	A	Future Work	Future Work	<title> tag will updates correctly in a meaningful way in each page.
2.4.3 Focus Order	A	Future Work	Future Work	In development phase correct and logical focus order will be put in place
2.4.04 Link Purpose (In Context)	A	Pass		text alternative will be provided for icons of home screen calendar and profile in development phase
2.5.1 Pointer Gestures	A	Pass		No multipoint or path-based gestures needed
2.5.2 Pointer Cancellation	A	Future Work	Future Work	In development phase Touch events are only triggered when touch is removed from a control
2.5.3 Label in Name	A	Pass		
2.5.4 Motion Actuation	A	Pass		No action is related to any sensor
3.1.1 Language of Page	A	Future Work	Future work	Language will be made programmatically determinable
3.2.1 On Focus	A	Future Work	Future Work	No context is going to change when focused
3.2.2 On Input	A	Pass	G80	Confirm button or Next button present in all pages
3.3.1 Error Identification	A	Future Work	Future work	in development phase: Providing an alert to identify when the message field is not completed for username and password
3.3.2 Labels or Instructions	A	Pass	G131	Descriptive lables are provided when input is needed
4.1.1 Parsing	A	Future Work	Future Work	To be taken care of in development phase
4.1.2 Name, Role, Value	A	Future Work	Future Work	To be taken care of in development phase
1.2.4 Captions (Live)	AA	Pass		No time-base media
1.2.5 Audio Description (Prerecorded)	AA	Pass		No time-base media
1.3.4 Orientation	AA	Future Work	Future Work	in development phase: allowing both landscape and portrait screen
1.3.5 Identify Input Purpose	AA	Future Work	Future Work	Autocomplete on login data will be implemented
1.4.03 Contrast (Minimum)	AA	Pass	G18	Already compliant in prototype phase (checked with Figma plugin Contrast checker)
1.4.04 Resize text	AA	Future Work	Future Work	Will be implemented in development phase
1.4.05 Images of Text	AA	Future Work		
1.4.10 Reflow	AA	Pass	G206	No horizontal scroll needed
1.4.11 Non-text Contrast	AA	Pass	G209	
1.4.12 Text spacing	AA	Future Work	Future work	Will be implemented in development phase
1.4.13 Content on Hover or Focus	AA	Pass	No Sufficient Techniques provided	No additional texts or content when hovering or focusing
2.4.05 Multiple Ways	AA	Pass	G125, G185	- all main pages can be reached thanks to links in the navbar in homepage. - most pages are steps of processes (entering attack or personal event) - there are links both in navbar and footer to reach the various pages
2.4.06 Headings and Labels	AA	Future Work	Future work	in development phase Headings and labels descriptive of the content of each section.
2.4.07 Focus Visible	AA	Future Work	Future work G165	Focus will bevisible at all time

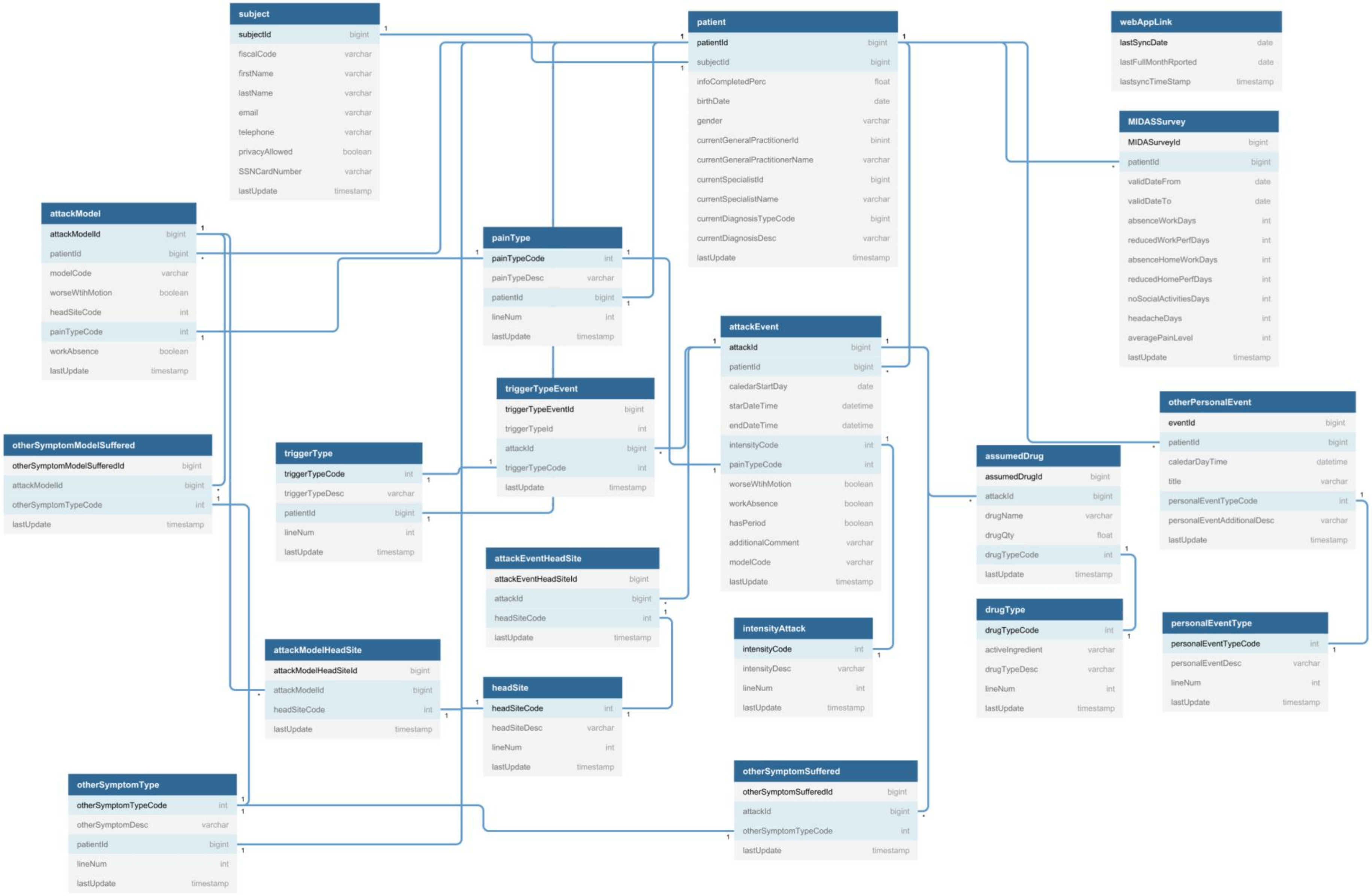


3.1.2 Language of Parts	AA	Pass		One language throughout the website. Wil be prorgammaticaly modifiable from Settings screen
3.2.3 Consistent Navigation	AA	Pass	G61	Consistent position of navbar in pages tht are not steps in the process. Consistent position of fillable steps in the middle of the screen either as checklist when more than one option is selectable or as set of buttons when only one option can be selected.
3.2.4 Consistent Identification	AA	Future Work	Future Work	Will be implemented in development phase
3.3.3 Error Suggestion	AA	Pass	G83	An alert is provided to identify when the message field is not completed as well as the name and email are missing in the form to submit
3.3.4 Error Prevention (Legal, Financial, Data)	AA	Pass		No legal commitments or financial transactions are caused by the website
4.1.3 Status Messages	AA	Pass	G199, Future Work	- Providing success feedback when a message is submitted successfully through a Dialog window - In development phase ARIA
1.2.6 Sign Language (Prerecorded)	AAA	Pass		No audio element present
1.2.7 Extended Audio Description (Prerecorded)	AAA	Pass		No audio element present
1.2.8 Media Alternative (Prerecorded)	AAA	Pass		No audio or video element present
1.2.9 Audio-only (Live)	AAA	Pass		No audio element present
1.3.6 Identify Purpose	AAA	Future Work	Future Work	
1.4.06 Contrast (Enhanced)	AAA	Fail		As it is, only level AA is satisfied all throughout the prototype. In order to make it compliant with this level, The gradient should be removed in the selected buttons.
1.4.07 Low or No Background Audio	AAA	Pass		no background audio
1.4.08 Visual Presentation	AAA	Future Work		
1.4.09 Images of Text (No Exception)	AAA	Future Work		
2.1.3 Keyboard (No Exception)	AAA	Future Work		
2.2.3 No Timing	AAA	Pass		no timed actions
2.2.4 Interruptions	AAA	Pass		no auto refresh nor interruptions
2.2.5 Re-authenticating	AAA	Future Work		no autentication needed
2.2.6 Timeouts	AAA	Pass		no timed actions
2.3.2 Three Flashes	AAA	Pass	G19	no flashing elements
2.3.3 Animation from Interactions	AAA	Pass		no animation
2.4.08 Location	AAA	Pass		navbar icon of current location is underlined
2.4.09 Link Purpose (Link Only)	AAA	Pass	G91	the links are all understandable from text only
2.4.10 Section Headings	AAA	Future Work		
2.5.5 Target Size	AAA	Pass		
2.5.6 Concurrent Input Mechanisms	AAA	Pass		Only using high-level, input-agnostic event handlers (focus, blur, click) in Javascript (operating systems/UAs fire these events for all input mechanisms)
3.1.3 Unusual Words	AAA	Unknown		the unusual words present are mainly the categories of drugs. Though it is expected that the patient is informed on the type of drugs they assume
3.1.4 Abbreviations	AAA	Pass		no abbreviations
3.1.5 Reading Level	AAA	Pass	G153	The text is easy to read
3.1.6 Pronunciation	AAA	Unknown		see 3.1.3
3.2.5 Change on Request	AAA	Pass		no auto update
3.3.5 Help	AAA	Fail		As of today the help on request is not available, though it may be added as future work
3.3.6 Error Prevention (All)	AAA	Pass		submit button under form

19 ANNEX 3: WEB Application Database



20 ANNEX 4: Mobile Application Database



subject	
subjectId	bigint
fiscalCode	varchar
firstName	varchar
lastName	varchar
email	varchar
telephone	varchar
privacyAllowed	boolean
SSNCardNumber	varchar
lastUpdate	timestamp

patient	
patientId	bigint
subjectId	bigint
infoCompletedPerc	float
birthDate	date
gender	varchar
currentGeneralPractitionerId	binint
currentGeneralPractitionerName	varchar
currentSpecialistId	bigint
currentSpecialistName	varchar
currentDiagnosisTypeCode	bigint
currentDiagnosisDesc	varchar
lastUpdate	timestamp

webAppLink	
lastSyncDate	date
lastFullMonthRported	date
lastsyncTimeStamp	timestamp

MIDASSurvey	
MIDASurveyId	bigint
patientId	bigint
validDateFrom	date
validDateTo	date
absenceWorkDays	int
reducedWorkPerfDays	int
absenceHomeWorkDays	int
reducedHomePerfDays	int
noSocialActivitiesDays	int
headacheDays	int
averagePainLevel	int
lastUpdate	timestamp

attackModel	
attackModelId	bigint
patientId	bigint
modelCode	varchar
worseWtihMotion	boolean
headSiteCode	int
painTypeCode	int
workAbsence	boolean
lastUpdate	timestamp

painType	
painTypeCode	int
painTypeDesc	varchar
patientId	bigint
lineNum	int
lastUpdate	timestamp

attackEvent	
attackId	bigint
patientId	bigint
caledarStartDay	date
starDateTime	datetime
endDateTime	datetime
intensityCode	int
painTypeCode	int
worseWtihMotion	boolean
workAbsence	boolean
hasPeriod	boolean
additionalComment	varchar
modelCode	varchar
lastUpdate	timestamp

triggerTypeEvent	
triggerTypeEventId	bigint
triggerTypeId	int
attackId	bigint
triggerTypeCode	int
lastUpdate	timestamp

otherPersonalEvent	
eventId	bigint
patientId	bigint
caledarDayTime	datetime
title	varchar
personalEventTypeCode	int
personalEventAdditionalDesc	varchar
lastUpdate	timestamp

otherSymptomModelSuffered	
otherSymptomModelSufferedId	bigint
attackModelId	bigint
otherSymptomTypeCode	int
lastUpdate	timestamp

triggerType	
triggerTypeCode	int
triggerTypeDesc	varchar
patientId	bigint
lineNum	int
lastUpdate	timestamp

assumedDrug	
assumedDrugId	bigint
attackId	bigint
drugName	varchar
drugQty	float
drugTypeCode	int
lastUpdate	timestamp

attackEventHeadSite	
attackEventHeadSiteId	bigint
attackId	bigint
headSiteCode	int
lastUpdate	timestamp

drugType	
drugTypeCode	int
activeIngredient	varchar
drugTypeDesc	varchar
lineNum	int
lastUpdate	timestamp

intensityAttack	
intensityCode	int
intensityDesc	varchar
lineNum	int
lastUpdate	timestamp

personalEventType	
personalEventTypeCode	int
personalEventDesc	varchar
lineNum	int
lastUpdate	timestamp

attackModelHeadSite	
attackModelHeadSiteId	bigint
attackModelId	bigint
headSiteCode	int
lastUpdate	timestamp

headSite	
headSiteCode	int
headSiteDesc	varchar
lineNum	int
lastUpdate	timestamp

otherSymptomType	
otherSymptomTypeCode	int
otherSymptomDesc	varchar
patientId	bigint
lineNum	int
lastUpdate	timestamp

otherSymptomSuffered	
otherSymptomSufferedId	bigint
attackId	bigint
otherSymptomTypeCode	int
lastUpdate	timestamp