

TECHNISCHE UNIVERSITÄT MÜNCHEN

Bachelor's Thesis in Informatics

A Web-based Application for Managing Shared Decision Made during the Treatment of Schizophrenia

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DEPARTMENT OF INFORMATICS

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Eine webbasierte Anwendung zur Verwaltung gemeinsamer Entscheidungen bei der Behandlung von Schizophrenie

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Munich, 15.08.2021	Jakob Waibel	

Abstract

The Treatment of Schizophrenia using antipsychotics (drugs used to treat psychological disorders) has several side effects at different risk. Knowing patients' tolerance to these side effects remarkably helps psychotherapists select the most effective and endurable medicines accordingly. Therefore, this Thesis proposed a Web-based application to realize a Shared Decision Making (SDM) approach that involves both patient and psychotherapist in prescription antipsychotics. Specifically, patients specify their tolerable degree to each side effect, which will serve as thresholds to rank antipsychotics based on their efficacy and risks of side effects. The study will explore which requirements are necessary to support the SDM approach between patient and physician and how these requirements can be implemented. A team of medical researchers at the MRI will help to define these requirements. Finally, it will evaluate how patients judge the Shared Decision Making Assitant (SDMA) usage and what improvements they suggest. The participants to evaluate the web application are research assistants/psychotherapists at Klinikum Rechts der Isar (MRI), practicing psychotherapists at the KBO-Isar-Amper clinic, and schizophrenic patients in treatment at both clinics.

Contents

A۱	ostra	ct		iii
1	Intr	oductio	on	1
	1.1	Motiv	ration	1
	1.2		rch Questions and Objectives	2
2	Bac	kgroun	d Knowledge	3
	2.1	Schizo	ophrenia	3
	2.2	Shared	d Decision Making	3
	2.3		3	4
3	Req	uireme	ents	5
	3.1	Functi	ional Requirements	5
		3.1.1	User Authentication and Authorization	5
		3.1.2	Session	5
		3.1.3	Patient Preferences	6
		3.1.4	Medical Information	6
		3.1.5	Shared Decision	7
		3.1.6	Session History	8
	3.2	Non-F	Functional Requirements	9
		3.2.1	Data Protection	9
4	Arc	hitectu	re	10
	4.1	Techn	ologies	10
	4.2	Data 1	model	10
		4.2.1	Users	10
		4.2.2	Medical Data	11
	4.3	Comp	onent overview and interaction	13
5	Imp	lement	ation	14
	5.1	Authe	entication and Authorization	14
		5.1.1	Securing REST endpoints	14

Contents

Bi	bliog	raphy		48
Li	st of	Figures		47
8	Con	clusion		46
7	Disc	cussion		44
		6.3.2	Improvements	43
		6.3.1	Impressions	41
	6.3	Patien	t feedback	41
		6.2.2	Improvements	41
		6.2.1	Impressions	40
	6.2	Doctor	r feedback	40
	6.1	Experi	ment setup	39
6	Eval	uation		39
		5.5.5	Final decision	37
		5.5.4	Adjustments during development	35
		5.5.3	Enable interaction with the data graphs	34
		5.5.2	Arranging the graphs	31
		5.5.1	Creating the data graphs	28
	5.5	Shared	d Decision Making	28
		5.4.3	Saving the information	28
		5.4.2	Doctor form	25
		5.4.1	Patient form	23
	5.4	Prefer	ences and Medical Information forms	23
	5.3	Session		21
	5.2		Panels	18
		5.1.2	Storing the JWT Token on the client	15

1 Introduction

1.1 Motivation

Schizophrenia is a mental disorder that disables an individual's behavior, perception, and feeling to reality [7]. When treating schizophrenia, physicians have a range of drugs available to them. These antipsychotics reduce the symptoms of schizophrenia with similar efficacy yet have substantial differences regarding various side effects [5]. These side effects include weight gain, fatigue, movement disorders, and sexual dysfunction. The tolerability of these side effects can vary from patient to patient drastically. If the side effects become unbearable for the patient, he might cancel his therapy or refuses to take his medication. Therefore, the attending doctor needs to be informed about the patient's preferences regarding the side effects he is willing to tolerate to increase treatment success.

Additionally, many patients feel not included enough in the decisions regarding medication [3]. In order to accommodate this wish and improve the patients' knowledge about their medical conditions and treatment options for other illnesses, the model of shared decision-making (SDM) has been advocated for in recent years [8]. Implementing the SDM approach in treating schizophrenia requires informing patients about the advantages and disadvantages of the treatment options. Informing patients and enabling them to voice their opinions on the various treatment options should actively encourage them to participate in the decision. This approach relies on presenting the patient with scientific evidence about the treatment options available in a way that is easy to understand to enable the patient to make evidence-based decisions.

Digital solutions like web applications can help display the scientific evidence understandably and compactly, helping the patient understand it without overwhelming them compared to paper-based approaches. Additionally, using a web application enables managing and documenting the decisions made during the decision-making process and the patients' preferences. By documenting the decision and its reasoning, the patient can later retrace why the medication was decided on and evaluate if it still applies. In order to evaluate whether the SDM approach described above improves the

results of the treatment of schizophrenia, a web application enabling this method is necessary.

1.2 Research Questions and Objectives

The main objective of this thesis is to describe a web application that enables antipsychotic patients and their physicians to make shared medication decisions. To achieve this, the following research questions:

- What are the requirements of a web application that supports the shared decisionmaking process of patients and psychiatrists during the treatment of schizophrenia?
- What is the architecture of a system that fulfills these requirements
- What requirements changed or were added during the development process?
- How does the web application improve the treatment effectiveness from the patients' and psychiatrists' perspectives?

2 Background Knowledge

2.1 Schizophrenia

Schizophrenia is a mental disease affecting how affected perceive reality. Schizophrenia is often diagnosed after the first episode of psychosis when individuals first display symptoms. These symptoms include hallucinations like hearing voices, but also irrational beliefs held firmly like paranoia. Next to these psychotic symptoms, which alter the patients' perception of reality, patients can also display negative symptoms. The patients can experience reduced motivation, and their life feels less enjoyable. Additionally, schizophrenic patients often have reduced cognitive capabilities. They have difficulty processing information, making decisions, and paying attention. Usually, these symptoms disable the patients from functioning in their everyday. The illness can cause severe distress to themselves and associated persons. Even though the causes of schizophrenia are not entirely understood, the psychotic symptoms can be reduced with antipsychotics. The antipsychotic is administered as pills or fluids daily or as an injection with a monthly schedule. Antipsychotics have side effects like weight gain, dry mouth, restlessness, and drowsiness. Sometimes these side effects cause patients to stop taking their medication, which can be dangerous and aggravate schizophrenic symptomatology. The recommended strategy for choosing medication is shared decision-making. [7]

2.2 Shared Decision Making

Shared decision-making is a practice aiming to help patients having informed and meaningful discussions about their treatment. In recent years it has emerged as the best practice for health care providers [8]. In order to make informed decisions, patients need objective information. When the tools and resources provided can offer this information, people can weigh it against their personal preferences. Shared decision-making is the suggested best practice for choosing treatment options in various medical fields. However, in the routine treatment of schizophrenia, SDM has not been

implemented yet. One factor stopping the transition towards patient choice is the additional workload on clinic personnel, which already suffers from time shortage. Furthermore, clinicians question schizophrenic patients' capability to understand the information and make decisions based on it [4].

2.3 Spring

Spring Boot [9] is an open-source Java framework that provides an easy way to set up web applications. It enables developers to develop stand-alone applications with minimal configuration. Among other things, Spring offers an easy way to provide web APIs. With other projects in the Spring framework like Spring Data and Spring Security, users can connect the application to databases conveniently and secure the provided endpoints. These features allow for the rapid development of a web service that clients can use to read and write data via HTTP requests.

3 Requirements

3.1 Functional Requirements

In order to apply the shared decision-making concept to the routine treatment of schizophrenia, the team of medical researchers at the MRI want to develop an aid supporting the decision process. They plan to evaluate this aid in a medical study to judge whether it improves the efficacy of the treatment. The SDMA should fulfill the requirements of the medical team, which is based on the scientific literature of decision aids. Additionally, it has to enable the execution of the medical study and the evaluation of the collected data during it.

3.1.1 User Authentication and Authorization

Each user has an username and a password to login and is afterwards presented with the functionality his specific role requires. The application differentiates between three essential roles. The administrator who is responsible for the treatment operations as a whole is able to add users into the system and assign them their username and password. Additionally, he is able to assign patients to doctors who are responsible for the treatment of the patient's psychosis. Doctors who are responsible for the treatment of one or multiple patient can see all patients assigned to them and all necessary information for the decision making process. Patients who are currently under treatment of their psychosis can see the information collected about them.

3.1.2 Session

The decision making process in encapsulated into sessions. The goal of each session is to find an optimal combination of anti-psychotics for the patient. A session can occur when the psychosis initially manifests, when the patient is unsatisfied with his current medication and wants to change the treatment plan or at any point during the treatment in order to check if the current treatment is still optimal for the patient. In

the application a doctor can create a session for patients assigned to him. This will prompt several steps that should eventually lead to a the doctor and the patient making together a decision about the future medication plan.

3.1.3 Patient Preferences

In order for the doctor to help the patient choosing an anti-psychotic he must understand what is important to the patient. Therefore the first step in a session is to collect the patients preferences regarding medication. To do this at the start of a session the patient is presented with a form asking for:

- The goals and expectations the patient has regarding his therapy.
- Which anti-psychotics the patient has taken in the past and whether or not he
 would take them again. This information is crucial as a basis for the discussion
 for the doctor and gives him a reference point to the patients previous therapy
 experience. The patient can select from a list of the most common anti-psychotics
 (i.e. Clozapin, Amisulprid) but has also the possibility of specifying other antipsychotics as free text.
- The side effects he wants to avoid the most is the most important decision the patient has to make as it is the primary basis for the decision-making. He can chose from a selection of the most common side effect where data for the anti-psychotics is available including weight gain, hyperprolactinemia and others. Free text input is also possible.
- Whether he prefers drops, pills or syringes for taking the anti-psychotic
- Additional wishes the patient has regarding his therapy

3.1.4 Medical Information

In parallel to the patient entering his preferences the doctor is asked to fill the medical information about the patient in the system. This information can later serve as a basis for the decision but is also necessary to analyze the effectiveness of shared decision during the evaluation of the medical study this application will be used in. The doctor is asked to enter information about the patient:

- Age
- Sex

- Time of initial manifestation of the psychosis.
- Current medication
- Concomitant diseases: Diseases that the patient has additional to his psychosis but are not part of the treatment. Each disease can pose additional risks depending on the anti-psychotic and must be kept in mind when making the decision.
- Which sub groups the patient belongs to. These sub groups include pregnancy, adolescence and seniors and can have influence on the risk of certain anti-psychotics and are therefore important for the selection.

3.1.5 Shared Decision

After both patient preferences and medical information is collected the doctor can start the shared decision making process. In this step the doctor and the patient together sit on one device and discuss about the medication. The application should support this discussion as best as possible it achieves that by showing the patient and the doctor plots of the relative risk of every side effect for each anti-psychotic combined with it's efficacy. Additionally, the information collected in the patient preferences and medical information forms is easily accessible.

The relative risk of a side effect and efficacy for a anti-psychotic collected in medical studies always consists of a mean and a statistical confidence interval with an upper and lower bound. This data is displayed a line representing the range between lower and upper bound with a dot at the mean.



Figure 3.1: The data representation for the mean and confidence interval of the relative risk/efficacy

The relative risk for one side effect is comparable over all anti-psychotics in order for the patient can see immediately for each anti-psychotics how it ranks in terms of relative risk of the side effects or the efficacy. In order to not overwhelm the patient with too much information only the efficacy of all anti-psychotics will shown at first. The patient can then step by step add data about the various side effects, presumably the side effects the patient wants to avoid. When patient and doctor are finished discussing one particular side effect they can remove it again to focus on the other side effects.

In order to narrow down the anti-psychotic and lead the discussion towards a selection of only one or two anti-psychotics patient and doctor are able to remove anti-psychotics from the comparison and can justify their decision in a free text input. Data from removed anti-psychotics is not displayed anymore and all removed anti-psychotics are visible in a folded table and can be added back to the comparison at any time. The intended procedure during the decision making consists of the patient and the doctor adding the side effect the patient wants to avoid the most to the comparison and then one by one eliminate anti-psychotics by weighing up the different side effect risks and the efficacy against each other in order to come to a decision.

During early testings many patients expressed the wish to select an anti-psychotic and see a risk overview for all side effects and the efficacy. To accommodate this request in the decision making overview an overview of each drug should be accessible. This drug overview includes a short info text about the drug, the prescription guides for this drug and an overview over the side effect risks and the efficacy. The side effect overview should include for each side effect if the drug is in the worst, middle, best third of all drugs regarding relative risk.

Additionally, during the initial tests many patients had troubles understanding the medical terminology for the side effects. For example side effects like hyperprolactinemia were not understood easily by the patients and they had to ask about them multiple times during the session. To solve this problem when clicking on a side effect a short explanation will pop up.

Finally, after doctor and patient reduced the selection of anti-psychotics to their liking they have the possibility to select a medication consisting of one or a combination of multiple anti-psychotics. They can also add any free text as comment to justify or specify their decision. During this final selection phase an summary of all information collected during the session is presented so they consider all aspects when making the final decision.

3.1.6 Session History

After a decision is made the session can not be altered and will be marked as finished. At this point the doctor can start a new session at any point should he feel the decision should be reconsidered. All sessions including all information collected and decisions made are stored in a session history. A doctor can always view the session history for each of his patients. The session history then can also be used for evaluation during the medical study later on.

3.2 Non-Functional Requirements

3.2.1 Data Protection

During the decision making a lot of detailed medical information is collected. This information falls under the medical confidentiality and therefore must be protected properly. Additionally the digital processing of personal data underlies additional restrictions and must be approved by a data protection officer. To accommodate for these additional requirements we deploy a few measurements to assure the can be used in the intended setting.

First of all in order to process any personal data digital patients must sign a consent form allowing us to save and process their information. Additionally the server on which the data is stored will be hosted at the data center of the university clinic MRI TUM. This ensures that no third party has access to any data collected for which we would additional consent from the patients.

Finally we want to prevent that the data we collect can be associated to any real identifier of the patients like their name even in the case of a complete data breach. In order to achieve this the SDMA app does not save any patient name or other external identifiers but only a pseudonym that is set by the administrator on the patient creation. For the operation during the eventual study a mapping from patient's pseudonym to name will be necessary but this will be kept on paper by the study administrator and is not at risk of a data breach.

4 Architecture

4.1 Technologies

The SDMA app is implemented as a web application. This gives the most flexibility on which devices the app is usable. On the front end side we must display the anti-psychotics data plots that change interactively with user input to achieve this React is used as it enables reactive web applications. An additional benefit is that the code can be easily migrated to react native should an native app be required in the future.

The back end server is implemented with Spring in Kotlin. Spring offers a fast and easy setup for a REST service and is an established framework with good support and various mature libraries. Especially the spring security library is very use full when implement the authentication and authorization processes the SDMA app requires. Kotlin is chosen over Java because it provides explicit data classes, superior handling of null values and a more readable syntax in my opinion.

As data base MongoDB is used because it has very good connection to spring including auto generated query methods. The data we store also fits more a object data base but we will see that in the next section.

4.2 Data model

4.2.1 Users

In order to implement authentication and authorization based on the three roles Administrator, Doctor and Patient we will need to save all users. This data model will be kept separate from the data model including the business data. For each user we will save a username, a bcrypt hash of their password and their role.

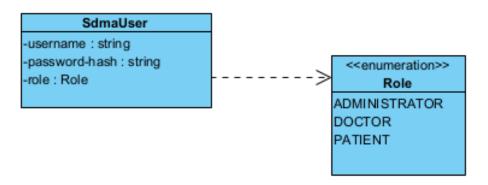


Figure 4.1: The user class diagram

4.2.2 Medical Data

The data that will be operated on is the Patients and the Sessions. For each patient, the attending doctor is saved. A session consists of all data provided during the session, including the input to forms described in Section 3.1.4 and Section 3.1.3. For each question, the predefined answer possibility is defined in an Enum. Furthermore, the log of a session consisting of all actions the users have taken on the interactive interface is saved. Saving the log allows to save a session and restore it to the point it was left. Additionally, it provides the opportunity to analyze how much a patient has interacted with the interface and what actions he has taken. A session log consists of actions on effects and antipsychotics. Each action consists of a type corresponding to an interaction possible in the interactive interface, a timestamp, and the payload, the effect or antipsychotic, respectively.

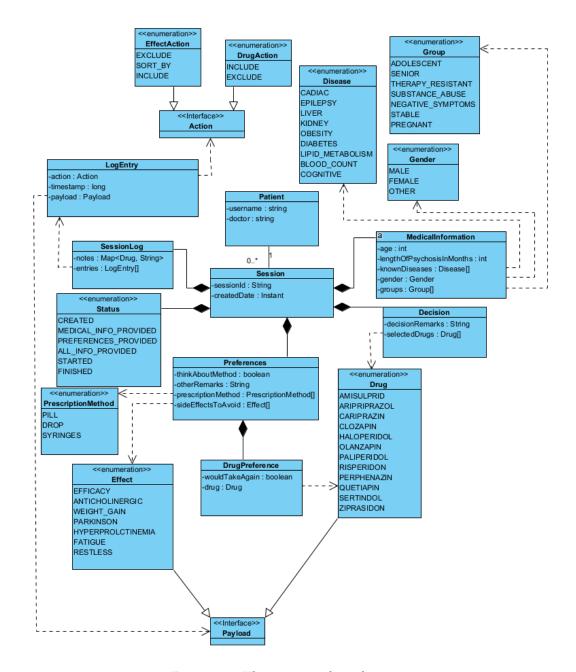


Figure 4.2: The session class diagram

4.3 Component overview and interaction

The SDMA application is separated in three main components. The web server where the React compiled code is hosted as a client rendered web page. The Spring back end component provides REST endpoints in order to login and fetch or send data. The path to the REST endpoints will be specified in the web page and therefore called by the client browser directly. The database component is only accessed by the Spring service in order to read or persist data.

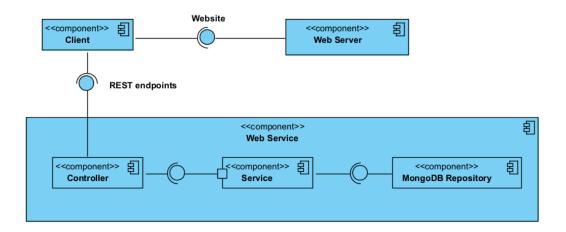


Figure 4.3: The component diagram of the SDMA

The architecture of the REST backend component follows the typical structure used with Spring. The service uses two separate data models. The data transfer model is used inside REST communication with the outside while the database model is used internally. For objects that are the same, the database model is also used for external communication. However, should the requirements for the data models change, it is easy to add a converter. The REST request arrives at the REST controller layer. Here the request is authorized and converted into the internal data model if necessary. Then the appropriate service method is called. The service layer executes the business logic and saves or reads data from the repository. Using the spring data MongoDB repositories allows automatically generated repository methods without writing any database query in the native MongoDB language. Especially since only simple save and find by operations are needed for this application.

5 Implementation

5.1 Authentication and Authorization

5.1.1 Securing REST endpoints

All users are stored in the database with their username and the bcrypt hash of their password. Only storing the bcrypt hash ensures that no passwords are leaked, even in the case of a data breach. Generally, all endpoints should only be available to authenticated users. One possibility of authentication would be HTTP Basic Auth. The user sends his username and password with every REST request. The password would then be hashed with the salt from the saved bcrypt hash. The resulting hash is then compared to the saved bcrypt hash to authenticate the user. This solution comes with the disadvantage of saving the password in plain text on the client. Once the user forgets to log out or his password is exposed otherwise through another website compromising its browser, an attacker has unhindered access. This problem can be circumvented by the server sending a session Id with the first request.

On every subsequent request, the client sends this session Id which then identifies the user. The session id is only valid for a limited amount of time. If the session id is compromised, an attacker can only use it until it is invalid. The drawback to this solution is that the server has to save every session in a database or in memory to map the session id to a user. When the number of concurrent requests from different users increases, this can lead to performance issues. In order to keep the SDMA app scalable, the SDMA app sends JWT tokens instead. A new login endpoint that can be called with HTTP Basic Auth provides the client with a JWT token. This token contains all information about the user, including name and role, and is encrypted by the server's secret key. For every subsequent REST request, the client sends the JWT token as authentication. The server can use his secret key to decrypt the JWT token to access the user information. The user information can be injected into the Spring Security Context by adding a RequestFilter.

Figure 5.1: Reading the JWT token and injecting the user information into the Spring security context

With the user authenticated, the user authorization for the method must be checked. The SDMA requires two levels of authorization. The first level is role-based authentication since some endpoints should only be for administrators or doctors. With Spring Security we can use method level security to set the allowed roles for each method individually with the annotation @RolesAllowed. The second level is whether the individual user has access to the resource he is requesting. Patients only have access to their own data and Doctors only have access to the data of the patients assigned to them. We check this by hand by comparing the user we injected in the security context with the attending doctor or the patient the session belongs to stored in the database.

5.1.2 Storing the JWT Token on the client

In order to access the secured REST endpoints the client calls a login Endpoint using HTTP Basic Authentication. For this the client starts with a login page asking the user for his username and his password. After receiving the JWT token the client calls an endpoint using the JWT token to receive the username and the role, the JWT token belongs to. JWT token, role and username are then stored in a redux store. Redux [6] is

used to save the application context and access it from any React component In order to access the secured REST endpoints the client calls a login Endpoint using HTTP Basic Authentication. For this the client starts with a login page asking the user for his username and his password. This form and all other UI elements are build by using the Ant design library [1].

After receiving the JWT token the client calls an endpoint using the JWT token to receive the username and the role, the JWT token belongs to. JWT token, role and username are then stored in a redux store. Redux is used to save the application context and access it from any React component.

With the Redux toolkit the redux store can be configured easily by creating a slice for each independent part of the store. For the user slice two actions also called reducers are relevant:

- logging in a new user: Saving the username, the role and the corresponding JWT token.
- logging out a current user: Erasing all saved user information from the Redux store.

With each subsequent REST request the client reads the JWT token from the Redux store and uses it for the authorization header.

```
import { createSlice } from "@reduxjs/toolkit"
export const ADMIN = "ADMINISTRATOR"
export const DOCTOR = "DOCTOR"
export const PATIENT = "PATIENT"
const nonUser = {
   username: "NONE",
   role: "None",
   jwtToken: "empty"
}
const initialState = {
   loggedIn: false,
   currentUser: nonUser
}
const userSlice = createSlice({
   name: 'user',
   initialState,
   reducers: {
       loginUser(state, action) {
           state.currentUser = action.payload
           state.loggedIn = true
       },
       logout(state, action) {
           state.loggedIn = false
           state.currentUser = nonUser
   }
})
export default userSlice.reducer
export const { loginUser, logout } = userSlice.actions
export const username = state => state.user.currentUser.username
export const isUserLoggedIn = state => state.user.loggedIn
export const userRole = state => state.user.currentUser.role
export const currentJwtToken = state => state.user.currentUser.jwtToken
```

Figure 5.2: The configuration of the Redux store and reducers using the createSlice() method of Redux toolkit

5.2 User Panels

When an administrator logs in, the SDMA shows the administration panel. The user has an overview of existing patients and their attending doctors. He can create doctors and patients and set their pseudonyms and password. When creating patients, he can select the supervising doctor from a list of all registered doctors. The administrator does set the username and is therefore responsible for the pseudonymization of the user data. The director of the medical trial should use the administration panel. He knows all participating doctors and patients and should add them as SDMA users. Depending on the requirements on the pseudonymization of the patient data, he can set the usernames himself.

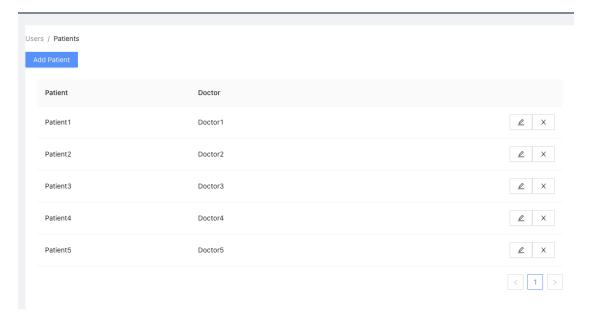


Figure 5.3: The list of all patients registered in the SDMA

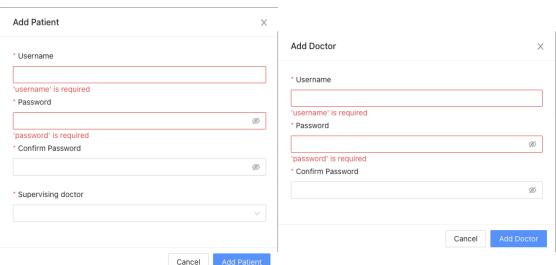


Figure 5.4: Creating a patient

Figure 5.5: Creating a doctor

The doctor can see a list of all patients assigned to him. The linked detail view of a patient contains all created sessions and the patient's medical information if the doctor provided it already. The doctor can create a new session on this patient detail page if all previous sessions are already finished. He reaches the session details view by clicking on a session from the list. The session details page consists of all information provided during the session, including medical information, preferences, and the final decision. Depending on the state of the session (compare Section 5.3), the physician can choose between providing the patient's medical information and starting the shared-decision making process.

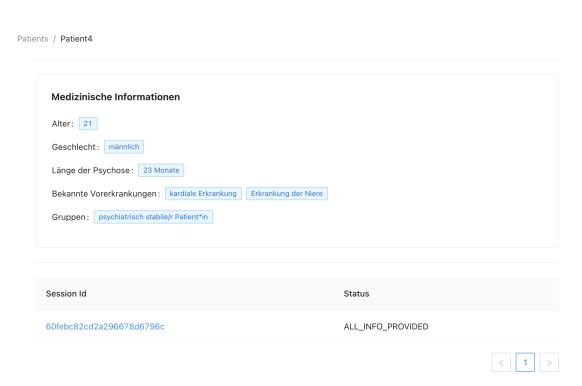


Figure 5.6: The patient details page

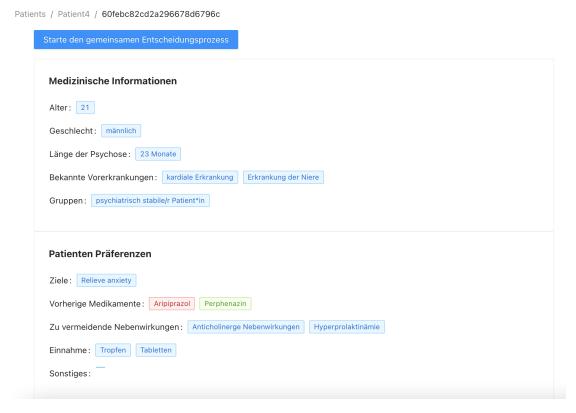


Figure 5.7: The session details page

5.3 Sessions

A session reflects the process of selecting medication within the decision assistant. The doctor creates the session for a specific patient. After creation, the doctor can submit the patient's medical information, and the patient can submit his preferences about the medication. These two steps are independent of each other and can be in any order. After both medical information and patient preferences are provided, the doctor can start the session and decide about the medication together with the patient. After they save their decision, the session is finished and can not be altered anymore. A session can have multiple states:

- CREATED, the session was created by a doctor for a specific patient, no other sessions for this patient can be created
- PREFERENCES PROVIDED, the patient has submitted his preferences about

medication and side effects as defined in section 2.1.3

- MEDICAL INFO PROVIDED, the doctor has submitted the relevant medical information of the patient as defined in section 2.1.4
- ALL INFO PROVIDED, both medical preferences and patient preferences are available the session is now ready for the shared decision.
- STARTED, the shared decision process has already started and a the provisional progress has been saved
- FINISHED, patient and doctor have come to a decision and selected a medication. At this point no information can be edited and a new session can be created again.

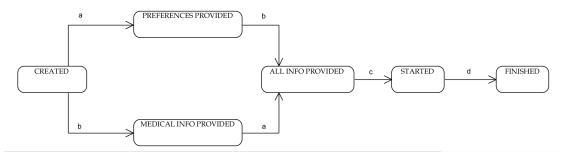


Figure 5.8: The state diagram of a session

- a The patient provides his preferences regarding his treatment
- b The doctor provides the medical information of the patient
- c Doctor and patient begin discussing the treatment together using the SDMA
- d Doctor and patient decide on the medication and save the decision in the SDMA

The server ensures this session flow is preserved by using a state machine. Before making any changes to the session, the corresponding event is registered at the session in question. If the event is not a valid transition from the current session state the state machine rejects the event and an exception is thrown. Should the event belong to a valid transition the resulting session state is returned and then saved at the session.

5.4 Preferences and Medical Information forms

5.4.1 Patient form

The forms for the patient preferences and the medical information are built with Ant design form components. Each question does have its format, depending on the type of answers expected. The goal is to make answering the questions as easy as possible to help patients who might be mentally impaired participate and doctors to save time when filling in the medical information. The input fields for the age and duration of psychosis are number fields restricting the input to numbers only. The sex of the patient in the form can be input by a radio selection since only one answer is sensible. The doctor can select from multiple options when specifying the current medication, the concomitant diseases, and the sub-groups. Therefore, there is a checkbox group with one checkbox for each option for each question. The doctor can check all anti-psychotics, diseases, and sub-groups that apply to the patient.

Fragebogen Was möchte ich durch die Behandlung erreichen? (Behandlungsziele) Relieve anxiety + Ziel hinzufügen Welche Medikamente habe ich in der Vergangenheit schon eingenommen? Würde ich diese noch einmal einnehmen? Mit welchen Medikamenten wurden Sie in der Vergangenheit bereits behandelt? Bitte wählen Sie aus der folgenden Liste aus (markieren Sie zusätzlich, ob Sie das Medikament noch einmal einnehmen würden). Amisulprid Paliperidon Würde ich nocheinmal nehmen Aripiprazol Risperidon JaNein Würde ich nocheinmal nehmen Cariprazin Perphenazin Ja Nein Clozapin Quetiapin Haloperidol Sertindol Olanzapin Ziprasidon

Figure 5.9: The form for the patients' preferences (Part 1)

We	lche Nebenwirkungen sollen vermieden werden?
Da	s sind die sechs häufige Nebenwirkungen. Bitte wählen Sie zwei davon aus, die Sie unbedingt vermeiden wollen.
	Mundtrockenheit, verschwommenes Sehen, Verstopfung (sog. anticholinerge Nebenwirkungen)
~	Steifigkeit der Muskulatur, Bewegungsstörungen, Zittern (sog. Parkinsonsymptome)
	weniger Lust auf Sex, sexuelle Funktionsstörung, Menstruationsbeschwerden
~	Gewichtszunahme
	Müdigkeit
	Unruhige Beine
Νo	dikamente können als Tabletten, Tropfen oder Spritze (in der Regel mehrwöchige Abstände) verabreicht werden. Ilen Sie sich bereits jetzt darüber Gedanken machen? Ja Nein
•	llen Sie sich bereits jetzt darüber Gedanken machen? Ja Nein
• Wie	llen Sie sich bereits jetzt darüber Gedanken machen?
Wie	llen Sie sich bereits jetzt darüber Gedanken machen? Ja Nein e können Sie sich vorstellen das Medikament verabreicht zu bekommen?
Wo ● Wie	Illen Sie sich bereits jetzt darüber Gedanken machen? Ja Nein können Sie sich vorstellen das Medikament verabreicht zu bekommen? Tablette
Wie	Ja Nein Rönnen Sie sich vorstellen das Medikament verabreicht zu bekommen? Tablette Tropfen

Figure 5.10: The form for the patients' preferences (Part 2)

5.4.2 Doctor form

When asking the patient about his goals and his additional wishes, he should be able to enter free text and structure it into multiple independent points. The patient has one text input line available but can add and remove lines to add additional goals or wishes if he wants to. The patient's preferences regarding anti-psychotics include

which anti-psychotic he has taken in the past. This is achieved by a checkbox group similar to the ones in the doctor forms mentioned above. Additionally, for each anti-psychotic the patient has checked, the patient can specify whether or not he would retake the anti-psychotic using a radio button with a yes and a no option. Finally, another checkbox group for the side effects the patient wants to avoid is also part of the form. Initially, all answers were validated when submitting. This validation made sure patients answered questions like they are expected to. For example, the patient could only select up to 4 side effects he wants to avoid making sure that he had to prioritize side effects and not just select all side effects. However, during patient tests during the development, the medical stakeholders decided that these limitations mostly confuse patients. With added complexity like this, it is more likely that patients need help filling out the form defeating the original purpose of saving the doctors time. Therefore the rules are removed, and the data model and code are adjusted so that questions can be left unanswered.

Alte	r:
Ges	chlecht: männlich weiblich sonstiges
Länç	ge der Erkrankung in Monaten:
lst e	ine der folgenden Erkrankungen bekannt?
	kardiale Erkrankung
[Epilepsie
[Erkrankung der Leber
	Erkrankung der Niere
	Adipositas
_ I	Diabetes mellitus
	Fettstoffwechselstörungen
	Blutbildveränderungen
	sognitive Veränderungen/Demenzen
Geh	ört ihr Patient/ ihre Patientin einer der folgenden Gruppen an?
	Jugendliche
	Senioren
	comorbider Substanzmissbrauch
_ (berwiegend Negativsymptome
	osychiatrisch stabile/r Patient*in
_ ·	Therapieresistenz
	Schwangere

Figure 5.11: The form for the medical information about the patient

5.4.3 Saving the information

When the patient or the doctor submits the form, the client calls the respective HTTP endpoint with the answers in a JSON body. The server handles the HTTP request in the controller, checking the authorization as described above. Then the controller calls the service layer where the state machine registers the respective event, and the session status is updated as described in the session subsection. Finally, the repository saves the medical information or the patient preferences at the session if the state machine does not throw an exception.

5.5 Shared Decision Making

The central part of the shared decision assistant is presenting the scientific data about the anti-psychotics to the patient and the doctor. As described in Section 3.1.5, the app should display the mean relative risk and the upper and lower bound for each drug and side-effect.

```
1 {
2     "ci_lb": "0.84",
3     "ci_up": "2.2",
4     "mean": "1.42",
5     "quantile": "1",
6     "rank": "14",
7     "type": "adverse event"
8 }
```

Figure 5.12: The JSON representation of one anti-psychotic/side-effect combination

5.5.1 Creating the data graphs

The graphs displaying this data are created with the javascript graph.js [2]. The library is free and is in contrast to other libraries tried like ApexCharts or FusionCharts it is possible to generate the data representation described in Section 3.1.5. This representation does not come out of the box, however. As seen in Figure 5.13 in a chart.js scatter chart, it is possible to create two datasets. The first contains the confidence interval lower and upper bound on the same y-coordinate, and with the

'showLine' option, the library draws a line between those two coordinates. By setting the point radius to zero, only the line is visible while the endpoints are not. The second dataset only holds the mean relative risk on the same y-coordinate as before and results in a single dot on the line created by the first dataset. The data is pulled from a JSON object seen in Figure 5.12 that exists for every combination of antipsychotics and side effects. This data was provided by Prof. Leucht's team and was collected during a metastudy [5].

```
new Chart(ctx, {
   type: 'scatter',
   data: {
       datasets: [
           {
               data: [
                   {
                      x: data.ci_lb,
                      y: 0
                   },
                   {
                      x: data.ci_up,
                      y: 0
                   }
               ],
               showLine: true,
               borderWidth: 2,
               pointRadius: 0,
               pointHoverRadius: 0
           },
{
               data: [
                   {
                      x: data.mean,
                      y: 0
                   }
               ],
               pointRadius: 5,
               pointHoverRadius: 5
           },
       ]
   },
   options: {
       legend: false,
       tooltips: false,
       display: false,
       maintainAspectRatio: false
   }
})
```

Figure 5.13: The (partial) configuration of the chart.js graph

The quantile depicted in Figure 5.12 describes in which 33.3% quantile the drug belongs. An antipsychotic with quantile 3 is under the 33.3% antipsychotics with the highest relative risk for this side effect. In an initial version of the application, the graphs were colored depending on their 33% quantile. The highest quantile would be colored red, the middle one yellow, and the lowest green for side effects and flipped coloring for efficacy. The paint should help patients understand the chart more easily as red suggests worse and green means better is naturally intuitive. This theory was confirmed in later tests with patients who found the coloring to be very intuitive to understand and helpful. However, during discussions with experts in shared decision aids, the medical stakeholders determined that the traffic light coloring was too suggestive. Especially since two antipsychotics of different quantiles often could be very close in actual relative risk or relative efficacy. Such expressive coloring could here really oversell the actual difference between two antipsychotics. Instead, the stakeholders suggested continuous color shading. Using the HSL color system, the color of the graph is generated based on the mean relative risk of the drug and the maximum relative risk of the specific side effect of all drugs. While hue is set to 240 and saturation is set to 100 for a blue color scale, the lightness is calculated dynamically.

$$Lightness = 50 + \frac{mean}{max} * 50$$

5.5.2 Arranging the graphs

The goal of the decision aid is to enable comparison between the antipsychotics. Additionally, the patient needs to weigh up the relative risk of different side effects and the relative efficacy against each other. Therefore, the relative risks and efficacy graphs are placed in a table. The rows consist of the antipsychotics and the columns of the side effects and the efficacy. Displaying all side effects in this table would be very overwhelming for most patients and would not fit most screen sizes. Therefore, the app only shows the relative efficacy in the initial state, as it is vital information for patients regardless of preferences. The patient and the doctor then can add other side effects to the comparison they are particularly interested in. These could be the side effects the patient wants to avoid the most, as asked in Section 3.1.3. The patient and the doctor can also remove antipsychotics deemed unfit from the table to narrow the selection of possibilities. Redux manages the internal state of the table. In parallel to the approach for the user credentials described in Section 5.1.2, the Redux toolkit creates a redux slice for both the antipsychotics and the side effects (including the efficacy). The Redux state for both consists of a list including all displayed side effects/antipsychotics and a list of the excluded ones.

```
1
2
      drugs: {
          included: ["AMISULPRID", "ARIPIPRAZOL", "CARIPRAZIN", "CLOZAPIN",
3
              "HALOPERIDOL", "OLANZAPIN", "PALIPERIDON", "RISPERIDON",
              "PERPHENAZIN", "QUETIAPIN", "SERTINDOL", "ZIPRASIDON"],
          excluded: []
4
      },
5
      effects: {
6
7
          included: ["EFFICACY", "FATIGUE"],
          excluded: ["ANTICHOLINERGIC", "WEIGHT_GAIN", "PARKINSON",
8
              "HYPERPROLACTINEMIA", "RESTLESS"]
9
10
```

Figure 5.14: Redux state representing the current stet of the table

Having the excluded elements in the state as well makes it easier to add them to the displayed elements later. Whenever the React component renders the table, it gets all included antipsychotics and side effects and creates a graph for each combination. Should the Redux state change from user input, the React component will automatically rerender and create or remove the necessary graphs without having to rerender all graphs that are unaffected.

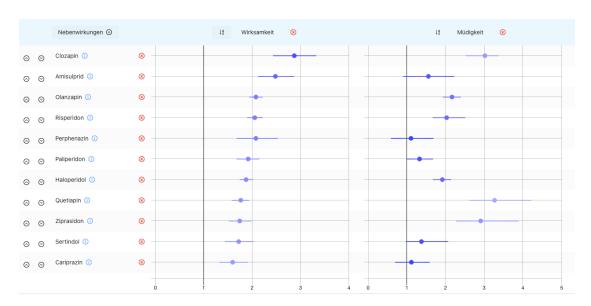


Figure 5.15: The comparison view for efficacy and fatigue

To ensure a good comparison of all relative risks for one side effect, the graphs in one column must all have the same scale. Otherwise, for one side effect, the dot in the graph might be more to the right than another side effect even though it has lower relative risk because its scale is bigger. However, having a fixed scale is not an option as depending on the side effect, the difference in the values can differ drastically. Additionally, even when removing the antipsychotics with extreme relative risks, antipsychotics with similar relative risks can be hard to compare as the scale is so big. Dynamically adjusting the scale based on all antipsychotics still in the comparison helps the patient and the doctor discern differences at all times. The scales are also managed inside a Redux slice. The scales depend on both the antipsychotic state and the side effect state. In order to calculate the scales, the included antipsychotics must be known since the scale depends on their values, and only the scales of included side effects should be calculated. Therefore, whenever one of the states changes, the reducer defined in the responsible Redux slice recalculates the scales. The Redux state consists of a scale for each side effect currently included. One scale object consists of a maximum for the graph and a stepsize. The maximum is the ceiling of the maximum upper bound of the confidence interval of all included antipsychotics. The stepsize is the maximum divided by five to avoid cluttering the graph with lines for more significant values.

When rendering the table, all necessary scales are fetched from the Redux state once and then passed down to the graph components, used to configure the graph's scale.

Additionally, at the bottom of the table, another row of graphs is rendered. This row holds no data but displays the scale for all rows above, configured not to show the scale. This makes the overview of multiple graphs stacked on top of each other much less confusing and easier to understand as they look like one graph with multiple data points.

5.5.3 Enable interaction with the data graphs

The patients and the doctors should also be able to interact with the shared decision-making assistant. First of all, as mentioned above, they can add other side effects to the comparison as initially only the relative efficacy is displayed. In the top left corner of the table, a button triggering a dropdown menu is rendered. A menu item is created using the menu component of ant design for each side effect in the "not-included" list of the Redux state. Choosing one dispatches an action registered at the Redux store, removing this side effect from the "not-included" list and adding it to the "included" list. As described above, the table automatically rerenders, adding another column with the data of the chosen side effect to the table.

When adding side effects to the comparison, the users eventually will have to exclude side effects they are no longer interested in from the overview. In the column header next to the name of the side effect, a red remove button is rendered, which will dispatch another action. When registered at the Redux store, this action moves the side effect from the included list to the not included list.

In parallel to including and excluding side effects from the comparison, the SDMA offers the same possibilities for antipsychotics to the users. In the row header, a remove button is placed. This button opens a modal window, where the patient or doctor might specify why they excluded this antipsychotic. This free text input is saved and can be used later to retrace the decision and evaluate if this reasoning is still valid. When confirming to exclude the antipsychotic, like for the side effects, an action is dispatched, and the antipsychotic is moved in the Redux state. Like all other UI components, the text input and the modal window are taken from the ant design library. In order to see all excluded antipsychotics, a collapsible table is placed beneath the table holding the graphs. This table shows the name of the antipsychotic, the specified reason the patient excluded it, and a button to include it in the comparison again.



Figure 5.16: The dialog for excluding an antipsychotic from the comparison

In the column header, the patient can click the sort button sorting the antipsychotics in the table from best to worst for this particular side effect of efficacy. In which order the antipsychotics appear depends not only on the mean of the relative risk/efficacy but also on how broad the confidence interval is. This ranking, seen in Figure 5.12, is provided by the medical team, also providing the other data. This feature should give an easily digestible overview of all antipsychotics when only focusing on one side effect. Again sorting is achieved by manipulating the Redux state within a reducer. The reducer fetches the data (compare Figure 5.12) of all included antipsychotics for the side effect or efficacy to be sorted by and then sorts the included list by the rank attribute. Since when rendering the table, the Redux is looped over, changing the order of elements in the list will change the order of rows inside the table but will not require the graphs to be rerendered. The DOM will rearrange the already rendered graph components.

Similar to that, the interactive overview also allows the patient to move rows up and down. The patient might put two antipsychotics next to each other to compare them more efficiently. Alternatively, they might put the current favorite antipsychotic on top. These actions manipulate the Redux state by swapping the antipsychotics with the element in front or behind it when moving up or down.

5.5.4 Adjustments during development

Since the interactive graph overview is the central part of the shared decision-making assistant, it was developed as a prototype from the beginning and, from that moment, tested with actual psychotic patients at the MRI clinic. The initial requirements and

implementation were refined during these tests and regular meetings with medical stakeholders at the MRI. Multiple patients during testing had problems associating the graph and the antipsychotic. To make it easier to follow the row, the stakeholder decided on coloring the columns in alternating colors. By using CSS, every second table cell was colored in a light blue. In later tests, no patient complained about not being able to follow the rows anymore, so this seemed to have solved the issue. Patients had problems understanding the side effects. Medical terms like hyperprolactinemia were not understood. To combat this, when clicking on a side effect, a short explanation of the side effect pops up.

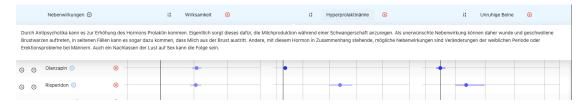


Figure 5.17: Short explanation for side effects

Additionally, patients missed the possibility to get an overview of one specific antipsychotic. Many patients wanted to overview all side effects of the medication they were taking or were taking in the past. In the prototype, users had to add every side effect to the comparison making the overview very convoluted. Besides that, the medical team wanted to include a short information text about the antipsychotic for the doctor. This info text includes a short description, warnings when not to prescribe the antipsychotic, and information on dosage. This text should remind doctors of critical facts about an antipsychotic they might have as much experience with. In order to address both these new requirements, the overview includes an information-modal for each antipsychotic. This modal opens when clicking the antipsychotic in the table, indicated by an information icon at the end of each antipsychotic. On the left side is the summary of the antipsychotic. On the right side is a graph displaying which 33%-quantile the antipsychotic belongs to for all side effects and the efficacy. In order to display the quantile, a chart is vertical bar chart with one bar for each side effect is rendered. Each bar has the quantile value seen in Figure 5.12 and is colored in the red-yellow-green schema that was first considered for coloring the graphs in the overview table. All the issues with this coloring discussed earlier still apply. However, lacking a better depiction for classifying the relative risks of antipsychotics, the stakeholders decided to keep this graph, giving patients and doctors a better overview.

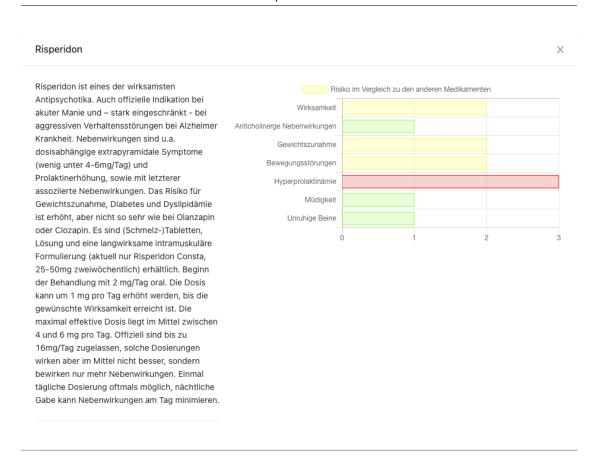


Figure 5.18: The information modal for antipsychotics

5.5.5 Final decision

The interactive data graphs are placed in the decision phase of a session. The user can freely switch between interactive data plots and the summary of all data collected in the forms described in Section 5.4. The client fetches the session from the backend server, including the medical information and the patient's preferences. This information then is displayed using the components that ant design offers for displaying data. The goal is for the patient and doctor to look at previous answers like the patient's preferences or medical preconditions and base their decisions on this information when taking actions in the interactive data plots. The patient overview and the interactive interface are placed on the same reactive page, making going back and forth as seamless as possible. Finally, after the patient and his doctor have worked on the interactive data graphs, they can progress to the selection page. Next to the overview of the patient's

information is a checkbox group with all antipsychotics not excluded in the step before. The users can select a combination of antipsychotics and write a comment regarding the decision. The interactive data plots are meant for the patient and his doctor to eliminate antipsychotics based on their side effect profile one by one. However, after excluding a few antipsychotics, the users might already have a clear picture of which medication they prefer. The application does not force them to exclude all other antipsychotics from the comparison table. They can check the antipsychotics they prefer for their medication, often consisting of one or two antipsychotics. Patients and their doctors can then comment on why they made this choice and what dosage they decided on. The SDMA client saves the decision data by sending an HTTP request to the SDMA server when submitting their decision.

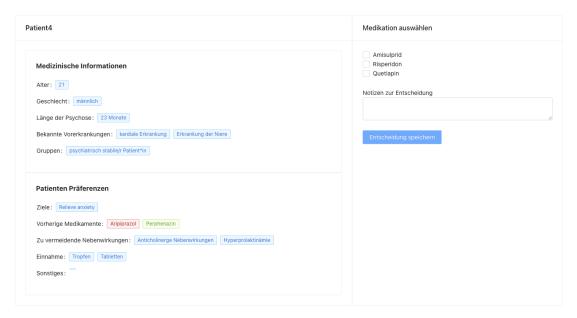


Figure 5.19: The page where patient and doctor make the final decision

6 Evaluation

The Shared Decision Making Assistant is evaluated in situations that are as close as possible to the eventual use case. Whether the presentation of the scientific evidence regarding the efficacy and side effects of the antipsychotics is understandable for individuals suffering under the symptoms of schizophrenia is of uttermost importance for the evaluation. This fact requires actual schizophrenic patients as testers for the application. Usually, most patients are more comfortable discussing their medical preferences with their physicians instead of total strangers, and for the evaluation, doctors' opinions are as important. Following these considerations, the tests should be performed with schizophrenic patients and their attending doctors when they need to decide on the patients' medication. This decision usually needs to be made during the patient's first episode of psychosis, when he is not satisfied with his current treatment or when the current antipsychotics are not effective enough.

The MRI team provided access to two psychiatric institutions to recruit test users for evaluating the decision aid. The medical team members helped find patients in the university hospital Rechts der Isar (located to the right of the Isar river) and in the KBO-Isar-Amper clinic. However, recruiting was more challenging than expected. Many physicians could not find time to participate in the user tests. Additionally, it proved difficult to recruit fitting patients. Many patients already had decided on their medication, and the attending doctors did not want to confuse them by taking part in the evaluation. Some patients were not deemed mentally fit enough to understand the process. Other patients could not be trusted with the tablet used to access the web application without destroying it. Finally, some patients did not want to participate at all.

6.1 Experiment setup

With the challenges recruiting representative users for the evaluation, the approach was shifted accordingly. In the university clinic, we visited an open psychiatric station. Since university clinics can decide which patients they treat, patients tend to be easier

to deal with there. Additionally, open stations mostly host individuals with less severe schizophrenic symptoms. Since we could not find doctors we decided to test the application with patients only. The

In the KBO-Isar-Amper clinic, which is a close First, the station doctors were introduced to the Shared Decision Making Assistant, its purpose, and functionality. After that, they stated their opinion on the general idea and their first expression. When they had a patient, they could try the application with they would go through the decision-making process and

6.2 Doctor feedback

6.2.1 Impressions

The Shared Decision Making Application was presented to four doctors in the KBO-Isar-Amper clinic. All of them expressed interest in using the application together with patients. However, only one could find a fitting patient and go through the shared decision-making process with him. All doctors agreed that the application could help them make better decisions. Often doctors make decisions based on experience and gut feeling. Having easy access to the scientific evidence that is also easily digestible can help challenging biases when prescribing antipsychotics. All doctors agreed that the application allows informing the patient more effectively beforehand without taking a disproportionate amount of time. Three doctors thought that the SDMA helps patients to comprehend better why their treatment was chosen

One tester mentioned, especially for inexperienced physicians lacking the experience else used to make the decisions about medication, the Shared Decision Making Assistant can help them make decisions. One physician mentioned the ability to document the process for finding the medication as an advantage compared to traditional approaches. Often when patients are transferred to another doctor, it is hard to understand why the previous treatment was chosen. Since schizophrenic patients can not always be trusted to remember the specific reasoning for choosing one antipsychotic over the other, documenting the decision-making process in the SDMA can smooth the transition from one attending doctor to another.

6.2.2 Improvements

Even though the feedback from doctors was primarily positive, some had suggestions to improve the usability of the application.

Suggestion	# doctors
Integrate the SDMA with other clinic internal information systems (Medico) or patient file to import patient information	3
Include the trade names for the antipsychotics, since patients usually only recognize the trade name(e.g. Haldol for Haloperidol)	3
Warn doctor and patient when antipsychotics can not be prescribed due to a medical preconditions. E.g. Clozapin can not be prescribed for patients with cardiac disease because it can cause heart failure. For these antipsychotics a warning should appear with the option to exclude them from the comparison.	3
Check antipsychotics selected in the final decision step for cross interaction with current medication	2
Possibility to enter current medication besides antipsychotics (e.g. antidepressants).	1
Edit medical information and patient preferences during the shared session	1
Add option to take over medical information from the previous session	1
Add date to the list of sessions for one patient	1
Add tooltips to the medical information form explaining the answer possibilities	1

6.3 Patient feedback

6.3.1 Impressions

In total, we use the SDMA together with five patients. One patient had problems with understanding the process. He had problems reading the texts in the interface designed for the patient and gave nonsensical answers. For example, he specified he had taken every antipsychotic and would not retake any of the thirteen. The discussion

with the patient about side effects did not lead to a decision. The patient could not understand what the goal of the process was. The other four patients had no problems understanding the process and were all interested in being more involved regarding their medication. They specified they would use the application. Three understood the graphs depicting the mean relative risk and the confidence interval immediately, while one other patient said he understood it after a short explanation. After a brief introduction to the application, all could navigate seamlessly.

6.3.2 Improvements

Suggestion to improve the application from the patients:

Suggestion	# patients
Include trade names of antipsychotics	3
Exclude the question of whether the patient wants to think about the application method. Always ask if he would like to take pills, drops or syringes	1
Exclude the question of whether the patient wants to think about the application method. Always ask if he would like to take pills, drops, or syringes.	1
Input date of the first psychotic episode instead of the duration of psychosis in months	1
Give the patient the option to see the comparison table before/while answering the preference questions	1
Include descriptions of the antipsychotics understandable for patients (the current description is targeted at doctors and therefore very technical)	1
Add more drugs (not only antipsychotics)	1
Add the possibility to write and read reviews for antipsychotics	1
Add possibility to change the reasoning for excluding an antipsychotic	1
Add date to the list of sessions for one patient	1
Add tooltips to the medical information form explaining the answer possibilities	1
Possible to enter a custom side effect to avoid	1
Add risk warnings to antipsychotics	1
Include pictures of the pills	1
Include information about the average dosis	1

7 Discussion

In the tests with patients and doctors, the SDMA proved to be effective in providing patients and even doctors with the scientific evidence to the antipsychotics. Even though patients and doctors had many suggestions for improving the data input and other administrative features, users positively evaluated the core functionality of comparing different side effects for multiple antipsychotics. The depiction of mean and confidence interval proved to be very intuitive while still providing a lot of statistical information lost in presentations based on a single value. Patients welcome the opportunity to be more informed about the treatment and are very interested in exploring the scientific evidence. Doctors judge the application as effective in improving treatment in general and regard it as a valuable tool in teaching doctors about the scientific evidence, further enhancing the overall treatment of schizophrenia.

However, the SDMA seems to be limited in its area of application. As demonstrated in our user recruitment, doctors deem many patients not capable of using the application alone. In these cases, using a shared-decision approach with the SDMA would need a lot of additional time investment from attending physicians. This time investment could be infeasible, taking into account medical institutions are often understaffed and overcrowded. For patients who are mentally more capable and interested in their treatment options, however, the SDMA provides a valuable tool for informing patients. An approach to bridge this discrepancy between patients of different mental capabilities could be introducing various degrees of complexity to the application. Less complex modes can be added by leaving out information and functionality. The attending physician could then select the complexity for his patient depending on how he asses the patient's ability to understand what is presented.

Besides, including other information like antipsychotic warnings, cross interaction between drugs, and interaction of antipsychotics with medical preconditions should be the improvements considered next. Patients, as well as doctors, expressed the wish to access this information, and the stakeholders at the MRI also consider this essential information. Additional, adding more tooltips to all medical terms where it does not exist yet is an improvement that should be prioritized. Explaining as much information as possible will improve usability for users that are not informed yet, like patients

during their first episode of psychosis. It also should enable more patients to educate themselves, saving clinic personnel time and increasing treatment efficiency.

The SDMA project is a cooperation between the MRI and the TUM Department of Informatics, which provided additional challenges. As already discussed, the SDMA must be hosted at the MRI data center to protect medical information. Therefore, the deployment of the application relied on access to virtual machines by the MRI IT team. However, I underestimated the time this external dependency would cost. Even though I requested the virtual machines 1.5 months before the submission date, no access has been granted to this date. The same situation occurred with the data protection officer, who has to approve the data protection concept before the SDMA can be used for medical trials. Since he did not evaluate and approve the security concept yet, maybe the SDMA must be adjusted before being authorized for medical studies with actual patients. In hindsight, these external dependencies had to be identified earlier, and advancing these processes should have been prioritized.

Even though the SDMA was developed to be used for a medical study at the MRI, it seems to be usable for other clinics with little extra effort. Depending on the hosting infrastructure of the hospital, it can deploy the three components, the web-server on an npm node, the web service on the JVM, and the MongoDB inside a docker container. To access the SDMA, users can use the browser of any device customized to their needs. The clinics can set up their user base using the administration panel. However, for a large number of users, an automated process that uses REST calls towards the back end can quickly be developed. Regarding pseudonymization, clinics can choose their own rules and even disable them entirely by inserting the actual names as usernames when adding users into the system.

8 Conclusion

In order to enable a shared decision-making approach based on scientific evidence, a web application has to provide a range of features. It should provide separate user accounts to protect sensitive data. These accounts must be manageable using an administrative interface. Making an informed decision requires not only scientific evidence but also a method of providing the patients' preferences regarding treatment and their medical information. The scientific data should be presented in a way that is easy to understand yet does not leave out critical information. An interactive interface that patients can configure themselves provides a good overview of the scientific data while also allowing patients to focus on the information they are interested in. Finally, the application should save decisions made and their reasoning to enable patients and doctors to retrace them at a later point in time. Keeping the decisions also allows analyzing them in medical trials to investigate under which circumstances an increase in treatment success can be measured.

These requirements are met by implementing a React front end that allows for an interactive website where patients can explore the scientific evidence by configuring a comparison table with data on antipsychotics and side effects. A web service manages user accounts, restricting information to authorized users and persisting patient information by providing HTTP endpoints, which the front end can call. When hosting the web service in the MRI datacenter, the sensitive medical data is protected. Even in case of a data breach, the web service only saves pseudonymized data, so attackers cannot associate the collected data to the patients' real names.

List of Figures

3.1	The data representation for the mean and confidence interval of the relative risk/efficacy	7
4.1	The user class diagram	11
4.2	The session class diagram	12
4.3	The component diagram of the SDMA	13
5.1	Reading the JWT token and injecting the user information into the Spring security context	15
5.2	The configuration of the Redux store and reducers using the createSlice()	
	method of Redux toolkit	17
5.3	The list of all patients registered in the SDMA	18
5.4	Creating a patient	19
5.5	Creating a doctor	19
5.6	The patient details page	20
5.7	The session details page	21
5.8	The state diagram of a session	22
5.9	The form for the patients' preferences (Part 1)	24
5.10	The form for the patients' preferences (Part 2)	25
5.11	The form for the medical information about the patient	27
5.12	The JSON representation of one anti-psychotic/side-effect combination	28
5.13	The (partial) configuration of the chart.js graph	30
5.14	Redux state representing the current stet of the table	32
5.15	The comparison view for efficacy and fatigue	33
5.16	The dialog for excluding an antipsychotic from the comparison	35
5.17	Short explanation for side effects	36
5.18	The information modal for antipsychotics	37
5.19	The page where patient and doctor make the final decision	38

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