Focus driven acquisition of patient consent information for COVID research

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Objective

Already dismissed COVID Patients consent in sharing medical data

Conclusion

Identifying all inpatient former COVID-19 patients and ask for consent

Introduction

Data integration centers (DIC) have been established to address a broad range of clinical patient data, where modern clinical research depends on. This data can only be used with a patient's explicit consent. A process has been established which allows responsible clinicians to ask readmitted patients for a consent.

Search Criteria

- persons, which have or had have an active COVID-19 infection while they were under treatment in UHG
- visiting the hospital now

Methods

We translated the criteria into a cohort definition within the software ATLAS, which is developed and maintained by Observational Health Data Sciences and Informatics (OHDSI).[2]
In the next step, we used the CTRSS, which is described by Gulden et al. to generate a list of the identified persons. [3]

Problem

The general data protection regulation (GDPR) of the EU requires an explicit written patient consent for most types of data usage within research studies.[1]
As we are allowed to use data of deceased patients or persons who signed up for other consent formulars, we can work with about 29.76% (n=206) of all technical available COVID-19 patients. The other 70.27% (n=487) must sign a consent document before we are allowed to use their data. These numbers are also shown in Figure 1.
The DIC's are now faced with a situation, that they are technically able to support centralized COVID research with deep phenotypic patient data but don't have a broad consent available for these patients.

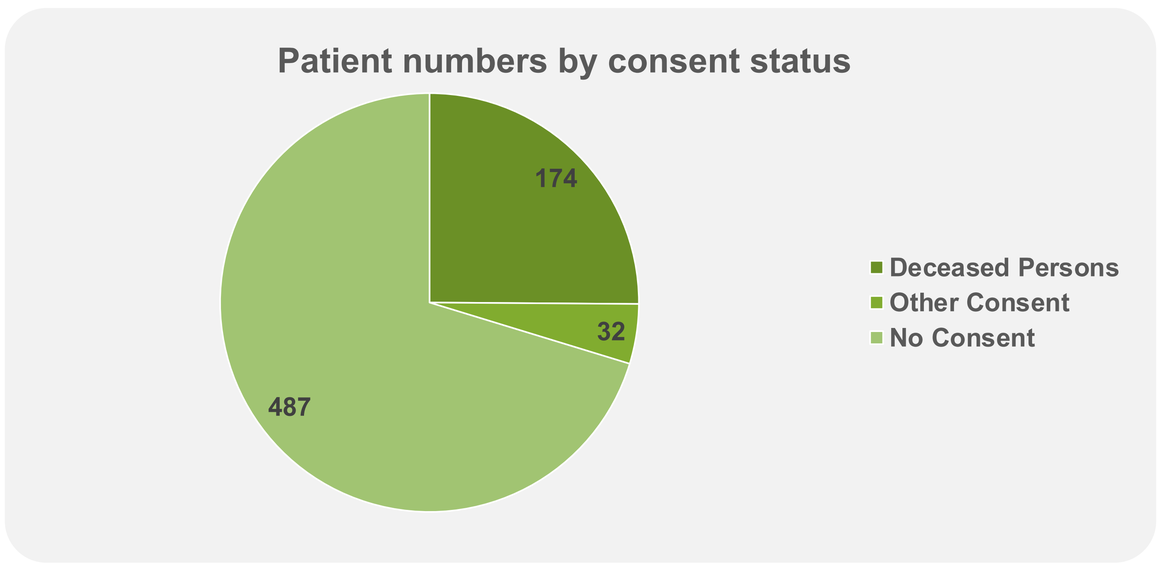

Figure 1 – Amount of different consent status of COVID patients

Results

The list is provided as a website, see Figure 2. When new persons are identified, a notification is sent to the responsible clinicians.

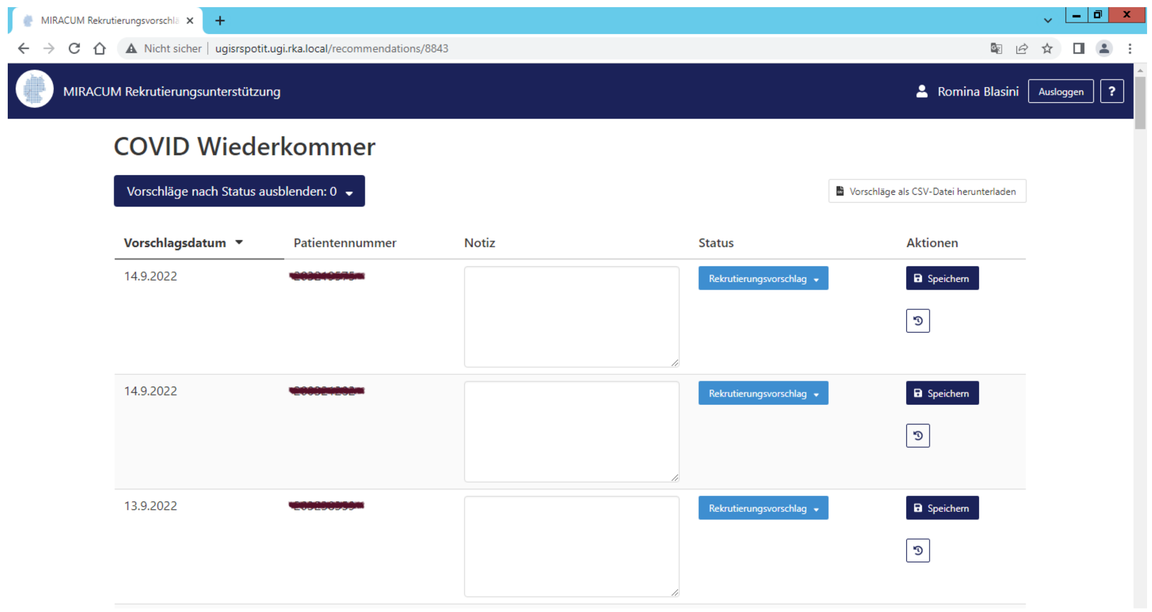

Figure 2 – Screenshot of Screening Website

Conclusion

As the launch of a hospital-wide broad consent for every treated patient is an organizational fastidious project and highly time-consuming, the requesting of individual persons with specific or rare diseases can be a fast solution to be able to do research across locations. The CTRSS developed in the MIRACUM project, together with the richness of data we already have available at the DIC of Giessen, can help to identify medical interesting persons and ask these specific persons for the consent of working with their clinical data.

References

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