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# Evaluation of a Digital Dementia Registry's IT Architecture After a Three-Year Period in Practice: digiDEM Bayern

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**Abstract.** Introduction: The project "digiDEM Bayern" aims to set up a registry with long-term follow-up data on people with dementia and their family caregivers. For that purpose an Electronic Data Capture (EDC) system linked with a Participant Management (PM) system has been established. This study evaluates the acceptance and usability of the IT tools supporting all data management processes in order to further improve the system and associated processes. Methods: For this purpose we collected the key numbers of the registry, and used the System Usability Scale (SUS) to evaluate the interactions of the data management systems in a wide area. Results: Thirty-six research partners (RP) and six study team (ST) members completed the anonymous online survey. The EDC system overall reached an average SUS score of 73.42 and the PM system of 77.92. Discussion: The two systems fulfil their required task and, therefore, simplify the work of the RP in the data collection process and of the ST during the data quality checks. Conclusion: Integrating the used systems is therefore recommended for registry studies in other medical areas.

**Keywords.** Evaluation, IT Architecture, Dementia, Registry, Online Survey

## 1. Introduction

### *1.1. Background*

Dementia is a widespread disease that currently affects over 55 million people worldwide, with annually almost 10 million new cases. Diagnosis and treatment for people with dementia is going to be one of the biggest challenges for healthcare systems worldwide [1]. Digitalisation offers additional opportunities to improve dementia care and health outcomes research to enhance national health planning [2,3]. Registries are a useful

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research tool for collecting long-term data. In addition, the registries provide insight into disease-related services [4].

### *1.2. Data Collection Process*

The "Digital Dementia Registry Bavaria – digiDEM Bayern" has the goal of recording the healthcare situation around dementia diseases and the long-term progression of dementia-related illnesses to improve the care situation of people with dementia and their family caregivers. Participants are people with mild cognitive impairment and mild to moderate dementia living at their own homes. Experts from various specialist areas of dementia care have defined the data set, which contains among other things data on sociodemographic, diagnoses, activities of daily living, use of resources, the burden on caregivers, needs of people with dementia. The survey instruments focus on the home environment and include caregivers' questions. Research partners (RP) are dementia care professionals from multiple related institutes, such as care facilities and clinics for people with dementia. A broad network of RPs is necessary to ensure geographical coverage throughout Bavaria. The participants are then questioned in a baseline interview (t0) followed by four follow-up surveys 6, 12, 24, and 36 months later [5]. The RPs collect the necessary data through online or face-to-face interviews. Data can be entered using stationary and mobile devices via the web browser. A permanent internet connection is required for data collection. In digiDEM Bayern, 117 active facilities currently participate as RPs (as of 30.09.2023). The RPs have included 1.068 people with cognitive impairments in the study. The geographical evaluation shows that most of the study area is covered. Each survey is subject to data quality assurance supported by the Electronic Data Capture software. Through timely feedback loops, missing values are added, and implausible values are corrected. The study team (ST) consists of six research fellows responsible for the quality control of the entered data and the administration of the follow-up surveys.

### *1.3. IT infrastructure*

The IT infrastructure provides standardized workflows to support an electronic collection of registry data and monitor every participant's study progress. To effectively provide these services, the IT architecture is divided into two components:

(1) Electronic Data Capture (EDC) Software: digiDEM Bayern uses the EDC system Research Electronic Data Capture (REDCap), a secure Web-based software platform designed to support EDC for studies to collect data.

(2) Participant Management (PM) Software: The registry uses a digital and automated monitoring process with escalation levels for the patient's progress. Therefore, webMODYS (web-based modular control and documentation system) was selected to manage the decentralized RP and participants' identity data and monitor the follow-up surveys' times.

The IT architecture of digiDEM Bayern was developed based on an iterative, stakeholder-oriented process that focuses on joint development regarding requirements and architecture [6]. The success of a registry study depends on two key factors: Recruiting the required number of participants [7] and their subsequent participation in the study [8]. The expected decrease in cognitive abilities and general health of dementia patients throughout this study may lead to additional challenges regarding the questioning format [9]. The RPs use the EDC system to enter the collected data digitally and the PM system to receive the visit dates of the follow-up surveys and the participants' master data. The RPs once transmit the patient master data electronically. The physical separation of the EDC system (survey data) and the PM system (master data) ensures higher security of the patient master data. The PM system is localised in the hospital's internal network and cannot be accessed externally. The RPs have no access to this system. Automatic reminder e-mails for the follow-up interviews and letters with the participants' master data are sent out. The ST uses the EDC system to check the quality of the data entered and the PM system to administer the follow-up surveys and master data of the study participants. This study aims to evaluate the IT architecture of digiDEM Bayern after a three-year period in practice. The well-known instrument, the System Usability Scale (SUS), was used to evaluate the interactions of the data management systems for the software architecture of a digital dementia register in a wide area.

## 2. Methods

For this work, corresponding indicators and usage data of the registry's IT architecture were analysed. We also conducted an anonymous online survey across RPs in Bavaria/Germany and the ST. The survey was carried out during a two-month period from the beginning of September to the end of October 2023. Invitations to participate in the survey were sent via e-mail; it included a cover letter describing the study's aim and providing the survey link. The content of the online questionnaire was developed based on scientific literature [10, 11]. It was developed using the online SoSci Survey program (www.soscisurvey.de) and made available online. Participants were asked to provide information about their professional background and use of technology. They gave their subjective assessment (on a scale of 1 to 10) and complete the SUS for the systems. The scale can take values between 0 and 100; the higher the value, the higher the user-friendliness is categorised [10]. Furthermore, the RPs and the ST were asked to name the most significant benefit and the most considerable problem associated with the systems they used.

## 3. Results

### *3.1. Registry key numbers*

Due to the integration of the EDC system and the PM system, tracking the dates of the follow-up surveys is possible. The PM system leads to reduced administration and is less time-consuming. Suppose an RP is unable to complete a survey. In that case, another RP can be granted access to the contact's specific master data and the corresponding data set in order to complete the survey. This procedure has been accomplished in 59 cases so far. Monitoring and ensuring timely follow-up surveys in the PM system leads to the high data quality of the registry data. Since the start of the project, only 27 of the 779 (3.47%) follow-up surveys have taken place outside the defined periods.

### *3.2. Feedback from the research partners*

146 people were asked to take part in the online survey by email. Thirty-six RPs completed the survey, resulting in a response rate of 25.53%. They were, on average, 51 years old, with an age range of 21 to 66, and predominantly female (91.67%). 16 people (44.44%) are professionally involved in counselling those affected (people with dementia and caregivers), 16 participants (44.44%) work in medical or nursing care, while 4 volunteers in the field of dementia (11.11%) also took part in the survey. They most frequently use modern technology (4.29) and rated their competence in dealing with modern technology as average (3.54), while fear of failure did not play a significant role (2.29). The Data entry via the web interface of the REDCap system achieved a score of 7.88 (out of 10) and an average SUS score of 71.77. The software for managing the follow-up surveys reached a score of 8.50 and an SUS score of 77.28.

The feedback from the research partners who collected the survey data using the software components described was predominantly positive. The most frequently mentioned benefit (16 responses) was the clarity of data entry, directly followed by the immediate transfer of data to the ST and the fact that no paper is required for data collection, with six responses each. Four people mentioned other program features as a benefit. To the open question about the most significant benefit, an RP answered, "Available everywhere and quickly, completeness of data entry is displayed, partial survey with later continuation possible." Another RP mentioned that the real-time input and the simultaneous access by several employees of an institution helped them a lot in the survey process. Some RPs (12 responses) were bothered by the effort required to familiarise themselves with the software or the sometimes cumbersome electronic case report forms. The problem is exacerbated if there is a significant time gap between individual surveys. Nine other RPs reported other technical or structural problems. Four other respondents were bothered by the fact that the device actively required internet access to enter data.

### *3.3. Feedback from the study team*

The ST consists of 6 people. They are, on average, 34 years old, with a wide age range between 27 and 55. Two of the scientists are male, while four are female. They frequently use modern technology (4.67), rated their competence in using modern technology as very high (4.67) and have no fear of failure (2.00). Their subjective assessment of the data entry via the web interface of the REDCap system was 8.83 (out of 10) and an average SUS score of 83.33. The software for managing the follow-up surveys reached a score of 8.50 and an SUS score of 81.76.

The feedback from the ST was unanimous. The PM system can monitor compliance with the deadlines for the follow-up survey in a transparent manner. One scientist noted that eliminating double documentation (first manually on paper, then digitally) means an enormous time advantage for them. The functions built into the EDC system also allow initial data evaluations. For example, this leads to time savings when checking the number of cases for individual scientific evaluations. The EDC system accelerates data quality control significantly. The display of missing or implausible values, such as a daily caregiving time of more than 24 hours. One research fellow named this the most significant benefit: "Checking the software for non-plausible data and inconsistencies as well as the possibility of checking missing values." However, it was also criticized for the system's inability to perform a general and fully automatic data quality check. The meaningfulness of the data still has to be checked manually by the researcher. Correcting some values is also sometimes time-consuming, as the built-in filters mean that some questions only appear when specific criteria are met.

## 4. Discussion

The SUS is often used to evaluate the usability of a stand-alone system [12]. In this study, it was used to evaluate the usability of the IT architecture as well as the complete data collection and data management process. As the IT architecture of the digital dementia register consists of several individual systems, the SUS was also used in this study to test their interaction in terms of user-friendliness. For this purpose, both the ST of the university and the RPs who carried out the data entry were surveyed. Bangor et al. describe that products with an SUS score of 90 points and above were rated as exceptional, products rated 80 points as good, and products rated 70 points as acceptable. Anything below 70 points had usability issues that were a cause for concern [14]. The statistically average SUS score (at the 50th percentile) is 68 [10]. That means all SUS assessments are above the average and at least rated as acceptable. The ST rating of the used systems was slightly better and therefore rated as good (EDC-system: 83.33, PM-system: 81.76). However, the RP rating was just above the acceptable limit (EDC-system: 71.77, PM-system: 77.28). In addition to that, the subjective assessment of the EDC system (RP: 7.88, ST: 8.83) and the PM system (RP: 8.5, ST: 8.5) was quite positive. These numbers suggest that the project-used systems were generally perceived positively by the two target groups in their application. However, the RPs report some difficulties. The missing availability of internet connection in most of the participants' homes leads to the problem that permanent internet access is required for data entry. According to the university's data protection regulations, no study data can be stored locally on a private device. This would have led to constantly checking a device for potentially high-risk applications, such as social media platforms. Checking all devices is time-consuming and vulnerable to mistakes; offline data collection and entry on private devices is not sustainable. One potential solution would be equipping researchers with mobile devices limited to preinstalled applications. The need for manual checking of data by the ST poses another problem. For some data entries, automatic filters can be defined that check the entries for plausibility. However, this is only possible in rare cases, as contextual information is necessary for an automatic plausibility check by the system. Another approach is increasing the input quality. For this purpose, the RPs are briefed on frequent entry errors and system-based features in binding regular training and follow-up training courses. Furthermore, the ST offers a monthly meeting to answer questions.

## 5. Conclusion

This evaluation showed that the feedback was largely positive. The two systems fulfil their required task and, therefore, simplify the work of the research partners in the data collection process and of the study team during the data quality checks. The partially automated process of informing research partners about upcoming follow-up interviews with participants and monitoring their timely implementation leads to accumulating high-quality data. Nevertheless, the software can only solve some problems in study registry data collection processes; process reorganization is sometimes needed.

Integrating an electronic data capture system and a participant management system is therefore recommended for registry studies in other medical areas.

## Declarations

*Authors' contribution:* Conceptualization: MZ, ND, HUP; Formal analysis: MZ; Methodology: MZ, ND, HUP; Project administration: PKR, EG, HUP; Supervision: MZ, ND, HUP; Writing - original draft: MZ; Writing - review and editing: MZ, NDI, HUP.

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*Conflict of Interest:* All authors state that they have no conflict of interests.

*Ethics vote:* Ethical approval was not required.

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