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Feasibility, comprehension and applicability of broad consent in the emergency department: an exploratory mixed-methods study

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ABSTRACT

Background The German Medical Informatics Initiative (MII) introduced a standardised Broad Consent (BC) form encompassing medical data, insurance data, contact information and biomaterials for health data research. This study assesses the feasibility of MII-BC in emergency departments (EDs), examining patient understanding and identifying implementation facilitators and barriers. Recommendations for implementation of MII-BC in EDs will be derived.

Methods Mixed-method data were collected in EDs of four German university hospitals (UHs) using pseudonymised participant observation with a focus on patient perspective and surveys from patients. Data included MII-BC acceptance rates, patient understanding, motivation to consent and implementation facilitators and barriers. Quantitative data were analysed descriptively; qualitative data underwent content analysis with deductive–inductive category formation.

Results The exploratory study involved 12 participant observations from four tertiary UHs, surfacing five key themes: (1) MII-BC patient information in the ED, (2) facilitators and (3) barriers in obtaining MII-BC in the ED, (4) patient perspectives on MII-BC and (5) recommendations for implementing MII-BC in EDs. Survey results (n=225) showed that most patients (89.8%) demonstrated high understanding of MII-BC patient information. Facilitators include empathetic engagement, clear communication and encouragement for questions. Hindering factors include estimating study time frames, ambient noises and study procedure interruptions. Adequate resources, such as trained staff and suitable premises, are crucial.

Conclusion Implementing MII-BC in the ED is feasible with appropriate resources, though ED-specific challenges must be addressed. Successful MII-BC implementation in EDs hinges on ensuring access to comprehensible information materials, transparent communication and a calm recruitment environment.

Trial registration number DRKS00030054.

BACKGROUND

Secondary use of health data plays an increasingly important role in medical research and care.[1] It forms the basis for research projects to optimise patient care and develop personalised medicine.[2–4] Particularly in times of global health crises, such as the COVID-19 pandemic, the need to share, analyse and disseminate information and knowledge to develop effective interventions and optimise healthcare is urgent.[5] Data sharing is widely supported by patients and the public, provided that certain conditions are met, such as social benefits, data security, transparency and accountability.[6] However, patients have varying levels of trust and concerns about privacy and autonomy, which are influenced by cultural, political and social factors, as well as personal experiences.[7]

In recent years, the concept of Broad Consent (BC) has been extensively discussed in the medical ethics debate.[6 8–10] BC allows patients to agree to the use of their data and, if applicable, samples without restricting it to a specific project or research question.[11] Implementing a broad secondary use of health data infrastructure is associated with technical, ethical and legal challenges.[3 12] Despite these challenges, the application of BC enables the legitimate use of data for future research purposes and facilitates data transfer within the research community.[13]

For this purpose, the Medical Informatics Initiative (MII)[14] in Germany has drafted a standardised modularised template form for patient BC,[3] which was approved for nationwide use at the Data Protection Conference on 15 April 2020.[15] The MII is a programme funded by the German Federal Ministry of Education and Research (BMBF) with the purpose of digitally networking university hospitals (UHs). The aim is to improve a nationwide infrastructure for the secondary use and exchange of health data and biomaterials for medical care planning and healthcare as well as biomedical research.[16]

The MII-BC aims at the secondary use of data and biomaterial for medical and scientific research purposes. Medical research is defined here as research to improve the diagnosis, treatment and prevention of diseases; discriminatory research or the development of biological weapons is explicitly excluded. MII-BC includes optional consent to provide data in four different modules over a period of 5 years: medical data, insurance data, contact information and biomaterials (eg, blood, urine or cells). After 5 years, patients will be asked for their consent again. The data and biomaterials can be stored and used for 30 years. Patient data will be used for a diverse array of medical research purposes benefiting society as a whole. Future research topics may encompass specific disease areas such as cancer/oncology or cardiovascular diseases for unforeseen research activities.[11] The standardised, modularised consent template is available in several languages

(German, English, Arabic and Turkish), and additional information videos and patient information in plain language have been provided by the MII.[17] Due to the complexity of the information, it is recommended that MII-BC topics and documents are presented in a concise and understandable manner, using simple language to facilitate comprehension. Constant and transparent communication of goals, procedures and sharing of data and materials are crucial for obtaining ethically acceptable consent to participate.[9]

Since then, there has been no consistent approach to health data consent in Europe. In many countries around the world, various initiatives are developing technical and organisational infrastructures to increase health data compatibility in different contexts of medical research purposes. Examples of initiatives include Findata[18] in Finland, where the collection of diagnostic specimens and data is permitted on an opt-out basis, allowing patients to opt out using an online form.[19] On the other hand, many countries prefer opt-in methods with BC concepts due to data protection issues. MII-BC is already used for inpatients at many UHs in Germany (eg, Heidelberg, Jena, Erlangen, Kiel[20]). However, knowledge about the implementation of MII-BC in emergency departments (EDs) is still very limited even though this approach would potentially offer the opportunity to include a wide-ranging, non-preselected spectrum of disease, encompassing both outpatient and inpatient cases, as well as varying degrees of disease severity.

This study applied a mixed-methods approach to investigate the applicability and impact of implementing MII-BC in EDs. The study focused on several key aspects: analysing the overall information and consent process, assessing patients' understanding of the MII-BC patient information and identifying facilitators and barriers to the implementation of MII-BC in EDs. In addition, this study addressed patient concerns about MII-BC and aimed to provide practical recommendations for the implementation of MII-BC in the ED.

METHODS

Study design

This study used an embedded mixed methods approach that allowed for the simultaneous collection of qualitative and quantitative data to gain comprehensive insight into the implementation of MII-BC in EDs.[21] The qualitative approach of participant observation is the focus of this paper, supplemented by selected quantitative data from a structured questionnaire (online supplemental file 1) on the understanding of MII-BC from a patients' perspective. In addition, study nurses completed a survey form for all potentially responsive patients (every 5th/30th person) to assess patient-related and organisational factors during the consent process to MII-BC in the ED. The data were analysed separately and triangulated for interpretation.[22] In the study, both qualitative and quantitative research standards were followed to ensure the quality and transparency of the research. To this end, the Standards for Reporting Qualitative Research (SRQR)[23] were used for reporting of qualitative research parts and the Strengthening the Reporting of Observational Studies in Epidemiology checklist (STROBE)[24] was used for the quantitative part.

Study setting

The study on MII-BC in EDs is a work package of CODEX+ (Collaborative Data Exchange and Usage),[25] an initiative which is part of the Network University Medicine.[26] It examines the use of MII's BC using BC consent template V.1.7.2[11] (online supplemental file 2) in EDs. Data collection took place in the EDs of four German tertiary UHs: Charité—University Hospital Berlin Mitte, University Hospital Regensburg, University Hospital Schleswig-Holstein—Lübeck and the University Emergency Centre, University of Freiburg Centre for Emergency and Rescue Medicine, Freiburg. Ethical considerations were central to determining the feasibility of the study in the ED context. There were no direct risks to participants as they continued to receive routine care in the ED, and the study process did not interfere with the normal course of treatment. Additionally, the study nurses, who are experienced in working with ED patients and familiar with the environment and specific challenges, were specially trained to conduct the informed consent process. They monitored participants for signs of discomfort during the whole study process. If a patient showed signs of stress or discomfort, the study was immediately interrupted and, if necessary, cancelled.

The study was registered with the German Clinical Trials Registry under DRKS00030054.

Participants

Patients were selected based on the following inclusion criteria: minimum age of 18 years, ability to consent, no German language barrier and understanding of the study. Patients were excluded if they were unable to give informed consent, for example, if they were sedated, demented, had a traumatic brain injury, were in excessive pain, were intubated, were being cared for, were infectious or were unable to understand the nature, significance and scope of the study. To reduce selection bias and create a sample that is representative of the local population of emergency patients, random sampling was used on inclusion. The sampling strategy was to attempt to contact every 5th (or every 30th patient at one site) admitted to the ED, regardless of the initially assigned triage category. Both self-referred patients and patients transported to the ED were included. Recruitment took place after administrative admission in the waiting area or other rooms in the ED and extended from September 2022 to December 2022.

Study procedure

The selected study sites varied in their level of consent due to ethical restrictions at some study sites. Two of the four participating sites hypothetically obtained MII-BC consent, while the other sites actually obtained MII-BC consent. In Regensburg and Freiburg, MII-BC could be implemented as part of the regular procedures and structural set-up, including ethical considerations, trust centres and data warehouses. In Berlin and Lübeck, the implementation of MII-BC was only hypothetical, as these established procedures and structures were lacking and could not be established during the time available for the study. The modules medical data, insurance data, contact information and biomaterials were requested at all locations, with the exception of University Hospital Regensburg, where no biomaterials were requested.

The study was divided into two parts to ensure that patients understood there were separate study parts and respective consent processes. In the first part, every 5th/30th patient was informed about the study 'Feasibility of Broad Consent of MII in the Emergency Department Setting' and asked for their actual consent to participate in this study. During the study process, they completed a questionnaire on demographic aspects and their understanding of the study. In the second part, patients were specifically informed about the 'Broad Consent' for

medical research by the German MII-BC, given the opportunity to (hypothetically) consent to the MII-BC.

Data collection

Participant observation

Prior to the observations, the ED managers and the nursing staff were informed about the implementation of the observations. The observations, conducted by a single research assistant employed at one of the study sites, took place between October and December 2022. All patients provided specific written consent to the observation after being informed about the participant observation and the purpose of the observer's presence; none refused to participate after being informed. Participant observation is a method suitable for gaining knowledge in a social situation that is difficult to observe from the outside.[27]

The study employed open-ended participant observations with passive participation based on a hypothesis-free and exploratory approach. The objective was to map the process of MII-BC information and the study process in the four participating EDs, emphasising the patient's perspective and collecting data on feasibility, acceptability and applicability of MII-BC in the ED. A total of 12 participant observations were conducted at all four study sites of patients who consented to participate in the study. Participant observations were carried out considering inclusion criteria and the sampling strategy, which involved attempting to contact every 5th (or every 30th patient at one site) admitted to the ED.

The entire study process was observed from the beginning of the approach to the patients until the completion of the patient questionnaire after consent was given. During the observation, the setting, verbal and non-verbal communication and body postures were documented. Although the quotation marks in the results section indicate verbatim speech, this is not verbatim documented speech, but a report from memory. The aim was to comprehensively describe the applicability of MII-BC in the ED setting, as well as the patients' understanding and required resources and to derive recommendations for the implementation of MII-BC. In addition, facilitating and hindering factors in obtaining MII-BC were addressed, as well as patients' concerns about MII-BC.

Observations were recorded using an observation log with prestructured sections divided into time and place of observation and characteristics of the participants. The section for documenting the observations was not structured in order to avoid limiting the observation data in advance. On completion of the observations, the field notes were recorded in observation logs. Regular reflection on the observation process took place during the data collection.

Ethical considerations for the observation process

In the ED environment, it was not always possible to avoid observing situations in which patients who had not consented to the study were present (eg, other patients in the waiting area of the ED). Therefore, the observer was strictly obliged to maintain confidentiality and had to adhere to medical–ethical restrictions (declaration of confidentiality). This plan received approval from both the ethics committee of the clinics and the management of the ED at the study sites.

Survey

Standardised questionnaires were developed to collect quantitative data. Two different survey forms were designed specifically for the study and were completed after completing the MII-BC consent form: (1) A survey form on study procedures and clinical data was completed by the study nurse. The survey form focused on the assessment of patient-related and organisational factors that influence the accessibility and implementation of patient consent. (2) A patient questionnaire to assess the feasibility of MII-BC in the ED setting, understanding of patient information and patient questions and concerns about MII-BC. In addition, voluntariness, recall, motivation and understanding of the study content were assessed, and socio-demographic data were collected. In this paper, the focus is on selected questions regarding patient-reported understanding of the MII-BC study information.

Data analysis

Participant observation

The observation protocols were checked for plausibility and comprehensibility, transferred from the paper version to a digital observation protocol and imported into MAXQDA 2022 software (VERBI, Berlin). All information that could be used to possibly identify participants was removed.[28] The observation protocols were analysed using reflexive thematic analysis according to Braun and Clarke with deductive–inductive category formation.[29] The overarching categories 'Factors facilitating and hindering obtaining MII-Broad Consent in the ED' and 'Recommendations for implementing MII-Broad Consent in EDs' were deductively derived from the research questions.

According to Braun and Clarke,[30] there are six phases to consider when undertaking thematic analysis. First, it is important to become familiar with the data. This involves rereading the observation protocols and noting down initial ideas that emerge. After becoming familiar with the data, the second step is to create initial codes. This involves systematically coding the entire data set to identify patterns and possible themes. In a third step, the codes are grouped into potential themes. Fourthly, the identified themes are reviewed in relation to the assigned codes and data to create a thematic map. In the fifth step, the individual themes are then refined through continuous analysis in order to clearly define and name them. Finally, the results are in a report. In addition, a 15-point checklist[30] supported the steps of the analysis process.

An objective approach was ensured by coding four randomly selected observation protocols not only by the author but also by an independent research assistant. The resulting category and code systems were continuously compared and revised on mutual consensus.

Compared with other research methods, thematic analysis offers theoretical freedom and the advantage of flexibility. According to Braun and Clarke, it also has the potential to provide a comprehensive and detailed account of data.[30]

Survey

Questionnaires were completed paper-based and later transferred to the Research Electronic Data Capture (REDCap) electronic data collection system or directly entered electronically via tablet devices. After the data collection was completed, the data were extracted from the REDCap documentation system. All data were analysed using the IBM SPSS Statistics V.27 programme. The quantitative characteristics were described descriptively.

RESULTS

Characteristics and description—participant observations

Participant observations were conducted from October to December 2022 at all four ED sites for 8 days (3 days in Berlin, 2 days in Freiburg and Regensburg, 1 day in Lübeck) in total. A

Table 1 Details about the different observation sites (university hospitals (UHs)), observation period, the duration and frequency of observations and the overall time spent observing each participant throughout the study period

Study sites	Charité UH Berlin	UH Freiburg	UH Lübeck	UH Regensburg
Observation period	October–November 2022	December 2022	December 2022	November 2022
Number of observations	5	1	1	5
Duration of observations	0:35 min–01:10 hours	0:56 min	0:32 min	0:12 min–01:57 hours
Total observation time	05:57 hours	0:56 min	0:32 min	05:28 hours

total of 12 participant observations were conducted at all sites with patients who consented to the MII-BC. The study included participants with ages ranging from a minimum of 24 to a maximum of 73 years and a mean age of 44 years. Three female and nine male patients with different reasons for presenting to the EDs were observed. Four of the patients were accompanied by someone during their stay in ED. Participant observations lasted between 12 and 117 min (mean=56 min). The total time of all 12 observations was 773 min (12.53 hours) (see table 1).

Key themes identified through thematic analysis

The thematic analysis of participant observations revealed five key themes related to the MII-BC process in the ED. The first theme, 'MII-Broad Consent patient information' includes the patient information setting, the information provided by the study nurse and the study materials involved in the patient information process. The second theme, 'Factors facilitating in obtaining MII-Broad Consent in the ED' describes factors such as empathy, autonomy, trust and responsive communication. Whereas 'Hindering factors in obtaining MII-Broad Consent in the ED' describes barriers including estimating the time frame required per patient, ambient noise and study procedure interruptions. In addition, 'Patient perspectives on MII-Broad Consent' examines patients' understanding of the information provided, questions they had about the MII-BC and the study process and their concerns and motivations for giving consent. The last theme, 'Recommendations for implementing MII-Broad Consent in EDs', focuses on flexibility and the patient information setting, study materials, clear information on data protection and offering training for study nurses.

Characteristics and description—survey

Two different questionnaires were completed for each event by the study nurse and the patient. It should be emphasised that only demographic data from the survey results collected from study nurses are reported in this paper. Comprehensive details are provided in Fischer-Rosinský et al.[31] In the period from September 2022 to December 2022, a total of 313 patients consented at all EDs. A total of 225 questionnaires (response rate of 71.9%) are available from the consented patients. The dropout rate can be attributed to several factors related to the ED environment. Interruptions during the consent process and difficulties in locating patients in the dynamic and often crowded ED were the main reasons for incomplete patient surveys. In some cases, patients could not be found in time to complete the questionnaire despite initial consent, either because they were transferred to other hospital departments or because they were discharged early.

The mean age of participants was 43.0 years (IQR 29.3–58.0). Of these, 86 (38.2%) were female, 133 (59.1%) were male, one person (0.4%) was diverse/non-binary and two people (0.9%) preferred not to answer. Age information was missing for three participants (1.3%).

According to the Manchester triage system, 1 patient (0.4%) required immediate medical contact (category 1), 18 patients (8.0%) were triaged to category 2 (very urgent), 65 patients (28.9%) to category 3 (urgent), 41 patients (18.2%) to category 4 (standard) and 10 patients (4.4%) to category 5 (non-urgent). There were 2 cases (0.9%) with unspecified triage categories and 88 cases (39.1%) were missing triage category information. 135 patients (60.0%) were treated as outpatients and 55 patients (24.4%) required hospital admission. No information on patient management was available in 35 cases (15.6%).

The following five sections present the findings of the empirical triangulation of the participant observations and surveys along five identified main themes.

Theme 1: MII-BC patient information

Patient information took place in the waiting areas and treatment rooms of the EDs. At one site, the study nurse discussed with the nursing staff which room could be used for the study enrolment (Observation (OB) 6). The study nurse approached the patients in the waiting area or called them by name. If the patients were already in the treatment rooms, they were addressed directly. In one case, a patient was called from the waiting area by the study nurse and taken to a plaster room for patient information (OB 6). In another case, the study assistant accompanied a patient who was lying on a stretcher from the triage cubicle to a corridor where he had to wait after triage (OB 7). The patient information in the waiting area was mostly surrounded by other patients.

The patient information began with a short introduction to the study, followed by the provision of the MII information video on a tablet. Afterwards, the patient information was handed out. The study nurse explained the voluntary nature of the study and that it would not affect medical treatment. Furthermore, the benefits and risks of participation and the use of the right of withdrawal were explained. It was also emphasised that only de-identified data would be collected for research purposes.

In some cases, patients wanted a quicker explanation because they were familiar with the study process (OB 8, OB 12) or they were very trusting about the study and did not need all the information before deciding to consent (OB 3). Following MII-BC consent, patients were given an evaluation form to assess their understanding of the patient information and information materials. In most cases, the study nurse was present during the MII-BC information to answer questions directly. At two sites, the study nurse was not present all the time and did other study-related tasks while the patients read the information materials. In this case, the patients' questions were answered after the return of the study nurse before written informed consent. Box 1 shows free-text statements made verbally by patients during the MII-BC study process—filled in by the study nurse.

Box 1 Free text comments on the MII-BC patient information process and patient information from the patient's perspective completed by the study nurse

- Anonymisation not sufficiently presented.
- More details on biomaterials needed.
- Interruptions in the patient information process.
- One patient wanted to take study documents with him to clarify with the health insurance company.
- Some patients refused to read patient information due to text overload.
- One patient dropped out of the study due to the duration of study procedures and inappropriate location (ED).
- One patient simply wanted to contribute to research; MII-BC content was less important.

ED, emergency department; MII-BC, Medical Informatics Initiative-Broad Consent.

Theme 2: factors facilitating obtaining MII-BC in the ED

During the observation of the interactions between the study nurse and the patients, several resources became apparent that positively influenced the patient information process, including empathy and autonomy, trust and responsive communication.

Empathy and autonomy

The study nurses showed a high degree of empathy during the study process and interactions with the patients:

The study nurses showed a high degree of empathy during the study process and interactions with the patients:

Another point was the consideration of the patients' autonomy. The study nurses reiterated that patients had the option to withdraw from the study at any time (OB 9). It was also emphasised that patients would not suffer any disadvantage if they decided not to consent to the MII-BC (OB 2). The individual needs of the patients were taken into account during the information session by giving them enough time to read the information independently, ask questions and make decisions at their own pace (OB 8, OB 11).

Trust

Compliance with ethical guidelines was clearly communicated to patients. One study nurse informed the patient that the study had been approved by an ethics committee. In addition, the de-identified nature of the patient's data was emphasised by explaining that the organisationally independent trusted third party was responsible for data management and for regulating the patient's withdrawal (OB 9). It was also explained that the patient's data 'will be provided to researchers and published in a de-identifiable form' (OB 10). Furthermore, potential risks of providing data for study purposes (eg, retracing of data through additional information like the Internet or social media) were discussed, and it was explained that patients in general could potentially benefit from the study by new research developments if they gave their consent. Another benefit mentioned was that 'study findings could inform health insurance companies regarding future re-funding of diagnostics and therapies' (OB 10).

Responsive communication

Responsive communication also played a crucial role during patient information. The study nurses provided information in a clear and structured way, repeating important points. They used examples to ensure that patients understood the process of the study and the risks and benefits associated with it. The patient information was adapted to the needs of the patients. In some cases, the study nurses explained each section of the study information in their own words.

> The study nurse explains the collection of biomaterials with an example based on the patient's story (eg, cancer diagnosis and tissue samples taken during surgery). (OB 6)

Open communication was promoted by the study nurses, encouraging the patients to ask questions if necessary, in order to avoid misunderstandings (OB 4).

Theme 3: hindering factors in obtaining MII-BC in the ED

During the observations, various obstacles and disruptive factors were identified that hindered obtaining MII-BC.

Time frame

First, it was noticeable that the entire study process took different amounts of time depending on the patient. Inactive phases of the study nurse were recorded while patients were reading the study information or were busy filling out the study materials.

> The study nurse and [the observer] stand at the edge of the corridor, a bit away from the patient. We [the study nurse and observer] watch the patient from a distance, so we can react quickly when the patient is through reading the patient information. (OB 7)

During the inactive phases, the study nurse usually withdrew and had to estimate when to return to the patients to continue the study process.

> The study nurse opens the door to the waiting area to see if the patient has finished reading. She seeks eye contact with [the observer], [the observer] makes clear to her with glances that the patient still needs some time to read. The study nurse goes back to the study room (OB 5).

Ambient noise

During the observation situation in the waiting area, there is a lot of noise and distraction in the surrounding area.

> Conversations are going loudly, people are talking on the phone and the security staff of the ED are talking loudly at the entrance of the waiting area (OB 1).

Additional background sounds were audible during the provision of patient information in a corridor near a ward base where several patient beds were located:

> A patient is snoring loudly, heart rate monitors are making noises and calls for a nurse by patients are clearly audible. (OB 7)

In another waiting area, it is also noisy because it is used as a passageway by patients and staff (OB 9). The observer notices that one consenting patient sometimes seems unfocused because of the noise volume and the ambient noise. The patient has difficulties understanding everything in the MII-BC information video and rewinds it on the tablet (OB 3). At the same time, another study nurse was informing other patients about a separate study. In addition, one informational procedure was conducted at the opposite side of the waiting area to create a quieter environment due to the restlessness caused by other patients. (OB 9)

Table 2 Understanding of the patient information on MII-BC and reasons for lack of understanding

Understanding MII-BC patient information		
	n=225	(100.0%)
Yes	202	(89.8%)
No	20	(8.9%)
Missing data	3	(1.3%)
Reasons for lack of understanding*		
Too long	12	(5.3%)
Too much information	10	(4.4%)
Too difficult language	8	(3.6%)
No understanding of technical terms	3	(1.3%)
Other	3	(1.3%)
The essentials were not clearly presented	2	(0.9%)
I was too excited	2	(0.9%)
I read too fast	1	(0.4%)

*Multiple answers possible.
MII-BC, Medical Informatics Initiative-Broad Consent.

Interruptions

It was observed that repeated interruptions occurred and caused delays in the study process. These interruptions required the study nurses to temporarily suspend the study process. Patients were called for triage or medical treatment. The study nurses had to adapt flexibly to the changing situation in order to continue the study after the medical treatment.

In addition, there were interruptions related to the medical procedures (eg, history taking by physicians, taking of blood samples or radiological procedures).

> A doctor enters the treatment room and says that he would like to take the patient to the computed tomography (CT) scanner while the patient watches the BC information video. (OB 10)
>
> The study nurse and the observer go back to the patient. She is taken straight away again, this time for obtaining an X-ray. (OB 10)

Theme 4: patient perspectives on MII-BC in the ED

Understanding the MII-BC information and consent process

Of the 225 respondents of the quantitative survey, 202 (89.8%) reported they understood the written MII-BC patient information; while 20 (8.9%) indicated that they did not comprehend the content (see table 2).

These quantitative results were complemented by qualitative findings of the observations, which revealed that in some cases patients were uncertain about their understanding of the MII-BC information: Patients who were accompanied by another person were observed not to answer the questions independently and to seek confirmation and support from their companion (OB 2, OB 4). It was noticeable that many patients felt overwhelmed by the amount of information and the number of questionnaires to complete. They expressed that the information material, including the information video, seemed 'endless' to them and expressed their potential frustration by moaning while filling it out (OB 2, OB 4, OB 5).

> After a short time, one patient asked: 'can we skip the video?' (OB 12).

Another patient emphasised the scope of the study documents by joking that the patient questionnaire could be used to assess an intelligence quotient (OB 9).

Box 2 Free text comments from the patient questionnaire on the patient information process and patient information

- Risks regarding data leakage to health insurance companies and employers.
- Fear of additional physical examinations due to consent.
- Data storage regarding various diseases.
- Legal consequences of non-reporting of previous healthcare system contacts during recontact with healthcare providers.
- Validity of study consent beyond emergency department stay.
- Fear of data disclosure to companies and commercial entities.

These qualitative results are also reflected in the quantitative results of the survey. The most common reasons why patients did not understand the MII-BC patient information were that the patient information was too long (12 patients, 5.3%), that it contained too much information (10 patients, 4.4%) and that it was written in a language that is too difficult to understand (8 patients, 3.6%) (see table 2).

Whilde conducting the the patient MII-BC information process, some patients started to talk about their medical history, for example, because one patient assumed that the study nurse was part of the medical staff (OB 6).

Questions and concerns on MII-BC

During the observation of the patients' information on MII-BC, several questions were posed to the study nurse. One of the questions was about the nature of the study:

> The patient asks if [the MII-BC] is about something 'physical'. (OB 1)

This qualitative result was also reflected in the free texts completed by the patients (see box 2).

Furthermore, the patients had questions about the scope of consent and whether consent to MII-BC had to be given a single time (OB 4). Patients also expressed concerns about the storage of their health data in the central register and wanted to know who would have access to this data (OB 10). This led to further questions about when the data would be collected and whether physicians would be able to access all previous data if the patients revisited the ED (OB 10). Free-text responses to the patient survey also increasingly included questions about data storage (see box 2).

Regarding data collection in the context of MII-BC, another patient wanted to know what specific data is collected by the health insurance company (OB 2). A companion and the patient inquired whether the data collected as part of the MII-BC would be exclusively internal to the hospital (OB 2).

Some patients expressed concerns or uncertainty about consent in MII-BC. One patient stated that he was agitated during his stay in the ED and doubted whether this was the appropriate place for such a survey. The patient's companion expressed the opinion that inpatients would be a better target group for the study (OB 2). However, the survey findings show that compared with the total population of all patients consulted, only n=2 (0.9%) patients reported being too excited (see table 2).

Concerns were also expressed about being contacted again after a visit to the ED (OB 1). Regarding the use of data, one patient felt it was important that research using his data is only done in Europe. With the importance of the anonymity of his data, he expressed several times that the possible detection of

rare diseases based on his data should only be communicated to him and his family (OB 6).

A number of patients as well as accompanying persons were critical towards the fact that the collected data is stored and accessible, especially with respect to genetic information:

> '…if it's anonymous, then I don't think it's so bad'. 'Except for genes and stuff…' (OB 2)

After a brief explanation of the individual modules to which patients can consent, one patient expressed in advance that he would like to consent to one of the modules, but not to the others. He also expressed concerns about providing data because he plans to immigrate to another country (OB 11).

Questions and concerns about the study process

In the different patient information situations, various questions and uncertainties about the study process arose. After watching the MII-BC information video, one of the patients asked whether patients of the German Armed Forces Health Insurance could also participate in the study. While reading the patient information sheet, he inquired whether the information was the same as in the video (OB 3).

Additionally, concerns were raised by one patient during the participant observations. She expressed concern that she might be called for treatment during the study process and that this might interrupt the study process (OB 9). The patient also had a question about the subsequent survey in relation to the MII-BC information:

> Is this question about what I read before? (OB 2)

Another patient was interested in whether he would be contacted again after his stay in the ED (OB 1). In addition, the question arose whether contact would be made by in-house staff as part of the study (OB 8).

Other questions that patients were interested in were how they would learn about the benefits of the research and over what time period the study would be conducted (OB 10). Regarding the withdrawal of consent, one patient asked if she could just call if she changed her mind (OB 10).

Motivation for consent

The patients showed a variety of reasons and motivations for agreeing to give their consent to participate in the study. The reasons range from personal benefit to altruistic motives and a strong connection to the research.

Reciprocity and gratitude

One patient expresses his willingness to sign the consent form immediately, without detailed information, because he strongly supports the study:

> You can take the [consent form] straight away, I'll do it straight away! (OB 3)

Furthermore, the patient agreed to the information in the video both verbally and by clearly nodding his head (OB 3).

Other patients perceived taking part in the study as a way of distracting themselves from their own health problems:

> I am happy when people can distract me from my pain. (OB 3)

Another patient was positive about taking part in the study because of a disease in her family. She reports about her mother's cancer from earlier in her life. At that time, she would have been very grateful for research (OB 10).

Box 3 Potential recommendations for implementing the Medical Informatics Initiative-Broad Consent in the emergency department

- Enable flexible times for patient information.
- Provide quiet, separate patient information rooms.
- Simplify patient information with specific examples.
- Shorten the information video for faster information intake.
- Provide clear communication about privacy and information access.
- Provide regular training for study nurses to become aware of their already applied skills.

Group benefit and solidarity

Furthermore, the willingness to consent was justified by the hope of helping others or receiving help themselves.

> If I can help someone or they can help me—why not? (OB 10)

A further patient showed understanding for the importance of the study by mentioning that he and his wife were a very 'research-friendly family' and had already agreed to other studies in the clinic (OB 12).

Belief in the importance of research

In addition, patients expressed a strong belief in the need for research and a desire to contribute to it. One patient wanted to consent to all MII-BC modules and replied: 'How else can you do research?' (OB 12).

Finally, the observation of a patient who voluntarily waited at the exit of the ED after discharge to complete the study (OB 9) demonstrates the commitment and willingness of the patients to actively support the research.

Theme 5: recommendations for implementing MII-BC in EDs

Based on the observations related to the patient information about MII-BC in ED, several recommendations emerge for the implementation of MII-BC in EDs (see box 3).

Flexibility

Due to unavoidable interruptions in the ED process, study nurses should be flexible and adapt the study schedule to prioritise clinical treatment and patient needs at all times.

Setting

EDs, by nature, are often busy and noisy places, which can significantly impact on the patient's ability to concentrate on the information process. MII-BC requires the patient's full attention in order to adequately understand the information and make an informed decision. A quiet and protected environment through a separate room in the ED could provide the necessary privacy for the patient.

Patient information

Patient information should be written in an easily comprehensible manner and, if necessary, illustrated with concrete examples. Overly detailed and linguistically complex information should be avoided in order to improve readability. The information video on the MII-BC from MII was well received, but could be made even shorter for quicker information absorption.

Privacy & Anonymity

It is crucial to provide patients with a clear understanding of how their data will be used and who will have access to it, especially with regard to genetic information. This could help to increase patients' trust in data protection.

Training of staff

Study nurses could receive regular training to ensure that they have the necessary skills to provide the information and to deal with patients' questions and concerns. Ideally, study nurses should have experience in the ED to better assess ED-related processes.

DISCUSSION

This mixed-methods study investigated the feasibility of applying the MII-BC in an ED environment. It pursued three aims: first, the study aimed to identify and descriptively explore facilitators and barriers to the implementation of MII-BC in EDs. Second, the study aimed to identify and describe the resources required to implement MII-BC in EDs, and the extent to which patients understand BC information. Third, the study aimed to derive recommendations for the implementation of MII-BC in EDs. While other studies report on the implementation of BC in inpatient settings,[10] the study at hand is the first to examine the implementation of MII-BC in the ED.

The ED setting with its specific processes and unique spatial environments appeared to have an impact on the implementation of informed consent in BC. Participant observations show that the study process was repeatedly interrupted by medical procedures such as diagnostic tests. However, the study nurses always ensured that the study could be resumed quickly after interruptions, for example, for medical treatment or diagnosis. Moreover, the ED environment is often characterised by a noisy and busy atmosphere. This limited patients' attention and affected a private atmosphere conducive to educating patients on the MII-BC. A study on obtaining BC in the inpatient setting listed similar findings regarding disruptive factors during the patient education.[10] Similarly, in the inpatient setting, factors like the mental or health status of the patient, as well as external influences, that is, routine care by nursing staff or fellow patients in the room, may influence the willingness of patients to deal with sensitive issues such as the BC.[10 32] A study on obtaining biomaterials in the hospital setting showed that patients felt influenced in their decision-making and did not want to engage in a conversation because other patients present could overhear.[33] Therefore, the physical location and environmental conditions need careful consideration to ensure adequate patient information as well as patient privacy.

Furthermore, the results of the present study show that the patient's needs should be taken into account by assessing their health situation and asking about their condition before approaching them. Information at a later point in time, for example, at discharge or at the end of treatment, could ensure that patients are less affected by their acute concerns and a sense of uncertainty before treatment. In this case, however, no further biospecimens could be collected, and the case-specific patient data could only be used with the consent of the retrospective module. This finding is in line with another study that highlights the importance of timing for information provision. Participants in another study expressed the desire to process the information at home before hospital admission.[34] This procedure, however, would have hardly been possible in the ED setting.

ED stays are sometimes associated with long waiting times.[35 36] The present study shows that waiting times in the ED can be used effectively for the MII-BC. Although obtaining BC can be partially interrupted during the stay in EDs, using waiting times effectively for other activities than waiting is possible and is positively perceived by the patients. Participant observation results of the present study indicated that patients appreciated spending their waiting time in the ED participating in the study due to distraction from pain, gratitude towards research, hoping for help for themselves or others and the belief that research is necessary. In their study on obtaining BC in the hospital setting, Barazzetti *et al*[10] observed that patients in hospital welcomed interaction with study recruiters as a means of breaking up the boredom of their hospital stay. The opportunity to talk about their condition and contribute to research as part of BC was perceived as a positive distraction from daily hospital routine.

The reasons for giving consent in MII-BC are in line with Fitzpatrick's study[37] about deferred consent in the ED and range from personal benefits and altruistic motives to a perceived benefit of research. However, it remains questionable whether it is even possible to conduct studies after discharge from the ED. In addition, bias could occur if only patients discharged from the ED were included in the study.

The present findings are consistent with other studies showing that empathetic and trusting relationships between recruiter and patients have a positive impact on handling the complexity of information and uncertainties associated with BC.[10 33] Studies also put an emphasis on the need for sufficient availability of resources such as time and opportunities for considering patient needs and conducting informed consent.[38] Besides the trust in—and presence of the study staff,[39] trained staff were found to be effective in educating information on BC and safely providing verbal information and answering questions.[10 34]

In addition, during the patient information process for the MII-BC, interactions occurred in which patients disclosed their personal medical history under the assumption that the study nurse was part of the medical team. This observation highlights the ethical implications of potential therapeutic and diagnostic misunderstandings during the informed consent process, as noted by Appelbaum,[40] who emphasised the challenges participants face in understanding how participation in a clinical trial differs from normal treatment. In addition, the prospect of personal benefits, such as medical screening, often influences participants' decisions in this consideration process. As found in a study by Nobile *et al*,[41] the expectation of personal benefits is an important motivating factor for many participants when deciding to enrol or remain in a study.

Furthermore, it is important to note that patients are often accompanied by others when attending the ED.[42] Overall, the interactions between patients and their companions show the essential role of companions in supporting patients in the consent process for studies. It is crucial to keep patients and their companions fully informed and to address their questions and concerns to ensure informed consent for study participation. Another study in the ED shows that companions can act as advocates for patients with lower levels of education and ask additional questions, which ensures patient understanding.[43] Similarly, this study demonstrated the importance of study personnel in improving patient understanding.

The majority of patients demonstrated a high level of understanding of MII-BC in the patient survey. 89.9% of n=225 patients reported understanding the patient information about MII-BC. Understanding of health information is associated with patient education level. A high rate of understanding may thus

be partly due to the study nurses and their 'translational work' in adapting information material to the individual circumstances of patients in the ED. It is important to create an environment that encourages patients to ask questions. This is evidenced by both qualitative and quantitative results that have raised questions on topics such as data protection and data storage. The qualitative study by Brown *et al*[44] about obtaining consent in emergency settings provided similar results. The study underscores the significance of the patient information process, highlighting the importance of providing reassurance and demonstrating empathy by study personnel to ensure that patients and their families fully comprehend the implications of their involvement in research. Several studies on other forms of consent have shown that overall understanding is low.[45]

The qualitative and quantitative results show that some patients, however, had difficulties in understanding the MII-BC information and had various questions and concerns about consenting to MII-BC. These need to be carefully addressed by study personnel. 8.9% (n=20) of the patients surveyed stated that they did not understand the patient information. The reasons given by these patients were that the information was too long (5.3%; n=12) or too much information was provided (4.4%; n=10). Understanding consent and study implications is a fundamental requirement for the consent itself and for conducting research ethically. Lack of understanding and awareness of data use is a barrier to data sharing.[6 10 46] The patient information process and information materials need to be easily comprehensible for patients.[47] This can be achieved by providing shorter and clearer information and using simple language.[8 48] A study on understanding BC of biobanks has shown that clear language in patient information can have a significant impact on understanding of consent forms.[20] The present findings reinforce that specific examples of the use of consented data in BC should be provided.[49] An explanation of MII-BC in plain language is already provided by the MII. This could be used in the future as part of the patient information, considering different levels of patient education and to avoid selection bias.

Limitations

The study is subject to certain limitations that must be taken into account when interpreting the results. The fact that the observations were conducted by a single observer may have led to limited attention and affected the objectivity and reliability of the data collected. In addition, the fact that participant observations were not conducted by independent staff may have introduced a bias into the observations.

This study was exploratory in nature and complemented a quantitative survey in the ED. Following the mixed-methods approach of the study, the participant observation's aim was to deepen certain aspects addressed in the survey while allowing for exploration of new emerging themes. The topics that it aimed to deepen were the overall information and consent process, assessing patients' understanding and concerns regarding the MII-BC; identifying facilitators and barriers and providing practical recommendations for implementing MII-BC in EDs. In total, we conducted n=12 participant observations, reaching theoretical saturation within our sample in the themes presented in this article's analysis. Nevertheless, the inclusion of settings (tertiary hospitals) and patients (mostly male participants) in the sample may result in limitations regarding the wider applicability of the themes presented; to validate the findings, we invite further research to engage in participant observation on the BC across a wider range of patients with the full spectrum of conditions typically encountered in EDs in urban and rural settings.

In addition, it is important to recognise that patient understanding is a subjective measure. A critical ethical consideration in asking patients for BC in an emergency setting is whether true informed consent can be achieved. Despite high reported levels of understanding of MII-BC patient information, these assessments are based on self-reporting, which may not fully capture the complexity of understanding in a high-stress environment. In the stressful and urgent environment of the ED, patients are often in severe pain, distressed or under the influence of medications that may impair their decision-making capacity. This vulnerability can lead to a critical ethical issue: the possibility that patients may feel pressured to give consent out of a sense of dependency or gratitude towards healthcare providers, rather than giving truly voluntary consent.

A potential limitation of our study could be that we did not use an independent measure to assess the quality of informed consent, such as the Brief Informed Consent Evaluation Protocol (BICEP). Although our patient questionnaire contained similar items to the ICAS (Informed Consent Aggregate Score) and TMAS (Therapeutic Misconception Aggregate Score) used in the paper by Sugarman *et al*,[50] our approach of having the same person who provided the information administer the questionnaire may have introduced bias. Future studies may benefit from using validated instruments such as BICEP or similar methods to provide a more objective and comprehensive assessment of patient understanding and the quality of informed consent.

Moreover, our study focuses on the implementation of the BC model of the MII in Germany. While this initiative provides a robust framework for the secondary use of health data and biospecimens, it is based on the General Data Protection Regulation, which is applicable across the European Union. This provides a degree of generalisability to other European countries, at least in terms of the legal foundation. However, cultural and organisational and other specific characteristics may vary between countries, potentially limiting the broader applicability of some of our findings.

The present study benefited from the range of diseases of the patients in ED, whereas other studies are largely limited to rare diseases. This might have affected the comparability of our results with other studies. Another limitation is that no information was available from patients who refused to participate in the study. This could have provided important information about the reasons for consent or refusal. In addition, a large number of ED patients may be unsuitable for the consent process, for example, if they are sedated, demented, have a traumatic brain injury, are in excessive pain, are intubated or are unable to understand the nature, significance and scope of the study. Therefore, it is not possible to carry out such a process for all ED patients, meaning that limited and potentially biased data may be available.

Despite these limitations, the mixed-method approach allowed for a robust analysis and provided valuable contextualisation to survey findings as well as in-depth understanding of the actual MII-BC process. Participant observation is an appropriate research method to understand the feasibility of implementing BC in the ED context.

CONCLUSION

Obtaining MII-BC in the ED is feasible, provided appropriate resources are available. In summary, a high level of understanding of MII-BC information is demonstrated by patients in the ED. Understanding of MII-BC information depends not only on the information material provided but also on how it is communicated by the study nurses. The study highlights the

importance of clear, understandable information materials, transparent communication and a calm environment to ensure ethical research. Additionally, resources such as trained staff, privacy measures and appropriate premises should be provided to make MII-BC collection efficient. Finally, the study shows that contextual and relational factors play a crucial role in obtaining MII-BC and can significantly influence the interaction between patients and study staff.

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Author note I used ChatGPT for English language and structure suggestions. The main reason for this was that I am not a native English speaker and the tool helped me to formulate and structure sentences in English. I did not use any of the information generated by ChatGPT in my manuscript. I wrote the content and text of my manuscript entirely by myself, based on my own knowledge and research.

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