Improving the care of severe, open fractures and post-operative infections of the lower extremities (Project EXPERT): Protocol for an interdisciplinary treatment approach

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Abstract

Background: Patients with open fractures often suffer complications in the course of their injury. The treatments incur high costs. Interdisciplinary cooperation between different medical disciplines in the EXPERT project may improve treatment outcomes. Such cooperation has not yet been envisaged in the German healthcare system.

Objective: The aim of the EXPERT project is to improve the treatment of fractures in terms of duration and sustainability with open soft tissue damage or postoperative complications in a region in north-west Germany. Largely standardized diagnostics and therapy are intended to optimize processes in hospitals. In addition, a reduction in the duration of treatment and treatment costs is to be achieved.

Methods: Using a digital platform, doctors from 31 hospitals present patient cases to an interdisciplinary group of experts from the fields of plastic surgery, infectiology, hygiene, and others. The group of experts from the environment of the University Hospital Münster promptly makes a joint treatment recommendation for the individual case. The extent to which the therapy recommendations are effective and contribute to cost reduction in the healthcare system is empirically investigated in a stepped-wedge cluster randomized design. In addition, medical and non-medical professional groups involved in EXPERT will be asked about their work in the project.

Results: The primary outcome is the complication rate of open fractures or the occurrence of postoperative complications over a period of six months. As secondary outcomes, the number of antibiotics administered, limb function, and quality of life are assessed. The health economic evaluation refers to the costs of health services and absenteeism. For the work-related evaluation, workload, work engagement, work-related resources, readiness for technology and ergonomic aspects of the new telemedical technology are collected. In addition, clinic employees give their assessments of the success of the project in a structured telephone interview based on scaled and open-ended questions.

Conclusions: Standardized treatment pathways in the standard care of patients with open fractures and postoperative infections will be established to reduce complications, improve chances of recovery and reduce costs. Unnecessary and redundant treatment steps are avoided by standardized diagnostics and therapy. The interdisciplinary treatment perspective allows for a more individualized therapy. In the medium term, outpatient or inpatient treatment centers specialized in the patient group could be set up, where the new diagnostic and therapeutic pathways could be competently applied. Clinical Trial: https://drks.de/search/de/trial/DRKS00031308

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Abstract

Background: Patients with open fractures often suffer complications during their injury. The treatments incur high costs. Interdisciplinary cooperation between different medical disciplines in the EXPERT project may improve treatment outcomes. Such cooperation has not yet been envisaged in the German healthcare system.

Objective: The aim of the EXPERT project is to improve the treatment of fractures in terms of duration and sustainability with open soft tissue damage or postoperative complications in a region in north-west Germany. Largely standardized diagnostics and therapy are intended to optimize processes in hospitals. In addition, a reduction in the duration of treatment and treatment costs is to be achieved.

Methods: Using a digital platform, doctors from 31 hospitals present patient cases to an interdisciplinary group of experts from the fields of plastic surgery, infectiology, hygiene, and others. The group of experts from the environment of the University Hospital Münster promptly makes a joint treatment recommendation for the individual case. The plan is to examine 3.300 patients with open fractures or surgical complications. As consortium partners there also are three statutory health insurance companies. The extent to which the therapy recommendations are effective and contribute to cost reduction in the healthcare system is empirically investigated in a stepped-wedge cluster randomized design. In addition, medical and non-medical professional groups involved in EXPERT will be asked about their work in the project (in total 248 clinic employees).

The primary outcome is the complication rate of open fractures or the occurrence of postoperative complications. As secondary outcomes, the number of antibiotics administered, limb function, and quality of life are assessed. The health economic evaluation refers to the costs of health services and absenteeism. For the work-related evaluation, workload, work engagement, work-related resources, readiness for technology and ergonomic aspects of the new telemedical technology are collected. In addition, clinic employees give their assessments of the success of the project in a structured telephone interview based on scaled and open-ended questions.

Results: The EXPERT project started in June 2022, data collection started in April 2023. As of mid-June, 2024, data from 425 patients have been included. 146 members of staff have taken part in the

questionnaire survey and 15 in the interviews.

Conclusions: Standardized treatment pathways in the standard care of patients with open fractures and postoperative infections will be established to reduce complications, improve chances of recovery, and reduce costs. Unnecessary and redundant treatment steps are avoided by standardized diagnostics and therapy. The interdisciplinary treatment perspective allows for a more individualized therapy. In the medium term, outpatient or inpatient treatment centers specialized in the patient group could be set up, where the new diagnostic and therapeutic pathways could be competently applied.

Keywords: open fracture, open soft tissue damage, telemedicine, plastic surgery, infectiology, limb function, health related quality of life, workload, work engagement, health economic evaluation

Introduction

Open fractures of the lower extremities are common, occurring with an incidence of about 11.5/100,000 [1]. Patients with open fractures often suffer complications in the course of the disease, such as soft tissue infections, bone inflammation, defective bone fuse, and increased tissue pressure around injury, with negative effects on blood supply and the nervous system [2, 3]. Even for highly experienced providers, it is often not possible to provide a sufficient quality of care for those disciplines, such as trauma, vascular and plastic surgery, infectiology, microbiology and hygiene [4]. However, such networked treatment has not been established in German primary and standard care, yet. Currently, many patients with complicated or incorrectly healed fractures, infections or chronically open wounds see several doctors in different hospitals combined with inpatient transfers, redundant diagnostics, and long sick leave [5, 6, 7]. In many cases, the healing process is significantly impaired, and it is not uncommon for serious restrictions to remain.
In addition to the physical and psychological consequences for those affected, there are also considerable costs in the care system [1, 8, 9]. Patients with open lower leg fractures incur almost twice as much (11,000 € = 12,000 $) as patients with closed fractures (6,600 € = 7,100 $) [5]. Open fractures with soft tissue infections lead to increased antibiotic use, additional surgeries, and longer hospital stays, which can increase costs sixfold [5, 10, 11]. Against the backdrop of demographic change [12, 13] as well as the increasing incidence of fractures due to comorbidities (e.g., osteoporosis, gait uncertainty, neurological diseases) and complications in the healing process from the age of 65 years onwards, improving treatment options for complicated fractures and reducing the complication rate are of extreme importance [14]. Main complications that are encountered in this context are pseudarthrosis and chronic osteomyelitis. Pseudarthrosis is defined as a problem in fracture healing with missing consolidation longer than 6 months after trauma. Chronic osteomyelitis is a state in which destructive changes within the bone occur due to an infectious process. Both conditions prolong the healing process and usually make several surgical procedures necessary. In some cases, even an amputation must be considered.

In the United Kingdom (UK) treatment structures have already been put in place to provide adequate and timely care to patients with these kinds of injuries. The British Orthopedic Association (BOA) and the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) introduced evidence-based standards of care for the treatment of severe, open lower leg fractures (BOAST) [15]. It has been demonstrated that an early transfer of patients to specialized trauma centers and cooperation between surgical and non-surgical disciplines significantly improve the course of treatment. Studies show a significant reduction in the infection rate, fewer additional surgeries, more successful limb reconstructions, and a reduction in treatment time [16, 17, 18, 19, 20].
Concrete guidelines for the treatment of complicated fractures with soft tissue damage thus not only

help to improve the chances of treatment and healing, but also to reduce the costs of medical care. In particular, the involvement of an interdisciplinary team is essential for high-quality and cost-effective care [21]. In a joint interdisciplinary case conference, information and expertise can be exchanged and treatment recommendations can be made based on broad expertise. This saves time, reduces redundant examinations and collisions of different treatment recommendations.

To consolidate treatment competence and ensure treatment quality, the standardization of specifications as well as diagnostic and treatment-related processes is essential. In the field of cancer therapy, interdisciplinary therapy recommendations have been established for decades within the framework of tumor boards. After intensive, interdisciplinary expert discussions, such a board makes a binding, patient-specific treatment recommendation, considering all disease-relevant aspects [22].

So far, there is nothing comparable in Germany for the treatment of trauma to the extremities. In some large centers, there are interdisciplinary structures that deal with complex treatment situations. However, there is still no established process for the regular implementation of therapy steps. To date, there is also no way to standardize postoperative complications and treat them with stringent treatment pathways. Currently, people who suffer an open fracture or, in this context, a postoperative complication are admitted to the primary care clinic and treated on a monodisciplinary basis. The healing process of complicated fractures is further complicated by the fact that there are no contact points that take over the management of further treatment when the treatment options of a clinic for primary and standard care have been exhausted.

Objectives

The aim of the EXPERT project is to improve the treatment of fractures with open soft tissue damage or postoperative complications in northwest Germany rapidly and sustainably. Reductions in the duration and costs of treatment are further aims.

To achieve this, an interdisciplinary group of medical experts with a wide range of university expertise (e.g., plastic surgery, infectiology, hygiene) will make joint treatment recommendations within the framework of video case presentations. Consortium partners are three German statutory health insurance companies (BARMER, Techniker Krankenkasse, AOK NordWest).

Physicians in standard care hospitals present their cases to the expert group (Extremity Board) via telemedicine software and receive treatment recommendations tailored to the respective patients in a timely manner. In this way, the treatment result can be improved by adapting the individual therapy at an early stage.

Based on the knowledge gained in the Extremity Boards, the interdisciplinary specialist group will define guidelines during the project to objectify decision-making paths, streamline processes and define therapy algorithms. Through the close cooperation of the expert group with hospitals of primary and standard care, a joint agreement can be reached on treatment and documentation standards that relate to both the care of acute symptoms and post-operative complication management. The introduction of a web-based software platform enables both a secure exchange of medical information across the boundaries of different professional groups and the provision of interdisciplinary expertise in rural, structurally weak regions and regions affected by a shortage of specialists.

The effects of the new form of care based on the interdisciplinary approach and the associated standardization of diagnostics and therapy will be scientifically evaluated. Patient-related clinical success criteria as well as economic outcomes will be collected. Since the new form of care has both content-related and organizational effects on the work in the clinics, work-related aspects will also be examined.

Research questions and hypotheses

Clinical and Health Economic Hypotheses

It is assumed that efficient telemedical access to an interdisciplinary expert forum (Extremity Board) with simultaneous therapy decisions in the treatment of fractures with open soft tissue damage and postoperative complications will achieve significant reductions in the length of inpatient stay, the total duration of treatment and the complication and re-operation rate [23]. The measures optimize therapy pathways, standardize them, and make them more cost-effective. The establishment of Extremity Boards leads to higher guideline adherence, standardization, documentation quality and consequently to reduced antibiotic consumption and to a reduction in unnecessary diagnostics.

Work-related Hypotheses

For the ergonomic evaluation of the EXPERT project, the Job-Demands-Resources-Model (JDR model) [24, 25, 26] on the influence of work resources and work requirements on work behavior will be used. In this theoretical model, which is backed up by a wide range of findings [27, 28, 29], work resources and work requirements are considered to be independent factors influencing work engagement and perceived stress from work. High cognitive, emotional, and physical demands such as time pressure, workload, complexity of tasks, emotional stress, etc. lead to high demands, which has long-term negative consequences for employees and the company (e.g., employee burnout, low job satisfaction, low productivity, etc. [30].

On the other hand, work resources such as social support, feedback, autonomy, meaningfulness, etc., have a motivating effect because they satisfy basic needs for self-efficacy, attachment, security, and control (cf. Grawe [31, 32]). Diverse work resources therefore lead to more work engagement, which has positive consequences for employees and the company (e.g., high job satisfaction, high productivity, etc.; [30]).

The JDR model also postulates that work requirements and work resources interact with each other, which affects the perception of stress and motivation. Thus, the availability of resources can mitigate the negative impact of the requirements. Resources seem to have a positive effect on motivation and work engagement, especially when work demands are high [33]. When work demands are high, employees increasingly perceive existing resources as helpful and useful, which helps them to cope with the demands. This results in a subjectively lower burden (coping hypothesis [34, 35]).

Based on the theoretical assumptions and empirical findings, the following hypotheses can be derived for the EXPERT project (cf. figure 1):

1. Hypothesis 1a: Work requirements and workload increase in the intervention phase of the EXPERT project.
   Hypothesis 1b: Work related resources like knowledge, competencies, and team support increase during the intervention phase.
   Hypothesis 1c: The technical competence of employees increases during the intervention phase.

Above- or below-average resources are recorded with the median of differences (pre-post estimates of resources) leading to another hypothesis:

2. Hypothesis 2: Above-average resources are associated with lower workload, below-average resources are associated with higher workload.
3. Hypothesis 3a: Above-average resources are associated with higher work engagement.
   Hypothesis 3b: When resources increase, work engagement increases.
4. Hypothesis 4a: If resources increase (exclusion of technical competence as a resource), then readiness for technology increases while the burden decreases.
5. Hypothesis 5a: As technical competence (resource) increases, the burden decreases.
   Hypothesis 5b: When technical competence (resource) decreases, the burden increases.

6. Hypothesis 6: Above-average work engagement leads to higher readiness for technology and below-average work engagement leads to lower readiness.

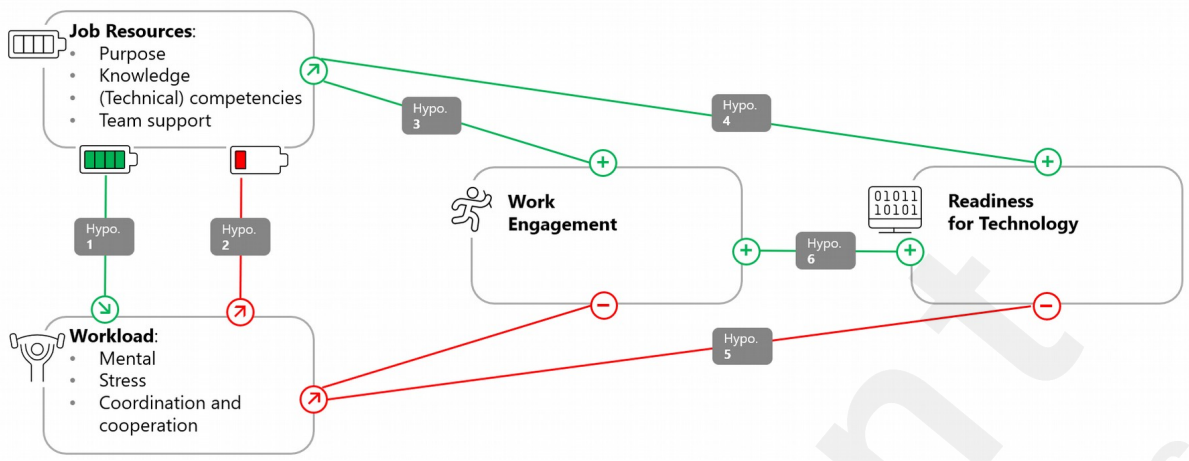

Figure 1: Overview of work-related hypotheses concerning the relationship of job resources, workload, work engagement, and readiness for technology.

Methods

Study Design

Clinical and Health Economic Evaluation

For the organization and evaluation of the new form of care, a stepped-wedge design was chosen [36, 37]. In a stepped wedge design, there are different clusters that start recruitment at the same time in the control phase. The individual clusters then move gradually into the intervention phase in randomized cohorts. In the EXPERT project, there is a transition phase between the control and intervention periods, which serves to implement and test the new form of care in the individual clinics as well as to train the staff.
Randomization in the EXPERT project will take place at the hospital level. There are 31 hospitals participating in the study. Each clinic forms a cluster that belongs to one of four cohorts. The clusters within a cohort always enter the next study phase (transition or intervention phase) at the same time. The study will be conducted over a period of 24 months (18 months recruitment period + 6 months follow-up of the last enrolled person). Data collection regarding the individual course of treatment takes place from the time of enrollment in the patient sample until six months later. Figure 2 shows the planned course of the study in the stepped-wedge design.

18-month recruitment period

Month	**1-3**	**4-6**	**7-9**	**10-12**	**13-15**	**16-18**
Cohort 1 *8 Clusters*	**Control phase**	**Transition phase**	**Intervention phase**			
Cohort 2 *8 Clusters*	**Control phase**		**Transition phase**	**Intervention phase**		
Cohort 3 *7 Clusters*	**Control phase**			**Transition phase**	**Intervention phase**	

Cohort 4 *8 Clusters*	Control phase	Transition phase	Intervention phase

Figure 2: Representation of the stepped-wedge design in the EXPERT project

Work-related Evaluation

For ergonomic evaluation, the "difference-in-difference" method is used within the stepped-wedge design [38]. This methodological approach includes a treatment group and a control group, each of which is examined at two measurement points (t0 and t1). In the treatment group, an intervention takes place between the measurement points, but not in the control group. The first difference that is measured refers to a possible change from measurement time t0 to measurement time t1. This is calculated for both the treatment and control groups. The second difference is the difference between these two differences, (i.e., the difference within the control group is subtracted from the difference within the treatment group). The result can be interpreted as a causal effect of an intervention [38, 39].
In the EXPERT project, the clinics that have not yet implemented the project measures serve as a control group, which will be evaluated at the same time as the clinics that are already implementing the new measures. Cohorts 1 and 2 are the treatment group, while cohorts 3 and 4 act as the control group.

Data Sampling

Clinical and Health Economic Evaluation

Studies show that in about 40% of cases, complications occur during treatment in open fractures [40]. The new form of care is realistically intended to reduce the complication rate to 30%. A type 1 error (alpha) of 5%, a type 2 error (beta) of 20% (power 80%) and an intra-class correlation coefficient of $\rho = 0.05$ are assumed [36]. Considering the transition phase and a dropout of 20%, the total number of cases required to demonstrate a treatment effect is N = 3,366 patients (of which 1,377 are in the control phase, 1,428 in the intervention phase and 561 in the transition phase). This equates to 17 patients per hospital per three-month interval.

Only patients who can give consent and who have statutory health insurance will be included in the project and will give their written consent to participate and share their data in the use of telemedicine. The study will include patients with fractures of the extremities with open soft tissue damage (according to Gustilo-Anderson, [41]) and/or with postoperative complications (according to the criteria of the AO Anti-Infection Task Force) or people with unplanned re-surgery within six months of initial surgery. Specifically, these are the ICD-10 diagnoses [42] related to open soft tissue damage in fractures or dislocations, amputations of the lower extremity, infections of joints and/or joint endoprostheses of the lower extremities [43], as well as pseudarthrosis and delayed fracture healing of the lower extremity (see list in table 1).

Table 1: ICD10 diagnoses to be included in the EXPERT study

ICD10 Code	Description of diagnosis
S71.87	Grade I soft tissue damage due to open fracture or dislocation of hip and thigh
S71.88	Grade II soft tissue damage due to open fracture or dislocation of hip and thigh
S71.89	Grade III soft tissue damage in open fracture or dislocation of hip

	and thigh
S81.87	Grade I soft tissue damage due to open fracture or dislocation of lower leg
S81.88	Grade II soft tissue damage due to open fracture or dislocation of lower leg
S91.88	Grade II soft tissue injury due to open fracture or dislocation of foot
S78	Traumatic amputation of hip and thigh
S88	Traumatic amputation of lower leg
S98	Traumatic amputation of upper ankle and foot
T84.6	Infection and inflammatory reaction due to internal osteosynthesis device [any localization]
T84.7	Infection and inflammatory reaction from other orthopaedic endoprostheses, implants or grafts

Patients who are not capable of giving consent, who do not give their consent to participate or to data transfer, or who do not have statutory health insurance will be excluded from the study. Also excluded are persons to whom the above ICD-10 diagnoses do not apply, i.e., who do not have a fracture of the extremities or extremities or have a closed fracture of the extremities without open soft tissue damage and who do not experience a postoperative complication within six months of initial surgery. The inclusion and exclusion criteria are summarized in table 2.

Table 2: Inclusion and exclusion criteria.

Inclusion Criteria	**Exclusion criteria**
	Formal criteria
Consent to study participation and data transfer	Lack of consent to study participation and data transfer
Legal capacity to consent to study participation	Unclear legal capacity / capacity to consent
Statutory health insurance	Not covered by statutory health insurance
	Clinical Criteria
Patients who meet at least one of the following two criteria:	*Patients who meet both of the following criteria:*
Fractures of the extremities with open soft tissue damage (according to Gustilo-Anderson)	No fracture of the extremities or closed fracture of the extremities without open soft tissue damage
OR	AND
postoperative complications (according to the criteria of the AO Anti-Infection Task Force) or unplanned re-operation within 6 months of initial surgery	No postoperative complication or unplanned re-operation within 6 months after initial surgery

These criteria are operationalized via the ICD-10 codes for: - Open soft tissue damage in fractures or dislocations, as well as amputations of the lower extremity - Infections of the lower extremity (excluding joints and joint arthroplasty): - Infections of joints and/or joint endoprostheses of the lower extremities: - Pseudarthrosis and delayed fracture healing of the lower extremity	

Work-related Evaluation

Doctors and nurses, who are or will be involved with the project, take part in the work-related evaluation. With medium to small effect sizes (Eta^2 >0.05 and <0.15), a type 1 error (alpha) of 5% and a type 2 error (beta) of 20% (power 80%), a minimum number of 120 people per measurement point is required for the work- and project-related evaluation, 60 people each in the control and treatment groups. Four employees per clinic at measurement time t0 and four employees at measurement time t1 are included in the sample. This results in 31 x 8 = 248 elevations. Care is taken to interview doctors and nurses in equal parts, all of whom are or will be involved in the project measures.

Regarding the interviews for the assessment of the objectives and project implementation, two persons from the nursing service and two persons from the medical profession are to be interviewed at time t1 in the clinics that are already implementing the new form of care. A total of about 72 people from at least 18 clinics take part in the interviews.

Ethics Approval

Ethical approval has been granted by the Ethics Committee of the Medical Chamber Westphalia-Lippe under the number 2023-067-f-S. This study is conducted per the tenets of the Declaration of Helsinki. All data have been collected, anonymized, analyzed, and stored in accordance with German General Data Protection Regulation legislation (DSGVO) based on the European General Data Protection Regulation. The accordance to these data protection standards is approved and enforced by OFFIS - Institute for Information Technology, an institute related to the University of Oldenburg specializing on research services and data protection.

Participation is voluntary and participants are required to provide oral and written consent to participate before entering the study. All participants received oral and written information before signing a consent form upon enrollment in the trial, and no financial compensation was made to participants in the study. The protocol was registered with the German Clinical Study Register database (DRKS00031308; online available at: https://drks.de/search/de/trial/DRKS00031308).

The clinical study is funded by the Innovation Fund of the Gemeinsamer Bundesausschuss (Joint Federal Committee, G-BA) under the number 01NVF21020 EXPERT. This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Outcomes and Measures

Clinical and Health Economic Evaluation

The primary outcome and various secondary clinical outcomes are recorded based on data from the clinical case file as well as routine data from the health insurance companies.
The primary clinical outcome is the complication rate of open fractures, or the occurrence of postoperative complications, which is collectively defined as a dichotomous outcome. Either the occurrence or non-occurrence of complications is observed. The following events are complications if they occur within six months of enrollment in the sample:

- Occurrence of pseudarthrosis (incomplete fracture healing; ICD10 M96.0)
- Occurrence of chronic osteomyelitis (ICD10 M86.69)
- Unplanned follow-up procedures such as wound revisions, NPWT, etc. (ICD10 S81.801)
- Deviation from standardized antibiotic therapy (extension of the duration of therapy, change or expansion of the active substance; ICD T36.95),
- Occurrence of antibiotic-associated complications (e.g., clostridia infection, allergy, etc.; ICD10 B96.7)
- Infection with resistant germs (e.g., MRSA) that occurred during inpatient treatment and did not exist at the time of trauma (ICD10 A49.02)
- Need for unplanned inpatient treatment
- Death of the patient related to the trauma (not due to other causes)

Secondary clinical outcomes include the number of antibiotics administered, limb function, and health-related quality of life (HRQoL [44, 45]).
Health economic outcomes are mapped by claims data from health insurance companies. These will be recorded for each patient included in the project up to six months after enrollment in the sample. Specifically, these are the following features: Use of health services (e.g., contacts with doctors and therapists, operations, inpatient stays)

- Costs of health care services (inpatient hospital costs, outpatient costs, rehabilitation costs, medical and medical aid costs, drug costs, total costs)
- Number of days on which there is incapacity for work
- Number of days on which sickness benefits are received

Table 3 gives an overview of the clinical and health economic outcomes used in this study.

Table 3: Clinical and health economic outcomes

Outcome	Data source	Measurement times
Primary Outcome		
Complication rate, defined as the occurrence of at least one of the following events within six months of	Clinical and claims data	6 months

trauma [42]:		
Occurrence of pseudarthrosis (incomplete fracture healing)	Clinical data	6 months
Occurrence of chronic osteomyelitis	Clinical data	6 months
Unplanned follow-up procedures such as wound revisions, NPWT, etc..	Clinical and claims data	6 months
Deviation from standardized antibiotic therapy (extension of the duration of therapy, change or expansion of the active substance),	Clinical and claims data	6 months
Occurrence of antibiotic-associated complications (e.g., clostridia infection, allergy, etc.)	Clinical and claims data	6 months
Infection with resistant germs (e.g., MRSA) that occurred during inpatient treatment and did not exist at the time of trauma [43]	Clinical data	6 months
Need for unplanned inpatient treatment	Clinical and claims data	6 months
Death of the patient related to the trauma (not due to other causes)	Clinical and claims data	6 months
Secondary Clinical Outcomes		
Number of antibiotics administered	Clinical and claims data	6 months
Limb function	Clinical data	6 months
HRQoL Measured using VR-36 [44) and EQ-5D [45,46]	Clinical data	0 and 6 months
Health Economic Outcomes		
Use of health care services	claims data	6 months
Costs of health care services	claims data	6 months
Days of incapacity to work	claims data	6 months
Sickness benefit days	claims data	6 months

Patients' health-related quality of life is assessed at the time of enrollment and six months later using two internationally used measuring instruments:

- the German-language version of the royalty-free Veterans RAND 36 Item Health Survey (VR-36) [44], and
- the German-language version of the EQ-5D of the EuroQol Group [45, 46]

The VR-36 is a generic profile questionnaire and measures health-related quality of life regarding the dimensions "Physical Functioning", "Role-Physical", "Role-Emotional", "General Health", "Social Functioning", "Vitality", “Bodily Pain” and "Mental Health".

The EQ-5D as a generic index instrument contains the five dimensions "Mobility", "Self-care", "Usual activities", "Pain/Discomfort" and "Anxiety/depression" as well as a visual analogue scale. The results of the EQ-5D can be used to create a health profile as well as to calculate an index value [46]. As an instrument validated in Germany, the index for health-related quality of

life recorded by the EQ-5D is particularly well suited as a health economic outcome measure [46].

Work-related Evaluation

Questionnaires: Building on experiences and results from previous ergonomics studies in the fields of medical care as well as outpatient and inpatient care [47, 48, 49] and using the JDR model as a theoretical frame of reference, work-related evaluation uses validated measurement tools that measure workload, work engagement, work-related resources, and technical readiness. Since the new form of care in the EXPERT project requires a competent application of telemedical technology, ergonomic aspects of the new telemedicine application are also recorded. The seven items for the usability of the telemedicine application are only given to the treatment group at the second measurement time. Therefore, the EXPERT questionnaire comprises four instruments with 31 items (without ergonomic aspects) and five instruments with 38 items (with ergonomic aspects), receptively. Empirical comparative values are available for all measuring instruments used.

Workload is measured using the NASA Task Load Index (NASA-TLX) [50] in a version for teamwork [51, 52]. For this study an abridged version of this questionnaire with eight items in the German translation is used. On a scale of 1 to 10 (1 = very low, 10 = very high), employees estimate the mental, time and performance-related work requirements, as well as the effort for exchange, organization of work, team effectiveness, and mutual support for the past three months, and give an assessment of their satisfaction with the cooperation. For example, a formulation is "How much effort was required to organize the work (e.g., coordination of who takes on which task, when which task is completed)?".

Work engagement is measured using the ultra-short form of the Utrecht Work Engagement Scale, which contains three items (UWES-3 [53]). The German translations "At work I am full of energy", "I am enthusiastic about my work" and "I am completely absorbed in my work" are used, which are rated on a scale from 0 to 6 (0 = never, 6 = always).

Work resources are recorded using the German-language questionnaire on resources and requirements in the world of work (ReA, [54]). For the EXPERT project, 11 items are used, which relate to the resources "Leadership Support", "Feedback", "Peer-Support", "Transparency", "Diversity", "Meaningfulness", "Role Clarity", "Learning Opportunity", "Knowledge Management", "Team Atmosphere" and "Qualification". All items are formulated as statements, e.g. "I will be informed about all important content when implementing the new measures." (resource "transparency"), which are rated on a scale of 1 to 6 (1 = not at all true, 6 = completely true).

Affinity for technology is measured using the German-language short scale for measuring readiness for technology (TB [55]). It is a questionnaire with 12 items in the three scales "TB acceptance", "TB control belief" and "TB competence", of which nine items are used in this study. The item formulations have been adapted to the EXPERT project, e.g. "I am very interested in the new telemedicine application" (TB acceptance), "It essentially depends on me whether I am successful in using the new telemedicine application." (TB control conviction) and "For me, dealing with technical innovations is usually too much to handle." (TB competence).

The software ergonomics of the new telemedicine application are assessed using the German-language questionnaire ISONORM 9241/10 [56, 57]. Based on this instrument, software is evaluated regarding “adaptivity to requirements”, "comprehensibility”, “task appropriateness", "ability to describe itself", "fault tolerance", "individualizable" and "learning conduciveness". The assessments of the seven items are made on a bipolar scale based on symbols (from “- - - “to “+++”).

Finally, employees provide information about their profession (doctor/nurse), whether they hold a management position (yes/no) and whether they already had experience in the use of telemedicine before the EXPERT project (yes/no).

Interviews: The structured telephone interview on the implementation of the project contains both predetermined and open-ended questions, the content of which is based on the planned course of the EXPERT project. For each of the four project phases "Preparation", "Development of new standards", "Cooperation with the Extremity Board" and "Implementation of therapy recommendations", 3 to 5 items were designed in the form of statements, which are assessed by the interviewees based on a 10-point scale. For example, one item regarding the project phase "Preparation" is: "All employees involved in the project were able to obtain sufficient information about the new work steps and tasks, e.g., through training. (1= not true at all, 10= completely true)." An example for the project phase "Collaboration with the Extremity Board" is: "The case presentations in the Extremity Board are helpful for the planning of treatments.".
The open questions of the interview relate to aspects that the interviewees consider to be particularly important for the transfer of the project measures into standard care. The questioning technique used here is a simplified modification of the Repertory Grid technique [58, 59]. Two open-ended questions refer to sequencing of steps within the project: 1. preparation phase, 2. development of new standards, 3. cooperation with the Extremity Board, and 4. implementation of the therapy recommendations. The subjects are asked to describe what they like or dislike within project steps. For the most likeable and the most undesirable aspects the subjects are asked how important these aspects are for the future implementation of an Extremity Board (1 = not important at all, 10 = very important). This results in eight aspects per interview that are relevant for the long-term implementation of the Extremity Board from the point of view of the hospital staff.

Data Analysis

Clinical and Health Economic Evaluation

The eligible patients are enrolled in the project by trained staff. Patients are informed about the objectives and course of the project and give their written consent to participate. Each case is summarized with all relevant information (e.g., anamnesis, findings, imaging) in a clinical case file using data-secure web-based software. The case files are checked for completeness and, after approval, transmitted digitally to the interdisciplinary expert group, the Extremity Board. This group of experts is recruited from the following disciplines: Trauma Surgery, Plastic Surgery, Vascular Surgery, Radiology, Angiology and Antibiotic Stewardship ABS (Microbiology/Hygiene/Infectiology/Pharmacy [43]. The experts meet at least weekly via web conference and, depending on the urgency, discuss the cases together. Agreed interdisciplinary therapy recommendations are written and transmitted back to the presenting clinic via the web-based software platform. In addition, guidelines will be defined in the course of the project on the basis of the findings gained by the Board in order to objectify decision-making paths, streamline processes, define therapy algorithms and enable the supra-regional applicability of these standards.
The clinical case files of all patients included in the EXPERT project will be merged with the respective patient-related health insurance data in an anonymized data file for each case, while maintaining data protection. Claims data from health insurance companies provide information about the use of health services and the costs that arise in doing so. To obtain information about the individual course of treatment after the introduction of the new form of care, claims data for the following six months are included in the evaluation for each patient from the time of enrollment in the sample. The clinical case file and the associated health insurance data thus depict the course of treatment of a patient, which is included in the evaluation.
To be able to evaluate the extent to which the new care measures improve the chances of recovery and reduce costs, various clinical and economic outcomes are collected.

First, the primary outcome of the complication rate as well as the secondary and health economic outcomes are evaluated descriptively using absolute and relative frequency distributions as well as position and scattering measures (e.g. median, variances, standard deviation; Representation by means of box plots or histograms). The differences between patients in the control and intervention phases are checked by appropriate statistical methods (e.g., Mann-Whitney U test [60, 61], Chi-Square test or odds ratio[62]). In addition, individual subgroups (e.g., by gender, age) are analyzed in order to check the data for possible biases.

This descriptive analysis is followed by interference statistical analyses. By means of suitable regression analyses (e.g., using generalized, linear regression models), it can be examined which regressors have an influence on the primary and secondary outcomes. In addition to the consideration of temporal and intervention-related effects, the influence of potential confounders is also controlled. This is because various patient- and trauma-associated factors are relevant risk factors for the development of a complication in the treatment of open fractures. For example, male gender, age >60 years, BMI > 40, use of non-steroidal anti-inflammatory drugs, diabetes mellitus and nicotine consumption are positively correlated with the development of an infection or fracture healing disorder [63] This also applies to fractures in the context of multiple injuries (polytrauma) or in the context of agricultural accidents [64, 65]. The quality of the statistical models is tested with the help of a residual analysis. Sensitivity analyses are carried out to check the stability of the evaluation and the assumptions made, for instance, the effects of changed influencing variables on the result.

As part of the health economic evaluation, the use as well as the costs of health services and absences from work are considered. For this purpose, a cost-effectiveness analysis is carried out, whereby the incremental cost-effectiveness ratio (ICER) will be calculated. The evaluation of routine statutory health insurance data is carried out according to the principles of good secondary data analysis [66], the recommendations of the Memorandum "Methods for Health Services Research" [67] and the standards of the German Society for Evaluation [68]. The data basis for the evaluation is formed by the statutory health insurance routine data, the data from the case file, as well as the collected data on the health economic quality of life.

Work-related Evaluation

The original item scaling of all four resp. five surveys was retained, and all items compiled into one questionnaire. Four versions of this questionnaire were created, which are identical in content, but have been - with relation to the instruction -slightly adapted to the group (treatment group vs. control group) and the time of measurement (before vs. after the implementation of the new measures). For example, the instruction before treatment reads ”Dear participant, …the clinic where you work … will soon start implementing the new measures” (treatment group)/… “will start implementing the new measures in the foreseeable future” (control group), whereas the instruction in the treatment group after implementing the new measures is “Dear participant, … the clinic where you work … is already implementing the new measures.” The questionnaire was implemented and postcards with a brief explanation and a QR code with link to each specific questionnaire versions were prepared. Interview guidelines and protocol sheets for the semi-structured interview were created and several fact sheets were written to inform the employees about the interrogation and data protection aspects.

In the practical implementation of ergonomic data collection, the project staff at Steinbeis University are supported by project staff from Muenster University Hospital (Universitätsklinikum Münster, UKM). Project staff from the UKM have contact with the clinics and recruit people there to take part in the questionnaire surveys and interviews.

Before the clinics of cohort 1 start implementing the new form of care in project month 7 (see Figure 1), both clinic staff of cohort 1 (treatment group A) and clinic staff of cohort 3 (control group A) will be examined with the EXPERT questionnaire in project months 4-5 (measurement time Pre A). In project months 12 -13, clinic staff from both cohorts will repeat the questionnaire (measurement time Post A). The same procedure will be followed for Cohort 2 (treatment group B) and Cohort 4

(control group B) three months and nine months later, respectively. Project staff from the UKM recruit enough people in the individual clinics for the surveys. Interested employees in the clinics who are or will be involved in the project can find out more about the survey in advance by means of an information text. The UKM project staff receive a questionnaire link as a QR code from the Steinbeis project staff for the respective measurement times, tailored to the respective group and cohort, and send this QR code to a contact person in the clinics. The contact persons pass on the QR code to the participants, who scan it on their mobile phone and answer the questions. Participants are requested to do so as soon as possible after receiving the link. The completed questionnaires are automatically stored anonymously on the Steinbeis University server and later evaluated in summary form.

The UKM staff draw attention to the project-related interviews in the clinics that are already implementing measures. Interested employees can find out more about the interviews by means of an information text and can contact the Steinbeis project staff to make an appointment for the telephone interview. They then receive an e-mail from Steinbeis with the confirmation of the appointment, the interview questions and the (renewed) promise that their e-mail address and telephone number will be deleted after completion of the project. The transcripts of the telephone interviews are anonymized by a code. The content collected in the interviews will be evaluated in summary, quantitatively and qualitatively.

Regarding the topics of workload, work engagement, work-related resources and readiness for technology, the main effects, and interactions of measurement time (before vs. after start of the Extremity board) and group of measures (treatment vs. control) are examined by variance analysis; the result is a 2x2 design with the factors time (before vs. after) and group (treatment vs. control group).

Ergonomic aspects of telemedicine technology are collected and descriptively evaluated at the second measurement point in about half of the clinics.

Since staff turnover in hospitals is high, it can be assumed that the groups of employees will be composed differently at the time of measurement. Therefore, no repeated measure design can be applied. The analyses will be performed as balanced grouping factors with the same number of subjects in all conditions (Pre vs. Post, and Treatment vs. Control). The measurements are considered as a grouping factor of a multiple analysis of variance (MANOVA).

The evaluation of the Repertory Grids yields two-dimensional representations of the negative and positive constructs mentioned by the interviewees during the interviews with respect to the different implementation steps namely preparation, development of new standards, interdisciplinary collaboration, and therapy implementation.

The combination of a questionnaire that can be used quickly and easily on a mobile phone and a telephone interview with both predetermined, scaled questions and open-ended evaluations according to the repertory grid technique results in a comprehensive picture of changes in pre-post working conditions and of the success factors accompanying the process, both in quantitative and qualitative terms. On the one hand, the online questionnaire before (Pre) and after the introduction (Post) of the new form of care quantitatively captures influences on workload, work engagement, work-related resources and readiness for technology and backs them up by the "difference-in-difference" design. On the other hand, central success factors regarding project implementation will be collected both quantitatively and qualitatively and made visible by means of the repertory grid technology as "mental maps" of the employees in the 31 participating clinics.

Results

The EXPERT project started in June 2022 with the necessary preparations and agreements between all partners involved. Data collection regarding patient data started in April 2023. As os June 13th,

2024, data from 425 patients have been included. The online survey of clinic employees began in July 2023, and the interviews started in February 2024. So far, 146 people have taken part in the questionnaire survey and 15 people in the interviews.

Discussion

Principal Findings

The aim of the EXPERT project is to improve the treatment of fractures with open soft tissue damage or postoperative complications rapidly and sustainably. To perform optimized multi-faceted treatment, we consider the following disciplines an essential part of the interdisciplinary team: trauma surgeons, vascular surgeons, plastic surgeons, ID specialists, radiologists, pharmacologists, hygienists, and microbiologists. We think an interdisciplinary board needs several disciplines to not only enable a complete interdisciplinary treatment approach but also to develop interdisciplinary treatment algorithms for infections or provide interdisciplinary prophylaxis in musculoskeletal surgery.
In addition to the evaluation of the clinical outcome, the cost-reduction and cost-effectiveness of the new intervention will be evaluated based on claims data provided by three major statutory health insurance funds. The focus will be on utilization of health services and their costs as well as the duration of incapacity for work and health-related quality-of-life.
Furthermore, a process evaluation will explore the impact on workload, job satisfaction and technology acceptance along the implementation phase and individual onboarding processes of the caretakers.

Comparison to Prior Work

The establishment of standardized treatment pathways in the standard care of patients with open fractures and postoperative infections may increase the chances of recovery for those affected and reduce costs. The previous heterogeneity of treatment methods, which is not expedient, can be reduced. Through largely standardized diagnostics and therapy, processes in the clinics can be optimized and service processes standardized. Unnecessary and redundant diagnostics and treatment steps may be avoided. At the same time, the interdisciplinary treatment perspective allows for a more individualized therapy. The study aims to show that this results in a reduction in direct treatment costs and length of stay in hospital as well as a reduction in secondary costs (e.g., due to long sick leave after discharge, revisiting practitioners, etc.). This is also in line with prior research findings.
Interdisciplinary support shortens hospital stays and reduces treatment costs, and standardized treatment pathways optimize clinic processes and reduce unnecessary steps [69]. Fractures impact function, quality of life, and psychological well-being. Interdisciplinary support can shorten hospital stays and reduce costs [70]. Patient-tailored treatment and multidisciplinary support shortens hospital stays, and an interdisciplinary approach reduces treatment costs [71]. Multidisciplinary approach and early diagnosis crucial for treatment success. Especially, an interdisciplinary approach reduces treatment costs for fracture-related infections and shortens hospital stays [72]. The importance of multidisciplinary collaboration for effective care for patient with hip fractures has been emphasized – resulting in shorter hospital stays and reduced costs [73].

Strengths and Limitations

When measuring the quality of treatment in trauma surgery, several influencing factors must be considered. The type of injury, the extent of anatomic reconstruction during surgery, soft-tissue management, perioperative management, and rehabilitation protocols as well as patient compliance

have a major influence on the outcome and make evaluation difficult. For our study, we chose four outcome measures: the complication rate after initial surgery (non-union, infection, unplanned surgical revision, need for prolonged antibiotic therapy), the number of applied antibiotics, the functionality of the injured limb, and health-related quality of life.
The clinical outcome is examined using a stepped wedge design, which allows for the statistical consideration of time effects. The design also has practical advantages, such as the easy implementation of a staggered roll-out. Among the weaknesses of a stepped-wedge design are time-sensitive recruitment efforts, complex randomization requirements when assigning hospitals to different cohorts or wedges, the assumption of high treatment schedule fidelity and effects of the observation (so called Hawthorne effect) [74].
We choose a difference-in-difference design, a widely used quasi-experimental design in clinical research, to evaluate work-related outcomes. This design eliminates confounding by comparing outcomes before and after treatment. However, the design relies on a parallel slopes assumption, which is hard to manage and may not always apply [75].

Conclusions

The interdisciplinary, cross-disciplinary, and cross-departmental coordination of service providers enables comprehensive interface management in the clinics. The perspective of service providers can increasingly focus on holistic, patient-oriented coordination of management processes, which provides patients with the best possible access to individualized therapy in a timely manner. In addition to health economic advantages, the multidisciplinary treatment is expected to improve the quality of the therapy, which is to be proven by clinical follow-up. In addition, it is conceivable to establish specialized outpatient or inpatient treatment centers for patients with open fractures and postoperative infections, in which the new diagnostic and therapeutic pathways are competently applied.

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Conflicts of Interest

The authors declare no conflict of interest.

Authors' Contribution

SR: Acquisiton, concept, writing, interpretation, review
ML: Management, data curation, interpretation, review
JH: Acquisiton, concept, writing, analysis, interpretation, review
SR: Concept, writing, analysis, interpretation, review
JG: Acquisiton, management, concept, writing, analysis, interpretation, review
WG: Acquisiton, concept, review
TH: Concept, interpretation, review
SW: Concept, interpretation, review
MR: Acquisiton, concept, review

Abbreviations

EXPERT: Extremitätenboards zur Prozessoptimierung, Evaluation, Risikominimierung und Therapieoptimierung bei Frakturen mit Weichteilschäden oder post-operativer Infektion der unteren Extremitäten im Traumanetzwerk (Extremity boards for process optimisation, evaluation, risk minimisation and therapy optimisation for fractures with soft tissue damage or post-operative infection of the lower extremities in the trauma network; acronym of the project)

EQ-5D: During 1987–1991 a European inter-disciplinary five-country group developed the EuroQol instrument, a five-dimensional three-level generic instrument termed the 'EQ-5D' measuring health status

ICD-10: 10th version of the International Statistical Classification of Diseases and Related Health Problems

MRSA: Methicillin-resistant Staphylococcus aureus bacteria

NASA: National Aeronautics and Space Administration, USA

NASA TLX: NASA Task Load Index (standardized method to measure workload)

ReA: Ressourcen und Anforderungen (ReA) in der Arbeitswelt (questionnaire on resources and requirements in the working world; part of the work-related online survey)

TB: Technikbereitschaft (scale on technical readiness; part of the work-related online survey)

VR-36: Veterans Rand-36 (36-item evaluation developed from the RAND 36-Item Health Survey for research with veterans)

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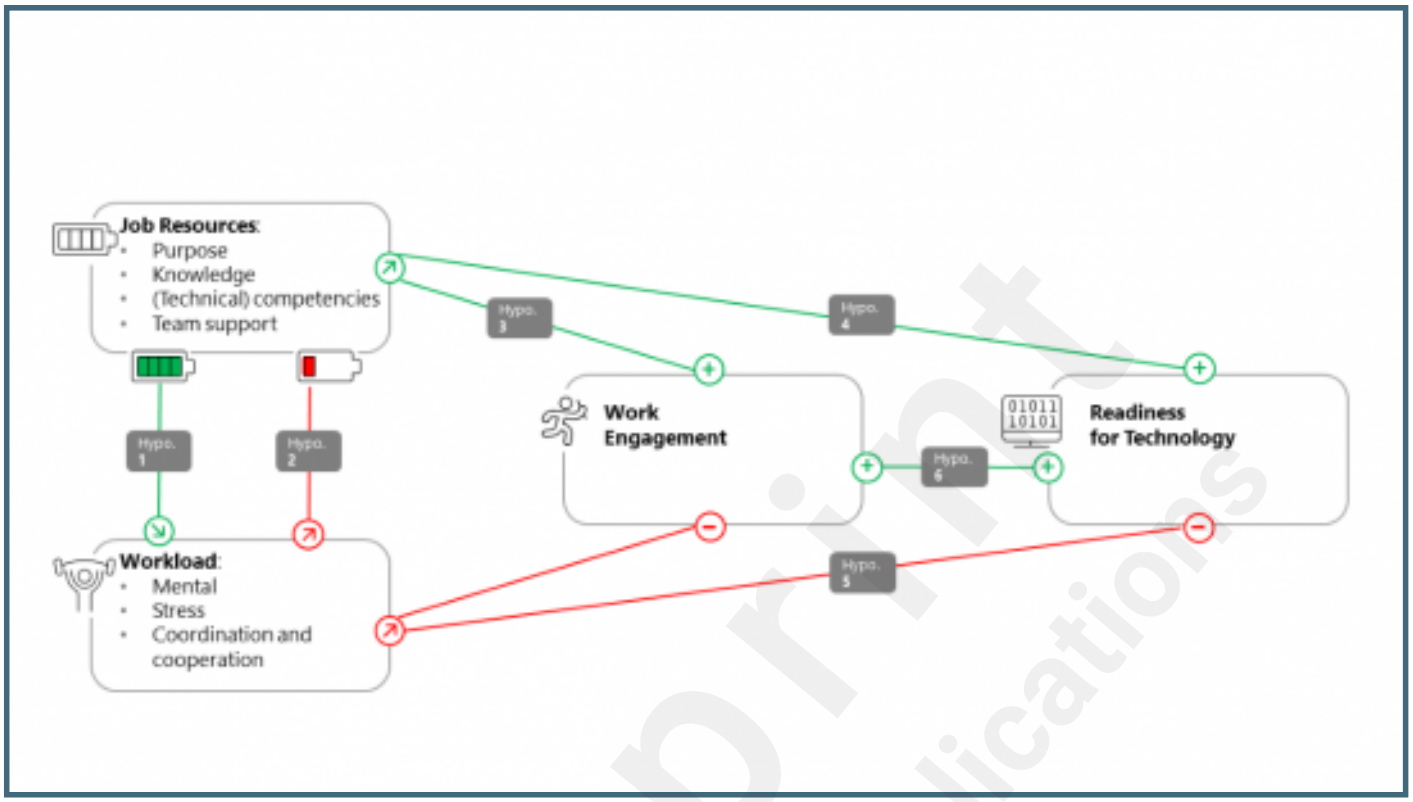
Supplementary Files

Evaluation of EXPERT project proposal by funding authority.
URL: http://asset.jmir.pub/assets/c23f0c62ddee1c40aed80338ddaf4737.docx

Figures

Overview of work-related hypotheses concerning the relationship of job resources, workload, work engagement, and readiness for technology.



Multimedia Appendixes

Evaluation of the EXPERT project proposal by the funding authority (Joint Federal Committee / DLR).
URL: http://asset.jmir.pub/assets/e86b74d86d43acf5adb93ea4c780cd16.pdf

TOC/Feature image for homepages

Virtual Board Meeting of Interdisciplinary EXPERT Board.