Transsektorale Optimierung der Patienten-sicherheit

Information for patients on participation in the project "Trans-sectoral optimisation of patient safety" (TOP)

Dear Patient,
We would like to provide you with this information for patients about the TOP project, which aims to improve the safety of medication therapy during a hospital stay and avoid adverse drug reactions, and encourage you to participate in the project.

What is the aim of the project?
When you are admitted to hospital there is often insufficient information available about your current medication and your medical history. In addition, hospital pharmacists rarely support the treating physicians in the treatment of patients in hospitals.
In the TOP project everyone works closely together to identify medication errors and avoid adverse drug reactions. With the help of specially developed software, hospital pharmacists check your medication and regularly exchange information for optimal medication therapy with your hospital doctors. In particular, patients who suffer from several illnesses and are taking several medications at the same time will benefit from this project. In this way, patients who have a particularly high risk of drug interactions due to their previous history or their current medication are also identified in time. They are monitored particularly closely by the hospital pharmacists.
Another new feature is that hospitals can now obtain information about your medical history from your statutory health insurance to help them plan and provide optimum care for your medication. For this purpose, participating hospitals are connected to the computer data centre commissioned by your statutory health insurance via a technical network. Using the software, hospitals receive information at short notice about which medicines, therapeutic aids and appliances have been prescribed to you in the last 3 years and which diagnoses and treatments are documented, as well as information about co-treating physicians and therapists. Additionally, the exchange with your general practitioner is ensured by structured discharge management in this project.

You can find further information in the "Information for patients on the processing of personal data".

Scientific evaluation
The TOP project is scientifically monitored and evaluated by the University of Wuppertal in cooperation with the University of Bielefeld and the University of Cologne. As part of the evaluation, the scientists check whether the new measures can prevent damage to health.
Scientific evaluation is carried out on the basis of data on your medical history and prescribed medications provided by your statutory health insurance and the data documented in the software. Surveys and interviews are another elementary component of the evaluation, because your personal experiences are of particular importance to us. Those data will be collected after your hospital stay. If you have agreed to be contacted by post, the questionnaires will be sent to you by your statutory health insurance. Further information on data collection for the evaluation is attached to this questionnaire.

How can I participate in the project?

After receiving detailed information about the project and the procedure, you state your willingness to participate in the project by signing the statement of participation and declaration of consent. This statement is also valid for further stays in the same hospital until the end of the project.
Participation begins on the day of signing. With your signature, you authorize the hospital to collect data on your medical history held by your statutory health insurance to check your medication therapy. Participation in the TOP project is voluntary and free of charge. There will be no disadvantages for you if you decide not to participate.

Can I end my participation in the TOP project?
Your participation ends automatically when your insurance relationship with your statutory health insurance ends or when the project ends. Your agreement to participate can be withdrawn at any time; you do not need to give any reasons for doing so, and this will not have any negative effects on your medical treatment. You only need to state in wirting that you wish to cancel your participation and send the cancellation letter to your statutory health insurance.
However, your withdrawal only takes effects from the time you declare it. It has no retroactive effect. The processing of your data up to that point in time remains lawful.

Information for patients on the processing of personal data (TOP) (abbreviated version)

First things first: BARMER, AOK Nordost, their contractual partners and the service providers involved are very conscientious about data protection.

Your personal data is processed on the basis of sections 63, 284 and 295a of Book V of the Social Code as well as the statement of consent to data processing given by you. As part of your participation in the TOP project, a variety of data and information collected from you and about your treatment is stored and processed:

Participation data
Your signed statement of participation and consent will be archived by the hospital in your medical records. In addition, your participation will be documented by your statutory health insurance in your electronic patient file.

Data on medical documentation
The hospitals participating in the project collect medical data from you as part of your inpatient treatment. This data is part of standard medical documentation. The documentation on your current treatment is stored on the hospital server. Your statutory health insurance has no access to the patient data generated at the hospital.

Data in connection with past treatments and prescriptions
As part of your participation in the TOP project, your statutory health insurance will provide the hospital with all the information about your medical history in the past 3 years that is necessary and important for your treatment. It will provide this information digitally using special software. By signing the statement of participation and declaration of consent, you agree that participating hospitals may view the data on your medical history held by your statutory health insurance as soon as you have signed the statement.

Use of software
The TOP project uses special software which transmits the health insurance data to the hospitals in encrypted form. This software also documents your current treatment data and medications. Only authorised hospital employees have access to the software and to your data. The hospital will access the software over a specially secured data connection from the hospital to the data centre of your statutory health insurance. At the end of the project or when a hospital leaves the project, the hospital`s access rights to your data will be blocked by your statutory health insurance.

Information for general practitioners on current prescriptions
In your general discharge documents, your referring doctors receive therapy recommendations for your further treatment. In addition to the current national medication plan, they will also receive information on whether and why the medication has been changed.

Scientific monitoring and evaluation without disclosure of your name
The University of Wuppertal in cooperation with the University of Bielefeld and University of Cologne will evaluate the medical data related to your personal treatment. This concerns data collected during your hospital stay, information documented in the software, and data from your statutory health insurance. In addition, data is collected via surveys and interviews. All this data will be linked together during scientific evaluation. The universities commissioned with this evaluation will only be provided with your personal data once it has been pseudonymised. This means that your name and other identifiers (e.g. insurance number) are replaced by labels. Therefore, it will not be possible to make inferences about your identity.

Data protection and data processing
Your personal data will be used only to carry out the contractual tasks of the project. The collection, processing and use of data are governed by applicable provisions on the protection of social data according to the German Social Code and on the protection of personal data in accordance with the General Data Protection Regulation (GDPR)) and, if applicable, the Federal Data Protection Act as amended from time to time. Your statutory health insurance and its project partners are obliged to comply with all data protection regulations. This also applies after your treatment ends.

Data storage at your statutory health insurance & at the hospital
Your participation data collected during the project and stored by your statutory health insurance will be deleted in accordance with statutory provisions when you leave this project, to the extent that they are no longer required for complying with statutory provisions, and otherwise no later than10 years after the end of your participation. At the end of the project or when a hospital leaves the project, the access rights of participating hospitals to patient-related data on their medical history will be blocked at your statutory health insurance.

Consent and revocation of consent to data processing
The data processing described is only permitted if you have consented to such processing. Your statement of consent forms part of your statement of participation. Without your consent, participation in the project is not possible. You can withdraw your statement of participation and declaration of consent at any time by writing your statutory health insurance; you do not need to give reasons. Further information can be found in "Information for patients on participation".

TOP Transsektorale Optimierung der Patienten-sicherheit

Statutory health insurance		
Name of the insured person		Date of birth
Cost unit identifier	Insured person number	Status
Registration number of healthcare institutions	Physician identifier	Date

QR-Code

DECLARATION OF CONSENT AND STATEMENT OF PARTICIPATION IN THE PROJECT: "TRANS-SECTORAL OPTIMISATION OF PATIENT SAFETY"

1. Statement of participation:

I hereby declare that
- I would like to participate in the TOP project.
- I have received detailed and understandable information about the contents and objectives of the project and the processing of my data that will be required to carry out the project. I have had sufficient opportunity to discuss the implementation of the project. All my questions were answered satisfactorily.
- I have received, read and understood the "Information for patients on participation" and the "Information for patients on data processing".
- I am aware that my participation in the project is voluntary.
- I am also aware that my participation in the project begins with the signing of this participation and consent form. My participation will end if I withdraw this statement, when the project ends or I am no longer insured with BARMER.

Cancellation policy
I can withdraw my statement of participation in writing, without giving reasons, at any time. I will not suffer any disadvantages.
By post:
E-mail:

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Date (DD.MM.YYYY) Signature of patient or legal representative

Information and declaration of consent for participation in TOP

2. Declaration of consent

I have received the “Information for patients on participation” and the “Information for patients on data processing” and have taken note of them. I consent to the collection, processing and storage of my personal data as described and required for the project.

I agree that:

- The hospital will transmit my participation data (name, date of birth, insurance number and start of participation) electronically to my statutory health insurance provider.
- During my hospital stay, the hospital may retrieve data on my treatments and prescriptions in the past 3 years from my statutory health insurance. Details are described in the "Information for patients" provided to me. I am aware that the data will be retrieved at any time after my signature. On the basis of this data hospital pharmacists will carry out a detailed review of my medication therapy.
- Upon discharge, the hospital will provide the referring doctors with a therapy recommendation for further medication and, if necessary, contact them for a personal discussion.
- My signed statement of participation and declaration of consent will be stored in my patient file at the hospital and my statement of participation is documented in the software. My statutory health insurance will store my participation data (start of participation, hospital) in the electronic insurance file (eFile).
- My data will be treated confidentially by the hospital and by my statutory health insurance in compliance with applicable data protection regulations.
- My health insurance data will be processed for the purposes of scientific analysis (evaluation) by the scientific institutes involved in the project. My medication data may be retrieved from the database held by my statutory health insurance for checking against the criteria for participation in the project and for the scientific evaluation. Pseudonymised means that my name and other identifiers (e.g. insurance number) will be replaced by labels that rule out me being identified.
- My statutory health insurance provider may send me survey questionnaires by post to evaluate the project.

I acknowledge that

- In the context of this project, personal data will be processed in a way that goes beyond the usual scope of medical treatment - but which is important for the success of the project.
- My data will be processed by the hospital, my statutory health insurance and the evaluation team in compliance with applicable data protection regulations.

Cancellation policy
I can withdraw my statement of participation in writing without giving reasons, at any time. I will not suffer any disadvantages.
By post:
E-mail:

. . _____

Date (DD.MM.YYYY) Signature of patient or legal representative

Information for patients on the scientific monitoring and evaluation of the project *„Trans-sectoral optimisation of patient safety“* (TOP)

Dear Sir or Madam,
We would like to ask you whether you would like to take part in the data collection (surveys, telephone interviews, document analysis, analysis of claims data) being carried out by the University of Wuppertal together with the University of Bielefeld and the University of Cologne. The data collection is part of the scientific monitoring of the project "Trans-sectoral Optimisation of Patient Safety - TOP", which was initiated by BARMER.

Please read the evaluation information carefully and ask questions if you do not understand something.

Medication therapy is an essential component of the medical treatment of patients. In hospitals, several parties are involved in the process of medication treatment from admission to discharge. Inadequate information transfer or coordination between hospital staff and general practitioners (GPs) can have various consequences for patients. For example, there is a risk of drug interactions occurring or the patient may be hospitalised again.By implementing a new form of care, the aim is to achieve intensified and therefore improved pharmaceutical care for patients. The medication process in hospital will be supported electronically from admission to inpatient treatment through to discharge. The aim is to avoid interactions and unnecessary hospitalisation and to improve quality of life.

With your support, we would like to analyse the effects of this new form of care. This will examinewhether an improvement in the medication management of hospitalized patients can be achieved.

What is the evaluation process and what data do we need?
The evaluation will run from August 2021 to May 2024, during which time the new form of care will be introduced in your hospital (by mid-2023 at the latest) alongside the normal form of care. The implementation of the new form of care will result in changes to hospital processes. It may therefore not be visible to you whether the new form of care has already been introduced in your hospital. Whether and to what extent the new form of care is implemented at the time of your stay in the hospital treating you will be decided at random.

If you have decided to participate in the project and the evaluation, you will receive **two questionnaires over a period of three months**. The questionnaires will be sent to you by post by your statutory health insurance provider (SHIP). Depending on when and in which department you were hospitalised, an employee of the University of Wuppertal will also contact **you by telephone** once after **your hospital discharge**.. In addition to the questionnaires and the telephone interview, project staff will gain **insight into your discharge documents.**

What happens to your data (data protection information)?
All information and statements that you provide in the written questionnaires and the information from the discharge documents are collected in pseudonymised form. Pseudonymisation means that your name and other identifiers (e.g. insurance number) are replaced by labels. Therefore, it will not be possible to make inferences about your identity.An identification list, which makes direct personal reference possible, is managed by project staff of SHIPs and kept under lock and key. These persons are bound to secrecy. In a further step, the pseudonymised data from the written surveys is linked to your pseudonymised claims data of SHIPs. The purpose of the link is to combine the data of the same person for scientific analysis. The data is linked using an encryption procedure and is carried out by an independent trust centre. The project team of the universities involved in the evaluation will be granted access to the linked data set for scientific analysis. In addition, your contact details (name, telephone number) may have been collected by the hospital project team during your hospital stay. After your consent to the scientific monitoring and evaluation, this information will be forwarded to the project team at the University of Wuppertal, who may contact you to arrange an appointment for the telephone interview.The telephone interview is recorded using a tape recorder and then transcribed. All information is anonymised, i.e. names, places and other personal details are changed so that it is no longer possible to draw conclusions about individual persons. The personal data (name, telephone number) will be stored separately from your survey and health data at the University of Wuppertal and will be completely deleted after the end of the research project. This ensures that the data is anonymised after the end of the project.

We assure you that all persons involved will comply with the data protection laws. The legal basis for the processing of the data is in accordance with the General Data Protection Regulation (GDPR).

Who can I contact if I have any questions?
The University of Wuppertal will be happy to answer your questions at any time.

Consent and revocation of consent
Participation in the evaluation is voluntary. If you agree to participate, please confirm your consent by signing the enclosed form (Declaration of consent for scientific monitoring and evaluation). You can revoke your declaration of consent at any time in writing without giving reasons and without any disadvantage to you. If you withdraw your consent, no further data will be collected. The data already collected and processed up to the time of your revocation will be anonymised and can therefore no longer be attributed to you personally. Your personal data (e.g. name, telephone number) will be deleted together with your entry in the identification list.

Information and declaration of consent for scientific monitoring and evaluation of TOP (abbreviated version)

Declaration of consent for patients for scientific monitoring and evaluation of the project *Trans-sectoral optimisation of patient safety* - TOP

I have been sufficiently informed about the contents of the evaluation and its procedure. I have read the enclosed "Information for patients on scientific monitoring and evaluation". I have had the opportunity to ask questions and have received satisfactory and complete answers. I have had sufficient time to decide to participate in the evaluation and realise that participation is voluntary. I am aware that my data will be processed pseudonymised. The withdrawal of consent does not affect the lawfulness of processing based on consent before its withdrawal. In the event of revocation, no further data will be collected. In this case, I can arrange for the data to be deleted.

I am aware that personal data about me, as described in the attached "Information for patients on scientific monitoring and evaluation", will be collected and recorded at the University of Wuppertal.
I agree that the data will be stored for at least 10 years after completion or discontinuation of the study and subsequently only archived in anonymised form (without personal reference).
Changes to the evaluation data (e.g. correction or deletion of individual details) are possible until the time of anonymisation (after the evaluation has ended). I know that I can withdraw my consent to participate in the evaluation at any time and without giving reasons, without any disadvantages for my further medical care. If I withdraw my participation, I can request the deletion of all data collected to date that has not been anonymised. To have the data deleted, please get in touch with the contact person at the University of Wuppertal..

I have been informed about my data protection rights. I agree to the collection, processing, storage and transmission of the data in pseudonymised form. I also agree that my pseudonymised data from the written survey may be linked to my pseudonymised claims data of SHIP and I also agree that if an employee of the hospital has recorded my contact details (name and telephone number) during my inpatient stay in order to organise the telephone interview, these will be forwarded to the University of Wuppertal.

I will not incur any costs or other obligations by participating in the evaluation. I have received a copy of the information sheet and this declaration of consent.

I hereby declare my voluntary participation in this evaluation. At the same time, I give my consent for the project team to conduct the surveys and interviews and to inspect my discharge documents. I also agree that my data from the written survey may be linked with my pseudonymised claims data of SHIP and, if applicable, with the medication data of the hospital for the scientific evaluation using an encryption procedure.

Participant:

Surname, first name *(block capitals)* ***Place and date*** *(to be filled in personally)* ***Signature***

Information and declaration of consent for scientific monitoring and evaluation of TOP (abbreviated version)