CASE STUDY

UNIVERSITY HOSPITAL BASEL

THE VALUABLE INSIGHTS OF PATIENTS: TWO CASE STUDIES

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Because of their lived experience, patients provide unique insights and perspectives on clinical research studies. This article presents two case studies from the University Hospital Basel that illustrate how researchers and patients can collaborate to shape research priorities and study design as well as assess study feasibility.

CASE STUDY 1: USING PATIENT INVOLVEMENT TO INFORM RCT STUDY DESIGN

Following weight loss surgery, 25–30% of patients experience hypoglycaemia after meals, which is a serious complication that can severely impact their quality of life. Since symptoms frequently arise well after surgery, they are often not identified at control visits. The underlying mechanisms of this hypoglycaemia are not well understood, and there is no approved medical treatment for its symptoms.

In a pilot study with a small group of patients conducted by Dr Matthias Hepprich, senior physician and researcher at the University Hospital Basel and the Cantonal Hospital Olten, two different drugs showed promising results in terms of reducing postprandial insulin release and preventing hypoglycaemia (Hepprich et al. 2020a). To design a larger randomised controlled trial (**RCT**), the study team wanted to measure patient-relevant outcomes and try to obtain new information about the underlying mechanism of the hypoglycaemic episodes (Hepprich et al. 2020b). Systematic searches of literature, relevant databases, patient resources, and groups on the internet did not yield helpful information. The team then approached several patients in the clinic and from the pilot study mentioned above to identify relevant topics using a preliminary questionnaire to guide discussions. Identified topics were ranked by two of the most severely affected patients in the clinic. Because a broad range of topics were identified as important, the researchers suggested measuring the quality of life.

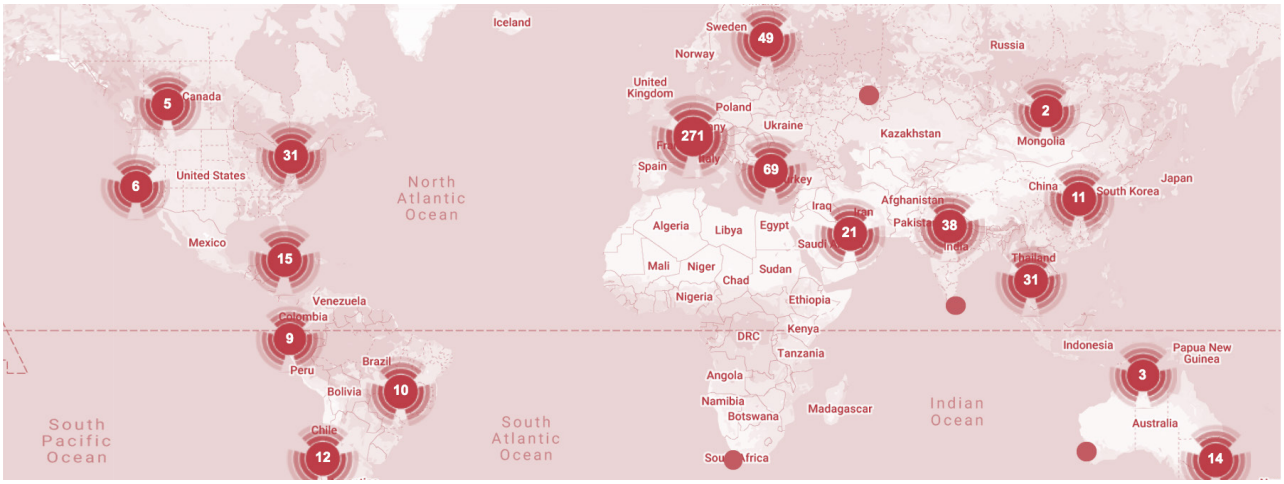
Study team

Based on the acquired information, an anonymous questionnaire containing questions on the primary endpoint and trial length along with information about patients' medical history was developed and distributed to patients with the help of healthcare providers. Filling out the questionnaire was voluntary, and the answers from it led researchers to include quality of life as a primary outcome along with the number of hypoglycaemic episodes in the trial design. In addition, the questionnaire helped researchers determine the length of the study's interventional phase.

Both Hepprich and one of the patient representatives involved in the generation of the questionnaire viewed the experience as positive. For Hepprich, the entire process – from searching literature to obtaining the results of the questionnaire – was very valuable, interesting, and fun. He found actively engaging in discussions with patients and learning more about their priorities to be tremendously rewarding (rather than solely generating his own theories or discussing ideas exclusively with research colleagues). As tips for other researchers, Hepprich recommends thoroughly researching what information from patient involvement is already available and if patient-relevant outcomes have already been established.

The patient representative interviewed reported that she would be happy to participate in the evaluation of clinical trial protocols again in the future; she finds that only through feedback can one ultimately achieve improvement. Moreover, she found that the discussions with Hepprich and his colleagues about the current study were not very time-consuming. She would be willing to participate in clinical studies as a participant in the future and offered some general tips for researchers planning a study. One tip is that participants are more motivated when, for example, their treating physician or care personnel approach them personally for participation than when they receive a standard letter or form in the mail. And when reading the participant information sheet, participants can tell if researchers have taken the time to write the information specifically for their trial or if it is a standard text. In addition, good coordination of the visit plan, for example coordination with routine treatment visits at the hospital, makes a significant difference.

CASE STUDY 2: PATIENT ADVOCATES AND SURGEONS JOIN FORCES TO IMPROVE BREAST CANCER SURGERY



Locations of OPBC members

Oncoplastic breast surgery combines traditional breast cancer surgery techniques and plastic surgery techniques with the aim of removing cancer while considering aesthetic outcomes and quality of life for the patient (Columbia Surgery n.d.). Professor Walter Paul Weber, Chief Physician of Breast Surgery and Head of the Department Brust, Bauch und Becken (department of breast, abdomen, and pelvis) at the University Hospital Basel, initiated the Oncoplastic Breast Consortium (**OPBC**) after having positive experiences with patient involvement. The OPBC brings together more than 500 breast cancer surgeons and 42 patient advocates from around the world with the mission to improve oncoplastic breast surgery through collaboration, research, and education. Patient advocates are involved in shaping research by:

1. evaluating clinical trial protocols in terms of feasibility, acceptability, and relevance from the patient's perspective

2. helping define research priorities and develop concrete research questions for OPBC researchers to address.

Jane Shaw, OPBC's Global Patient Advocacy Lead, coordinates the patient advocacy group and meets regularly with Weber.[1]

A recent OPBC initiative brought together patient advocates and surgeons to define the 15 most important knowledge gaps in oncoplastic breast surgery and select 7 research priorities based on these gaps (Weber et al. 2020). Currently, the OPBC is starting its first patient-driven research project centred on aesthetic flat closure. This specific surgical option consists of a mastectomy without reconstruction, executed to rebuild the shape of the chest wall so it appears flat. First, a questionnaire for OPBC surgeons will gather information about their awareness, practices, and attitudes related to this option. Second, patients' experiences with the aesthetic flat closure option will be evaluated.

For researchers interested in patient involvement, Weber recommends getting in touch with patients early – as soon as an abstract of a planned study has been developed – to discuss the endpoints and feasibility of the study. By doing this, researchers can ensure that they investigate aspects relevant to patients, and they have the chance to improve recruitment and retention rates in their studies. Working with patient advocates can be demanding because both sides have different perspectives and experiences. However, patient involvement has an obvious added value and helps ensure that researchers do not miss the mark in terms of addressing patients' needs.

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[1] More information about Jane Shaw and her journey to patient advocacy can be found in an online article in the *Henley Standard* newspaper.