



Knowledge Gaps in Oncoplastic Surgery

Scientific secretaries

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Background

The Oncoplastic Breast Consortium (OPBC) is committed to bringing safe and effective oncoplastic breast surgery to routine patient care, namely oncoplastic breast-conserving surgery, as well as nipple- and skin-sparing mastectomy (NSM/SSM) with immediate reconstruction. The OPBC pursues this mission by performing relevant clinical research projects, by offering oncoplastic training courses and by bringing international experts together to address controversial topics.

The OPBC features national coordinators, expert panelists and members from private and public settings with different experience in oncologic, oncoplastic and reconstructive breast surgery.¹ The OPBC currently has more than 400 members from 68 countries across all continents and includes a strong patient advocacy group.

The Association of Breast Surgery Gap Analysis Working Group recently identified current key breast surgical research gaps.² Moreover, several knowledge gaps have recently been identified in two consensus conferences in the fields of oncoplastic breast conserving surgery³ and nipple-sparing mastectomy with immediate reconstruction¹.

Aim

The OPBC plans to identify and prioritize knowledge gaps in the field of oncoplastic surgery and propose concrete strategies to address them.

Methods

Modified Delphi process performed by the OPBC. OPBC coordinators and panelists reflect permanent positions within the OPBC. They were selected and actively recruited based on evident expertise in breast cancer management with a practice primarily dedicated to breast cancer.¹ The OPBC patient advocacy group consists of patients who underwent oncologic breast surgery in the past and volunteered to support the mission of the OPBC. The rest of the OPBC membership consists of breast surgeons from various backgrounds and with different levels of experience who decided to join the mission by self-registration on the OPBC website (www.oncoplasticbc.org).

For the Delphi process, we a priori plan to recruit a minimum of 85 OPBC members from around the world as key stakeholders, representing the clinical experts (i.e., surgeons, gynecologists and plastic surgeons) who are responsible for indication and performance of oncoplastic surgery. In addition, we plan to recruit a minimum of 15 patient advocates from different countries.

A questionnaire will be sent to all OPBC members assessing their role (surgeon vs patient). Patients will be asked to provide information on their personal history on a strictly volunteer basis (S/p breast conserving surgery, mastectomy without reconstruction, mastectomy with implant-based reconstruction, mastectomy with autologous reconstruction). Professionals will be asked about their surgical discipline of origin (gynecologist vs surgeon vs plastic surgeon), years of experience, annual surgical caseload, sex, type of breast center (private vs public vs academic) and membership in national and international societies that have a focus on breast cancer. The modified Delphi process will consist of two rounds of electronic questionnaires followed by a consensus meeting. The consensus conference will involve a group of experts for face-to-face discussion and voting. Responses will be summarized using purely descriptive statistics.

List of knowledge gaps

The section leaders of the scientific secretariat will be tasked with identifying key knowledge gaps in oncoplastic surgery practice and research based on voting results of prior consensus conferences, expert opinion and systematic searches of the literature.^{1,3} All knowledge gaps that were identified by significant disagreement ($\geq 25\%$) among experts when addressing the respective questions during the first international consensus conference on OPS³ and the first OPBC consensus conference on NSM¹ will be included in this list.

Preparation for the Delphi process

All OPBC members will be informed via OPBC newsletter on the upcoming Delphi process and will be able to give feedback, as well as report additional knowledge gaps, two weeks prior to the start of the Delphi process. The scientific secretaries will complete the list of knowledge gaps according to these comments.

Delphi process

- Phase 1 (Questionnaire): Priorities

The modified Delphi method will include two rounds of surveys assessing the importance of knowledge gaps with anonymized feed-back of results. **Importance will be defined as the urgent need of knowledge to guide clinical practice and research, as opposed to knowledge of theoretical or purely scientific interest.** After each round, two reminders will be sent by email in two-week intervals to optimize response rates. The Delphi process will be coordinated by a facilitator from the Department of Clinical Research at the University of Basel.

- Round 1:

The chairs will send out personalized access links to the electronic round 1 questionnaire to all OPBC members. Participating members are asked to rank the importance of every knowledge gap on a 9-point Likert scale from 1 (not important) to 9 (extremely important) within 2.5 weeks after receipt. In addition, participants will be asked to select a maximum of 10 topics recommended for the OPBC research agenda that will be discussed at the consensus conference. A total of two reminders will be sent during that time. **First-round non-responders will be considered to have declined study participation and will not be contacted again for the second round.**

- Round 2:

All participants of round 1 will be sent a second personalized access link to the electronic round 2 questionnaire. The round 2 questionnaire will consist of the same list of knowledge gaps as in round 1. In addition, the median rating of round 1, as well as the number of recommendations for the OPBC research agenda to be discussed at the conference will be indicated separately for medical professionals and patient advocates. Participants will then

be asked to complete the questionnaire again within two weeks to reprioritize the respective knowledge gaps. A total of two reminders will be sent during that time. Feedback from round 1 will be used for all participants that completed round 1 but did not complete round 2.

- Recommendations of knowledge gaps for the OPBC research agenda to be discussed at the conference:

At the OPBC consensus conference, a maximum of 15 knowledge gaps will be discussed, taking into account the preferences of patient advocates and medical professionals. Therefore, the proportion of recommendations for the research agenda as well as the median rating of each topic will be calculated separately for medical professionals and patient advocates. The mean of the proportion of recommendations and Likert ratings of the two groups will then be used for the ranking of knowledge gaps. The ranking is determined first by descending proportion of selections and second by descending median Likert rating.

- **Phase 2 (in-person consensus meeting): Research agenda**

Thursday, 12 Sept 2019, 2.00 p.m. - 7.00 p.m., followed by faculty dinner, University Hospital Basel

In phase 2, an expert panel will meet face to face to agree on the final list of the most important knowledge gaps and the best methods to address them. These research priorities will constitute the future OPBC research agenda.

The OPBC panel, consisting of the official OPBC coordinators and OPBC panelists, as well as selected OPBC trainees, OPBC patient advocates and special guests will be invited to meet in Basel on 12 September 2019. Special guests will be selected based on their expertise in radiation oncology, medical oncology, clinical trial methodology, as well as their role as representatives of funding agencies.

Before the conference, the top 15 most important knowledge gaps selected during the Delphi process will be sent to the panel with detailed voting results (exact percentage of 7-9 scores and mean score). In addition, a concise strategy proposal to address each of the top 15 knowledge gaps will be provided by the scientific secretaries.

In the first half of the meeting, panel members will present specific topics that were selected by the scientific secretaries, followed by an interactive discussion. In the second half, the top 15 most important knowledge gaps identified during the Delphi method will be brought forward to the consensus conference. The panel will be asked to vote for each knowledge gap separately if it should be added to the final OPBC research agenda based on the urgency to obtain guidance in clinical practice or research. Voting will be in the format yes, no or abstain. Simple majority will be defined by agreement among 51–75% of the panelists and consensus by agreement above 75%. In case of consensus to add a knowledge gap to the agenda, the proposed strategy to address this gap will be discussed and adjusted as needed, followed by voting. In case of only majority voting to add a knowledge gap to the research agenda, discussion and re-voting is encouraged. **The aim of the Delphi process and the conference is to achieve consensus on the research agenda for the OPBC in terms of the most important knowledge gaps and the best strategies to address them.**

Timeline

Newsletter with protocol	April 5
Delphi Round I	April 24
Reminder I	April 29
Reminder II	May 6
Deadline Round I	May 12
Newsletter with results	June 14
Delphi Round II	June 24
Reminder I	July 1
Reminder II	July 4
Deadline Round II	July 7
Newsletter with results	August 23
Consensus conference	September 12

Program of in-person meeting on 12 September 2019

Time	Speaker	Topic
2.00-2.10	Joerg Heil	Welcome and introduction
2.10-2.30	Walter Weber	Update OPBC
2.30-2.45 (+5min discussion)	Monica Morrow	Challenges in breast surgical research
2.50-3.05 (+5min discussion)	Shelley Potter	Opportunities and priorities in breast surgical research ²
3.10-4.15	Consensus conference part 1	
4.15-4.45	Coffee break	
4.45-7.00	Consensus conference part 2	

References

1. Weber WP, Haug M, Kurzeder C, et al. Oncoplastic Breast Consortium consensus conference on nipple-sparing mastectomy. *Breast Cancer Res Treat* 2018; **172**(3): 523-37.
2. Cutress RI, McIntosh SA, Potter S, et al. Opportunities and priorities for breast surgical research. *Lancet Oncol* 2018; **19**(10): e521-e33.

3. Weber WP, Soysal SD, El-Tamer M, et al. First international consensus conference on standardization of oncoplastic breast conserving surgery. *Breast Cancer Res Treat* 2017; **165**(1): 139-49.
4. Ford I, Norrie J. Pragmatic Trials. *N Engl J Med* 2016; **375**(5): 454-63.
5. McCulloch P, Feinberg J, Philippou Y, et al. Progress in clinical research in surgery and IDEAL. *Lancet* 2018; **392**(10141): 88-94.
6. Potter S, Holcombe C, Ward JA, Blazeby JM, Group BS. Development of a core outcome set for research and audit studies in reconstructive breast surgery. *Br J Surg* 2015; **102**(11): 1360-71.



Walter Weber, 29 March 2019

Amendments

26 April 2019:

After sending the questionnaire to all OPBC members, several patient advocates immediately contacted Walter P. Weber by email to point out that explanations for laypeople should be provided with the questions. Therefore, the chairs decided to provide an explanation for every single question and send the questionnaire again to all patient advocates. The explanations were prepared by three scientific secretaries and edited by a patient advocate who has been editing communication material in her role as Global Integration Management Officer at a large healthcare company for 30 years. This patient advocate also prepared a separate glossary, which was edited by two scientific secretaries and added to the email that delivered the questionnaire with the explanations for laypeople.



Walter Weber, 26 April 2019

13 May 2019:

After the deadline of the first round on 12 May 2019, 22 of 34 patients completed the questionnaire. Due to the amendment above, patient advocates received only one reminder. After internal discussion (facilitator and three scientific secretaries), we decided to send the second reminder to the patient advocates who have not yet responded after the initial deadline, on 13 May 2019.



Walter Weber, 13 May 2019

20 May 2019:

Due to the excessive efforts provided by Giacomo Montagna, Mathilde Ritter and Ramon Saccilotto during the Delphi process, we have decided to include them to the team of scientific secretaries.

Change in the timeline of the protocol: Delphi Round II will be initiated on 17 June 2019 (one week earlier than originally planned) due to absence of the Delphi facilitator.



Walter Weber, 20 May 2019

08 July 2019:

Due to the summer break, we decided to extend the deadline for the second Delphi round to 14 July 2019 and send the second reminder on 08 July 2019.



Walter Weber, 08 July 2019

26 July 2019:

The secretaries have decided that a minimum of 10 knowledge gaps is needed for the OPBC research agenda. Therefore, if less than 10 are selected with a consensus during the conference, further gaps will be added. In this case, all questions will be ranked according to voting results and the highest ranked will be selected.



Walter Weber, 26 July 2019