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ILEEM-survey on the Heart Team approach and team training for lead extraction procedures

Starck, Christoph T ; Bracke, Frank ; Delnoy, Peter-Paul ; Freedman, Roger A ; Kutarski, Andrzej ; Gallagher, Mark ; Shoda, Morio ; Peyton, Robert ; Sohal, Manav ; Gadler, Frederik ; Sedlacek, Kamil ; Hartikainen, Juha ; Mazzone, Patrizio ; Breitenstein, Alexander ; Lever, Nigel

Abstract: **BACKGROUND** The Heart Team approach has become an integral part of modern cardiovascular medicine. To evaluate current opinions and real-world practice among lead extraction practitioners, an online survey was created and distributed among a pool of lead extraction specialists participating in the International Lead Extraction Expert Meeting (ILEEM) 2018. **METHODS** The online survey consisted of 10 questions and was performed using an online survey tool (www.surveymonkey.com). The collector link was sent to 48 lead extraction experts via email. **RESULTS** A total of 43 answers were collected (89% return rate) from lead extraction experts in 16 different countries. A great majority (83.7%) of the respondents performed more than 30 lead extraction procedures per year. The most common procedural environment in this survey was the hybrid operating room (67.4%). Most procedures were performed by electrophysiologists and cardiologists (80.9%). Important additional members of the current lead extraction teams were cardiac surgeons (79.1%), anesthesiologists (95.3%) and operating room scrub nurses (76.7%). An extended Heart Team is regarded beneficial for patient care by 86.0%, with potential further members being infectious diseases specialists, intensivists and radiologists. Team training activities are performed in 48.8% of participating centers. **CONCLUSIONS** This survey supports the importance of establishing lead extraction Heart Teams in specialized lead extraction centers to potentially improve patient outcomes. The concept of a core and an extended heart team approach in lead extraction procedures is introduced.

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ILEEM-survey on the Heart Team approach and team training for lead extraction procedures

Running head: Lead extraction Heart Team approach

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Abstract

Background: The Heart Team approach has become an integral part of modern cardiovascular medicine. To evaluate current opinions and real world practice among lead extraction practitioners, an online survey was created and distributed among a pool of lead extraction specialists participating in the International Lead Extraction Expert Meeting (ILEEM) 2018.

Methods: The online survey consisted of 10 questions and was performed using an online survey tool (www.surveymonkey.com). The collector link was sent to 48 lead extraction experts via email.

Results: A total of 43 answers were collected (89% return rate) from lead extraction experts in 16 different countries. A great majority (83.7%) of the respondents performed more than 30 lead extraction procedures per year. The most common procedural environment in this survey was the hybrid operating room (67.4%). Most procedures are performed by electrophysiologists and cardiologists (80.9%). Important additional members of current lead extraction teams are cardiac surgeons (79.1%), anesthesiologists (95.3%) and operating room scrub nurses (76.7%). An extended Heart Team is regarded beneficial for patient care by 86.0%, with potential further members being infectious diseases specialists, intensivists and radiologists. Team training activities are performed in 48.8% of participating centers.

Conclusions: This survey supports the importance of establishing lead extraction Heart Teams in specialized lead extraction centers to potentially improve patient outcome. The concept of a core and an extended heart team approach in lead extraction procedures is introduced.

Key words: lead extraction, heart team, team training, pacemaker, ICD

Introduction

The Heart Team approach plays an important role in modern cardiovascular medicine. The main purpose of the heart team is to determine the best available therapy in an individual patient using a multidisciplinary team approach with balancing the risks and benefits of

different therapeutic strategies. The implementation of a multidisciplinary team approach has been recommended in multiple European Society of Cardiology guidelines (e.g. management of valvular disease, myocardial revascularization, management of atrial fibrillation, heart failure, infective endocarditis) [1–5].

For transvenous lead extraction (TLE) procedures the multidisciplinary team approach is noted in section 11.1 (“Personnel”) of the current 2017 Heart Rhythm Society expert consensus statement. As members of this multidisciplinary team, cardiologists, electrophysiologists, cardiothoracic surgeons (in centers where the primary operator is not a surgeon), interventional radiologists, vascular surgeons are suggested. For centers that perform lead extractions in children or young adults, pediatric cardiologists as well as pediatric electrophysiologists should also be included. In section 8.1 (“Cardiovascular Implantable Electronic Device Infection”) an evaluation by physicians with specific expertise in cardiovascular implantable electronic devices (CIED) infection and lead extraction is recommended for patients with documented (class I recommendation, level of evidence C) and suspected (class IIa recommendation, level of evidence C) CIED infection [6]. Putting the given information together with the assumption that in most cases worldwide the primary operator is an electrophysiologist or cardiologist [7], the suggested Heart Team for lead extraction procedures exists of the following specialists: electrophysiologist or cardiologist, cardiothoracic surgeon, interventional radiologist, vascular surgeon, infectious disease specialist (in CIED infection cases) and pediatric cardiologist/electrophysiologist (in children/young adults).

In order to evaluate current opinions and real world practice among lead extraction experts a short online survey was created and distributed among a pool of lead extraction specialists who were participants of the International Lead Extraction Expert Meeting (ILEEM) 2018.

Methods

A short survey was created by formulating 10 questions: 9 closed-ended questions (2 dichotomous question [22.2%], 7 multiple choice questions [77.8%]) and 1 open-ended question (question on country of work) (Table 1). 7 of the 9 (77.8%) closed-ended questions had the additional option to enter details on not available answer items (“other”). The goal was to generate relevant questions that could be answered in less than 5 min of time, in order to get a maximum response rate. The invitation to participate was sent out by email amongst lead extraction specialists who were recruited from the participant pool of the ILEEM, which

is held annually in Berlin, Germany. The recipients were encouraged to forward the invitation to other lead extraction practitioners.

The survey was performed by using the online tool SurveyMonkey (www.surveymonkey.com; SurveyMonkey Inc., San Mateo, California, USA).

Statistics

Answers were analyzed with the tool provided by SurveyMonkey (www.surveymonkey.com; SurveyMonkey Inc., San Mateo, California, USA). Categorical variables are presented as numbers and percentages.

Results

The invitation to participate was sent to 48 lead extraction specialists by email with a collector link to the internet-based survey at the end of October 2018. The survey was closed at the end of November 2018 and 43 answers of the survey were recorded, a return rate of 89%. The average time spent for completing the survey was 2 min 38 s.

Participant countries

Forty one participants of this survey were located in 16 different countries with the following distributions of answers: Austria (3), Czech Republic (1), Denmark (1), Finland (1), Germany (2), Italy (2), Japan (3), Netherlands (1), New Zealand (1), Poland (11), Spain (2), Sweden (1), Switzerland (4), Thailand (1), United Kingdom (3), United States (4). Two respondents did not answer country of origin.

Annual volume of TLE procedures

This question was answered by all participants. The detailed answers are shown in Figure 1. More than 30 procedures per year, being a common definition of high volume centers, were performed in 83.7% of centers.

Procedural environment

The answer rate on this question was 100%. The detailed answers are shown in Figure 2. Eighty-six percent of all participants performed lead extraction procedures in an operating room (OR), with most procedures done in a hybrid OR. Two answers were “others” and specified as operating room and a mixture of operating room and hybrid OR.

Primary operator in lead extraction procedures

This answer was completed by 42 participants. The primary operator is an electrophysiologist in 24 (57.1%) centers, a cardiologist in 10 (23.8%) centers and a cardiac surgeon in 8 (19.1%) centers. Five additional comments were given mainly stressing the presence of a cardiac surgeon when the procedure is performed by an electrophysiologist or cardiologist.

Current team composition in lead extraction procedures

All participants answered this question. The detailed answers are shown in Figure 3. Given answers were physicians (cardiologist, electrophysiologist, cardiac surgeon, anesthesiologist) as well as non-physician members (perfusionist, OR scrub nurse, Cath/EP Lab technician, radiology technician).

Performance of TEE during lead extraction procedures

This answer was completed by 42 participants. In most cases transesophageal echocardiography (TEE) is performed by an anesthesiologist (n = 25; 59.5%). In 17 (40.5%) centers TEE is performed by a cardiologist. Two (4.8%) centers have a specific echocardiography technician for this task. In almost 10% (4 centers; 9.5%) TEE is not routinely performed during TLE procedures. In 1 (2.4%) center intracardiac echocardiography (ICE) is used as ultrasound monitoring tool during TLE procedures.

Cardiac surgical backup

Forty one participants answered this question. In all of the responses, participating centers had cardiac surgical backup is available and present but with differing access and extent. The detailed results are shown in Table 2.

Extended Heart Team approach in TLE procedures

To collect the opinion of participants on an “extended heart team approach” in TLE procedures, the following question was posed: “Would you consider an “Extended Heart Team Approach” as beneficial for the treatment quality of patients requiring TLE procedures?”. This answer was answered by 100% of participants.

Thirty seven participants of the survey (86.0%) considered the extended Heart Team approach as beneficial, whereas for 6 (14.0%) it was not considered as beneficial.

Members of an “Extended Heart Team” for TLE procedures

This answer was completed by 41 participants. Besides the electrophysiologist (80.5%) and the cardiologist (48.8%), the cardiac surgeon (95.1%), the anesthesiologist (90.2%) and the infectious disease specialist (78.0%) were considered important members of an extended lead extraction heart team. The detailed results are shown in Figure 4.

One respondent was uncertain about the terminology of an “Extended Heart Team”, highlighting the potential for a broad team definition or composition. Additional potential members such as an echocardiography specialist were suggested. The quality, experience and skill mix of the team membership was also considered to be important.

Training TLE teams

This question was answered by 100% of the survey participants. 48.8% (21) of the centers perform specific team training with their TLE team, whereas 51.2% currently do not perform team training.

Additional information was supplied by 15 responders. These comments included reporting the frequency of trainings as monthly, quarterly, twice annually or when a new member enters the team. The format of training comprised: workshops, seminars, clinical conferences, emergency procedure training, review of techniques, external trainings and simulation.

Discussion

A multidisciplinary team approach is now considered an integral part of current methods for providing patient-centered therapy for many cardiovascular conditions. In patients with complex coronary artery disease, it has been shown that the process of decision making in a Heart Team is reproducible and that outcomes are successfully implemented in a majority of cases [8, 9].

The 2017 European Society of Cardiology guidelines on the management of valvular diseases recommended the concepts of a Heart Team approach and establishment of heart

valve centers. Requirements of a heart valve center include a multidisciplinary team which meets on a regular basis, works with standard operating procedures (SOP), availability of multiple high-quality imaging techniques, conducts regular consultations with extracardiac departments and other hospitals, availability of back-up services and implementation of data review [1].

Given the results of this survey on the current composition of a Heart Team in lead extraction procedures and the majority of participants regarding the extended Heart Team approach to be beneficial for the treatment quality of patients, the requirements for a Heart Team approach in lead extraction procedures can be summarized similarly to those for valvular heart disease: regular meetings, SOP-based approaches, availability of imaging specialists, infectious disease specialists as well as intensivists, close contact to referring non-extraction centers and implementation of data review for quality assurance purposes (Table 3).

The composition of the Heart Team is an important aspect. Based on the results of this survey, physicians of different specialties as well as non-physician members should be members of a lead extraction Heart Team. The definition or composition was deliberately not defined, in the survey in order to draw comment and not to influence the answers. Based on the results of this survey we propose the concept of a combined core and extended Heart Team in TLE procedures (Fig. 5). The core lead extraction Heart Team should consist of all professionals involved in the actual lead extraction procedure: electrophysiologist/cardiologist (mandatory), cardiac surgeon (mandatory), anesthesiologist (mandatory), perfusionist (mandatory), Cath/EP Lab technician/nurse or OR scrub nurse (mandatory) and radiology technician (optional). The extended heart team in TLE procedures additionally consists of the following professionals: Infectious diseases specialist (in cases with documented or suspected CIED infection), intensive care specialists (especially in TLE procedures in heart failure patients or when sepsis or multiorgan support is required), radiologist/imaging specialist (when special imaging modalities are required pre-operatively). The wider membership is important when considering the pre- and post-procedure management and does not exclude the need for consultation outside of the group. The role of the group should not be restricted to the performance of the procedure alone, but to be involved in pre-, peri- and post-procedure management.

The composition of the core TLE Heart Team is already well accepted by most centers. The concept of an extended lead extraction Heart Team still needs to be established and defined amongst the wider clinical cardiology community. It is a fact that performing lead extraction procedures at specialized lead extraction centers leads to higher procedure volume and better patient outcomes, with a well-documented volume-outcome relationship for lead extraction procedures [7, 10]. The two most common causes of non-procedure related in-hospital mortality in the ELECTRa registry were sepsis and heart failure. In this registry, amongst others, predictors of increased all-cause mortality during hospitalization were found to be systemic infection (odds ratio 4.93, 95% confidence interval 2.72–8.93) and New York Heart Association class III/IV (odds ratio 4.08, 95% confidence interval 2.24–7.43) [7]. Consequently, regular involvement of specialist physicians for the treatment of septic complications or heart failure makes good clinical sense in order to improve outcomes for these sub-groups of lead extraction patients. This makes the infectious disease specialist service of particular importance for patients with CIED infections (especially systemic infections). For heart failure patients, especially for those having cardiac resynchronization systems extracted, the intensivists and/or heart failure teams have important roles in helping manage and improve post-procedure survival. Furthermore, the availability of extracorporeal life support (ECLS) and short-term mechanical circulatory support may be beneficial for selected heart failure patients. In certain patients special imaging techniques may be required to confirm a suspected diagnosis (e.g. FDG/PET CT scan for suspected pocket infection), to assess special anatomical situations (e.g. CT angiography for venous occlusion or CT scan to confirm inadvertently placed leads in the left ventricle) or to assess lead course in relation to critical anatomical structures (e.g. superior vena cava, tricuspid valve) [11, 12]. The vast majority (86%) of this survey's participants considered an extended Heart Team approach as beneficial for improving the quality of TLE procedural planning and performance.

Last but not least, this survey revealed that approximately half of the contacted centers (48.8%) undertook team training. Furthermore, the responses show a large heterogeneity in terms of the frequency and format of such team training. This is probably due to the fact that training teams specifically in lead extraction procedures remains in its infancy. There is considerable surgical team training predominantly for the non-technical skill sets that have been adopted in many centers which is applicable and transferable. Since many TLE procedures are performed in Hybrid surgical environments, team training routines already exist for the more generic tasks. Specific team training for TLE work should be considered since the volume of procedures for all teams members may be small in comparison to other

work performed (other cardiac surgical procedures, electrophysiology procedures). Possible targets for team trainings are rehearsals of uncomplicated lead extraction procedures to improve familiarization and situational awareness with such work as well as crisis management for peri-procedural complications and management of postoperative care. With regard to procedural task training (performance of the procedure and management of complications) the use of virtual reality (VR) or augmented reality (AR) techniques may be beneficial but are as yet unproven and not specifically available for TLE procedures. Besides being used in training scenarios these VR and AR technologies may also be used as an adjunct for optimizing procedure planning and rehearsal prior to the case. These are important areas for future development.

Limitations of the study

This survey provides a consensus group opinion from a select group of clinicians who are or have been participants of the International Lead Extraction Meeting (ILEEM) in Berlin, Germany (www.ileem.com). Therefore the survey participants do not represent an average group of physicians in real world practice, especially with regard to low and medium volume extraction centers. All participants perform TLE procedures using a variety of tools and techniques with 83.7% of all participants undertaking more than 30 TLE procedures annually, a common definition for a high volume center [7]. Almost 40% of the contacted centers performed more than 70 procedures per year, highlighting the expertise amongst respondents to this survey. Only lead extraction experts involved with ILEEM provided opinions which may not reflect other experience and opinions, e.g. in low volume centers or other geographical regions views. The survey was designed to gain an understanding of current opinions about the importance of team approach to TLE procedures and provoke further discussion within the community

The impact on clinical outcomes of such an extended Heart Team approach has to be investigated in future studies as a verification of this current expert opinion on the benefits of such an approach by solid data.

Conclusions

This survey supports the importance of establishing lead extraction Heart Teams in specialized lead extraction centers to potentially improve patient outcomes. The concept of a

core and an extended Heart Team approach in lead extraction procedures was introduced. The clinical benefits have to be proven in future studies.

Conflict of interest: None declared

Table 1. Questions of the online International Lead Extraction Meeting (ILEEM) survey on Heart Team approach in lead extraction procedures.

Questions of ILEEM survey on Heart Team approach in lead extraction procedures	Question type
1. In which country are you working?	Open-ended
2. How many TLE procedures are performed in your clinic per year?	Closed-ended (multiple choice)
3. Where are TLE procedures performed in your hospital?	Closed-ended (multiple choice)
4. Who is predominantly performing TLE procedures in your hospital?	Closed-ended (multiple choice)
5. Who is part of your team performing TLE procedures?	closed-ended (multiple choice)
6. Who is performing TEE during TLE procedures in your hospital?	Closed-ended (multiple choice)
7. How is cardiac surgical backup for TLE procedures organized in your hospital?	Closed-ended (multiple choice)
8. Would you consider an “Extended Heart Team Approach” as beneficial for the treatment quality of patients requiring TLE procedures?	Closed-ended (dichotomous question)
9. In your opinion who should be the members of an “Extended Heart Team” for TLE procedures?	Closed-ended (multiple choice)
10. Do you perform team trainings with your TLE team?	Closed-ended (dichotomous question)

All closed-ended multiple choice questions had the additional option to enter details on not available answer items (“other”). TLE — transvenous lead extraction; TEE — transesophageal echocardiography

Table 2. Cardiac surgical backup during transvenous lead extraction procedures (participants: 43, answered: 41, skipped: 2).

Cardiac surgical backup	Responses
Cardiac surgeon scrubbed and present during the procedure	17 (41.5%)
Cardiac surgeon in the operating room — not scrubbed	13 (31.7%)
Cardiac surgeon in the hospital	11 (26.8%)
No cardiac surgeon available	0 (0%)

Table 3. Requirements for a heart team approach in lead extraction procedures.

Requirements for a lead extraction Heart Team approach
Regular meetings
Standard operating procedures-based approaches
Availability of specialists: <ul style="list-style-type: none"> • imaging specialists/radiologists • infectious disease specialists • intensivists
Close contact to referring non-extraction centers
Implementation of data review for quality assurance purposes

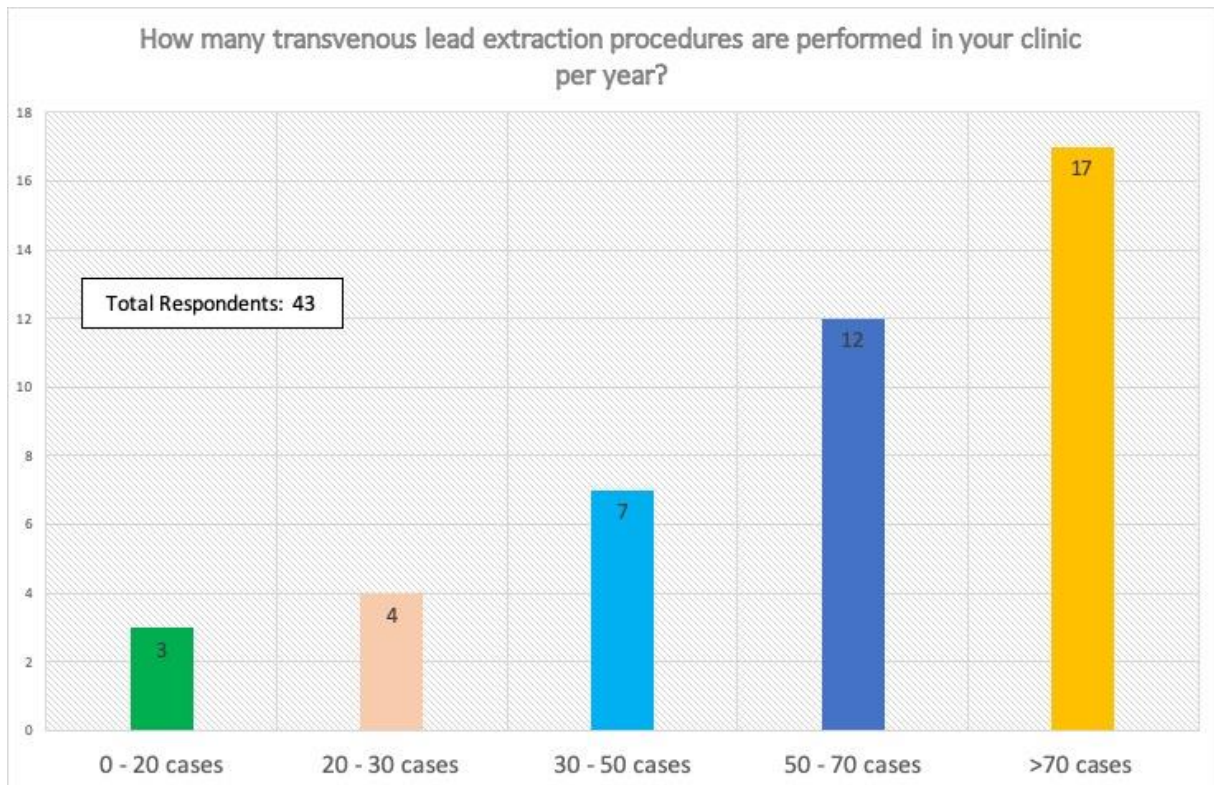


Figure 1. Annual center volume of transvenous lead extraction procedures amongst survey participants.

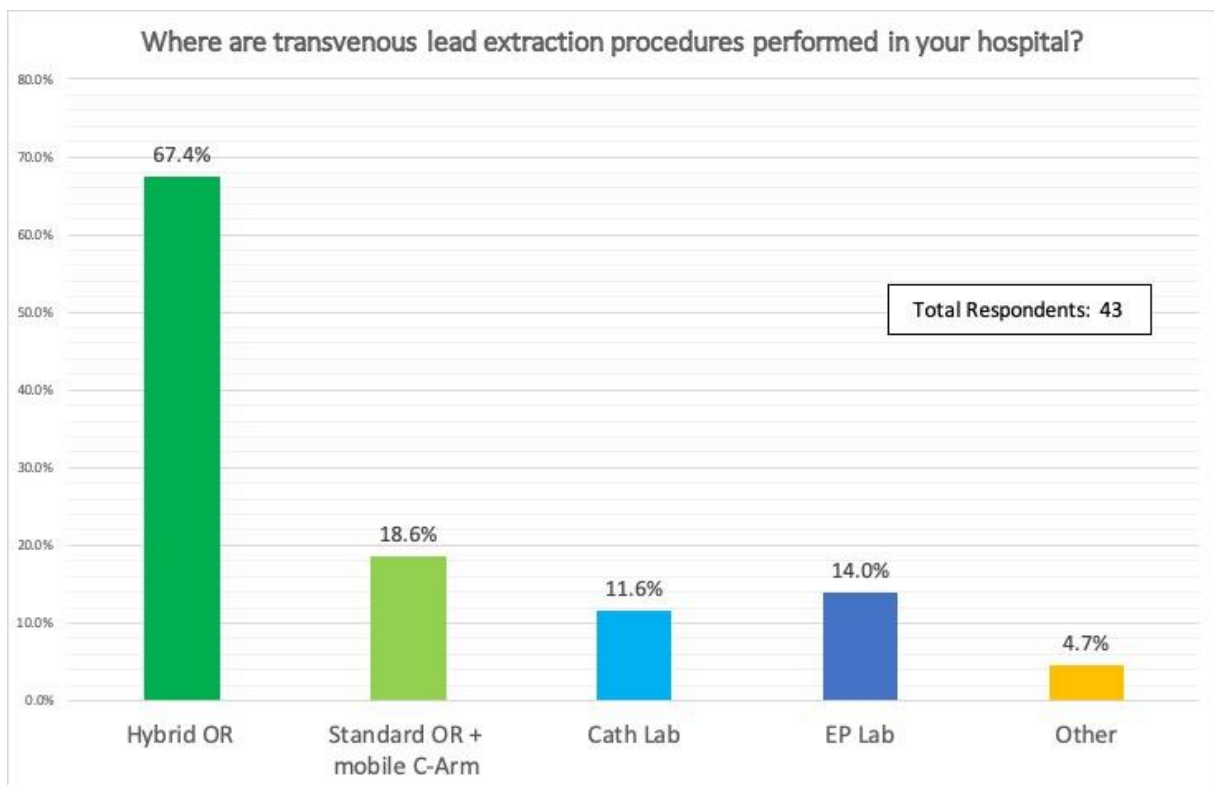


Figure 2. Procedural environment of transvenous lead extraction procedures. (Multiple responses were allowed. Percentages calculated in relation to the total number of respondents).

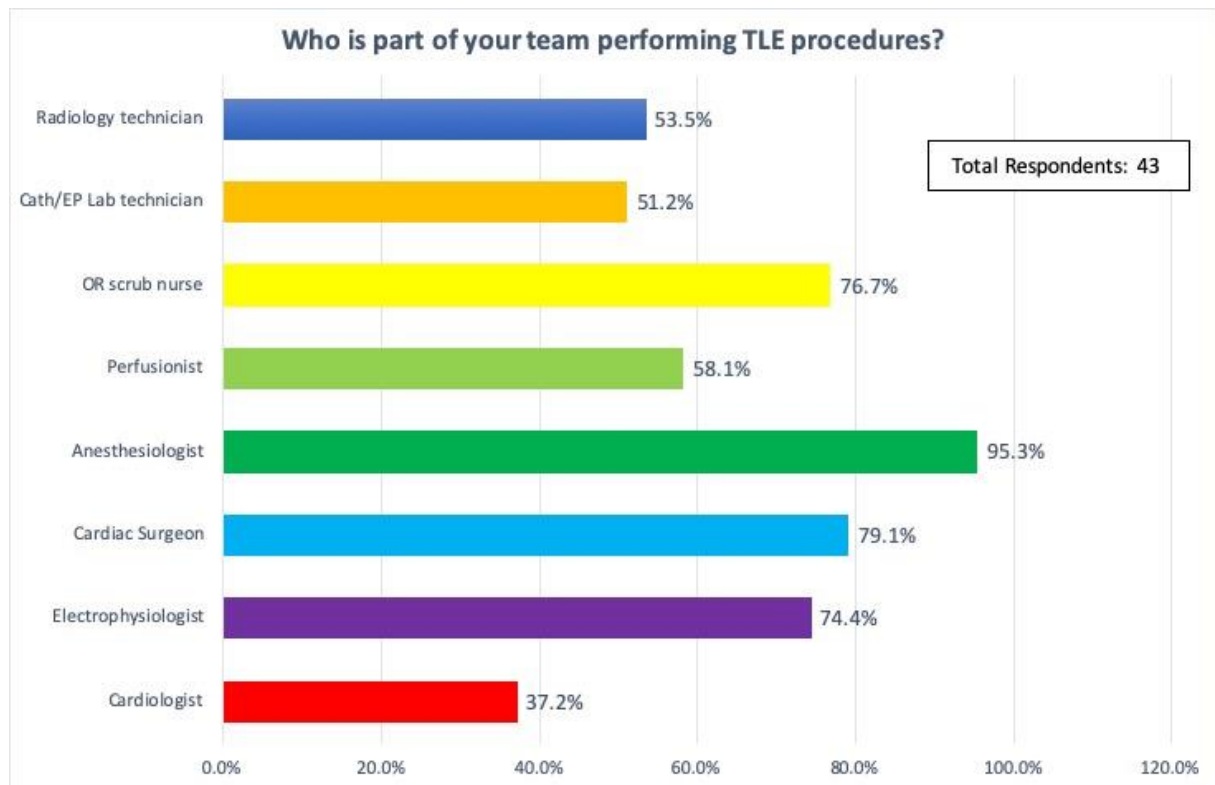


Figure 3. Current team members of lead extraction teams. (Multiple responses were allowed. Percentages calculated in relation to the total number of respondents).

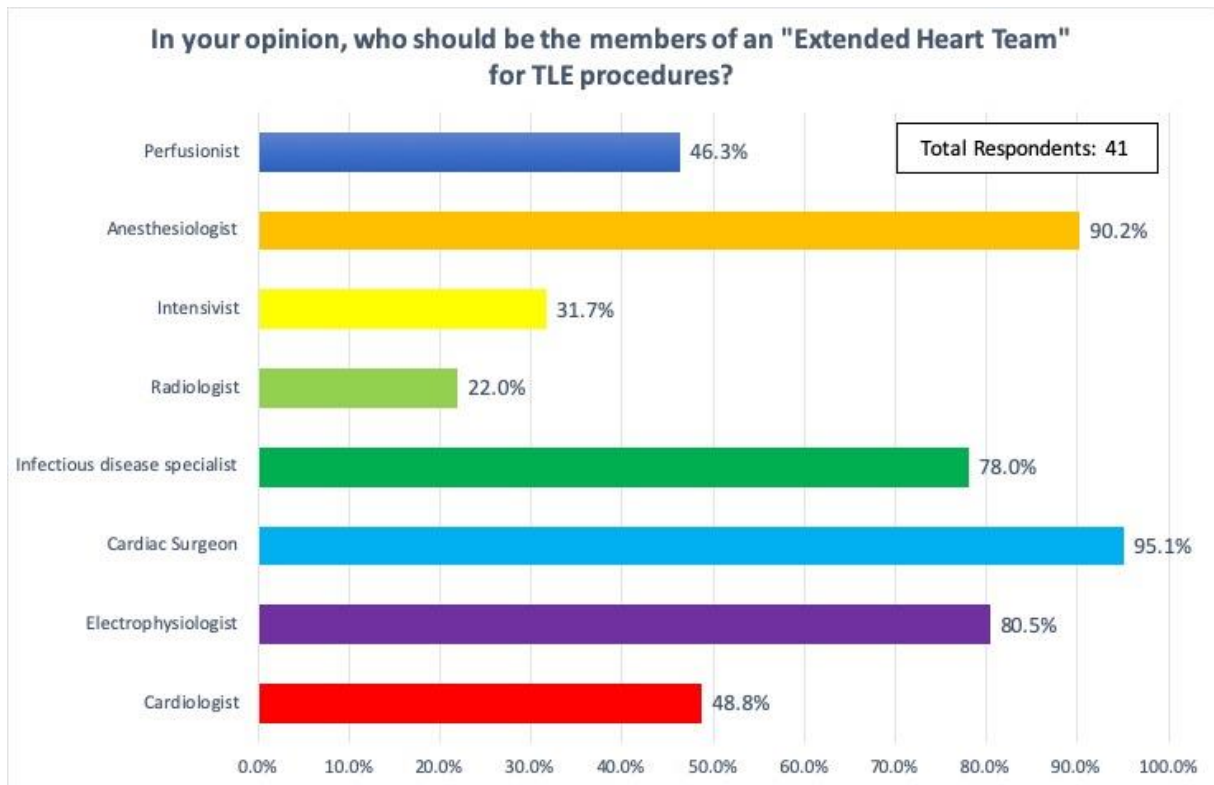


Figure 4. Opinion of the survey participants on the composition of an extended Heart Team in transvenous lead extraction procedures. (Multiple responses were allowed. Percentages calculated in relation to the total number of respondents).

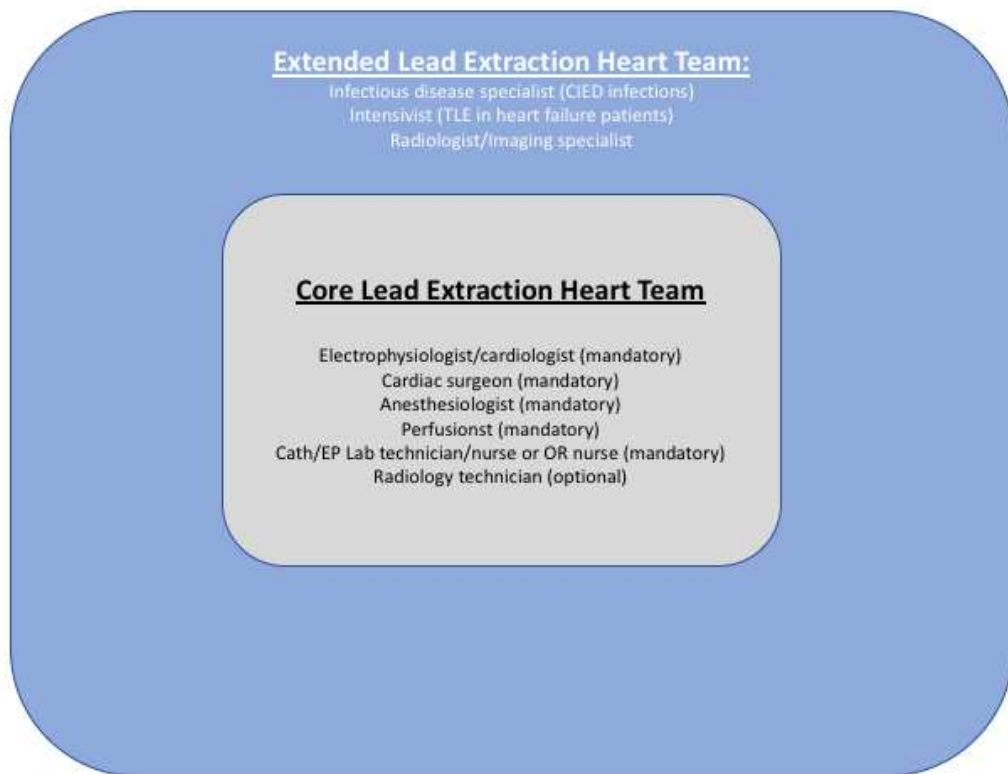
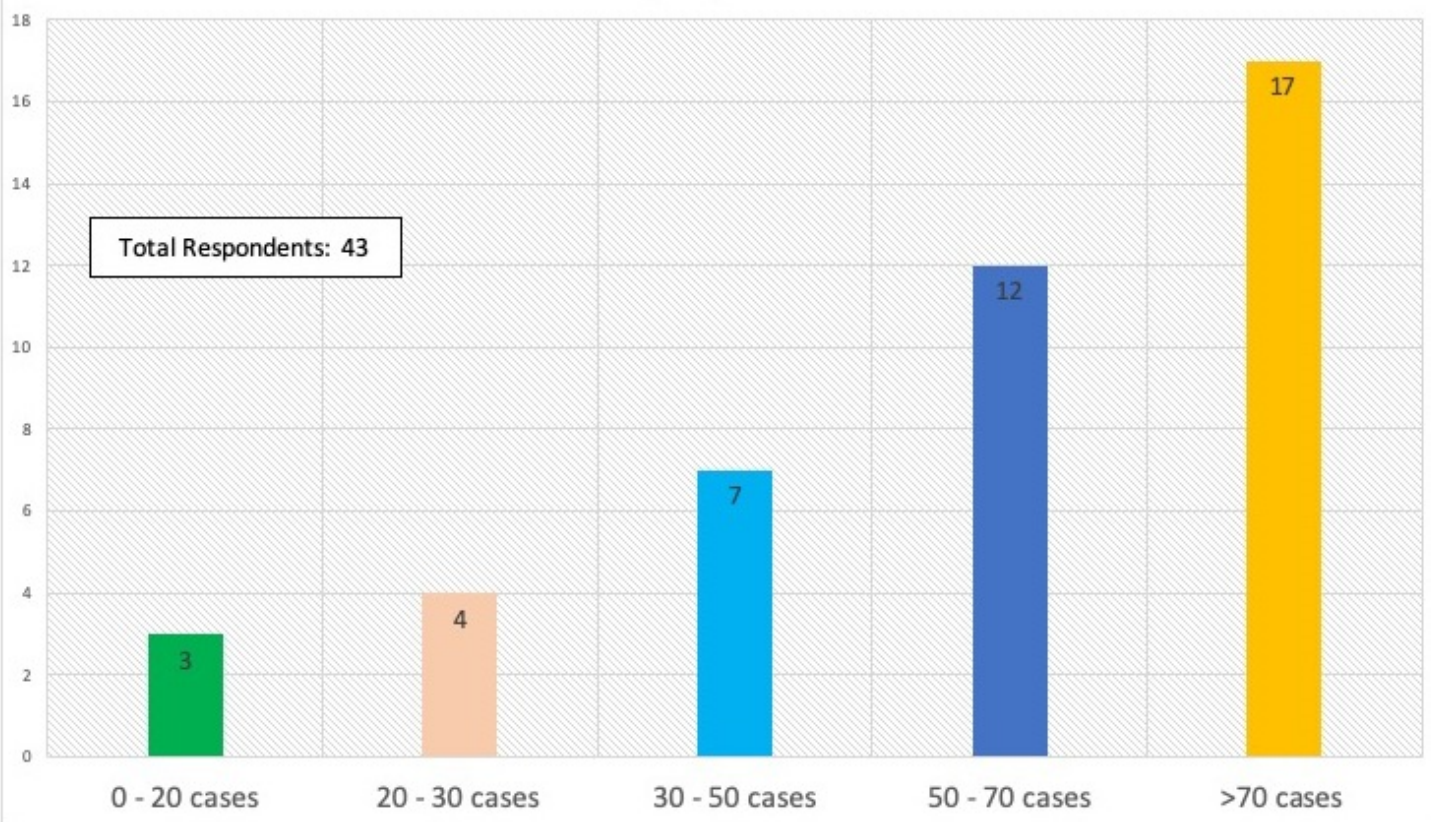
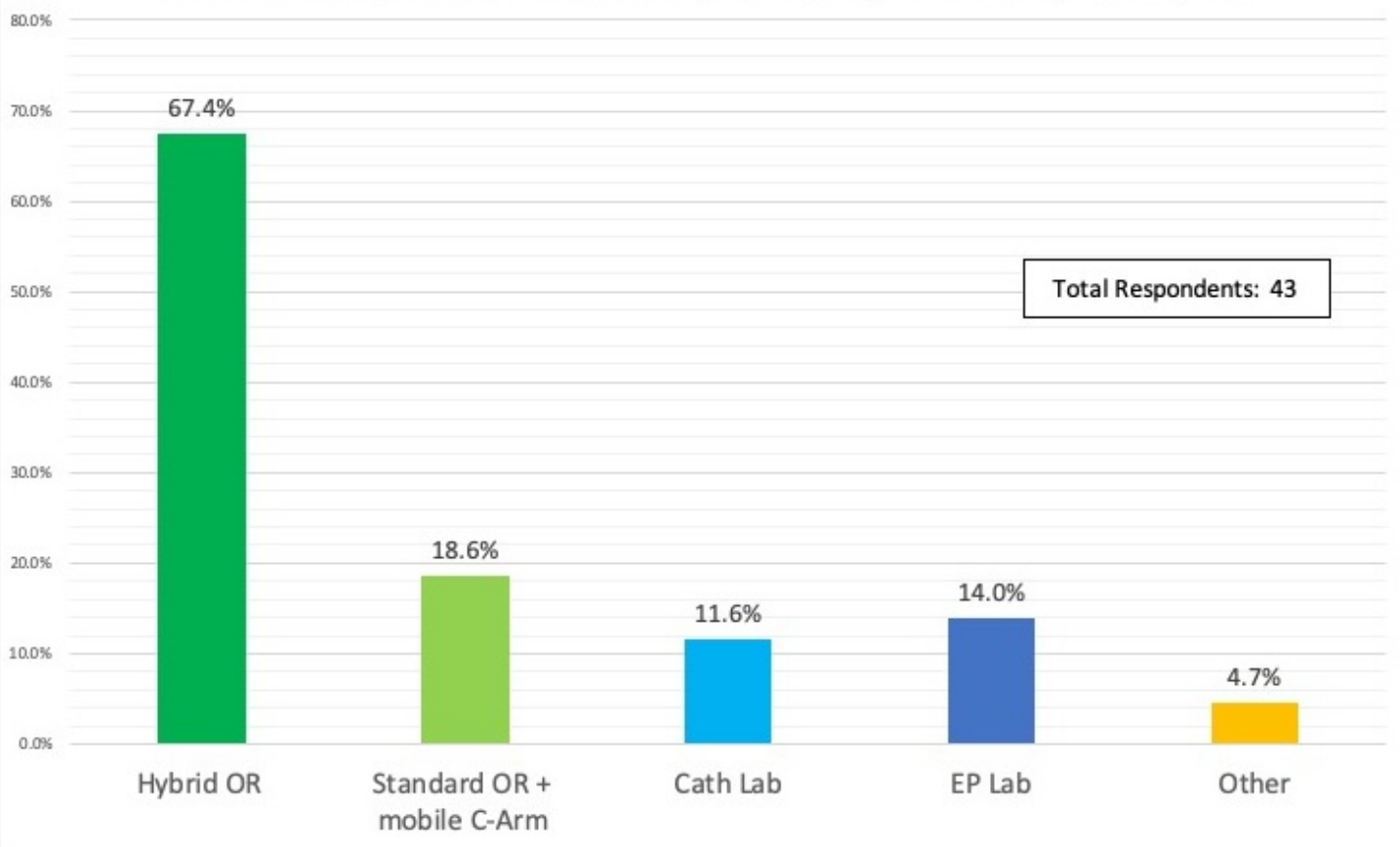


Figure 5. Concept of a core and an extended lead extraction Heart Team approach.

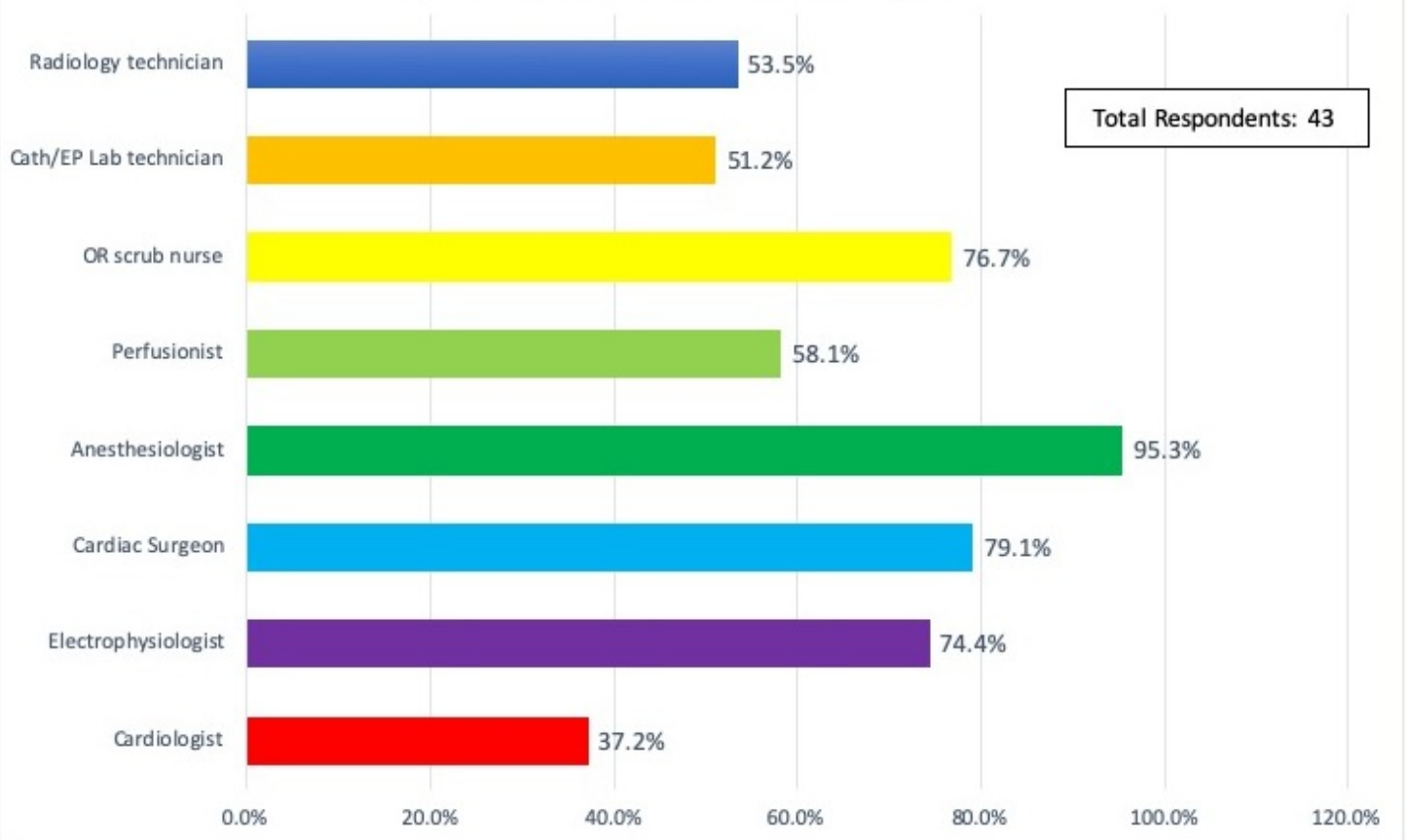
How many transvenous lead extraction procedures are performed in your clinic per year?



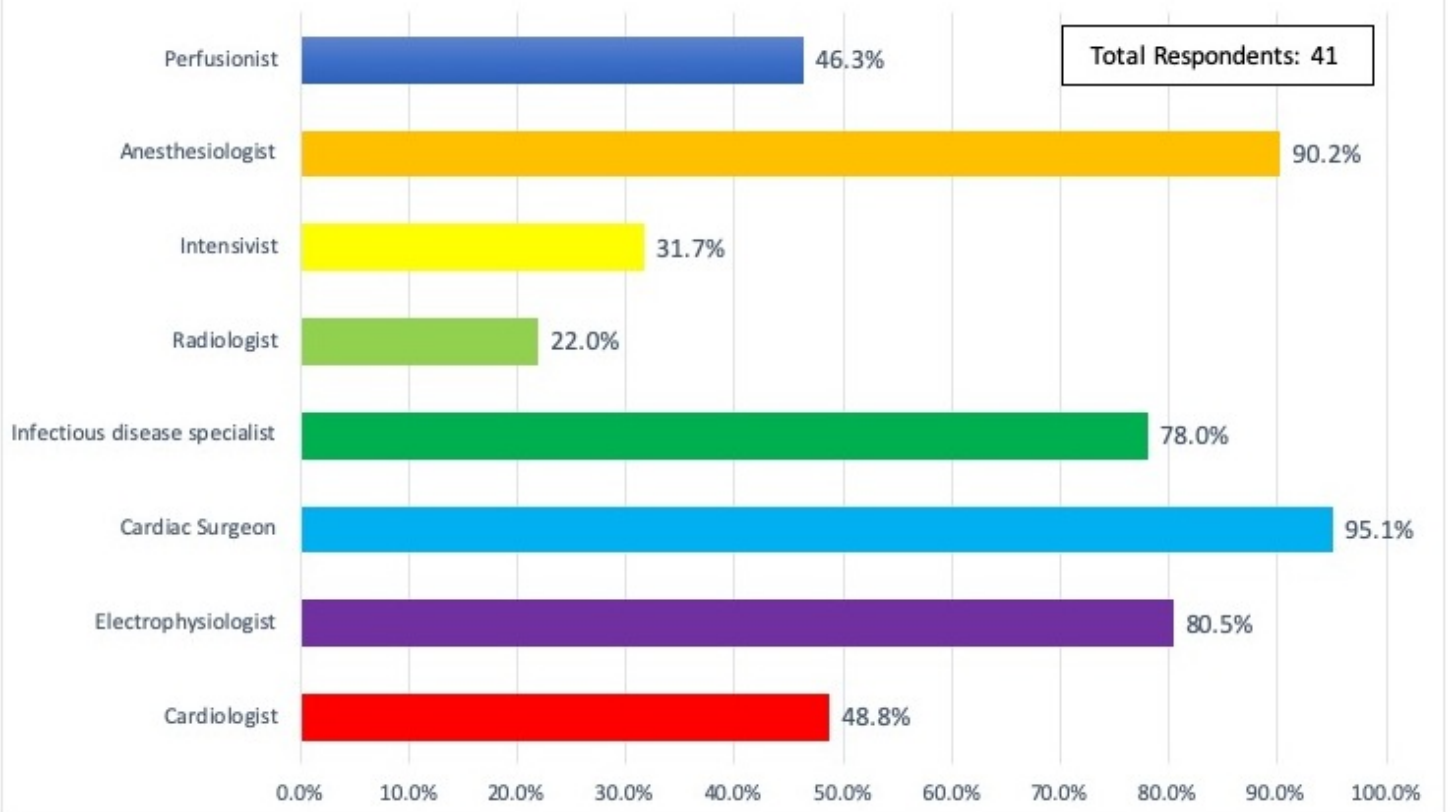
Where are transvenous lead extraction procedures performed in your hospital?



Who is part of your team performing TLE procedures?



In your opinion, who should be the members of an "Extended Heart Team" for TLE procedures?



Extended Lead Extraction Heart Team:

Infectious disease specialist (CIED infections)
Intensivist (TLE in heart failure patients)
Radiologist/Imaging specialist

Core Lead Extraction Heart Team

Electrophysiologist/cardiologist (mandatory)
Cardiac surgeon (mandatory)
Anesthesiologist (mandatory)
Perfusionist (mandatory)
Cath/EP Lab technician/nurse or OR nurse (mandatory)
Radiology technician (optional)