

# Osseointegration programmatic development: interdisciplinary team with a patient-centered approach

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**Abstract** Successful implementation of an osseointegration program requires a skilled and committed interdisciplinary team engaged in supporting patients and their families throughout the OI process. The roles and responsibilities of clinical and ancillary team members are described in detail, along with a discussion of the needed patient and family support resources. Time spent developing the interdisciplinary team, with strong regulatory support and engagement of hospital administration and the health system, will promote higher patient satisfaction and outcomes and innovative future directions.

**Keywords:** osseointegration program, interdisciplinary team, patient-centered

Building an OI program requires a dedicated interdisciplinary team committed to partnering with the patient and their families in seeking the best preoperative and postoperative outcomes. A programmatic approach ensures that the patient is being evaluated and treated holistically. In addition to the medical team, a successful OI program needs additional regulatory, patient, research, and administrative support within its hospital or system. While it takes time to develop an integrated program, onboarding experts from across disciplines, as outlined below, and facilitating their patient-centered collaboration is foundational to comprehensive support of the OI patient. The elements that provide for a strong osseointegration program are described

below. However, it should be noted that there is considerable heterogeneity in staffing models and resources across programs. Teams should leverage existing clinicians and resources. Full-time staff dedicated to an osseointegration program is not typical or, at most sites, necessary. Prioritize identifying colleagues that demonstrate commitment and enthusiasm for caring for this unique patient population.

## 1. Building the Program: Roles and Responsibilities

The configuration of a dynamic, collaborative, and experienced surgical and medical team, typically anchored by an orthopaedic

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surgeon and a physiatrist, enhances the patient experience and functional outcomes following OI. The physicians on the team need to have partnerships with the prosthetists, physical and occupational therapists, weight management/nutrition teams, and behavioral health professionals, as well as other surgeons (eg, plastic surgery). Moreover, selecting navigators to be liaisons for all members of the team and improve pathways for the patient to access the team gives cohesiveness to the months-long process. Finally, enlisting research professionals to provide data collection and robust program evaluation is key to ongoing administrative support and optimal patient care. An example of a patient's interaction with the members of the OI program is provided in Figure 1 to highlight the need for a cohesive and collaborative program.

1.1. Orthopaedic Surgeon

Osseointegration candidacy requires a multifaceted and detailed surgical assessment as patient selection involves concerted efforts to modify extrinsic and intrinsic elements prior to operative intervention. The Orthopedic Surgeon considers the patient factors driving osseointegration candidacy, commonly poor socket fit, inability to achieve optimal outcomes in a socket, and/or residual limb pain with socket wear. Beyond multiple comorbidity consideration, bone health, soft tissue morphology, weight management and nutrition, smoking cessation, alcohol intake moderation, and psychological stability are all attributes that contribute to the complex decision-making process. Patient interviews, radiographs, laboratory work, and referrals to and conferencing with other disciplines help provide a full overview of surgical candidacy. Finally, preparing the patient for postoperative discharge timing, expectations for rehabilitation participation, and wound care instructions allows for seamless transitions in the postsurgical period (see article in this supplement by Stoneback et al for a further discussion of patient selection).<sup>1</sup>

Skilled performance of OI requires that the surgeon be trained by a surgical expert as the bone preparation, soft tissue

management, and nerve work are of upmost importance to the success of the procedure. Additionally, working closely with the manufacturer of the prosthetic interfaces is paramount in surgical timing and maximizing abutment fit.

Following the stages of OI, surgeons prescribe advancements in weight-bearing based on cellular health, matrix construction and tissue integrity and balanced by objective findings, laboratory results, and derivatives of evidence-based practice protocols.

1.2. Physical Medicine and Rehabilitation Physician

The Physical Medicine and Rehabilitation (PM&R) physician, also known as a physiatrist, provides a holistic medical partnership with the multidisciplinary team and the patient. Providing oversight and professional viewpoints in patient selection are invaluable as the physiatrist's understanding of the postoperative recovery of function is specialized. The distinctive skill set of a physiatrist to assess suboptimal physiological status and mechanical mobility challenges and prognosticate postoperative recovery of function underscores the value their feedback can add to the decision-making process. Skilled enhancement of socket fit to complement the patient's goals and activity level while mitigating pain is one of physiatry's pivotal roles in candidacy consideration.

As PM&R manages the sequelae of multiple diseases across the life spectrum, their ability to give information on nuanced findings in psychology, immunology, pain mediators, and wound care are exceptional. Wound management can be a demanding role postoperatively related to the complexities of the surgeries and the associated comorbidities, but it is critical to protocol progression. PM&R works in tandem with physical and occupational therapists and prosthetists to optimize prosthetic fit and provide justification for prosthetic componentry and assistive devices to third party insurers. The role of the physiatrist is quite extensive and exceedingly integral to avoiding unpredictable outcomes postoperatively. Physiatry continues to be a gateway for functional optimization across the patient's lifetime.

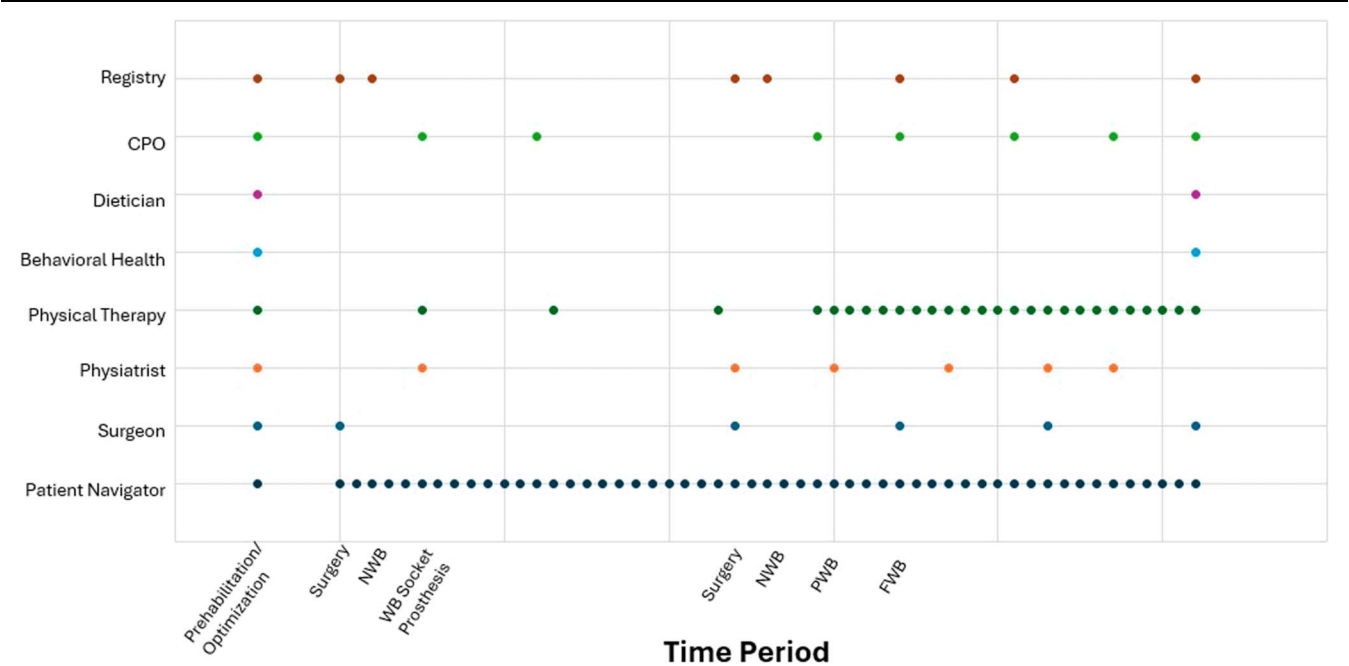


Figure 1. Example of frequency of patient interaction with OI program team members over time for 2-stage surgery.

### 1.3. Advanced Practice Providers

Programs providing OI care may benefit from the use of Advanced Practice Providers (APPs), including Physician Assistants and Nurse Practitioners. APPs enhance patient access and coordination of care. APPs provide care to patients in the clinic setting independently and in conjunction with their supervising physician. They perform consultations, perioperative education, and postoperative management. APPs can be the first line of clinician communication with any perioperative issues. They allow additional access to clinical care for unplanned visits outside of the surgeon's scheduled clinics. They fluidly communicate with the surgeon and team to ensure all issues and concerns are adequately addressed. Programs can engage APPs with expertise and training in orthopaedics, plastic surgery, or specific to osseointegration (cross-trained in plastics, vascular, infectious disease, orthopaedics). Common clinic needs addressed by APPs include documentation clarifications, wound care, antibiotic prescription, pain management, durable medical equipment coordination, infectious disease coordination, wound vacuum management, and xenograft application. In addition to their role in the clinic, APPs can also serve as surgical first assistants in OI operative cases, manage operative orders, provide medication management, and perform postoperative rounding in the hospital setting. They also participate in program initiatives and quality improvement to enhance patient outcomes.

### 1.4. Physical Therapist

While it is essential to have a Physical Therapist (PT) with knowledge in treating prosthetic impairments, OI requires an additional specialized skill set because of the uniqueness of the direct structural interface between the bone and the prosthesis. Generating sound movement and recovery of activity post-OI begins with "prehabilitation" (defined as preoperatively providing physical conditioning) to improve the foundation for OI surgical application and to enhance recovery outcomes. The postoperative knowledge base of weight bearing advancement, exercises to meet the confines of the protocol, and abutment site management is quite different from traditional prosthetics. Building a therapeutic relationship with a patient requires the therapist to have interpersonal skills of a coach, encourager, listener, and educator while being an intermediary for translating atypical findings to the other team members. This is especially important when the patient resides outside of a commutable catchment area. Employing digital resources for rehabilitative exercise and activity can be valuable for home follow-through between visits. Due to the visit frequency across the entire OI process, the PT has a vital role in monitoring functional progress, assessing prosthetic fit in collaboration with the prosthetist and physiatrist, cumulatively analyzing multiple variables that can negatively impact outcomes and connecting the patient to appropriate resources (see article in this supplement by Melton et al for further discussion of prehabilitation and rehabilitation in OI).<sup>2</sup>

### 1.5. Patient Navigator

Elective osseointegration is a multifaceted process that strategically employs an interdisciplinary health care team for optimized outcomes. The Patient Navigator can serve as a conduit for patient and team member information dissemination and coordination. By conducting frequent virtual check-ins

preoperatively and postoperatively, the navigator can triage patient concerns to the appropriate members of the team. This also simplifies the process for the patient, who would otherwise have to discern which clinician to contact and the process for contacting that person. With a patient navigator, the patient has one single point of contact (Fig. 2). The navigator can also coordinate follow-up appointments with all disciplines as needed. The navigator collaborates with research staff to obtain time sensitive research data. Since the patient navigator knows OI patients well, they can also connect patients with peers as part of the process. Finally, having a dedicated person familiar with insurance systems and FDA approvals can help to expedite those processes and decrease patient intake turnaround time.

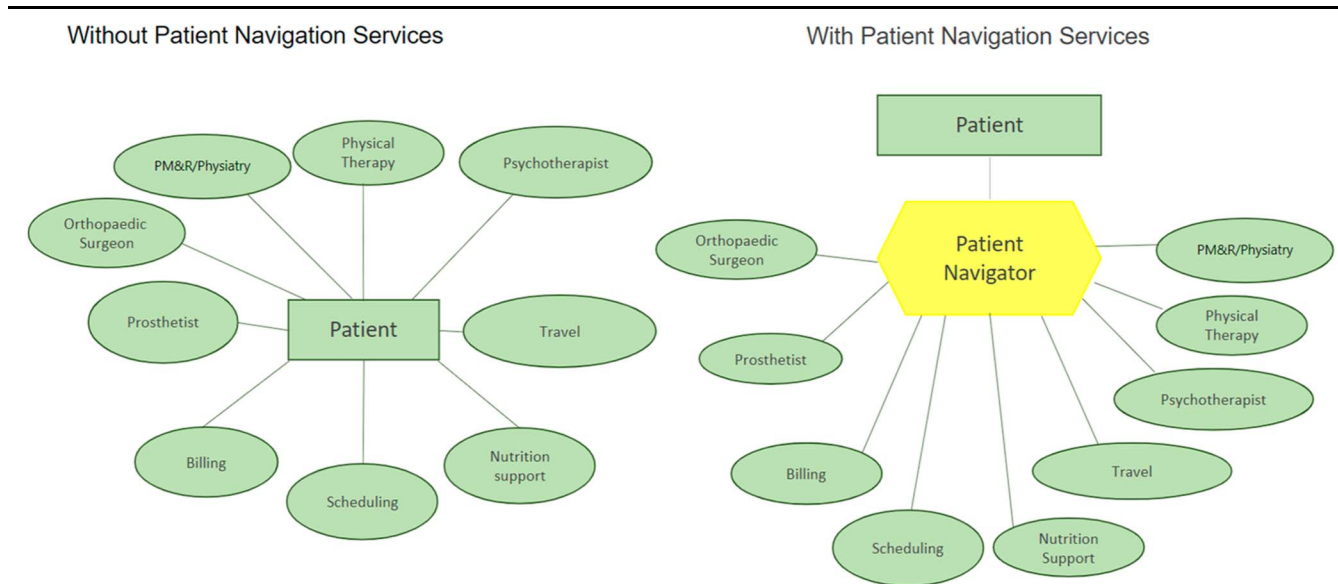
The navigator role promotes and enriches collaboration among all team members. For example, they can host monthly multidisciplinary virtual calls providing a platform for team members to discuss patient care across the continuum of OI. The navigator's organization and continual entries on a digital Patient Tracker spreadsheet allows the team to stay informed to aid comprehensive patient care. This system also provides demographics, amputation level, surgical dates, weight-bearing status and expected progression dates, upcoming appointments and pertinent prosthetic and therapy details to promote customized, expedient, and relevant communication with the patient.

The Patient Navigator provides leadership for patient care through education, connection, tracking and follow-up, and patient-related program development strategies. Providing education materials regarding surgical expectations, protocols, team member roles, patient responsibility, and contact information is crucial to helping the patient comprehend this robust process. Additionally, the patient navigator may serve as the liaison between the clinical personnel and the OI patients. This helps to further promote a positive relationship between clinicians, the navigator and the patient. Finally, it is not only essential for the patient navigator to ensure the patient has full comprehension of the OI process from the start to finish, helps to foster a trusting relationship. Establishing an open line of communication between the patients and their OI team allows for a smooth transition preoperatively and resourceful benefits across the needs of a life span.

For medical centers treating patients who live remote to the surgical team, activating a Travel/Global Navigator can be very beneficial. This team member can concentrate efforts to coordinate travel services, insurance information and other visitor details is essential for surgery and post-care access. Navigators are a proxy for access into the OI multidisciplinary medical community and a key to optimizing patient experience and sustaining patient quality of life.

### 1.6. Occupational Therapist

Similar to the physical therapist, the Occupational Therapist (OT) provides essential insight, and a specialized skill set when assisting upper extremity amputees returning to their day-to-day. It is common to see persons with upper extremity amputations opt out of using a prosthesis; many see it as easier to use their sound limb rather than learn how to use a prosthesis. OI, however, offers something that the traditional prosthetic device does not: a quick, direct attachment with a secure connection, instead of a socket that may continuously slip off the residual limb. While data collection is underway to evaluate differences in prosthetic usage, our anecdotal observations among the authors indicate that



**Figure 2.** Patient communication with services, with and without patient navigation services.

patients undergoing transhumeral OI surgery use their prosthesis more regularly than amputees with traditional sockets.

Prospective OI candidates should attend OT prehabilitation for baseline measurements, testing, education, exercise prescription and goal setting. Postoperatively, OT follows the associated OI protocols to enhance the use, competence, and confidence of the integrated prosthesis in activities of daily living and community and vocational roles. Similar to the PT role described above, OT also communicates atypical findings to the team, assesses the prosthetic fit in collaboration with the prosthetist and physiatrist, and connects the patient to appropriate resources to enrich outcomes and assist the patient with meeting personal goals. Since OI eliminates the socket, greater movement opportunities abound. Inclusion of a skilled OT on the OI interdisciplinary team further supports patients in achieving their highest potential, highest potential, developing new abilities, and gaining assurance to become bimanual again.

### 1.7. Certified Prosthetist

The expertise of a prosthetist certified in managing OI componentry is essential to delivering care to patients. There are several activities unique to osseointegration that are needed to develop a highly integrated interdisciplinary team. These additional activities fall into a few categories, including insurance authorization and device acquisition, iterations of determining prosthetic fit and alignment, and coordination with local and remote clinicians (ie, physiatrists, physical therapists, prosthetists). Close collaboration with the OI team is critical. First, a support staff adept at assisting the prosthetist with care coordination, including securing insurance authorization and acquisition of device components and documenting the reasons why a traditional socket was unsuccessful, promotes prompt engagement with the prosthetic application throughout the OI protocol. Optimal fit under the constraints of OI precautions, morphology characteristics, insurance authorized componentry for the bone anchored limb prosthesis and patient-specific activity attributions require higher level decision making because the bone is weightbearing, not the residual limb. Prosthetists working with OI may require more consistent patient education as related to exudative

expectations and management, hygiene, cleaning and maintenance of the bone anchored connector. Due to the lack of general knowledge about OI in the medical community at large, the prosthetist's educational role will likely expand, especially to remote sites providing therapy and other prosthetic-related services. Video conferencing for troubleshooting patient concerns is often an expectation for prosthetists addressing needs of patients residing outside of a commutable distance from the index surgical facility.

### 1.8. Behavioral Health

Utilizing a patient-centered and biopsychosocial approach toward surgical candidacy is essential as it acknowledges the emotional and mental wellbeing of a patient. The biopsychosocial model represents a comprehensive approach to understanding health and illness, which considers the interplay of biological, psychological, and social factors in shaping an individual's well-being. This model acknowledges that, while biological elements influence health, psychological and social factors equally determine health. It also recognizes that the success of osseointegration is not solely dependent on the surgical technique or the implant itself. The patient's psychological status and social context also drives patient outcome.

Some centers actively engage a psychiatrist as a core member of the OI team. Others include behavioral health clinicians such as licensed clinical social workers or psychologists. These team members assess the patients' psychological readiness for surgery, coping skills, emotional responses to the procedure, and the presence of mental health issues such as anxiety, depression, or cognitive concerns. These clinicians can also perform various testing such as the Montreal Cognitive Assessment,<sup>3</sup> Michigan Alcoholism Screening Test,<sup>4</sup> Drug Abuse Screening Test,<sup>5</sup> among others, to screen for cognitive impairment and substance use disorders that may adversely impact surgical outcomes. While the depth of psychological and cognitive screening varies, osseointegration programs should have behavioral health referral systems in place to assist patients throughout the surgical and rehabilitative processes.

Psychological support and supportive therapeutic interventions can help promote emotional resilience and enhance the

patient's overall mental health during the osseointegration process to ensure that they are better equipped to manage pain and the challenges associated with decreased mobility. Exploring social determinants of health, particularly support networks and socioeconomic factors, provides a cornerstone for enhancing the patient's capacity to adhere to the post-operative protocol and adapt to the implant. Fortifying these aspects prior to surgery is a catalyst to optimized recovery.

In essence, the biopsychosocial model for osseointegration underscores that the procedure's success does not hinge solely on surgical technique. Instead, it recognizes patient outcomes are profoundly influenced by a holistic, patient-centered approach to psychological and social well-being (Fig. 3).

### 1.9. Registered Dietician

Individuals selecting osseointegration (OI) as a definitive outcome due to unrelenting pain with traditional socket wear, poorly fitting and/or functioning prosthetic componentry have often become cumulatively less active.<sup>6-8</sup> Poor eating habits, depression from lack of quality of life, past medical history characteristics and stress can add to weight gain, accelerating body mass index (BMI) values in this population. Optimizing BMI before and after surgery is critical to healing and physical functioning success. The partnership with a registered dietician in this team gives the OI patient at any income level an opportunity to learn how to build a healthy diet and follow-through at home. Frequent virtual or in-person visits keep accountability higher across the continuum of OI.

### 1.10. Research Team

Researchers are critical members of the osseointegration team. First, research professionals have knowledge and expertise about

the regulatory pathways required for approval of implants that the United States Food and Drug Administration (FDA) has not yet fully approved. Second, documentation and data capture are critical given the number of unanswered questions about the emerging field of osseointegration. Engaging researchers on the OI team is an essential element to support the regulatory requirements, monitor patient safety and outcomes for quality assurance, and to contribute to the emerging peer-reviewed literature.

## 2. Regulatory

The United States FDA's role is to evaluate safety and effectiveness of medical products pre- and post-market, and to regulate companies who manufacture, repackage, relabel, and/or import medical products. The Center for Devices and Radiological Health division provides oversight for medical devices. There are a number of FDA premarket submission and approval pathways for medical devices: Premarket Notification (510K), Premarket Approval, and expanded use with Investigation Device Exemption, Humanitarian Device Exemption and Compassionate Use Exemption. The Expanded access provides a pathway for patients with serious and life-threatening disease and conditions to access investigational medical devices that have not approved or cleared by the FDA for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options.<sup>9</sup> In the last decade, FDA expanded access pathways has provided the amputee community in the United States access to non-traditional prosthesis options like osseointegration surgery and bone-anchored implant systems approved in the European Union.

Expanded access includes emergency use, compassionate use, and treatment investigational device exemption. The Compassionate Use application is most relevant to amputee patients and osseointegrated prostheses. The Compassionate Use Expanded Access was established in 1987 to provide access to patients with life-threatening or serious disease or condition. In these cases, there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. The potential benefit must justify the potential risks of the medical device. It is a patient request process in which the physician and the device company work in conjunction to receive FDA approval. The physician may not treat the patient until they receive both FDA and Institutional Review Board (IRB) approval for the intended patient.

To request FDA approval for compassionate use of a bone-anchored implant, the physician will provide the following documents for device company, FDA and IRB approvals prior to initiation of treatment.

### 2.1. Step 1: Initial Submission to Device Company

To assess the suitability of the device for the patient, the following items must be submitted to the device company prior to engaging with the FDA and IRB:

- Radiographic images of the patient along with consultation notes justifying the use of the device.
- A treatment plan including a detailed description of the device.

The device company will review these submissions and, if deemed appropriate, will issue an approval letter.



**Figure 3.** Team approach to quality-of-life recovery postosseointegration.



## 2.2. Step 2: Submission to FDA

Following approval from the device company, the physician and/or device company must submit the following documents to the FDA:

- An approval letter from the device company authorizing the use and supply of the device.
- A letter from the surgeon detailing the patient's condition and the medical necessity of the treatment.
- An informed consent document which provides sufficient information to help the patient make an informed decision regarding the treatment.
- An independent assessment letter from an uninvolved physician.
- The FDA will have 30 days from the receipt of the submission to respond with an approval, an approval with conditions, or a disapproval.

## 2.3. Step 3: Submission to IRB

Once FDA approval is obtained, the physician must submit the complete FDA submission documents along with the approval letter to the IRB for their review and approval.

## 2.4. Step 4: Initiation of Treatment

Upon receiving IRB approval, the surgeon may proceed with initiating the treatment.

## 2.5. Step 5: Follow-Up and Reporting to FDA

After FDA approval and 45 days following the initiation of treatment, a report summarizing the patient's outcome, including any adverse events and complications, must be submitted to the FDA.

This structured process ensures compliance with regulatory requirements and guarantees that the patient receives the most appropriate and safe treatment using the device.

## 3. Research and Registry Participation

Osseointegration has a growing literature base, but many unanswered questions remain. There remains a need to define concepts, provide support for indications, document the incidence of complications, and test strategies to ameliorate common challenges. Furthermore, given the interdisciplinary nature of osseointegration care, research can help to integrate knowledge from different disciplines to establish best practices. Participating in an established registry allows OI programs to collaboratively optimize safety, analyze outcomes, and explore new directions. Given the relatively small OI population, generating statistical power requires multisite and multinational data.

### 3.1. Patient Support

Osseointegration is a months-long staged set of surgical procedures and life-long commitment to maintain function and quality of life. Therefore, providing patient support to enhance overall well-being while meeting milestones in function and quality of life are critical program elements. Patients undergoing amputation are likely to benefit mentally, emotionally, and spiritually from connecting with other amputees and those who

have experienced traumatic events rendering physical impairment. Peer support is critical and can be offered 1:1 or as a group. These connections can be beneficial at all stages of the process. Patient Navigators can also help connect prospective patients to established OI patients to assist in their decision-making. This helps them better understand the concerns, risks, necessary support, rehabilitation, and recovery process before making the decision to move forward. While strategies for patient support can and should vary widely, integrating an intentional approach to support is a critical element of an Osseointegration Program.

Support groups, offered in person or virtually, can meet important psychosocial needs for patients and their families. Established programs, including the Trauma Survivors Network (TSN), are available in many Level 1 and Level 2 trauma centers.<sup>10</sup> The TSN serves a wide range of patients and their families and is not specific to amputees. The TSN offers in-person and virtual support groups directly through hospitals. However, the team also developed a 6-week online class modeled after the Chronic Disease Self-Management Program called, "Next Steps," available virtually to all.<sup>11</sup> Many institutions have amputee-specific support groups that are yet another pillar of support that can be leveraged by the osseointegration program. These support groups provide a network among patients to check in with one another and compare how their journey has differed from others. They can be helpful in keeping an individual from feelings of loneliness during their recovery; it is beneficial to both their mental and physical health and creates a greater opportunity for individuals to excel in the rehabilitation process. Patient Navigators can connect patients to existing support groups or develop osseointegration specific groups, in person or virtually.

Ongoing modifications to existing patient education materials and commitment to tailoring or redesigning the program based on patient and caregiver feedback is an expectation to address patient support and a blueprint for the multiple layers of this procedure. To consistently partner with patients and caregivers across a spectrum of conditions, ages, abilities, and interests, an ongoing dialogue within the team and implementation of strategies to address patient feedback is an important role of the navigator. Program satisfaction hinges on education and resources; therefore, a concerted effort to provide appealing and helpful materials is essential.

### 3.2. Engaging Hospital Administration

Clear communication with hospital administration is essential. Before a program is created, the interested clinicians should address personnel needs, implants contracts, and other resources with administration and coordinate an operation plan. Framing a scenario in which both the patients and the hospital benefits is key: Patients must return not only for surgery but also follow-up care (eg, complications, rehabilitation, maintenance). This is not a "one and done" surgery, but a lifelong commitment. The physical and mental benefits of OI may also be highlighted so that the administration gains a better understanding of what will come from standing up an Osseointegration Program: increased revenue through returning patients, patients experiencing greater physical and mental health, and achieving recognition nationally and internationally for performing a novel procedure.

Hospital administrative support is fundamental in launching an OI program to address scaling needs for operating rooms and support during the acute hospitalization and/or inpatient rehabilitation. Demonstrating an evidence-based practice prototype within a business model that highlights commitment to a

long-term patient-focused care while building revenue profitability margins is key to ensuring administrative support. Detailing ancillary resources necessary for success should be discussed as regulatory involvement and surgeon and staff training are essential for adhering to FDA and IRB guidelines and developing and adhering to safety protocols. Finally, establishing follow-up at the administrative level to document benchmark achievements, review metrics, and provide directions for transformation and innovation allows an OI program to evolve and flourish.

#### 4. Conclusion

Successful implementation of an osseointegration program requires a skilled and committed interdisciplinary team engaged in supporting patients and their families throughout the OI process. Patients often need episodic care and access to OI expertise long after they have become independent, so the collaboration of this team is over a user's lifetime. Additionally, to address safety and design future directions, research staff needs to be integrated and active in data collection and analysis. Engagement of hospital administration will require time to build in the resources needed to promote this multilayered paradigm. Ultimately, the authors believe time spent developing a robust and detailed team approach with concerted efforts to adapt and modify their programs over time and contribute to registry research will promote higher patient satisfaction and outcomes and innovative future directions.

#### Appendix 1. Collaborators

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