The role of a clinical engineer within a mechanical circulatory support device program: a single center's experience

With the rapidly growing world of mechanical circulatory support device programs, a variety of multidisciplinary team models have been successful. Most include nurses, nurse practitioners, perfusionists, and/or clinical engineers, with patient care and education primarily directed by nurses. At Aurora St Luke's Medical Center, the team includes transplant surgeons, transplant cardiologists, nurse practitioners, clinical engineers, perfusionists, and nurses who serve as transplant coordinators and research coordinators, but the team is unique in having clinical engineers at the center of patient care. The clinical engineers and the transplant coordinators split many of the duties of a typical ventricular assist device coordinator. The role of the clinical engineer within the program is elucidated by discussing the history of the program, the structure of the clinical engineering team, the duties related to mechanical circulatory support devices and the additional responsibilities of the clinical engineers. (*Progress in Transplantation.* 2010;20:148-154)

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With the rapidly growing world of mechanical circulatory support device (MCSD) programs, a variety of multidisciplinary team models have been successful. Most teams include nurses, nurse practitioners, perfusionists, and/or clinical engineers,[1-3] with patient care and education primarily directed by nurses. At Aurora St Luke's Medical Center, a premier 938-bed cardiac tertiary care hospital in Milwaukee, Wisconsin, the MCSD team includes transplant surgeons, transplant cardiologists, nurse practitioners, clinical engineers, perfusionists, and nurses who serve as transplant coordinators and research coordinators, but the team is unique in having clinical engineers at the center of patient care. Every member of the MCSD team has a specific role in relation to the program. The clinical engineers and the transplant coordinators split many of the duties of a typical ventricular assist device (VAD) coordinator. This article discusses the role of the clinical engineer within our program by discussing the history of the program, the structure of the clinical engineering team, and the MCSD-related duties and other responsibilities of the clinical engineers.

Not the Usual Biomedical Engineering Department

Although every hospital has a biomedical engineering department, a department that consists of technicians who repair hospital equipment when it is not interfaced with a patient, the clinical engineers associated with the MCSD program are a separate department. They focus on clinically troubleshooting the equipment while it is attached to a patient. The engineers assist the nurses and physicians in actively resolving problems by making adjustments on equipment based on clinical observations. The engineer's clinical training includes such things as analyzing hemodynamics and electrocardiography tracings, learning cardiac drugs, and obtaining Adult Cardiac Life Support certification.

Within our staff of engineers, we do have one engineer who has a joint appointment. He spends half of his time as a clinical engineer in the MCSD program and the other half in the hospital-wide biomedical engineering department. He is responsible for fixing any of the MCSD equipment and performing the preventative maintenance as required.

Table 1 A sample from the clinical engineer competency checklist

Device	Mechanism for evaluating competency	Verified date	Preceptor's initials
Abiomed Impella (Abiomed Inc, Danvers, Massachusetts)	1. Do an implant alone	1.	1.
	2. Do an explant alone	2.	2.
	3. Demonstrate emergency procedures	3.	3.
	4. Verbalize anticoagulation protocol	4.	4.
	5. Demonstrate how to do a bolus	5.	5.
	6. Demonstrate how to switch out purge solution	6.	6.
	7. Verbalize alarms	7.	7.
	8. Verbalize weaning procedures	8.	8.
	9. Teach hands-on	9.	9.
HeartMate II (Thoratec Inc, Pleasanton, California)	1. Do an implant alone	1.	1.
	2. Do an explant alone	2.	2.
	3. Perform a controller self-test	3.	3.
	4. Save data on programmer	4.	4.
	5. E-mail data to company	5.	5.
	6. Program back-up controller	6.	6.
	7. Demonstrate emergency procedures	7.	7.
	8. Verbalize alarms	8.	8.
	9. Teach patient release class	9.	9.
	10. Teach hands-on to nurses and patients' family members	10.	10.
	11. Place binder on patient	11.	11.
	12. Discharge a patient home	12.	12.
	13. Do a shower with patient	13.	13.
Thoratec VAD (Thoratec Inc, Pleasanton, California)	1. Do an implant alone	1.	1.
	2. Do an explant alone	2.	2.
	3. Verbalize anticoagulation protocol	3.	3.
	4. Verbalize the weaning procedure	4.	4.
	5. Demonstrate emergency procedures	5.	5.
	6. Change a patient to the portable	6.	6.
	7. Teach hands-on	7.	7.

History

The MCSD program at Aurora St Luke's Medical Center began in 1986. More than 400 VADs and 14 total artificial hearts have been implanted since that time. Clinical engineers have been involved with this program since its inception; initially, only 1 engineer was on staff.[4] Over the years, patient volumes have increased significantly; currently, 3 full-time and 3 part-time engineers staff between 6 AM and 11 PM Monday through Friday and a day shift on Saturday. The day shift is staffed more heavily than the evening shift. As the program continues to grow, we will continue to reassess our staffing needs and adjust accordingly. An engineer is on call at all times to be available to all hospital staff, physicians, patients, and patients' families.

Clinical Engineering Orientation

The clinical engineering position requires a bachelor's degree in biomedical engineering from an accredited university. The biomedical engineering degree has several options (eg, biocomputing, bioelectronics, and biomechanics), but this position does not give precedence to a particular subspecialty. Most candidates for the position have little or no experience with MCSDs, so we anticipate and plan for a comprehensive and intensive training period. When interviewing a candidate, it is important to look for someone with a strong work ethic who can handle the demands of the job, while having a personable demeanor that would work well when interacting with the staff, patients, and patients' families.

The clinical engineer orientation involves two 6-month training periods. During the first 6-month period, the new engineer is on call 24 hours a day, 7 days a week with 1 weekend off a month. If the primary engineer is called in for an emergent implant or a clinical situation that requires direct assistance, the orientee is called in as well. This allows exposure to clinical situations and an exchange of integral knowledge to occur from the primary engineer to the orientee. Daily instruction by the senior engineers also plays an important part during the first 6-month phase. This instruction involves educating the orientee on device management and clinical care of the patient. The orientee has a checklist of skills involving all devices and equipment in the intensive care unit (ICU) that must be checked off (Table 1). Typically within this period, the orientee is able to help take care of patients within 3 months. After the supervisor of the VAD program has determined that the orientee has met all of the skills necessary, the orientee is allowed to progress to the second phase of orientation.

The second phase of orientation (6 months) involves preparing the orientee to be on call by him or herself. The employee is on call during this period also, but for the last 3 months, the orientee functions as the primary on-call engineer with a backup senior engineer. The senior engineer is available to answer questions about clinical aspects that are unfamiliar to the new engineer. Once again, the orientee has a checklist of experiences to complete. Once this checklist is complete, the supervisor removes the "orientation" status of the new engineer.

Before and After Implantation

When a patient is being evaluated for a device, one of the engineers meets with the patient and family. The engineer shows them the device, explains how it works, informs them of their responsibilities with the device, and answers any questions they have. The patient is then given some written information on the device and a business card to call with any additional questions. Last, as part of our Joint Commission performance improvement plan, the patient is given an SF-36 questionnaire.[5] The SF-36 is measured before implant, then again at 3, 6, 9, and 12-month intervals. The SF-36 is a tool to track how a patient is doing both physically and mentally. The scores from the interval periods after implantation are compared with the scores from before implantation to ensure that the patient is getting better. If a decline is noted, a plan is put into place to help the patient.

At implantation, the engineer gathers the supplies needed and brings them to the operating room. The engineer works with the surgical technician to prepare the device and ensures that the necessary tools are sterilized.[6,7] The surgical technician does the sterile preparation, while the engineer does the nonsterile portion. The engineer serves as a resource to the surgical technician, because it may have been a long time since the technician has implanted a VAD. The engineer has a quality assurance checklist that he/she completes as the case continues to make sure that all necessary steps have been performed. The engineer completes all necessary paperwork such as the device tracking sheet and documentation of any research information.

The engineer starts up the device when the surgeon is ready. Communication among the engineer, the perfusionist, the surgeon, and the anesthesiologist is crucial at this phase. The engineer also records any electronic data that are required for a clinical study. After the procedure is complete, the engineer accompanies the patient and surgical staff to the ICU. Before leaving the unit, the engineer verifies that all equipment is present and the nurse is comfortable with the device. Although the nurses are trained on the devices, they can page the engineers if they need any help with troubleshooting technical and/or clinical problems.

When the device is explanted, the engineer accompanies the patient to the operating suite. The engineer operates the device throughout the procedure and turns the device off when the surgeon places the patient on bypass. If the device is a research device, the engineer takes any necessary pictures and fills out any required paperwork. The engineer collects the pump so that it can be returned to the company later.

If a patient needs to go back to surgery for any reason, such as bleeding or general surgical issues, the engineer always accompanies the patient. If a patient is taken back to surgery for a general procedure, the engineer is often the only team member present who is trained on the device. In this challenging scenario, the engineer may do some brief education with the anesthesiologist and nurses throughout the case to explain what is happening clinically.

The engineer also maintains the entire surgical and equipment inventory. At the beginning of the month, a complete inventory is taken, ensuring that all expiration dates are acceptable. Throughout the month, the engineers verify that replacement surgical supplies have arrived once an implant has been completed. The engineers also order any equipment that is necessary for patient discharges. The challenge is to keep enough stock on hand to be ready for an implant, but not so much that supplies expire.

Patient Care

At least one of the engineers rounds on each inpatient every scheduled workday to check the patient's recovery, evaluate teaching needs, examine device parameters, and troubleshoot any problems. In addition, the engineers take the patients to all invasive procedures. If the patient is on the step-down unit or if the ICU nurse is not comfortable taking a patient alone, the engineer can take the patient to all tests. The engineers, along with the cardiac rehabilitation staff, take the patients to the inpatient gym. They also work with the patients to alleviate their boredom by taking them outside, down to the cafeteria, to the auditorium for "big screen movie nights," to art therapy, to an in-house apartment, or to an area within the hospital to participate in recreational or leisure activities. These activities would otherwise not be possible, as nursing does not have the staff available for prolonged trips off the unit.

Along with the transplant cardiologist and the nurse transplant coordinator, the engineer sees all patients with a device when they are in the outpatient clinic. At this visit, the engineer checks the patient's equipment to verify that it is functioning properly. He or she obtains a set of numbers from the device and records any electronic data if necessary. The engineer answers any questions and addresses any device-related concerns. The device parameters that the patient records

Table 2 Retesting competency checklist for the HeartMate II

Aurora St Luke's Medical Center
Milwaukee, Wisconsin

HeartMate II VAD System

Patient Recertification Checklist

The participant must complete these requirements:

1.) Demonstrate how to switch out the controller. _____

2.) Discuss the numbers on the display screen. _____

3.) Demonstrate how to listen to the pump with a stethoscope. _____

4.) Verbalize who needs to be contacted when the patient comes to the hospital for an unscheduled reason. _____

5.) Demonstrate paging the engineer. _____

Participant's name (please print)_____

Participant's signature_____Date_____

Instructor's signature_____Date_____

at home are also assessed for irregularities. Every other month, the engineer retests the patient on his or her device competency. This retesting consists of a hands-on checklist that verifies that the patient can perform all emergency procedures and knows whom to contact in an emergency (Table 2). Initially the engineers did this every 6 months, but found their retention of information to be poor, so now retesting is done every 2 months. The engineer administers the SF-36 questionnaire every 3 months for the first year. In addition, he or she gives the patient any needed supplies and fills out the charge sheet as appropriate.

The engineers play an active role in emergency care for the MCSD patients. Because of the number of devices used, the large number of emergency department staff, and the infrequent nature of emergency visits for MCSD patients, it is difficult to maintain ongoing staff competency. Instead, when a device patient comes to the emergency department, an engineer is deployed to be with the patient the entire visit. The patients are trained to page an engineer before they come to the emergency department so that one can meet them there.

Teaching

The engineers write all the class handouts, competency checklists, tests, and annual reviews for each device (Table 3). The engineer structures these materials on the basis of classes from the device manufacturer and the instructions for use and other materials that the company provides.[6,7]

The engineers teach the devices to the nurses in the ICU and the general-care unit; nurse practitioners; nurse transplant coordinators; nurse research coordinators; physical, occupational, and recreational therapists; cardiac rehabilitation staff; and the Visiting Nurses Association. This teaching includes the initial training and the annual reviews and is customized to the role of the caregiver in patient care. In addition, the engineers do frequent and ongoing bedside teaching for the staff. Staff can page the engineer if they have not taken care of a patient with the device recently and require a review.

The engineers teach the device to the patient and all companions. Engineers present all classes. Patients are not relied on to train their companions or caregivers. After the initial class, the engineers administer a written test and a hands-on competency evaluation to each person. Teaching styles and evaluation of competency are tailored to the needs of both the patient and the patient's caregiver or companion. The engineers chart the patient's progress with teaching, so that the entire MCSD team is aware of the patient's status.

Additional MCSD Responsibilities for Engineers

The engineers are responsible for contacting the patient's local provider of emergency medical services (EMS). The engineer discusses the needs of the patient and describes the device. The engineer sends the EMS providers a letter from the physician and a summary of the particular device that the patient is on

Table 3 Example of a HeartMate II patient test (page 1 of 3)

HeartMate II VAD System
with Go Gear
Written test for patient and companions

Name_____
Date_____ Grade_____

True or False. Please circle the appropriate answer.

1.) The red broken heart is a noncritical alarm.
True False

2.) The controller draws electricity from both batteries at the same time.
True False

3.) The pump can operate on just one battery.
True False

4.) The patient should never sleep on battery power.
True False

5.) The patient can play "full contact" sports.
True False

6.) The patient can take a bath if he/she uses the protective bag.
True False

7.) The controller has a built-in backup system that will operate the pump if the controller fails.
True False

Please answer the following questions.

1.) What does it mean if 2 lights appear on the battery fuel gauge when you press the "alarm reset" button on the controller?

(see Figure). The engineer also makes a laminated card for the patient with the emergency contact numbers on it. This card includes phone numbers for the engineer, the transplant clinic, the surgeon, and EMS. The engineers also contact the patient's power company to let them know that the patient is on life-support equipment.

The engineers enter all data into INTERMACS, the national VAD database. The nurse research coordinators obtain the consent from the patient. Once the patient has given consent, 1 of the full-time engineers does the chart reviews and enters the information into the database. The engineers also enter data into their own internal database for VADs, including the results of the SF-36. These data are used for the program's 4 performance measures: all-cause mortality, functional capacity, infection, and length of stay.

The engineers maintain the device tracking sheets and any device accountability logs for research devices. They maintain patient files that have copies of the device flow sheet, the device tracking sheets, the implant sheets, the quality assurance checklist from surgery, and all teaching competencies.

The engineers are responsible for obtaining research devices explanted from patients, whether for a transplant or death. If the patient has died, the engineer goes to the morgue to tell the pathologist how to remove the device. The device is prepared according to the manufacturer's recommendations and then shipped to the appropriate address.

An important aspect of delivering excellent care to the patients and staff is to ensure that the engineers have excellent communication within the team. Although the hospital employs several engineers, they work varying shifts. To facilitate communication, a daily report sheet is used. The report sheet describes what was found during rounds. Each engineer also lists what happened during his or her shift. The report sheet has a running list of all current device patients and all potential patients. The engineers also e-mail this report sheet to the nurse transplant coordinator that is in charge of the VAD patients and to the nurse research coordinators so that everyone is informed about what is happening with the patients.

Once a week, one of the engineers is responsible for checking the devices for all inpatients. This check includes wiping down the cart and the equipment, verifying that the patient has a stabilizing belt on their driveline, and blowing dust out of any fans located within the equipment.

The engineers work closely with the billing, coding, and auditing departments to make sure that billing is done correctly for these patients. This responsibility includes informing each department whenever a new patient receives an implant. The engineers tell them if the patient has a research device or not, so that staff know how to code the device properly. In addition, by informing staff if the patient is in a research study or not, the billing department is informed about whether or not they can mark up the cost of the device.

The engineers participate in weekly team rounds, where the entire MCSD team meets to discuss inpatient needs. Every other week, the engineers present a PowerPoint presentation at the MCSD selection meeting about the status of every patient in the MCSD program. Future, potential patients are also discussed at this meeting. The engineers record the minutes from these meetings.

Joint Commission Readiness

The supervisor of the VAD program also ensures that the program is in a constant state of Joint Commission readiness. The supervisor leads quality improvement via monthly quality meetings, where the group discusses performance improvement measures for the program and any quality issues that arise. The supervisor also reports these data at quarterly transplant advisory meetings and yearly quality council meetings. The engineers help the supervisor prepare the performance improvement reports by ensuring the internal patient database is kept up to date.

Mr Smith
Fire Chief

Dear Mr Smith:

One of our patients, Mr X, is living in xxxx with an implanted left ventricular assist device (LVAD) called the HeartMate II VAD. The Heartmate II is an axial flow device that provides partial support to the patient's left ventricle. The VAD has no valves and provides nonpulsatile blood flow. The device is run at a speed that maintains adequate cardiac output often without the patient having a palpable pulse.

Because the VAD provides nonpulsatile flow, physical examination of the patient may be challenging. The patient may not have a palpable pulse even if mean arterial pressure is adequate. Also, automatic blood pressure cuffs may not provide an accurate blood pressure; consider taking manual blood pressures instead. Contact a clinical engineer immediately by paging 414-xxx-xxxx if there is any question on the patient's or the VAD's status.

The patient and the patient's family members have been trained to evaluate alarm conditions and to manage mechanical problems concerning this device. The patient may have one of these trained companions with him during the transport.

The patient has been trained to handle any emergencies with the VAD, but may still require your medical assistance. Occasionally, this device will stop, and the patient may not be able to restart the pump even after following all troubleshooting steps. With this in mind, this patient should never receive compressions. Compressions may dislodge the VAD from the heart. If the VAD does not support the patient's circulation during arrhythmias, the patient may be externally defibrillated. Defibrillation will not cause any damage to the device or its components. The patient also has an activated implantable cardioverter defibrillator to convert arrhythmias.

If the patient should require emergency care, he needs to be transported as soon as possible to St Luke's Medical Center, 2900 West Oklahoma Avenue, Milwaukee, Wisconsin. St Luke's is the closest hospital that is trained on this ventricular assist device. The phone numbers for the surgeon, the engineer on-call, and the cardiovascular intensive care unit are taped to his device. In the event that the St Luke's emergency department is diverting, this patient should still be brought to St Luke's. Please inform the emergency department that the incoming patient is on a VAD. The Milwaukee County Emergency Medical Services Board has approved this process.

I have included some additional materials on axial flow devices and the HeartMate II system. If you have any questions, please feel free to contact my office at (414)xxx-xxxx or the clinical engineer, at (414) xxx-xxxx. The 24-hour engineer on-call pager number is (414) xxx-xxxx.

Mr X's address and phone number are xxxxx.

Sincerely,

Surgeon's Signature

Figure Sample letter to the provider of emergency medical services for a patient with a HeartMate II.

Non-MCSD Related Responsibilities of Engineers

In order for the engineers to have a strong clinical background, it is very important for them to be involved with other equipment, not just MCSDs. Another benefit of being the resources for other hospital equipment is that doing so requires more engineers to be on staff. Therefore, on-call responsibilities can be divided among several staff to avoid burnout.

In addition to mechanical circulatory support devices, the engineers are also the resources for 5 ICUs and 2 step-down units for the following equipment:

- Intra-aortic balloon pumps
- Continuous renal replacement therapy
- Ultrafiltration
- Pacemakers
- Bedside monitors
- Defibrillators
- Intravenous infusion pumps
- Epidural pumps
- Continuous cardiac output monitors
- Point-of-care devices
- Activated clotting time machine

Being a resource for these devices includes teaching the initial classes and annual reviews for all staff and being available 24 hours a day, 7 days a week to answer any questions and help troubleshoot equipment. The engineers admit patients to the ICU with an intra-aortic balloon pump. Thus the nurse can focus on the clinical needs of the patient, while the engineer manages the technical aspects of the equipment. The engineers set up the continuous renal replacement therapy and ultrafiltration circuits for the nurses when patient care demands are high. At times, the engineers also watch new nurses set up these circuits to help them do it correctly.

If a department has staffing issues, the engineer may sit bedside for a shift to run any of the equipment (ie, VAD, intra-aortic balloon pump, and/or continuous renal replacement therapy) so that what would normally be a 1-to-1 assignment can now be paired. Engineers also round through the ICU every 2 hours to check on patients and equipment and help out as needed.

The engineer evaluates new products and equipment to see if there is a benefit to the patient. If a clinical trial for the product is underway, the engineer

leads the trial and addresses any issues that arise. The engineer also processes all equipment and supply recalls.

Conclusion

Clinical engineers are uniquely qualified to serve as valuable members of a MCSD program. Through their technical backgrounds, they are able to help staff and patients troubleshoot problems with devices. The engineers provide surgical, patient care, and teaching services. They also play an integral role in preparing for and maintaining Joint Commission certification. Clinical engineers are also available to help with technical issues and teaching on additional ICU equipment. At Aurora St Luke's Medical Center, having clinical engineers as members of our MCSD care team has helped our program maintain its status as a prominent part of a growing cardiac continuum of excellence.

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