2023 CCE Written Exam Review Webinar Series

August 9, 2023, through October 11, 2023

Session #4: Technology Management II

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About the host/moderator

Jeff Hooper

Jeff Hooper, PhD is the Senior Manager of Medical Device Security at Children's National Hospital in Washington DC. He is an adjunct professor and lectures at the Catholic University of America in the biomedical engineering division.

In addition, he is on the Advisory Board for the school of biomedical engineering at The University of the District of Columbia. Jeff has over 35 years of experience in healthcare technology management.

Logistics

- **All attendees have their microphones muted during the presentation.**
- **Questions to the faculty must be submitted via the "Q&A" feature in Zoom at any time. They will be addressed at the Q&A portion.**
- **If there is any urgent issue, please use the "chat" feature to communicate with the host/moderator.**
- **Please remember to complete the webinar evaluation after attending. A link will be provided at the end.**

About the Faculty

Kindall Druker, MS, CCE

Kindall Druker is a Biomedical Engineer for the Department of Veterans Affairs, serving in Veterans Integrated Service Network (VISN) 15. Prior to her role as a VISN Biomedical Engineer, Kindall worked as a Clinical Equipment Planner for BJC Healthcare in St Louis, MO. As a Biomedical Engineer for the VA, Kindall has successfully executed multiple interoperability projects including implementing TeleICU across VISN 15 and installing both a Clinical Information System for the ICUs and an Anesthesia Record Keeper to transition providers from paper charting to an integrated Electronic Health Record (EHR). She began her career at the VA under the Office of Informatics, after which she transitioned to Healthcare Technology Management (HTM). Presently, she spearheads project implementations and is a program manager for technologies that will allow the VA to navigate their transition to a commercial EHR.

Kindall earned her Bachelor of Science in Biomedical Engineering from Texas A&M University and a Master of Science in Biomedical Engineering from the University of Connecticut as part of their Clinical Engineering Internship Program. Continuing her love of education, Kindall earned her Certificate in Clinical Engineering (CCE) in 2022.

When Kindall is not leading projects, she can be found sprinting around an Ultimate Frisbee field or honing her skills in her woodworking shop.

Learning Objectives & Locations in the 2023 CCE Study Guide

Technology Management 5.1

- Life Cycle Analysis – Section L
- Return on Investment (ROI) – Section O
- Project Management – Section C
- Equipment Installation – Section N

Education of Others 5.5

- Technician Education – Section A
- Device User / Nurse Training – Section B
- Develop/Manage Staff Training Plan – Section C
- Engineering Education – Section D
- Other Education Responsibilities – Section E
- International Healthcare Technology Management – Section F

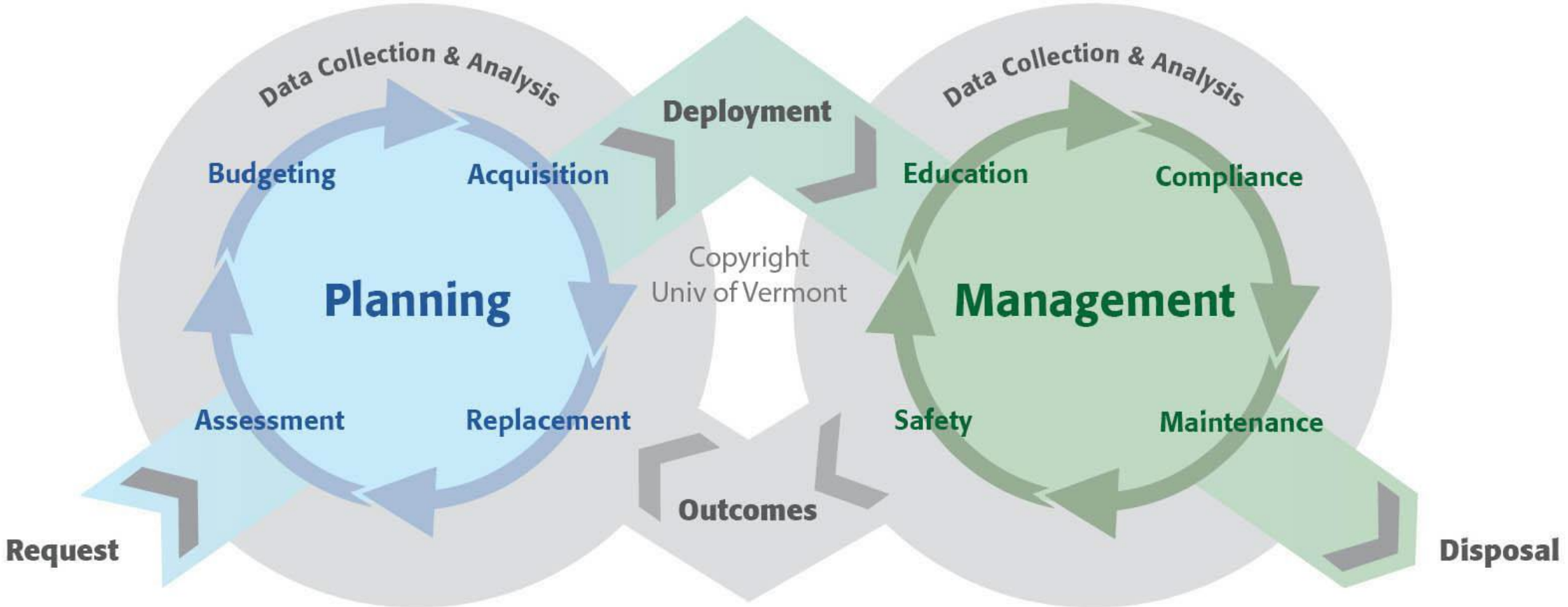
Technology Management

STUDY GUIDE SECTION 5.1

Technology Management at a Glance

- Managing medical equipment through its entire life cycle
- Purchasing, Maintenance, Disposition
  - All the things in between!
- Cradle to grave

What is a Lifecyle?

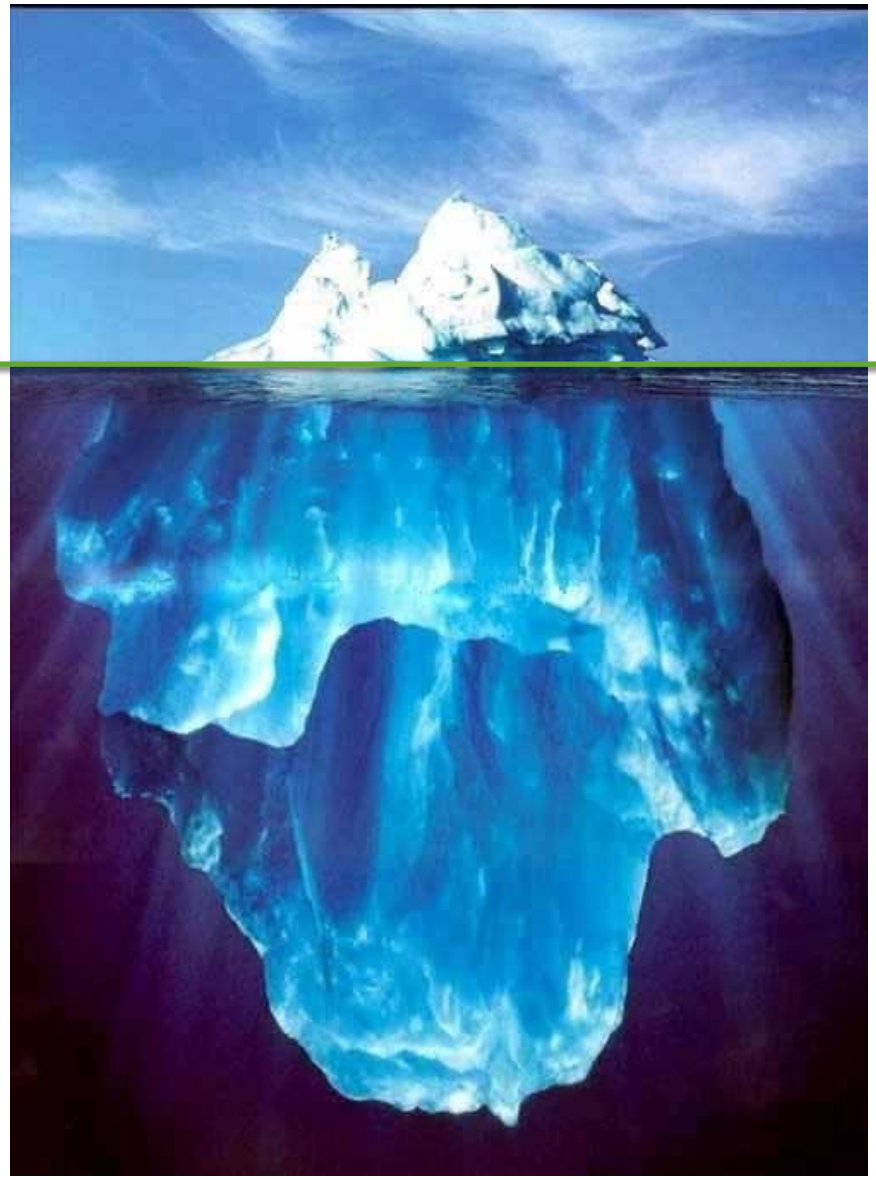


Lifecycle Cost Analysis

- Is a decision-making technique used to compare high cost, alternative means for providing a service, or to determine whether a technology has a positive or negative economic value
- Used to determine if you should buy something outright, lease or rent it, or use a lease to purchase plan or compare
- Determine if one vendor has a lower LCC than another for the same type of equipment
- What costs are in a lifecycle?

Acquisition

- The initial cost may represent half of the total lifetime cost of acquiring, operating and maintaining the equipment



- Purchase Price
- Shipping
- Installation

- Staffing & Training
- Maintenance (Parts and Cost/Hour)
- Consumables & Utilities
- Upgrades
- Software Licenses
- Financing
- Compliance
- Quality Assurance
- De-installation and Disposal

Estimating the Typical Cost of Ownership for an Infant Radiant Warmer

The costs reported in this table represent typical quotation and purchase costs reported to ECRI's Capital Guide and Supply Guide databases, respectively. These figures are provided as a guide only and may vary significantly.

Our cost estimates are for warmers with an integrated scale and resuscitator. They do not include the cost of a UPS.

Factor	Typical Cost	Assumptions
Purchase Costs		
Capital cost	$18,000	Based on average quoted price in ECRI's Capital Guide database.
Typical accessories	$0	Included in capital costs.
Warranty	$0	Included in capital costs.
Clinical staff training	$0	Typically included in purchase cost.
Biomedical staff training	$0	Typically included in purchase cost.
Infrastructure modifications	$0	None anticipated.
Total purchase cost	$18,000	—
Annual Operational Costs		
Consumables	$2,800/yr	Assumes: ▪ One mattress/year @ $75 each. ▪ 100 skin temperature probes/year @ $25 each. ▪ 10 T-piece resuscitators/year @ $25 each.
Expected part replacement—averaged throughout life of product	$590/yr	UPS batteries represent approximately half this cost. The number of batteries and frequency of replacement will depend on the battery technology. Lead-acid batteries will cost less per battery but require more frequent replacement than lithium-ion. The remainder of this cost will be parts replacement.
Service	$180/yr	Inspections require approximately an hour. UPS battery replacement will require approximately half an hour every one to four years. The remainder of this cost is anticipated repair times. Our calculations assume that the hourly cost of a biomedical engineer is $75.
Annual license fee	$0	No manufacturers have reported an annual license fee.
Average annual operational cost	$3,500	Average cost under warranty in the first year is $2,800. Average yearly cost after the warranty expires is $3,600.
Estimated Total Cost of Ownership (for an estimated life of 15 years)	**$71,000**	Total purchase cost + (annual operational cost × estimated life)

https://www.ecri.org/components/HDJournal/Pages/Evaluation-Background-Infant-Radiant-Warmers.aspx?tab=2#TAG_cost

ECRI Example of an Infant Radiant Warmer

ECRI's LCC Calculator

ECRI

Life-Cycle Cost Calculator

*All costs can be overwritten.

**Fields marked with a star (vendor/model name and life-cycle/agreement term) must be filled to activate columns.

Vendor / Model:	★	Steris V-Pro S2	Steris Amsco 600 39"	Steris InnoWave Unity	Steris Amsco 2532	
Acquisition Type:		Purchase	Purchase	Purchase	Purchase	
Life-Cycle/Agreement Term (in yrs) ★ 20						
Warranty Period (in yrs)		1	1	1	1	
Purchase						
Purchase Price		$ 55,540	$ 107,396	$ 27,360	$ 51,772	
Residual Value						
Balance		$ 55,540	$ 107,396	$ 27,360	$ 51,772	$ -
Rental / Lease						
Monthly						
OR						
Annual						
Annual (Calculated)		$ -	$ -	$ -	$ -	$ -
TERM		$ -	$ -	$ -	$ -	$ -
Buyout						
Fee per Use / Reagent Rental						
Annual						
OR						
Procedure 1						
Procedure 2						
Procedure 3						
Annual		$ -	$ -	$ -	$ -	$ -
TERM		$ -	$ -	$ -	$ -	$ -
Buyout						

Procedures (per yr)						
Procedure 1						
Procedure 2						
Procedure 3						
Annual		0	0	0	0	0
TERM		0	0	0	0	0
Consumable Cost	3.0 %					
Annual						
Application Sites						
Procedure 1						
Procedure 2						
Procedure 3						
Cost for Year 1		$ -	$ -	$ -	$ -	$ -
TERM		$ -	$ -	$ -	$ -	$ -
Reimbursement						
Procedure 1						
Procedure 2						
Procedure 3						
Revenue for Year 1		$ -	$ -	$ -	$ -	$ -
TERM		$ -	$ -	$ -	$ -	$ -
Labor	*Inflation Rate* %					
Annual						
OR						
Procedure 1						
Procedure 2						
Procedure 3						
Cost for Year 1		$ -	$ -	$ -	$ -	$ -
TERM		$ -	$ -	$ -	$ -	$ -
Service	*Inflation Rate* 0.0 %					
Cost for Year 1		$ 3,360	$ 6,573	$ 4,335	$ 3,906	
TERM		$ 63,840	$ 124,887	$ 82,365	$ 74,214	$ -

Bottom Line	*Discount Rate* ## %					
Cost Per Procedure		$ -	$ -	$ -	$ -	$ -
Total Cost for Term		$ 119,380	$ 232,283	$ 109,725	$ 125,986	$ -
Revenue for Term		$ -	$ -	$ -	$ -	$ -
Profit for Term		$ (119,380)	$ (232,283)	$ (109,725)	$ (125,986)	$ -
Net Present Value (NPV)		$ (117,656)	$ (228,911)	$ (107,501)	$ (123,982)	$ -

Payback Period vs NPV

- Payback period calculates how long it will take to recoup an investment
  - Fails to account for the time value of money (i.e. inflation)
  - When do we break even?
    - Example, costs for a new CT scanner compared to the amount earned from reimbursements for taking the images
- Net Present Value (NPV)
  - Takes a future stream of cashflows and discounts those back to the present day, so you can decide how much you would pay today for those stream of cashflows in the future
  - Adds in a return rate (value of money over time)
  - Compares the rates of returns for different equipment
- Very Simplified Example of NPV using inflation
  - $100 in 1950 is equivalent to $1,300 today
  - Each day that $100 is worth a little less
  - NPV takes a future value and makes it “today’s” value

Period	Cash Flow	Net Present Value
Month 1	$25,000	$\frac{\$25,000}{(1+0.0064)^1} = \$24,841.02$
Month 2	$25,000	$\frac{\$25,000}{(1+0.0064)^2} = \$24,683.05$
Month 3	$25,000	$\frac{\$25,000}{(1+0.0064)^3} = \$24,526.08$
Month 4	$25,000	$\frac{\$25,000}{(1+0.0064)^4} = \$24,370.11$
Month 5	$25,000	$\frac{\$25,000}{(1+0.0064)^5} = \$24,215.13$

ECRI's LCC Calculator

Cash Flow Summary

Steris V-Pro S2						
Cash Flow Summary	**Term:**	**5**	**years**			
Year	**Initial**	**1**	**2**	**3**	**4**	**5**
Revenue						
Reimbursements		$ -	$ -	$ -	$ -	$ -
Residual Value						$ -
Total Revenue		$ -	$ -	$ -	$ -	$ -
Investment						
Purchase	$ 55,540					
Lease		$ -	$ -	$ -	$ -	$ -
Fee per Use		$ -	$ -	$ -	$ -	$ -
Buyout						
Costs						
Labor		$ -	$ -	$ -	$ -	$ -
Service		$ -	$ 3,360	$ 3,360	$ 3,360	$ 3,360
Consumables		$ -	$ -	$ -	$ -	$ -
Total Costs		$ -	$ 3,360	$ 3,360	$ 3,360	$ 3,360
Net Cash Flow	$ (55,540)	$ -	$ (3,360)	$ (3,360)	$ (3,360)	$ (3,360)
Cumulative Net Cash Flow	$ (55,540)	$ (55,540)	$ (58,900)	$ (62,260)	$ (65,620)	$ (68,980)
Net Present Value (NPV)	**$ (68,863)**					

LCC Varies with Technology

Laboratory Analyzers

- High Consumable Cost
- Equipment is given at “no cost”

Infusion Therapy or Contrast Injectors

- High Consumable Cost

Cobalt Radiation Therapy

- High radioactive core replacement & disposal costs

External Defibrillator

- Battery Replacements

Return on Investment (ROI)

- Performance measure, used to evaluate the efficiency of an investment or compare the efficiency of a number of different investments
- Does not take into account the risk of the investment

$$ROI = \frac{(\text{Gain from Investment} - \text{Cost of Investment})}{\text{Cost of Investment}}$$

Costs & Returns

Non – Recurring	Recurring	Gains/Benefits/Returns
Equipment or System Purchase (hardware or software)	Leases (Equipment or Buildings)	Reimbursement for Procedures
Equipment Installation	Equipment Maintenance	Elimination of a Lease
Building or Infrastructure Modifications/Renovations	Staffing (Additional staff or the need for a specialist)	Elimination of a Fee Basing
Initial User Training – Clinical and Service	Refresher User Training	Elimination of Service Contract
	Annual Fees (software licenses)	Reduction in staff costs due to more automation
	Supplies, Disposables, or Reusables	
	Equipment Cleaning (Special cleaning supplies or reprocessing of reusable medical equipment)	

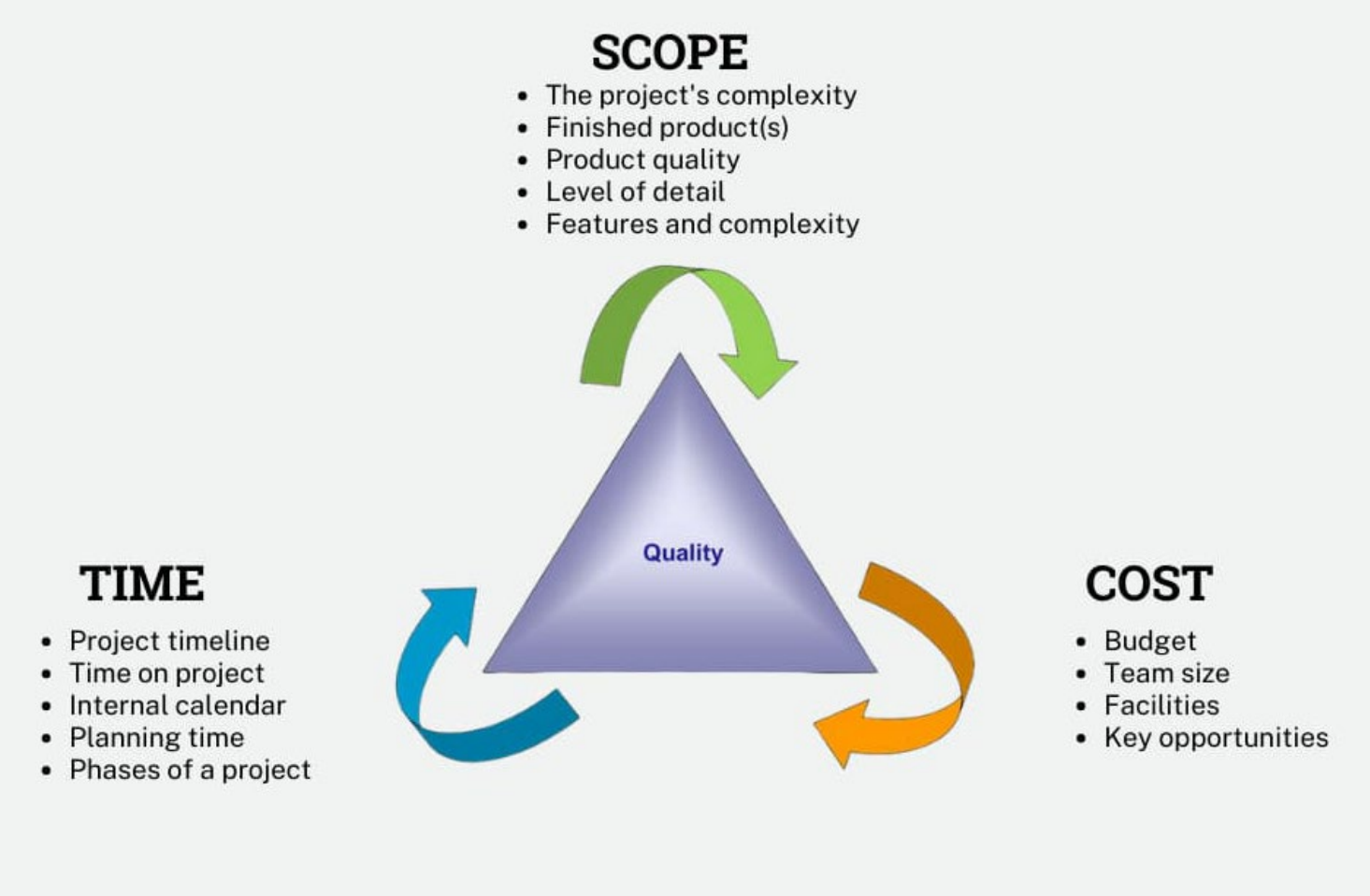
Intangible Benefits

- Patient Safety
- Staff Time Saving
- Standardization
- Better or More Advanced Technology
- Serviceability
- Upgradeability

*Try to quantify the intangible benefits to support your ROI, these may outweigh a lower cost

Project Management as a Clinical Engineer

- You've done your LCC Analysis and ROI and chosen a medical device, now what?
- Project Management is organizing and managing resources (such as people, time, money) in such a way that the project is completed within the defined scope, quality, time and cost constraints.



Project Management Triangle

Project Driver is your least flexible constraint

Defining the Project

- Goals Must Be
  - Specific
  - Measurable
  - Agreed Upon
  - Attainable
  - Within a time-frame
  - Clear and Simple
- For example, don't say "Replace the ICU monitoring system." Say "Install a replacement ICU monitoring system by August 15, 2023 at a cost of $500,000 or less by using a team of seven hospital employees"

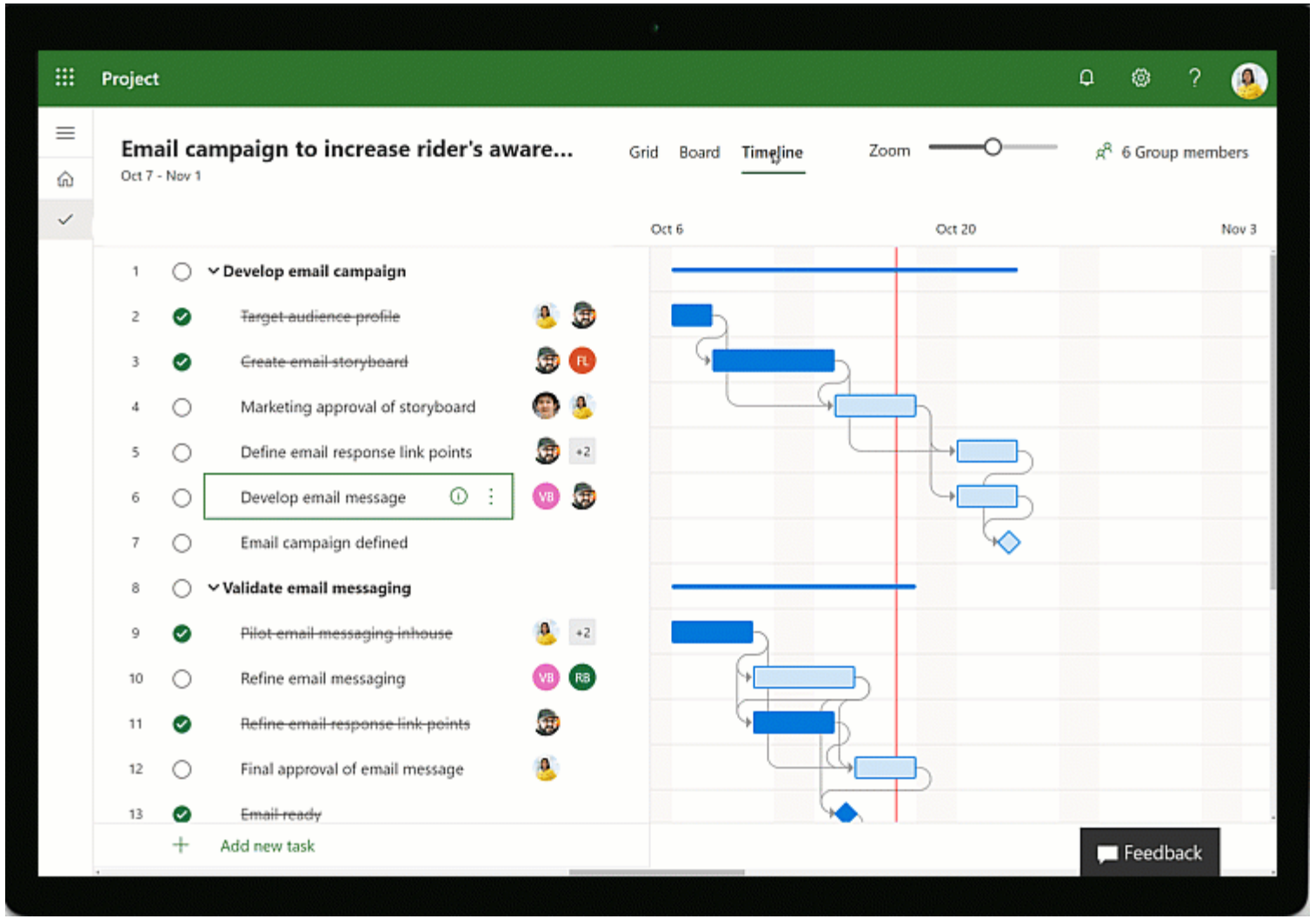
Project Team Members

- Clinical Engineering
- Information Technology
- Purchasing
- Physicians
- Nurses
- Administration
- Project Sponsor
- Facilities
- Logistics
- SPS

Successful Project Managers

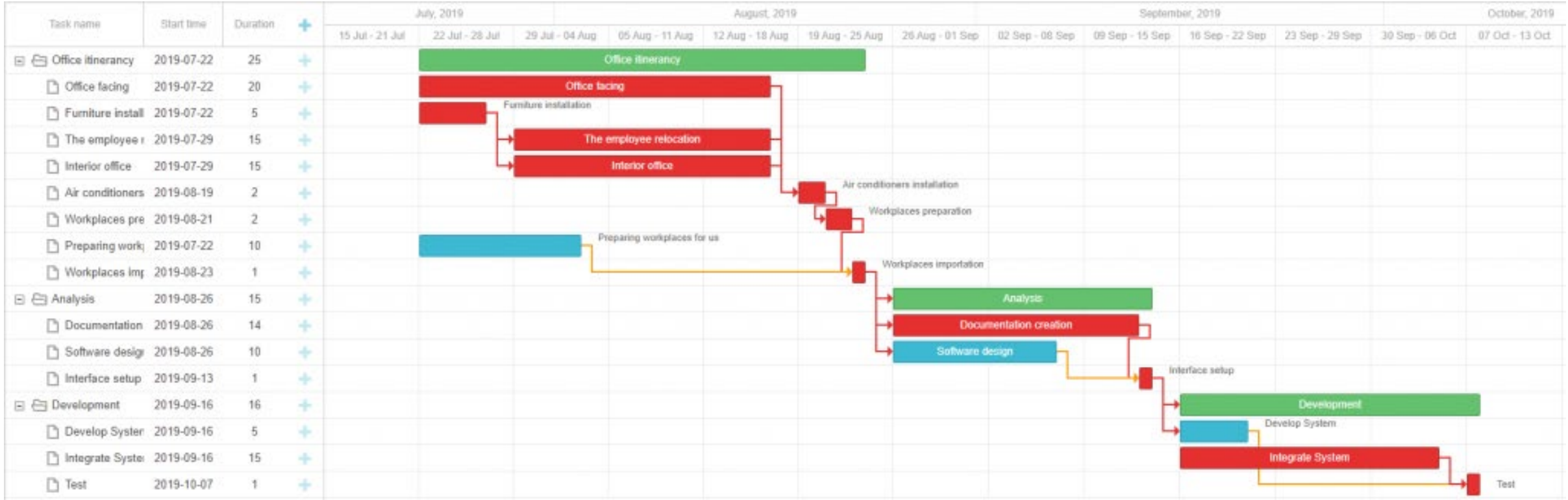
- Run Effective Meetings
  - Communication beforehand
  - Keeping the meeting on point, on track, and on time
- Maintain good records
  - Meeting minutes
  - Communication documents
  - Notes on conversations
  - Emails
  - Issues Log & Milestones Tracking
  - To Do List
  - Punch List
- Communicate Progress
  - Publish updates of the project status
  - Accomplishments
  - Milestones
  - Status of Deliverables
- Manage Resources (People, Time, Money)
- Follow Up

Ways to Track a Project



- Microsoft Project
- Gantt Charts
- Milestone Trackers

Critical Path



Project Close Out

- Once all punch list items are complete
- Celebrate!
- Perform a Lessons Learned exercise
  - Did we meet our goal?
  - What went well?
  - What were the challenges?
  - What should we do differently in the future?

Equipment Installation

- Getting from purchase to first use

CE's Role in Equipment Installation

- Four Major Parameters
  - Space
  - Utilities
  - Mounting and Location
  - Transport
- Monitoring of the Parameters
  - Checking installation progress against architectural or vendor designs
  - Monitoring for issues
  - Being the go-between the vendor and clinical staff
- Completion
  - Go Live Day
  - Sign off on the project
  - Close out documents

Space

- Consider the footprint and the weight of the equipment
  - Consider interstitial space between floors if additional bracing or shielding is required
- Clearance requirements
  - For Utility Connections
  - For Service
- Is the equipment moveable for service?
  - If not is there a housing area for access
- CE may work with an architect, facilities, vendor, installation team (may require union workers), various trades (HVAC, Plumbing etc)

Utilities

- Electrical Supply
  - Proper voltage available and that the supply has adequate current capability
  - Grounding requirements
  - Emergency Power
  - Power Quality
    - Do we need a UPS or a Power Conditioner?
- Water Requirements
  - Pressure, Flow, Temperature, and quality of the source
  - May require additional treatment of the water before connection to the equipment
- Gas Supplies
  - Compressed Air, Oxygen, Nitrogen Carbon Dioxide etc
  - Supply source may need additional housing and piping if the gas is not available from the facilities gas piping system.
  - Remote Manifold with piping to the equipment
- Room Controls
  - Adequate heating, ventilation, and air conditioning
  - Air exchanges
  - Tracking on temperature
- Low Voltage
  - Data or telephone
- Lighting
  - Work with users to determine what they need to see

Mounting and Location

- Should be incorporated in installation plans so that anything behind the walls, floors or ceiling is accounted for
- Seismic Considerations
- If the equipment is freestanding
  - Does it need to be attached to the floor, walls or ceiling for stability
  - Work with a structural engineer
- Ceiling Mounted
  - Requires a suspension system above the finished ceiling
  - Ensuring the item won't swing into other equipment
- Wall Mounting
  - Backing plates

Transport

- Map out path of install
- Access through the building to the installation site
  - Removing doors
  - Cutting walls
  - Hiring riggers
  - Elevator weight limits
  - Shutting down a street to have a crane lift a radiology device into place
- Wall or Flooring protection along the path of the install
- Sequencing - Leaving a wall unbuilt until after the equipment is delivered

After Celebrating Your Installation

- Ensuring your equipment has a long life

Education of Others

STUDY GUIDE SECTION 5.5

Technician Education

- Biomedical Equipment Technicians (BMETs)
  - Entry positions require 2-3 year associate degree in Biomedical Engineering Technology or completion of a US military BMET program
  - Can obtain CBET (Certified Biomedical Equipment Technician) through AAMI Credential Institute (ACI)
- Specializations
  - Certified Radiology Equipment Specialist (CRES)
  - Certified Laboratory Equipment Specialist (CLES)
  - CHTM (Certified Healthcare Technology Manager)
  - Emerging: Information System BMETs

Technician Continued Education

- Emerging technology requires continuous education
  - Training through on-the-job experience from other technicians
  - Vendor in-services
    - Purchasing new technology
    - Include technician training and manuals in the contract for the new equipment
  - Vendor schools
- Technicians Training Others
  - Emerging technology, new model of a type of equipment, new users will require in-servicing of hospital staff
  - Technicians will need to understand the principals of how the device works
  - Training staff how to reboot a device
  - Who to call when a device malfunctions
    - After hours

Device User/Nurse Training

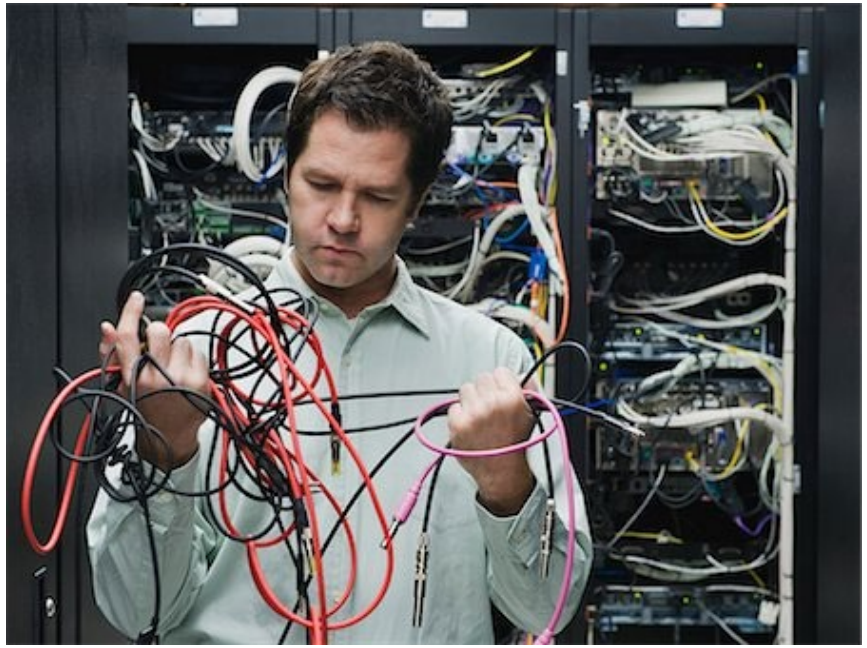
- Proper use of a device increases safety
  - Average age of nurses is increasing
    - Shortage of new nurses
  - Overworked staff
  - Proper use of a device and attention to workflow of a device should decrease the burden on the staff
- BMETs may be asked to provide user/nurse training
  - In service from manufacturer when a device is purchased
  - Train the trainer (identifying Super Users)
- BMETs can pre-empt issues by providing vendor contact information
  - Labeling the equipment with 800 numbers that nursing staff can call for clinical questions
  - Applying quick reference guides to the equipment

Device User/Nurse Training

- Nursing Responsibilities
  - Know how to use simple devices as part of their nursing training
  - Identify what devices they may need to be trained on
  - What to do if equipment malfunctions
    - Who to report this to
    - Fill out an Incident report
    - Involve CE and request more training if appropriate
- Use of Medical Devices
  - A piece of equipment should never be used by someone who isn't trained on that device
  - A medical device must always be used for its "intended purpose"
    - Special approvals are required for "Off Label Use"
      - Ex: Investigational Use in Clinical Studies
      - Ex: Stents were initially approved for arteries, but used "off-label" for veins
- Use Error
  - Indicates more training may be needed
  - Review service records

Why Develop a Staff Training Plan?

- Preparing and supporting clinical and technical staff as new technologies emerge
- Decreasing preventative maintenance for emerging technologies mean technicians won't encounter the equipment as often and may forget skills they learned when the device was in-serviced
- Delays in repair times or harm to a patient if the device is in use during the failure



Planning for Future Training

- Identifying Gaps and Forecasting Training Needs
  - CEs should be keeping an eye on emerging technologies
    - Vendor Fairs, AAMI, Trade Shows etc
  - Work with Capital Equipment Funding divisions to decipher what services the hospital may decide to use in the future
    - Perform Environmental Rounds
    - What skills may be needed to support the new technology?
    - Are those skills covered by the manufacturer or is additional training needed

Ongoing Training Needs

- Define Training/Education Strategy for BMET Staff
  - Assess current knowledge base
  - Understand national and local training requirements
    - Joint Commission requires training and competency records for clinical and technical staff
  - Determine the competency needed
    - Develop a training plan to meet that competency
  - Determine if a certain competency is needed for participation in a merit program
    - Determining a raise or promotion
  - Identify Resources and Develop a Budget
    - Allow for training time as part of staff's normal working hours
      - Need to account for coverage so staff can attend training and still keep up with daily hospital work
    - Include training with procurements
      - Training prior to go live of the device
      - On-going trainings as part of service support agreements
  - Account for Staff Retirement, Double Coverage, Leave, etc.

Simulation Labs

- Scenario training
- Gives hospitals discounts on malpractice insurance
- CEs can observe simulated events to better understand provider workflows
  - Improve technology performance

BMET Training Program Summary

Identify Gaps and Forecast Needs	Determine Competencies	Develop a Budget	Train-The-Trainer
Capital Equipment Planning	Understand national and local training requirements (i.e. Joint Commission/CMS requirements)	Account for training time	Determine staff strengths for future training of new employees
Future Technology Trends (ex. medical device integration)	Determine competencies for each position	Understand cost in advance – plan multiple years out	What can be done in house vs. vendor trained?
Future additions to CE responsibilities (ex. CE takes on beds or nurse call)	Each staff member should have personalized competency plan to identify gaps in training	Communication with C-Suite	Use all resources (is your facility part of a hospital system?)
		Include training costs in equipment purchases where applicable	

Engineering Education – The Basics

- Two main components for engineering degrees
  - Academic curriculum with highly technical content
    - 4-year programs for a BS in an engineering field
  - Practical content i.e., field experience
    - Specifically for Clinical Engineering
      - Choosing a University with an Internship Program
      - Internships or Volunteering at Hospitals
      - Attending conferences
      - Networking with other CEs

Other Educational Responsibilities

- Have a basic knowledge of
  - Financial management, organization behavior, managerial accounting, cybersecurity, labor laws, marketing, information systems
    - IT and Cybersecurity are becoming more and more baseline needs for CEs
    - Taking selective classes in these topics
- Institutions
  - AAMI, ACCE, HIMSS, RSNA
  - Attending annual conferences and seminars/workshops
  - Webinars that your facility may subscribe to (ex ACCE or ECRI)
- All with the goal of continuous self-improvement

Education Summary

Academic Curriculum	Continuing Education	Professional Credentials
AS, BS, MS, PhD	Advanced Academic Degrees	Certified Clinical Engineer (CCE)
Practical-Targeted Clinical Engineering Graduate Education (ex. University of Connecticut Clinical Engineering Program run by Carol Davis-Smith)	Targeted Educational Development: Administrative / Finance Project Management Information Technology Human Factors & Ergonomics	Certified Biomedical Equipment Technician (CBET)
	Teleconferences (ex. ECRI or ACCE monthly education opportunities)	Certified Healthcare Technology Manager (CHTM)
	Purchased Educational Services from Manufacturers	Certified Industrial Sterilization Specialist (CISS)
		Certified Radiology Equipment Specialist (CRES)

Challenges of International Healthcare Technology Management

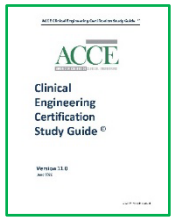
- Ineffective maintenance service and poor management lead to equipment failures which leads to poor healthcare delivery
  - Lack of national policy for healthcare technology management
  - Limited resources (i.e. infrastructure)
  - Lack of human resources
  - Constraints on aid agencies
  - Poor decisions during the life cycle of the equipment
    - Most equipment needs replacing every 5-20 years, but no investment plan exists, and replacement occurs on an ad-hoc basis

International Healthcare Technology Management

- Issues Include
  - Inappropriate acquisition of equipment in the first place
    - Countries depend on foreign aid and donations
    - Don’t consider long term impact of certain items
    - Don’t consider the environment the device will be used in (utilities available, staff, etc.)
  - Training and retention of specialist maintenance technicians
    - Private sector salaries are higher than in the public sector
  - Medical inventories are not up to date
    - Without knowing the equipment downtime, cost of repairs, and causes of failures
      - Difficult to allocate funds to replace equipment with issues
  - No national strategy for the use of healthcare technology
    - No replacement plan (Infrastructure and Equipment)

References from this presentation

1. University of Vermont Healthcare Technology Management - https://www.uvm.edu/research/tsp/who-we-are
2. FDA Off Label Use https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices
3. AAMI Credentials Institute Handbook https://www.aami.org/docs/default-source/aci/aci-candidate-handbook-6_6_23.pdf?sfvrsn=c11014c5_3
4. ECRI https://www.ecri.org/members/ *requires membership
5. Financial Calculations Explained https://www.investopedia.com/terms/n/npv.asp
6. Critical Paths https://dhtmlx.com/blog/critical-path-method-important/
7. CCE Study Guide V12



ACCE CCE Study Guide, v12.0, 2023

Questions & Discussions

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