GLOBAL CLINICAL ENGINEERING ALLIANCE™

With **LIVE translated captions**

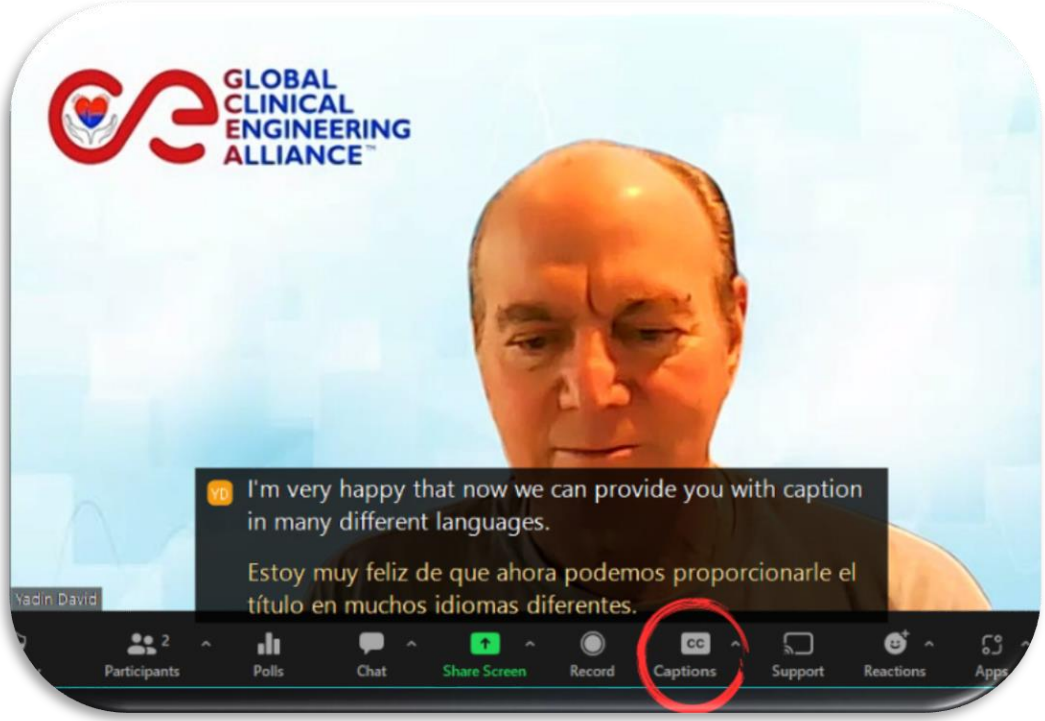
WEBINAR

Procurement process for medical equipment and service delivery

Wednesday
JULY **12** | 2pm UTC | 10am NY

Register for free: https://tinyurl.com/GCEA-procurement

GCEA is excited to announce the addition of a new **live translation** feature that we believe **will bridge the language gap and enhance your video conferencing experience** through Global Clinical Engineering Alliance programs even further. As part of our commitment to delivering innovative and educational video communications training, we have incorporated a new captioning option that facilitates the ability of our members to elevate their understanding of the spoken content during GCEA education and meeting events, by simultaneously customizing captions in their preferred language.



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Medical Devices – Specification and Evaluation

Andrew Gammie

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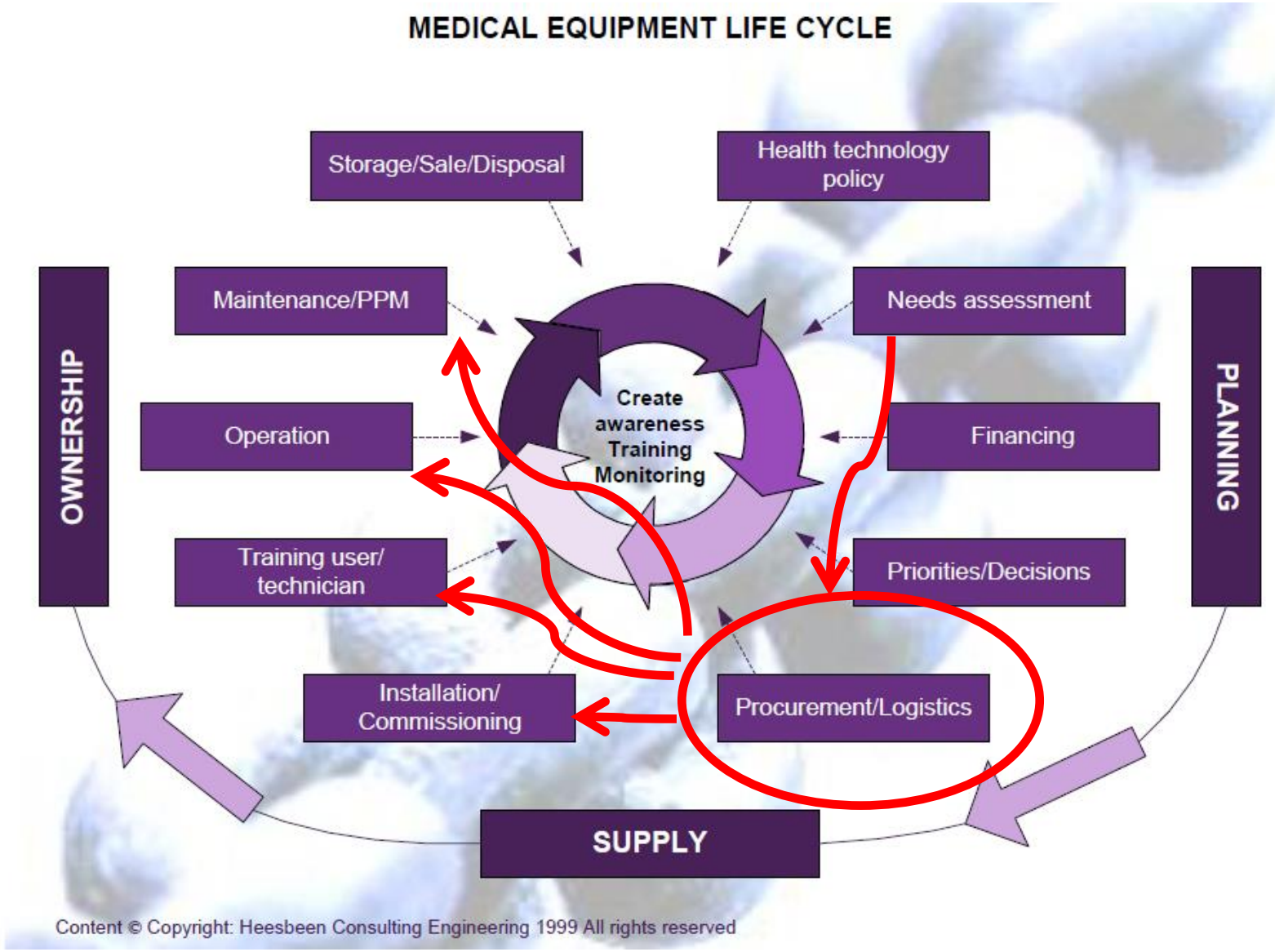
Clinical Engineer, Fishtail Consulting Ltd, UK

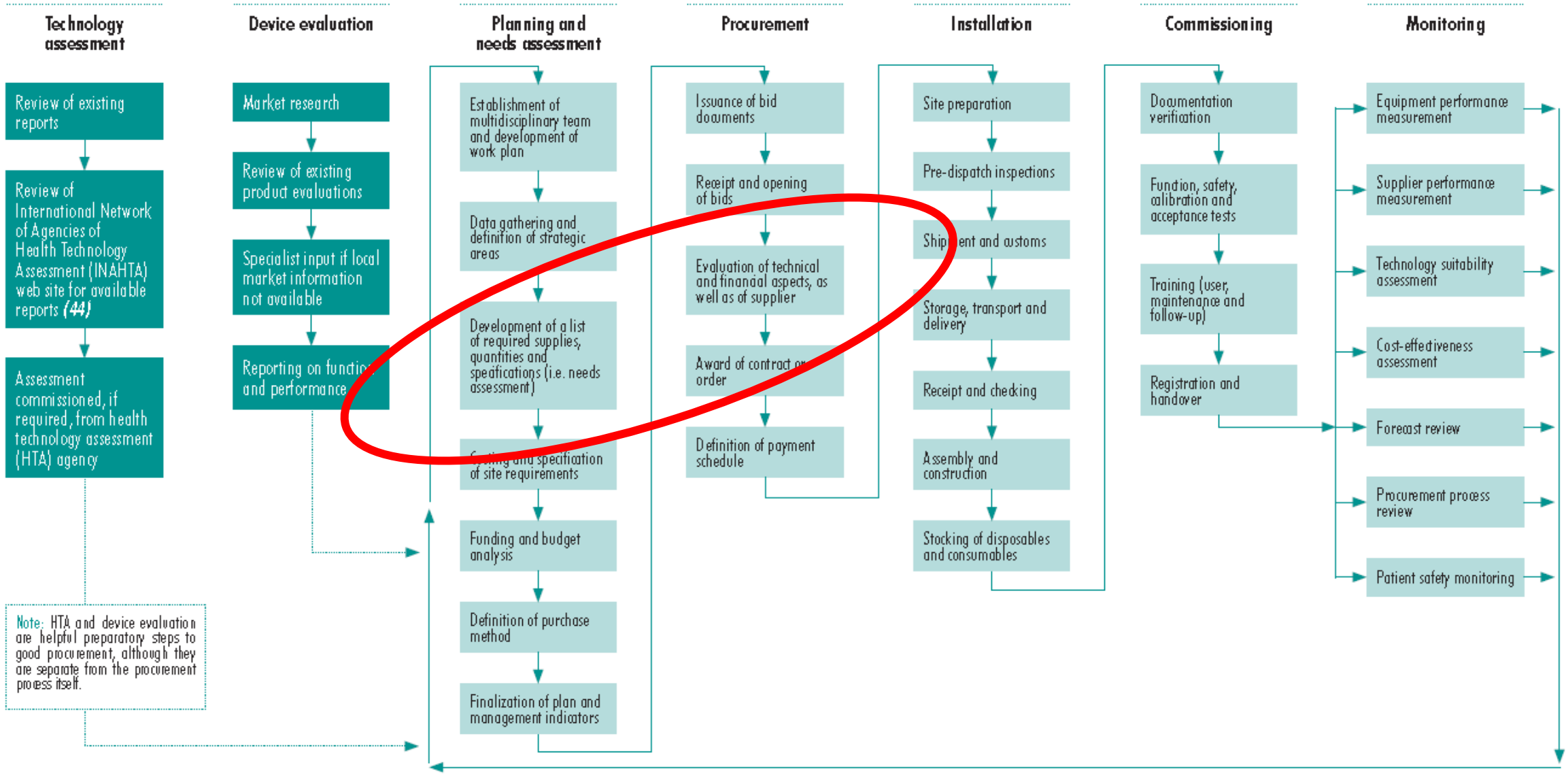
Specification and evaluation of bids – part of the whole



WHO Procurement Process Guide 2011

- *Good procurement brings:*
  - **safe, quality healthcare services**
  - **the best deal for the organization's needs**
  - **timely delivery and handover**
  - **satisfactory delivery, installation, commissioning and training**
  - **effective payment and warranty**
  - **satisfactory after-sales service**
  - **greater interest in submitting offers in the future**
  - **transparent and trustworthy systems**
- *The right product of the right quality at the right price of the right quantity at the right place and time (Bailey, 1994)*

WHO Procurement Process Guide 2011



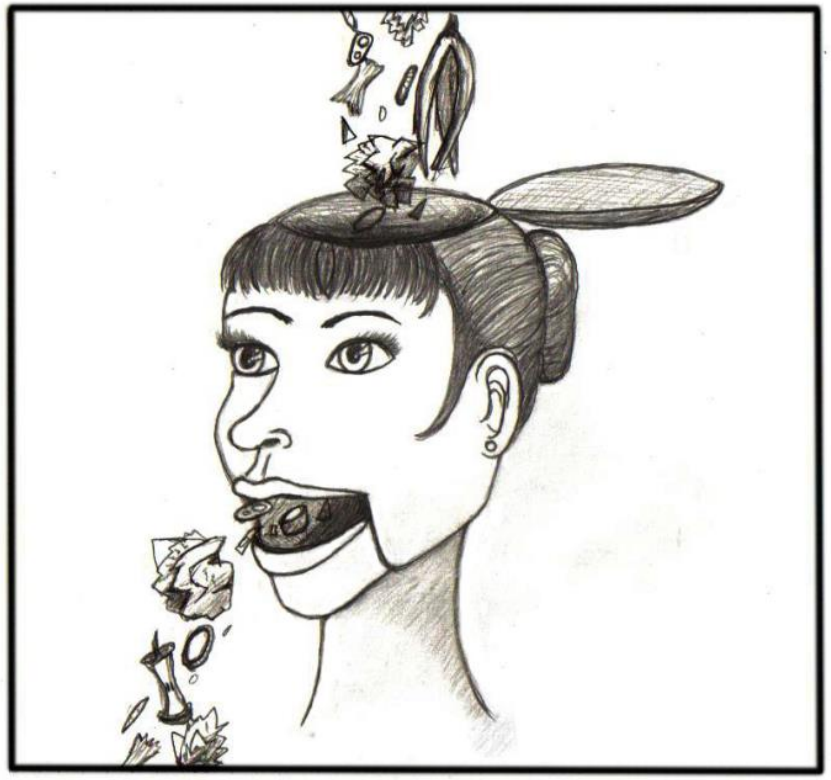
Garbage in, garbage out

Computer software.....

....and procurement

"To obtain the **right product or service** ..... a clear specification is required."

WHO Procurement Process
Resource Guide 2011



Poor procurement - examples

- Pulse oximeter with disposable probes
- user manuals in German
- 120V mains supply

Specifications - goals

- Get what you want
- Sufficient quality
- Good value

- Get what you want
- Sufficient quality
- Good value

Get what you want

- Describe function
  - What does it do? (Not “how?”)
  - Check with users

- Get what you want
- Sufficient quality
- Good value

Get what you want

- Describe function
- Describe clearly
  - Standard names
  - ‘Must / shall’ not ‘should’
  - One item at a time
  - Use testable words
    - E.g. not ‘modern’, ‘fast’

- Get what you want
- Sufficient quality
- Good value

Get what you want

- Describe function
- Describe clearly
- Describe fully
  - Use template to remember:
    - spares, accessories, power, environment, training, manuals, standards

- Get what you want
- Sufficient quality
- Good value

Get what you want

- Describe function
- Describe clearly
- Describe fully
- Write to evaluate
  - Will I know when I have the right device?

Specifications - goals

- Get what you want
- Sufficient quality
- Good value

- Get what you want
- Sufficient quality
- Good value

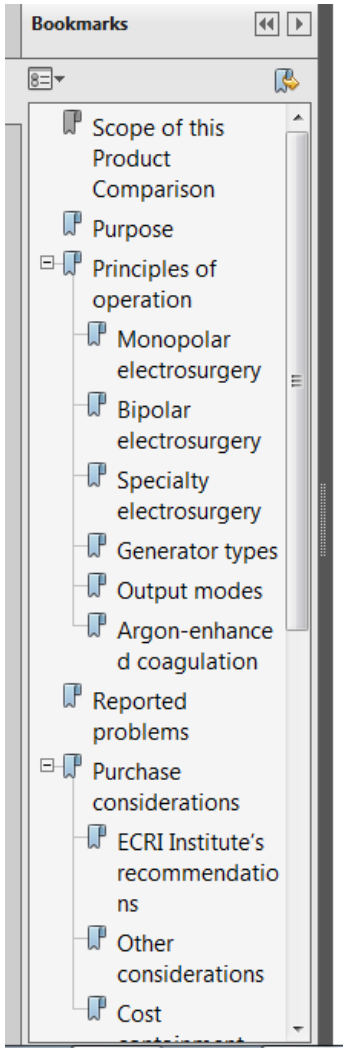
Sufficient quality

- Set limits and ranges
  - What is actually needed?

Sufficient quality

- Set limits and ranges
- Get help
  - Use but don’t copy:
    - Other specifications
    - Manufacturer specifications
    - ECRI

ECRI Healthcare Product Comparison System



Healthcare Product Comparison System

ECRI Institute
The Discipline of Science. The Integrity of Independence.

Electrosurgical Units; Argon-Enhanced Coagulation

Scope of this Product Comparison

This Product Comparison covers electrosurgical units (ESUs) that are used in most hospital operating rooms (ORs); low-power and special-purpose ESUs that perform one function exclusively (e.g., cutting, coagulating); ESUs that administer argon-enhanced coagulation; and stand-alone gas-delivery units that can provide argon-enhanced coagulation when used with certain ESUs. This report excludes accessories such as active and return electrodes, which are frequently purchased from sources other than ESU manufacturers.

Purpose

ESUs are used for surgical cutting and for controlling bleeding by causing coagulation (hemostasis) at the surgical site. They deliver high-frequency electrical current through an active electrode tip, causing desiccation, vaporization, or charring by resistive heating in the target tissue.

ECRI Healthcare Product Comparison System

Chart A: Electrosurgical Units

MODEL	ECRI INSTITUTE'S RECOMMENDED SPECIFICATIONS[1] Electrosurgical Units	AARON/BOVIE Aaron A1250	AARON/BOVIE Aaron A2250	AARON/BOVIE Aaron A800EU : A900
WHERE MARKETED		Worldwide	Worldwide	Worldwide
FDA CLEARANCE		Yes	Yes	Yes
CE MARK (MDD)		Yes	Yes	Yes
GENERATOR TYPE	Solid-state	Solid-state	Solid-state	Solid-state
FREQUENCY, kHz	Typical: 300-1,000	357-800	490	550
OUTPUTS				
Monopolar	Isolated	Isolated	Isolated	Ground referenced
Handswitch	Yes	Yes	Yes	Yes
Footswitch	Yes	Yes	Yes	Yes
Bipolar	Preferred	Yes	Yes	Yes
MODES				
Monopolar		Pure, blend, coagulate, fulgurate	Pure, blend, pinpoint, spray	Coagulate, desiccate, fulgurate
Cut				
Maximum watts at (rated Ω)	300	120 (500)	200 (300)	NA
Maximum voltage, Vp-p	2,000	2,500	2,500	NA
Coagulate				
Maximum watts at (rated Ω)	120	80 (1,000)	120 (500)	30 (1,000)
Maximum voltage, Vp-p	6,000	4,500, 6,500	3,500	10,000
Bipolar		Coagulate	Coagulate	Coagulate
Cut				
Maximum watts at (rated Ω)		NA	NA	NA
Maximum voltage, Vp-p		NA	NA	NA
Coagulate				
Maximum watts at (rated Ω)	50	30 (200)	80 (150)	30 (200)

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Specification libraries available

- ECRI www.ecri.org
  - US-based
  - Subscription service
  - Comparisons and guidelines
- UNICEF https://supply.unicef.org/
  - Fixed catalogue
  - Specifications therefore limited
- CENETEC http://www.cenetec.salud.gob.mx/contenidos/biomedica/cet.html
  - Useful spread of devices
  - Spanish language
- AFIB https://afib.asso.fr/
  - French language
- India: https://nhsrcindia.org/technical-resource
- WHO – 74 items
  - https://www.who.int/publications/m/item/who-technical-specifications-for-61-medical-devices

WHO template

	A	B
2		***MEDICAL DEVICE SPECIFICATION*** ***(including information on the following where relevant/appropriate, but not limited to)***
9	**NAME, CATEGORY AND CODING**	
23	**PURPOSE OF USE**	
28	**TECHNICAL CHARACTERISTICS**	
32	**PHYSICAL/CHEMICAL CHARACTERISTICS**	
36	**UTILITY REQUIREMENTS**	
38	**ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS**	
44	**PACKAGING**	
49	**ENVIRONMENTAL REQUIREMENTS**	
51	**TRAINING, INSTALLATION AND UTILISATION**	
56	**WARRANTY AND MAINTENANCE**	
62	**DOCUMENTATION**	
64	**DECOMMISSIONING**	
66	**SAFETY AND STANDARDS**	

WHO

9	2	Generic name	Centrifuge
10	3	Specific type or variations	N/A
11	4	GMDN name	General-purpose table-top centrifuge
12	5	GMDN code(s)	36465
13	6	GMDN category	04 Electro mechanical medical devices 16 Laboratory equipment
14	7	UMDNS name	Centrifuges, Table-top, Low-Speed
15	8	UMDNS code	18-264
26	**TECHNICAL CHARACTERISTICS**		
27	18	Detailed requirements	1. Maximum speed to be at least 10,000 revolutions per minute (rpm). 2. User operated timer to allow up to at least 60 min. operation before automatic stop. 3. Tachometer display of rpm required, with accuracy of better than 10%. 4. Supplied with both fixed-angle and horizontal (swinging bucket) rotor fittings. 5. At least six samples to be contained at one time. 6. A single size of sample tube is acceptable, which must be within the range 5 ml to 15 ml. 7. Electric braking feature incorporated. 8. Lid interlock required, locking lid while motor is running. 9. Power on button to be mounted on front panel. 10. Brushless motors are preferred. 11. Refrigeration is not required. 12. Closed lid security system during operation.
	19	Display parameters	1. Alert indicators are required for imbalance, lid open and cycle complete. 2. Timer display required, showing cycle time remaining.

Page 1

Sufficient quality

- Set limits and ranges
- Get help
- Decide what matters
  - Leave out unnecessary

Specifications - goals

- Get what you want
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- Good value

Good value

- Allow competition
  - No brand names, no precise values

- Get what you want
- Sufficient quality
- Good value

Good value

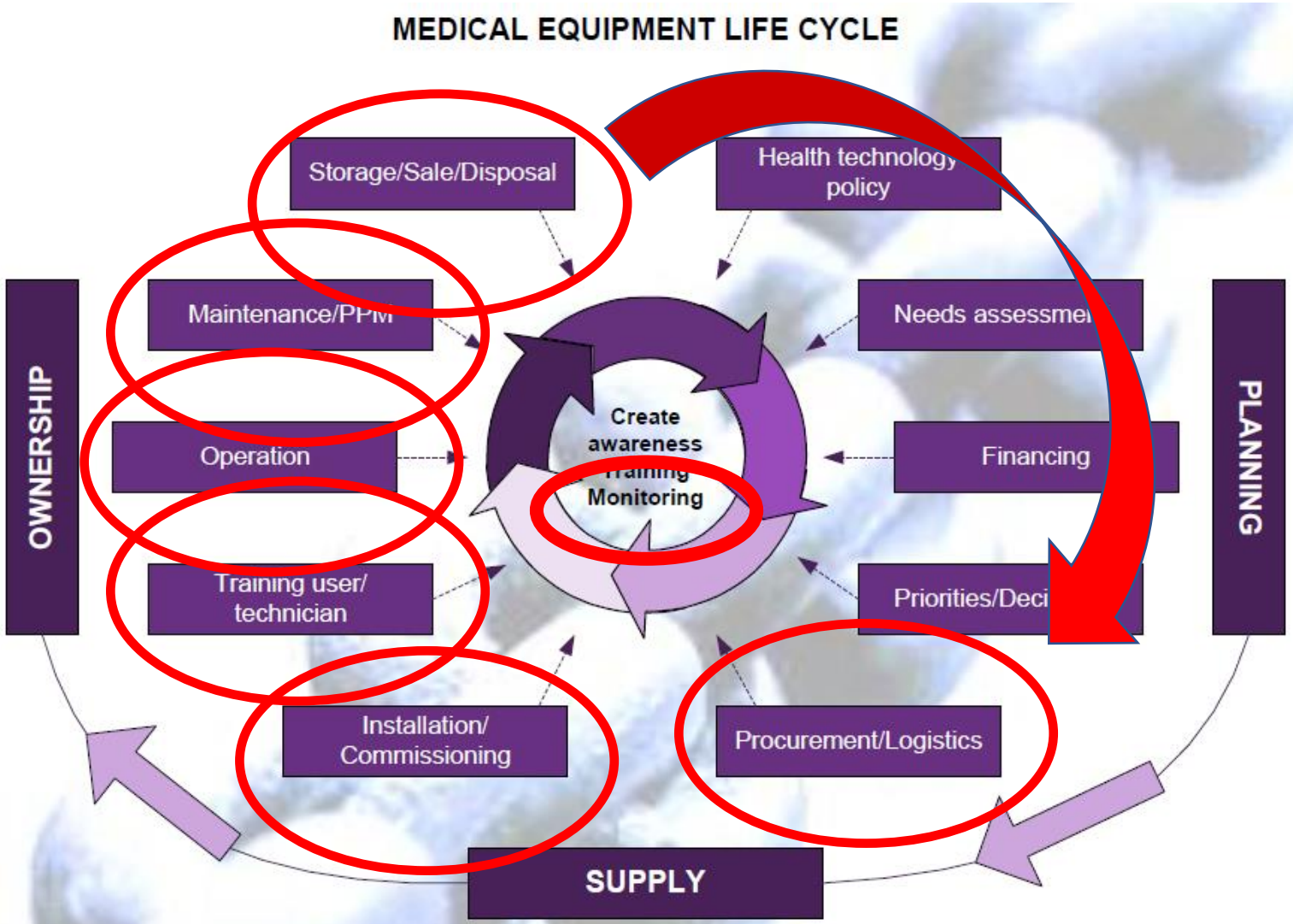
- Allow competition
- Know what's out there
  - ECRI
  - Internet search
  - Pre-bid meeting

- Get what you want
- Sufficient quality
- Good value

Review before sending

- Check it makes sense
- External review
- Aim for evaluation

Completing the picture



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Good Specifications

Get what you want	Describe function	What does it do? (Not “how?”)
		Check with users
	Describe clearly	Standard names
		‘Must / shall’ not ‘should’
		One item at a time
		Use testable words, e.g. not ‘modern’, ‘fast’
Sufficient quality	Describe fully	Use template to remember
	Write to evaluate	Will I know when I have the right device?
	Set limits and ranges	What is actually needed?
	Get help	Use others but don’t copy
	Decide what matters	Leave out unnecessary
Good value	Allow competition	No brand names, no precise values
	Know what’s out there	ECRI, Internet search, Pre-bid meeting

Evaluation – checking the bid submissions

- Develop a good recording system
  - Step by step through specification and bid response
  - Who said what, when
- Ensure evaluator does not see prices
- Check certificates
  - e.g. BSIF Is-it-Genuine-2023.pdf
  - Use notified bodies web services

Valid from: Sep. 01, 2009	Valid until: Aug. 31, 2019
Valid from: Sep. 01 , 2019	Valid until: Aug. 31 , 2022

- Ask for clarifications
  - e.g. “Please state if the spares pack includes batteries”
- Make clear final recommendation:
  - Acceptable / Not acceptable

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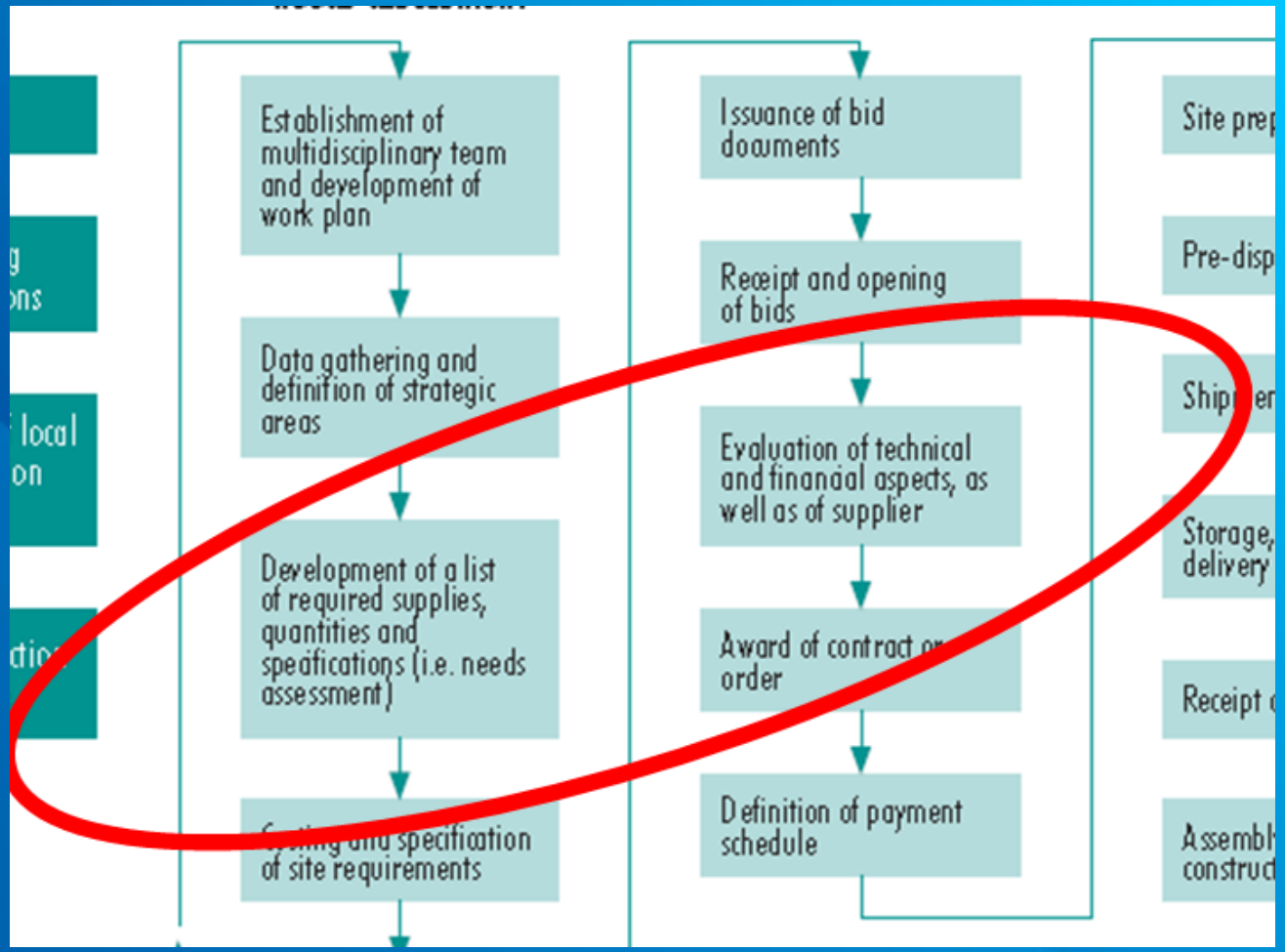

Procurement Process for Service Delivery

Adrian Richards

Board Member, College of BME, Engineers Australia

Member, National Committee on Clinical Engineering, Engineers Australia

Collaborator IFMBE, Clinical Engineering Division

The Australian Context

- Tertiary Healthcare is largely public, being funded and run by the government
- Treatment is free of charge
- The majority of Clinical Engineers are government employees
- A private healthcare system runs in parallel for those who choose to take out private insurance

Selecting CE Service Providers - Scenarios

1 A full CE service

- Most common in the private system, small hospitals or chains

2 Some elements of an established in-house service

- Very common in the public system

Full CE service

- Small hospitals in which setting up a comprehensive service is not viable
- Bring strengths of a large provider in terms of skill set and systems/processes
- In principle strategy – contracting of support services
- Political agenda

Elements of an Existing Service

- Support of complex technologies
- Reducing cost for limited installed base
- Managing staffing resource
- Lack of training/software accessibility (right to repair)
- Mitigating financial risk or uncertainty
- Reliable access to upgrades
- Making best use of existing skill set

Whole Service – Key issues

- Clearly specify scope of service via a formal process
  - Technologies that are included and excluded – process to vary this
- Organisational expectations beyond HTM – e.g. committee roles, R and D support
- Service levels including performance and hours
- Number and level of staff – relationship to meeting KPIs
- Review process including client satisfaction
- Duration of contract and right of renewal
- Dispute resolution

Elements of an Existing Service

- Greater focus on operational and performance elements
- Response times and up-time guarantees – capacity to handle work
- Personnel undertaking work – qualifications and experience
- Reporting arrangements
- Dispute resolution
- Contract vs fee for service
- Reference clients – how to assess

Elements of an Existing Service

Note

- In this scenario you may not be getting a CE service by the true definition, but rather a repair and maintenance service
- Support under a vendor contract is a good example of this

- Nothing wrong with this, but you need to be aware of the difference

Key Take Home Messages

- Be very clear on your expectations and gain evidence that a provider can fulfil them competently
- Ensure a provider has capacity to fulfil their obligations appropriately
- Assess past performance at other sites
  - Speak to many clients not just selected ones
  - Use your networks
- Get a “feel” for the service provider and your ability to work with them

Thank You

Questions or Discussion

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Q&A

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A list of additional topics and dates for next webinars will be soon announced through email campaign and on our website www.GlobalCEA.org

THANK YOU
for your participation