Purchasing of surgical instruments

Introduction

- Frank Raymaekers
- Expert sterile medical devices
- Unitmanager material management
Erasmus MC university medical center Rotterdam:

<table>
<thead>
<tr>
<th>Primary function</th>
<th>City Hospital</th>
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<tbody>
<tr>
<td></td>
<td>University Medical Center</td>
</tr>
<tr>
<td>Beds</td>
<td>1221</td>
</tr>
<tr>
<td>Employees</td>
<td>10,000</td>
</tr>
<tr>
<td>Number of admittance</td>
<td>36,204</td>
</tr>
<tr>
<td>Budget</td>
<td>€ 743,000,000</td>
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<tr>
<td>Organization</td>
<td>Sophia children’s Hospital</td>
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<td></td>
<td>Daniel den Hoed oncology</td>
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<td></td>
<td>Thoracic centre</td>
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<tr>
<td></td>
<td>Centre location</td>
</tr>
<tr>
<td>Yearly production CSD</td>
<td>Sets: 95,000</td>
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<tr>
<td></td>
<td>Single Instruments: 110,000</td>
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<tr>
<td></td>
<td>Yearly increase: 2.7 percent (last two years)</td>
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**Unit material management**

- Material manager
- Quality manager
- Material manager
- Material manager

**Corebusiness:**
- Material management
- Management of the Quality management system
- Consultancy
- Project management
- Troubleshooting
Material Manager: tasks in relation to purchasing

- The material manager is the intermediate between the purchasing department and the users of medical devices.
- "Translates" wishes and demands in Program of Demands
- Coordinates implementation
- Registers and coordinates faults and complaints regarding medical devices

<table>
<thead>
<tr>
<th>Professional purchasing process</th>
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</thead>
<tbody>
<tr>
<td><strong>Customer</strong></td>
</tr>
<tr>
<td>Strategic purchasing</td>
</tr>
<tr>
<td>Specificate</td>
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<tr>
<td>High Influence on costing</td>
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Influence on costing:

- High Strategic purchasing
- Low Operational Purchasing
Main objective of surgical instruments in the past

- “only conditions that brought patients near death warranted the risk of surgical intervention. If patients survived the operation, infection was nearly inevitable and death by overwhelming sepsis was knocking at their door”
- Instruments were made by blacksmiths or by surgeons themselves
- The primary purchasing demand was of course..... sharpness!

Stakeholders purchasing complex surgical instruments
Personal choices

My Purchasing Process

Rationalization
Choice of Brand
Research

Gather opinions
I wonder who else owns one
Emotional Connection through emotional memory and experience
Visualization: I can see myself using that product

The surgeon’s purchasing demands

Quality of care
Innovation
Shortening of hospitalization
Faster recovery
Less scarring
Less pain
Initial costs
The CSD's purchasing demands

- Quality of care
- Decontamination
- Maintenance costs
- Reprocessing costs
- Legislation
- Initial costs

The combined purchasing demands

- Quality of care
- Innovation
- Decontamination
- Maintenance costs
- Reprocessing costs
- Legislation
- Initial costs
- Shortening of hospitalization
- Faster recovery
- Less scarring
- Less pain
Who’s demands tips the scale?

- The surgeon?
- The CSD’?
- Infection prevention?
- Controller?

Purchasing route:

- Buying is achieved through a direct contact between the customer and the Purchasing Department, without having a structured operational meeting related to the product

- Purchasing through multi-disciplinary consultations on the product that is needed.
  - A Program of Demands is an important aid!
The Program of Demands is a structural list with conditions to which the offered solution must comply

- by describing the different expectations precisely
- making an inventory, structuring and there where necessary giving direction to the expectations
- keeping the oversight
- a means of communication between the team members, the buying and the selling party
- final selection, objective, measurable, transparent and simple
- exchange of Programs of Demands provides standardization, harmonization and “not inventing the wheel” time and time again
- the Program of Demands provides cost reduction and supports the discussion to go ahead with the purchase

Conditions for the Program of Demands:

- no solution should be formulated
- space needs to be given to innovations, where wanted
- “hard” conditions based on validated data
- “soft” conditions must be made measurable
- conditions to be interpreted in a single manner
- prevent unwanted variations in the offerings
- all aspects of the product (functional) have to be covered
Example

What can we learn from a PoD: The retractor

- Designed in the early nineties
- No more modifications since then

www.medicaldevice.nl
www.nvilg.nl
Functional demands

- The retractor should not damage the tissue of a child more than conventional retractors used in adults.
- The product needs to retract a lung, stomach, liver, kidney or spleen without the help of other instruments.
- The functions of the product should be clear or comparable with existing instruments.
- The retractor should lift at least 261 gr. (this is the right lob of the liver of a two year old, and is the biggest organ to be retracted)
Legal demands

- The retractor complies to the Medical Directive 93/42
  - Thus complying to the essential requirements

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

3. Infection and microbial contamination

3.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

Legal demands: Classification

Rule 8

All surgically invasive devices intended for transient use are in Class IIIa unless they are:

- Reusable surgical instruments, in which case they are in class I

This means that the Technical Files regarding surgical instruments are not evaluated by Notified Bodies.
Decontamination demands

- The instrument must be suitable for decontamination
- The instrument must be compatible with the decontamination process on site.

Decontamination instructions

<table>
<thead>
<tr>
<th>Step</th>
<th>Instructions</th>
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</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>- 30 minutes of soaking in a detergent,</td>
</tr>
<tr>
<td></td>
<td>- flush the lumen minimal 3 times with 50 cc,</td>
</tr>
<tr>
<td></td>
<td>- Bring the instrument in a angulated position and wiggle the distal tip</td>
</tr>
<tr>
<td></td>
<td>for a minimum of 3 times:</td>
</tr>
<tr>
<td>Step 2</td>
<td>After cleaning rinse with aqua dest. Via the flush opening</td>
</tr>
<tr>
<td>Step 3</td>
<td>20 minutes in a ultra soon</td>
</tr>
<tr>
<td>Step 4</td>
<td>After the ultra soon rinse again with aqua dest.</td>
</tr>
<tr>
<td>Step 5</td>
<td>Automated disinfection isn’t included in this instruction</td>
</tr>
<tr>
<td>Step 6</td>
<td>Lubricate the instrument thoroughly every time</td>
</tr>
<tr>
<td>Step 7</td>
<td>3 minutes of drying time before</td>
</tr>
<tr>
<td></td>
<td>Autoclaving</td>
</tr>
<tr>
<td>Step 8</td>
<td>Autoclaving</td>
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</tbody>
</table>
Commercial demands

- initial purchasing costs within budget
- Total Cost of ownership within budget

Professional Purchasing Process

adequate specification can lead to initial cost reduction
Total cost of ownership (TCO)

- Is a method of calculating both the direct and the hidden costs of an equipment purchase.
- In many cases a product's hidden costs are greater than its actual purchase price.
  - Initial costs
  - Decontamination costs
  - Maintenance costs
  - Operating costs
  - Service costs
  - Disposal costs
Developments

- Natural Orifice Translumenal Endoscopic Surgery (NOTES)
- Surgery for Obese
- Further development of Minimal invasive surgery
- Nanotechnology (coating of instruments)

Keynotes

- A lot of stakeholders
- With a lot of different demands
- Therefore purchasing of surgical instruments can be complex and time-consuming
- Nevertheless it is necessary to gain insight prior to the purchase of instruments regarding:
  - Total cost of ownership
  - Consequences for other disciplines
    - CSD
    - OR staff
    - Logistics.
- A Program of Demands and a TCO analysis are important aids
- My recommendation is that a standardized PoD with the demands of the stakeholders is available for surgeons and OR’s
Thank you for your attention!

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