MANAGEMENT OF MEDICAL DEVICES

Areas requiring further strengthening

Global Forum on Medical Devices,
Bangkok 2010
“It may seem a strange principle to note but the prime duty of a hospital is to do the sick no harm” Florence Nightingale, 1860

“As a body accountable for taxpayers’ money, we should be able to itemize, track and monitor all medical equipment purchased” CEO Greater Glasgow Health Board, 1986
Example from Scotland

Source: Unified NHS Board Summary Accounts 2007/08
1. What is the current position? Organisations need to establish a baseline position that identifies their current assets and how well these are contributing to supporting service delivery. What condition the assets are in and how suitable they are.

2. What are the plans for healthcare in the future, and what assets are needed to support current and future service needs?

3. Is there a strategy that outlines how the organisation will move from its current position to its future position? This means developing an action plan that covers future asset acquisitions, disposals and maintenance.

Source: Adapted from Towards Better Management of Public Sector Assets, Sir Michael Lyon, 2004
1. **Planning** – what assets are required and when.

2. **Acquisition** – how assets are funded and which partners might be involved.

3. **Operation and maintenance** – ensuring assets are maintained and performing adequately & safely.

4. **Disposal** – what the best future use is for an asset.

5. **Performance management and monitoring** – collecting and managing data to inform asset management.
DETAILED ISSUES WITHIN KEY ELEMENTS

Source: Audit Scotland adapted from Sustaining our assets: Government Asset Management Policy Statement, Department of Treasury and Finance, State Government Victoria, 2000
AREAS OF CONCERN IN LIFE CYCLE

- **Service Objective**
- **Identify options & appraise life-cycle costs**
- **Performance Management, Risk Assessment & Monitoring Inventory / Records / Audits**
- **Decide procurement mode & allocate funds**
- **Procurement (incl. technical specifications)**
- **Delivery, installation & training**
- **Keep maintained**
- **Review use & replacement needs**
- **New needs & priorities**
- **Plans & strategies**
- **Disposal**
- **Operation**
• The essence of financial appraisal is to place a financial value on all life cycle costs, benefits and risks so that a thorough evaluation can be made of the relative merits of various equipment options and methods of funding.

• The most common methodology for public sector capital equipment procurement, is to use the net present value technique (PV) under which all costs and benefits are recalculated to represent their net value to the institution today, thus making comparisons more accurate.

• "Jam today is worth more than jam tomorrow". For public sector financing, more value is placed on current costs and benefits than on those which might apply in the future. To bring future costs and benefits into the same perspective as current ones a "discount rate" is applied.
## LIFE-CYCLE COST ANALYSIS

### ESTIMATED LIFE-CYCLE COSTS OF RADIOLOGICAL SERVICE IN NEPAL (Rs Present Values)

<table>
<thead>
<tr>
<th>Cost (incl. installation)</th>
<th>$30,000</th>
<th>Discount Rate</th>
<th>0.0388</th>
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</thead>
<tbody>
<tr>
<td>RoE : Rs per $US</td>
<td>68.75</td>
<td>Present Value Factor</td>
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<tr>
<td>Inflation rate</td>
<td>0.03</td>
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<tr>
<td>Deposit Rate</td>
<td>0.07</td>
<td>No. exams per day</td>
<td>4 (actual at Lahan DH - June’00)</td>
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<tr>
<td>Lifetime (years)</td>
<td>15</td>
<td>Working days per month</td>
<td>24</td>
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(* based on WHIS-RAD system at Lahan DH)

<table>
<thead>
<tr>
<th>Year</th>
<th>Capital Cost</th>
<th>Staff Costs</th>
<th>Consumables</th>
<th>Maintenance</th>
<th>Buildings</th>
<th>Overheads</th>
<th>Total</th>
<th>PV Function</th>
<th>Present Value</th>
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<th>Year</th>
<th>Capital Cost</th>
<th>Staff Costs</th>
<th>Consumables</th>
<th>Maintenance</th>
<th>Buildings</th>
<th>Overheads</th>
<th>Total</th>
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<th>Present Value</th>
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### Notes
- **Capital Cost:** For WHIS-RAD 100mA X-ray machine (as purchased for Lahan DH)
- **Overheads:** Based on one radiographer at basic salary Rs 4,900 per month
- **Consumables:** Based on film (12x15) and reagent costs of Rs 45, per standard exam
- **Maintenance:** Based on annual contract at 4% per annum of replacement cost
- **Buildings:** Based on 50 sq.m. @ asset value of Rs 5,000 per sq.m., depreciated over 50 years plus 1% per year for maintenance
- **Overheads:** Based on 20% of staff costs; for administration & logistic services/support and utilities

### Cost/X-ray (Rs)

<table>
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<tr>
<th>No. per year</th>
<th>Cost/X-ray (Rs)</th>
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</thead>
<tbody>
<tr>
<td>5,000</td>
<td>110</td>
</tr>
<tr>
<td>4,000</td>
<td>127</td>
</tr>
<tr>
<td>2,000</td>
<td>208</td>
</tr>
<tr>
<td>1,000</td>
<td>371</td>
</tr>
<tr>
<td>500</td>
<td>699</td>
</tr>
</tbody>
</table>
LCC OF WHIS-RAD X-RAY OVER 15 YEARS
(4 exams per day)

- Buildings: 4%
- Overheads: 3%
- Capital Cost: 39%
- Staff Costs: 17%
- Consumables: 15%
- Maintenance: 22%

LCC OF INDIAN 100mA X-RAY OVER 15 YRS
(average 6.5 exams per day)

- Buildings: 7%
- Overheads: 6%
- Capital Cost: 13%
- Staff Costs: 28%
- Consumables: 39%
- Maintenance: 7%
No. of radiographs per day

20

15

13

11

10

6

3

4600 exams/year

Lahan DH - WHIS-RAD- June’00

Surkhet DH - Indian GE - June’00

Cost per X-ray (Rs)

700

600

500

400

300

200

100

0

Porter, 2000
COMPONENTS OF COST PER IPD IN AN 8-BEDDED ICU DEPARTMENT

- **Consumables**: 47%
- **Staff Costs**: 19%
- **Maintenance**: 5%
- **Overheads**: 19%
- **Capital Cost**: 2%
- **Other Capex**: 6%
- **Blgd (D&M)**: 2%

BO% = 60%

*Porter et al., 2003*
Survey of 87 units

RANGE (exams per month)

- A65 (33)
- A66 (23)
- A67 (31)

Porter et al., 1997
Survey of 182 units

Percentage

Range (times per month)

0-25
26-50
51-100
101-200
>200

Porter et al., 1997
### NOS. OF OPERATING ROOMS REQUIRED

- **Nos. of working days/week**: 6
- **Surgical operations/year**: 6,500
- **Average no. of cases/session**: 1.5
- **No. of operating sessions required/year**: 4,333
- **No. of sessions/OR/week (6 work days/week)**: 12
- **PPM (done on day 7): sessions off/week/OR**: 1
- **Available sessions/week/OR**: 11
- **Additional sessions/week**: 12
  
  *(with 1 OR reserved for emergencies)*
- **Working weeks/year**: 50

**Estimated Nos. of ORs needed** *(rounded up)*: 9
No. of ORs Required Vs Operations Load
(assuming 3 ops/OR/day, 300 days per year)

- Number of ORs needed
- Number of operations per year

From Porter et al., 2003
INEFFICIENT USE OF OR EQUIPMENT

No. of ORs Required Vs Operations Load
(assuming 3 ops/OR/day, 300 days per year)

Number of operations per year

Nos. ORs required  Y2005 DHB Hospitals  UK: 7.4ops/OR/day

Porter et al., 2003
2. TYPES OF TECHNICAL SPECIFICATION

1. **Functional** - those which define the function or duty to be performed by the product

2. **Performance** - those which define the performance required of an item

3. **Technical** - those which define the technical and physical characteristics of an item in terms of such things as physical dimensions, power input and output, number of knobs and dials, their location and purpose, the materials to be used etc.
Functional and performance specifications are preferred because they:

- encourage other parties (e.g. a manufacturer who may be more expert) to offer alternative innovative solutions;
- discourage bias;
- minimise resources and effort to prepare the specification;
- reduce resources required by suppliers to prepare detailed responses;
- focus on results, not on technical characteristics.
Product resulting from a strictly ‘technical’ specification

Source: OT, Genesis 6:14-16
A MORE RECENT ‘DEVICE’ PROJECT

Product from a ‘functional-cum-performance’ specification

Source: O. Wright, 1907
3. **RISKS TO BE ASSESSED**

<table>
<thead>
<tr>
<th>Category</th>
<th>Risk Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning</td>
<td>• reliability of management information</td>
</tr>
<tr>
<td></td>
<td>• business-case justification <em>(where appropriate)</em></td>
</tr>
<tr>
<td></td>
<td>• efficacy &amp; safety <em>(HTA etc; latter ongoing)</em></td>
</tr>
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<td>• HR &amp; infrastructure preparedness</td>
</tr>
<tr>
<td>Procurement &amp; Acceptance</td>
<td>• transparency of processes</td>
</tr>
<tr>
<td></td>
<td>• bid evaluation methodology</td>
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<td>• quality of devices &amp; workmanship</td>
</tr>
<tr>
<td>Operation &amp; Maintenance</td>
<td>• security of operating budget</td>
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<td>• HR diligence in operation, care &amp; records</td>
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<td></td>
<td>• quality of support services <em>(incl. Q.C. measures)</em></td>
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<tr>
<td>Obsolescence &amp; Disposal</td>
<td>• economic lifetime <em>(based on experience)</em></td>
</tr>
<tr>
<td></td>
<td>• repair Vs dispose decision criteria</td>
</tr>
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<td>• environmental impact</td>
</tr>
</tbody>
</table>
AGE SPECTRUM IN DEVELOPED COUNTRY

‘All Scotland’ age profiles for selected examples of medical equipment

Approximately 25% of these items of medical equipment are older than the standard life.

Standard life of equipment

mostly 10 years

8 - 10 years

5 - 7 years

Total number of items

- Mobile X-ray units
- General purpose X-ray units
- Fixed X-ray units with fluoroscopy
- ECG recorders
- Defibrillators
- Dental X-ray units
- Gamma cameras
- Dialysis machines
- Volumetric pumps
- Angiographic units
- Syringe pumps
- MRI scanners
- CT scanners
- Flexible endoscopes
- Diagnostic ultrasound scanners

Percentage ‘age profile’

Beyond standard life

Reached standard life

Within standard life

Source: Audit Scotland, 2003
<table>
<thead>
<tr>
<th>Repair life (yrs)</th>
<th>Normal Life-Expectancy of Device (yrs)</th>
<th>Limit to Repair Cost as Percentage of Replacement @ discount rate: 6.0%</th>
</tr>
</thead>
<tbody>
<tr>
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<td>7</td>
<td>8</td>
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</table>
These can take the form of:

- planned & random **spot checks**
- regular **technology strategy reviews**
- Investigation by national/parliamentary authorities e.g. **Govt. Audits, Vigilance Bodies**
- Oversight by representatives of ‘**civil society**’.

*Why is this necessary?*
1. **Insufficient health budgets** due to deteriorating economic conditions, combined with burgeoning health problems such as the global HIV-AIDS pandemic, have led to an acute shortage of health workers (WHO 2006), shortage of drug and medical supplies, inadequate or non-payment of health workers salaries, poor quality of care, and inequitable health care services in many low income and transition countries. With **corruption as both a cause and effect** the result has been deterioration of general health and degrading of the health system in developing countries.

2. **Former Health Minister Jailed for Corruption**

The Anti-Corruption Court on Friday sentenced the nation’s former health minister, to two years and three months in jail for his role in a 2003 graft case that involved **inflating the budget for contracts to supply medical equipment** to remote regions.

and executives from the two companies had manipulated the per-unit equipment prices by **up to 5,000 percent above retail**.
3. Former vice-president of the UK subsidiary of US company, jailed for 12 months for helping arrange £4.5 million worth of bribes in for conspiring to make corrupt payments to health officials, primarily surgeons, to entice them to recommend ’s orthopaedic products and other medical equipment to the national health service.

The prices paid for the equipment were double what was paid elsewhere in Europe.
THE ELEPHANT IN THE ROOM

% OF FIRMS EXPECTING TO GIVE GIFTS TO SECURE GOVT. CONTRACT FROM SURVEYS IN 35 SUB-SAHARAN COUNTRIES

Source: Africa Development Indicators 2010, World Bank
Source: Transparency International Annual Report 2006
RISK AREAS IN HEALTH CARE & CONSEQUENCES

Possible High Risk Sources:

- Health Care Professionals
- Health Ministry and Management Personnel
- Distribution of Drugs and Services
- Budget Allocation
- Procurement of Drugs and Medical Equipment

Outcomes:

- Reduces Resources
- Lowers Quality
- Reduces Equity and Efficiency
- Increases Cost
- Decreases Effectiveness and Volume

Source: Weerasuriya, 2004
Independent oversight, to ensure

- **Good governance** *(management systems, risk assessment procedures, records as indicated in place)*

- **Accountability** *(internal and external auditing of planning, procurement & operational activities, especially regarding finance & value-for-money)*.

- **Minimisation of fraud & corruption** *(pro-active good governance and accountability action plans for major investment projects & vigorous investigation / prosecution of suspected malfeasance)*.
1. **LCCA**: essential tool in all investment & replacement decisions. *Develop guidance manual/ready reckoner/software package*

2. **Technical specifications**: shift to functional & performance types. *Working group, incl. industry reps, to formulate templates for selected devices*

3. **Risk assessments**: more comprehensively than current practice. *Develop guidelines with key indicators*

4. **Independent oversight**: see previous slide. *Develop & implement accountability action plan.*
THANK YOU