

Medical Equipment Maintenance Strategies

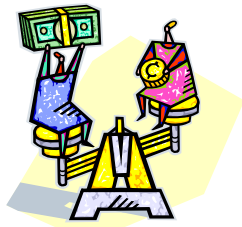
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Healthcare

Medical Equipment Maintenance Strategies

How to balance limited resources with increased customer expectations?



JCAHO Clinical Engineering Standards

Study Group: (T Cohen, E Furst, O Keil, M Ridgway, B Stiefel, B Wang)

Presented by Binseng Wang,
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Background

- Two years ago in Boston, I reported that a bunch of naive "natives" (**Gang of Six**) suggested JCAHO should allow the healthcare organizations to develop their own, **responsible** medical equipment mgmt program by using these guidelines:

- Organization-defined inclusion criteria
- Life support to be treated as one of the attributes
- Organization-defined performance measures, with emphasis on outcomes
- Requirement on continuous improvement rather than artificial, fixed targets



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Background

- Well, it seems that JCAHO does not like to be told what to do. Instead, it told us to ...
- So, we decided to published our recommendations (*BIT*, June 2006) and share our views with the CE professionals.

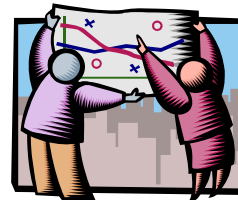


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- Traditional Medical Equipment Management Strategy
- Changes in Customer Expectations
- "New" Maintenance Strategy
 - Goals and objectives
 - Implementation
- Discussion



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Traditional Maintenance Strategy

- Fennigkoh's risk-based (or similar) inclusion criteria
 - Each piece of equipment is given a value for each of the following criteria
 - Function: 2-10
 - Physical Risk: 1-5
 - Maintenance Requirements : 1-5
- An Equipment Management (EM) number is then calculated using the following equation
 - **EM = Function + Physical Risk + Maintenance Requirements**
- Inventory divided into 2 groups using EM
 - "Excluded" equipment: EM < 12
 - "Included" equipment: EM ≥ 12
- Maintenance strategy
 - Excluded equipment: repaired as needed
 - Included equipment: "preventive" (scheduled) maintenance, monthly, quarterly, semi-annually or annually

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Traditional Maintenance Strategy

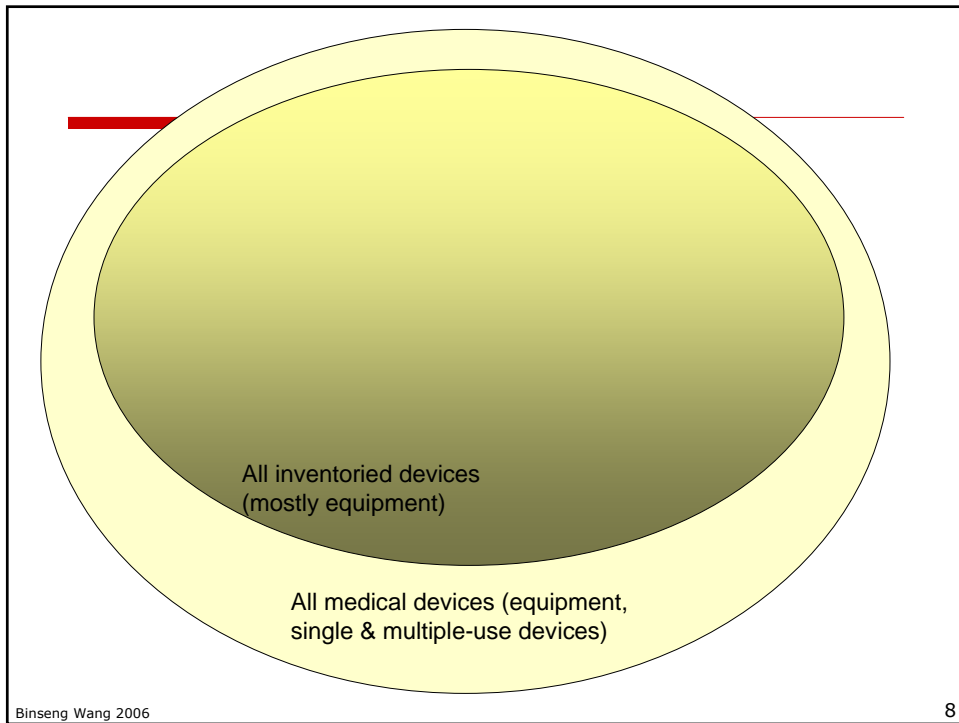
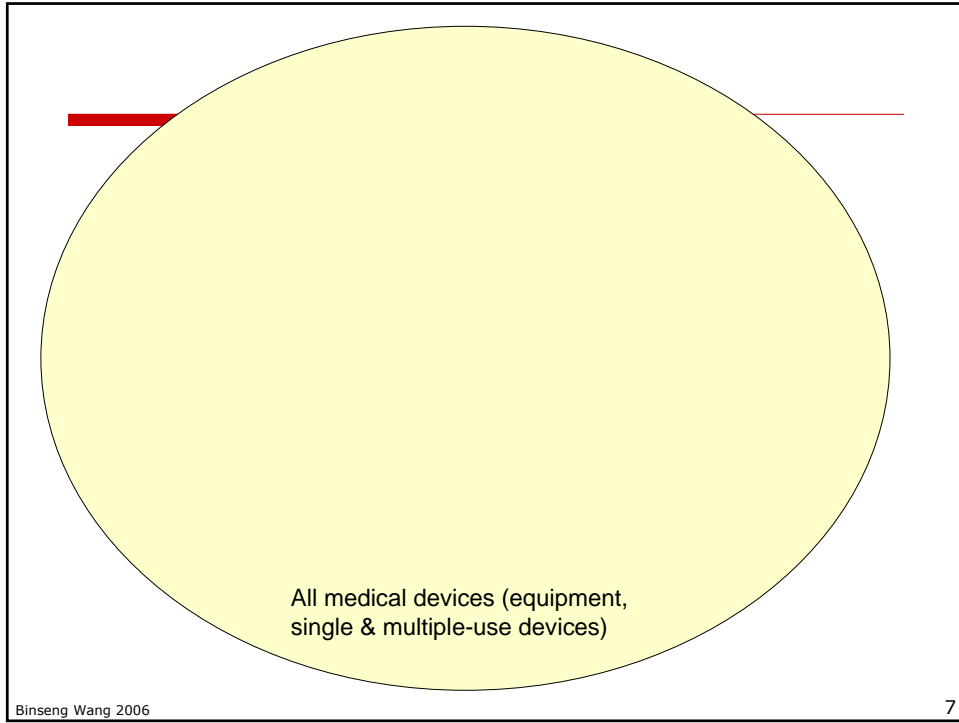
- Advantages
 - Easy to understand and implement
 - Satisfied JCAHO requirements
 - Reduced individual patient risks
- Disadvantages
 - Does not keep up with the progress of medical equipment design and construction
 - Ignores the impact on organization's overall mission to serve the community and all the patients
 - Lack of synergy with organization's needs and users' desires
 - Spend more resources yet may miss Mgmt expectations

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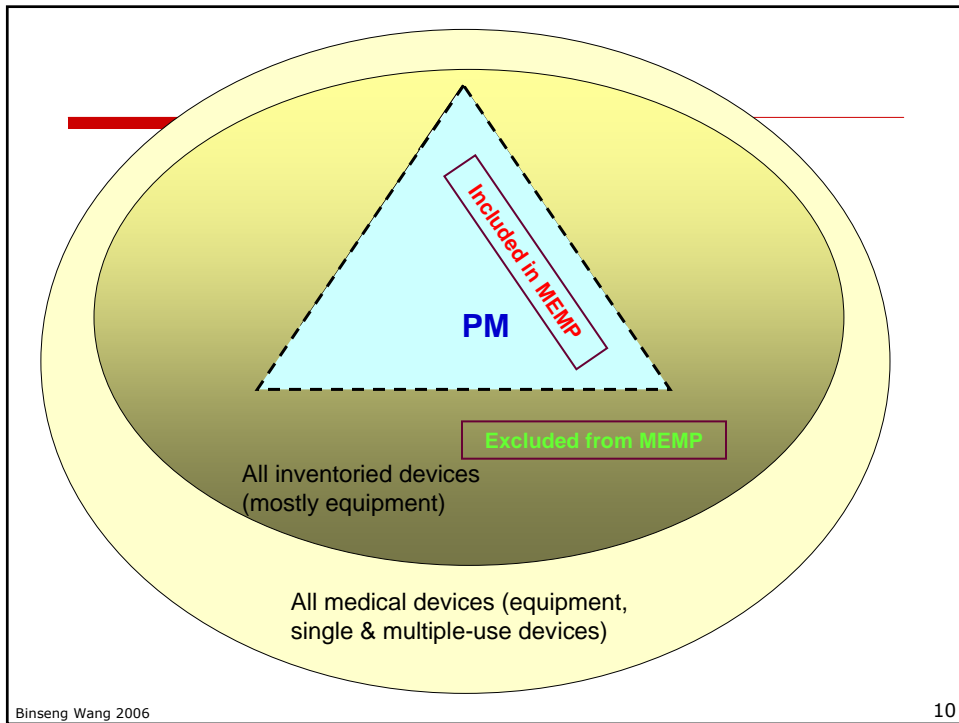
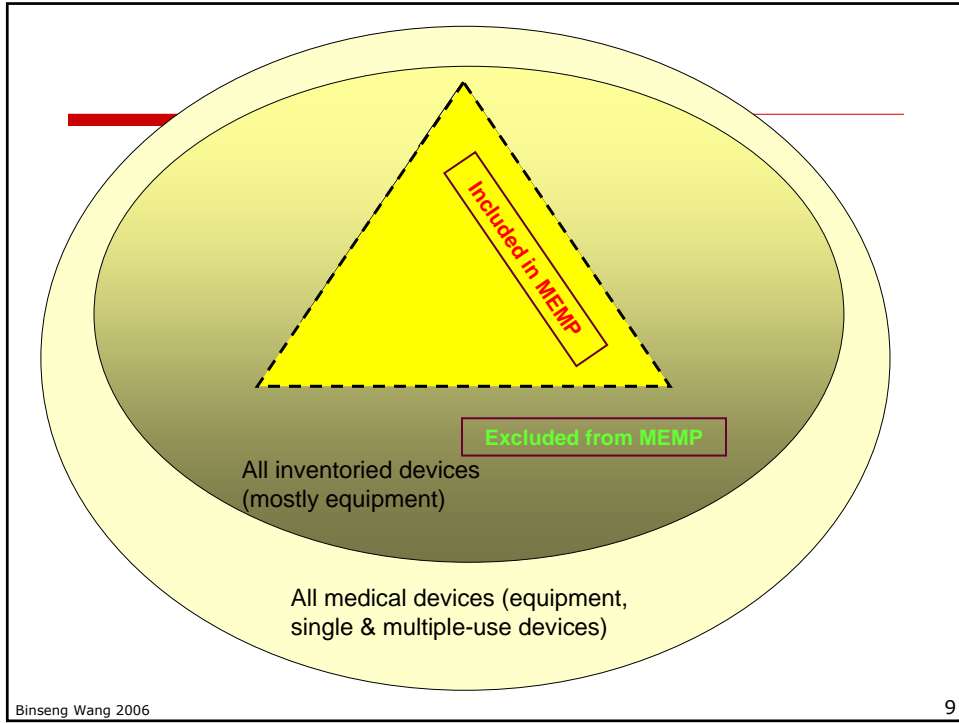
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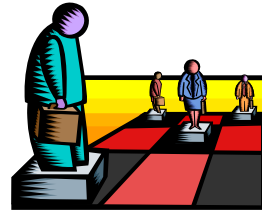


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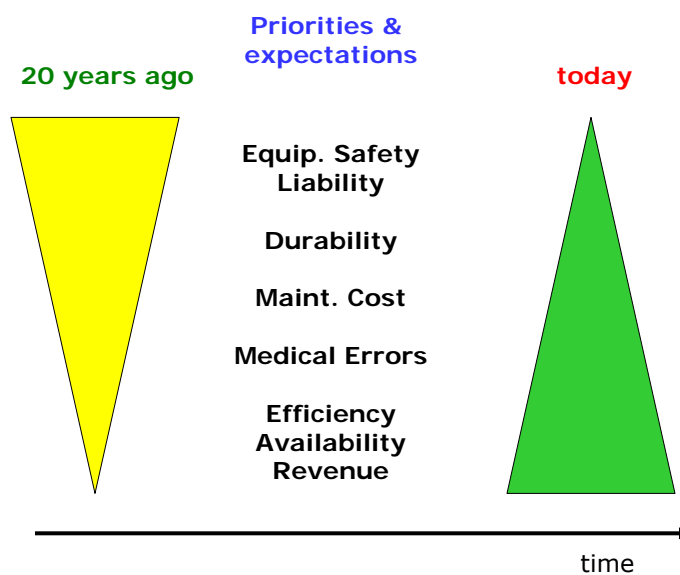
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Changing priorities & expectations



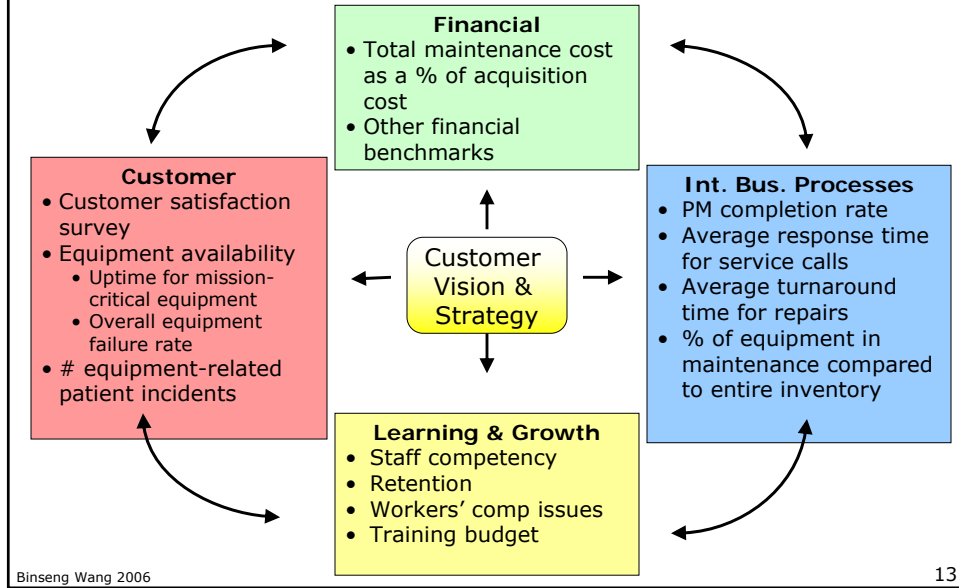
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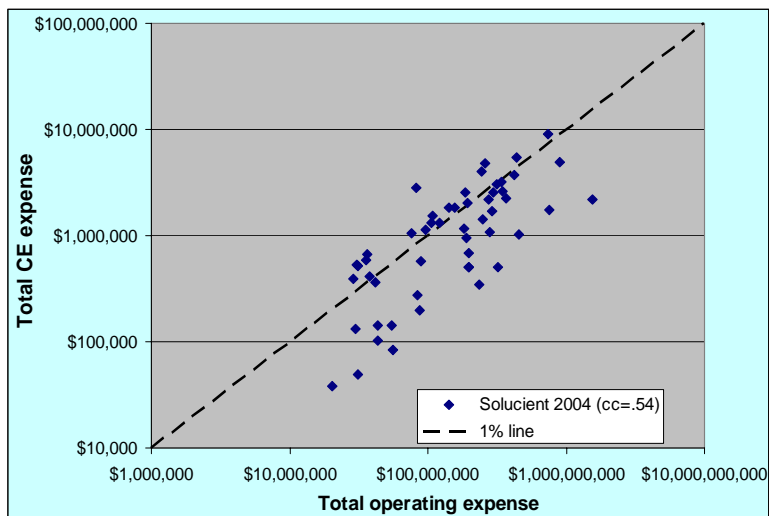
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Current customer expectations



Total CE expense is only ~1% of total operating expense!

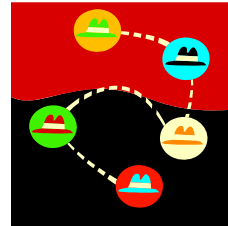


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“New” Maintenance Strategy

PRIMARY GOALS AND OBJECTIVES

- Maintain highest level of **availability** of medical equipment to clinical users (availability affects both safety and revenue)
- Continuously seek opportunities for quality improvement and **cost reduction**
- Comply with applicable regulations and standards
- Reduce the need of premature replacement of equipment [this is \neq “extend useful life”]

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“New” Maintenance Strategy₂

SECONDARY GOALS AND OBJECTIVES

- Reduce unnecessary workload
- Refocus attention where customer expectations are higher (paradigm shift)

Explanation to hospital mgmt and clinical users:

- This is not to reduce costs or “cut corners” but to redirect attention to fit your needs (e.g., covering previously “excluded” equipment & increased vigilance on mission-critical equipment)

Explanation to CE staff

- This is not to decrease FTEs but to redirect resources to where more attention is needed (e.g., mission critical equipment, user training, & accessories check)
- In essence -> a **win-win strategy**

Implementation of “New” Maint. Strategy

- Equipment classification
 - 3-tier model
 - Visualization of the paradigm shift
- PM planning (decision process)
- SPI planning (decision process)
- Continual Improvement
- Expected impacts and results

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Equipment Classification

- Classification parameters:
 - **Patient risk** (death, injury, misdiagnosis, etc.): **high**, **medium** or **low**, including the 3 risk criteria specified by JCAHO: **equipment function, physical risk and incident history**.
 - **Mission criticality** or “operational impact” (availability for patient care), including availability of backups: **critical**, **important** or **necessary**
- Divide the equipment into 3 tiers:

	Patient Risk	High	Medium	Low
Mission				
Critical		tier 1	tier 1	tier 1
Important		tier 1	tier 2	tier 3
Necessary		tier 1	tier 3	tier 3

Examples for the 3 tiers

Patient Risk	High	Medium	Low
Mission			
Critical	tier 1 anesthesia equip, ventilator, radiotherapy	tier 1 CT scanner, cath lab, auto chem. analyzer	tier 1 electron microscope
Important	tier 1 PCA pump, infant incubator, defib, telemetry system	tier 2 infusion pump, hypo/hyperthermia, pt monitor, ESU, blood gas analyzer, ultrasound scanner	tier 3 special procedure table, lab microplate reader, cine projector
Necessary	tier 1 bariatric pt lift, laminar airflow	tier 3 enteral feeding pump, ECG, pulse oximeter	tier 3 pt scale, examination light, treadmill

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Inclusion of “equipment incident history”

“Equipment incident history” is used for escalation of risk classification:

- Initially, a level (i.e., high, medium or low) is assigned for Risk considering:
 - Function: the energy delivered to the patient and consequences if the energy is interrupted
 - Physical risks: potential effects to the patient if equipment fails
- Next, incident history is used to escalate the initial level.
 - The level will be “bumped up” by one (level not tier) if there were one or more serious injury or deaths traced to equipment malfunction (i.e, not related to use errors or other environmental issues) in the last 12 months.
 - If there were no serious injury or deaths, three patient incidents will still trigger a level increase.

Inclusion of “equipment incident history”₂

- The incident history factor will be reviewed and recalculated periodically (annually), as equipment may have been upgraded or recalled since the initial incidents.
- In addition, remember that the **mission criticality** parameter also considers function in the context of the entire patient-care process.

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Relationship of tiers to JCAHO standards

- **Tier 1** ≡ JCAHO MEM Plan ("reportable" equipment), including life-support equipment. **Almost certainly** will require SPI but only some will benefit from PM.
- **Tier 2**: equipment excluded from JCAHO MEM Plan but still **may** require PM or SPI to reduce risks of financial loss, operational efficiency (patient flow), or impact on the quality of patient care.
- **Tier 3**: equipment excluded from JCAHO MEM Plan and managed for the purpose of recalls, replacement planning, asset control, etc., with **no** need for PM or SPI (repair or replace as needed).

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Visualization of paradigm shift

The following sequence of slides show the difference between the current approach and the proposed approach

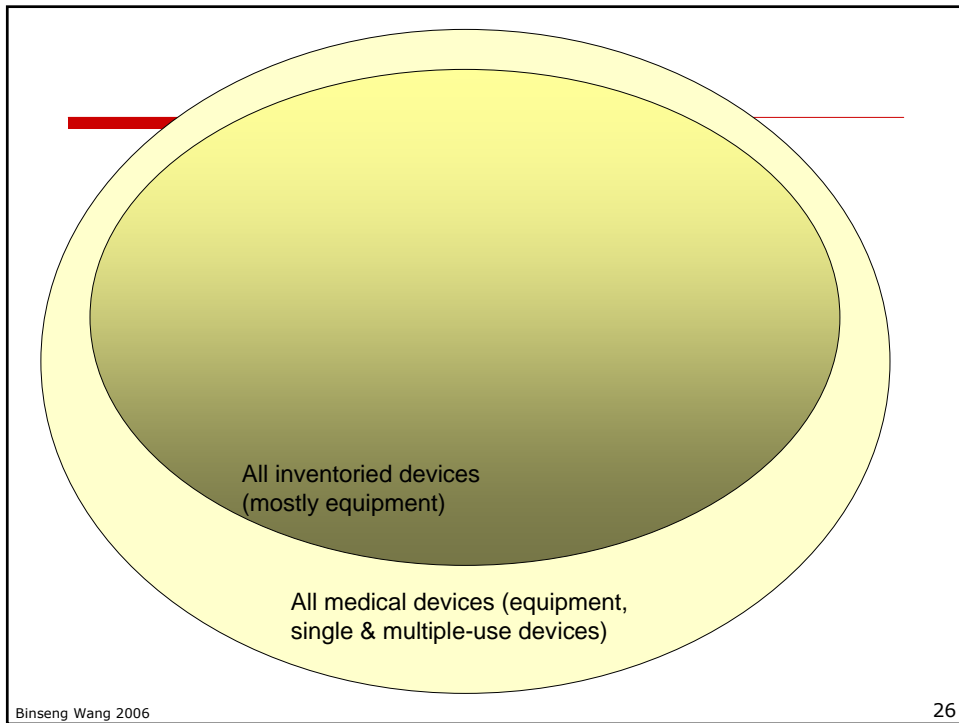
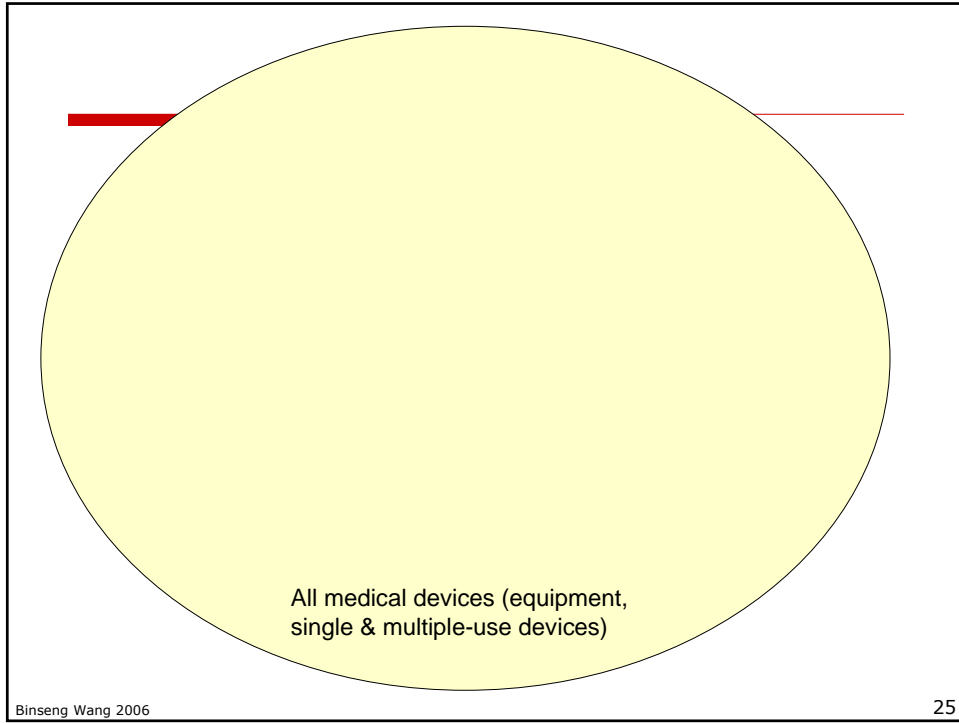


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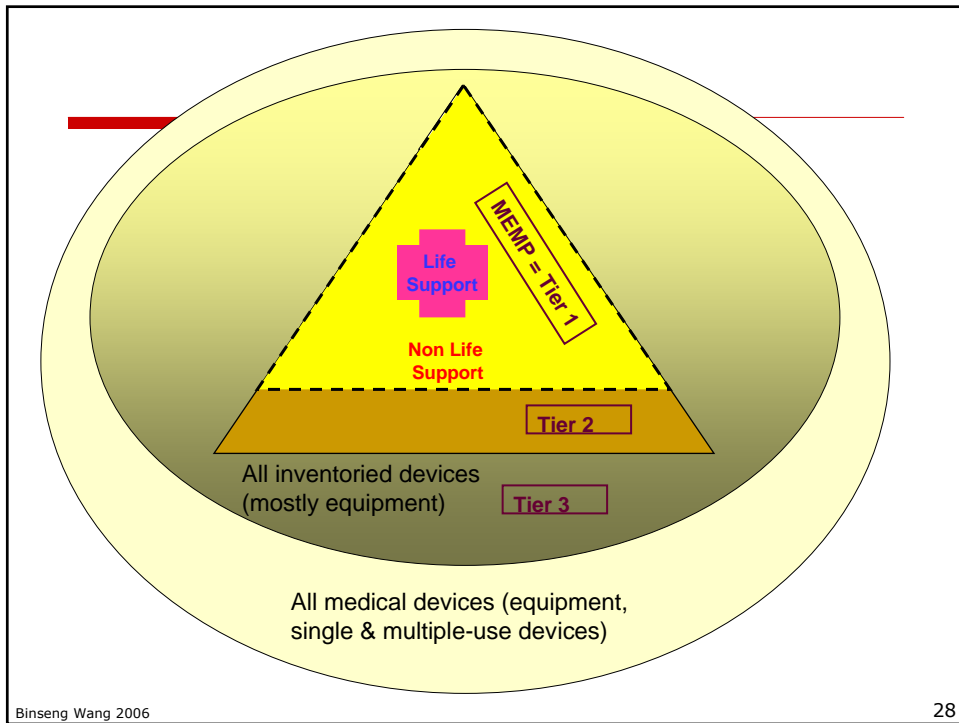
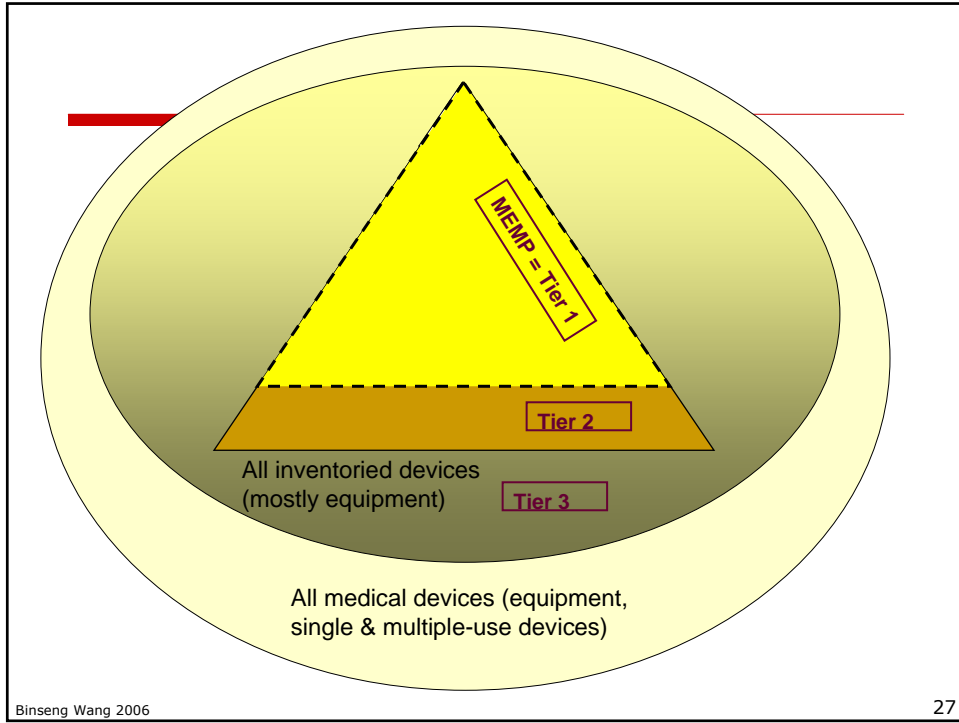
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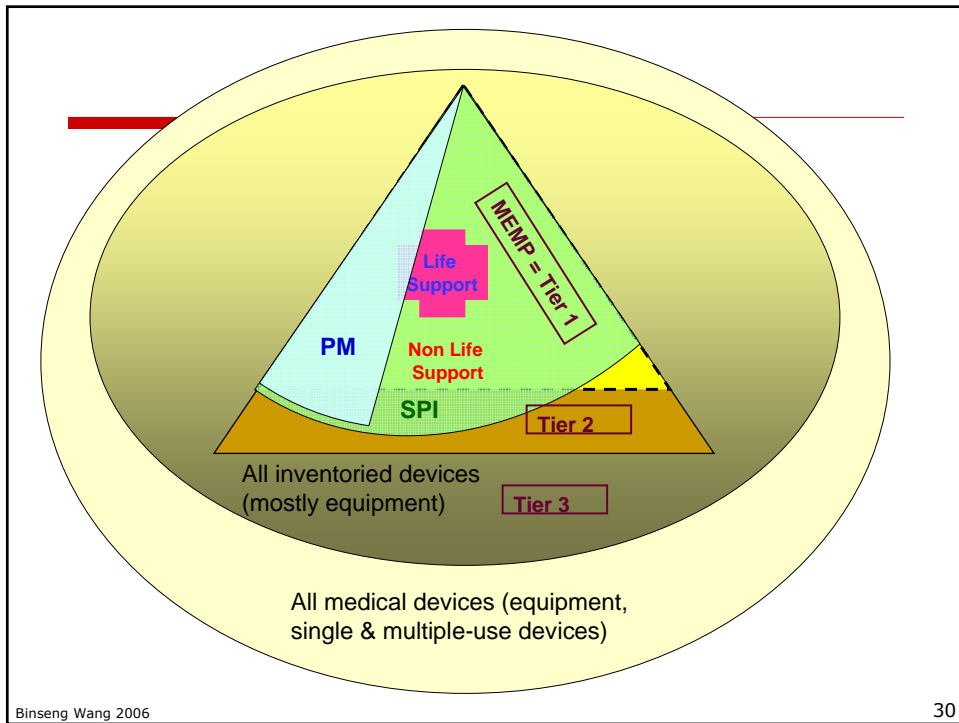
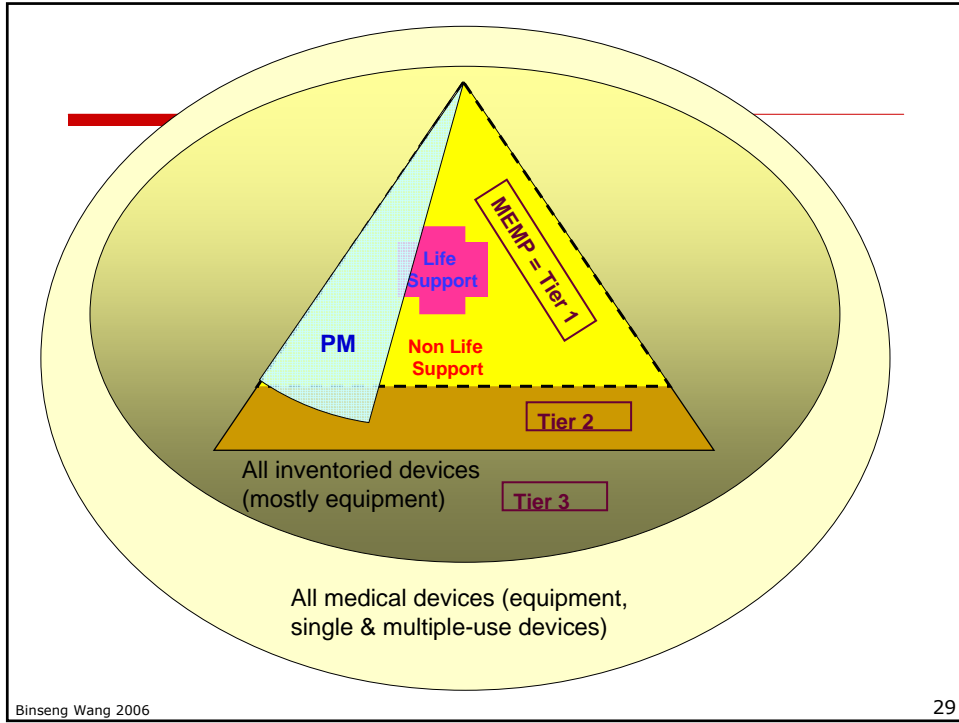
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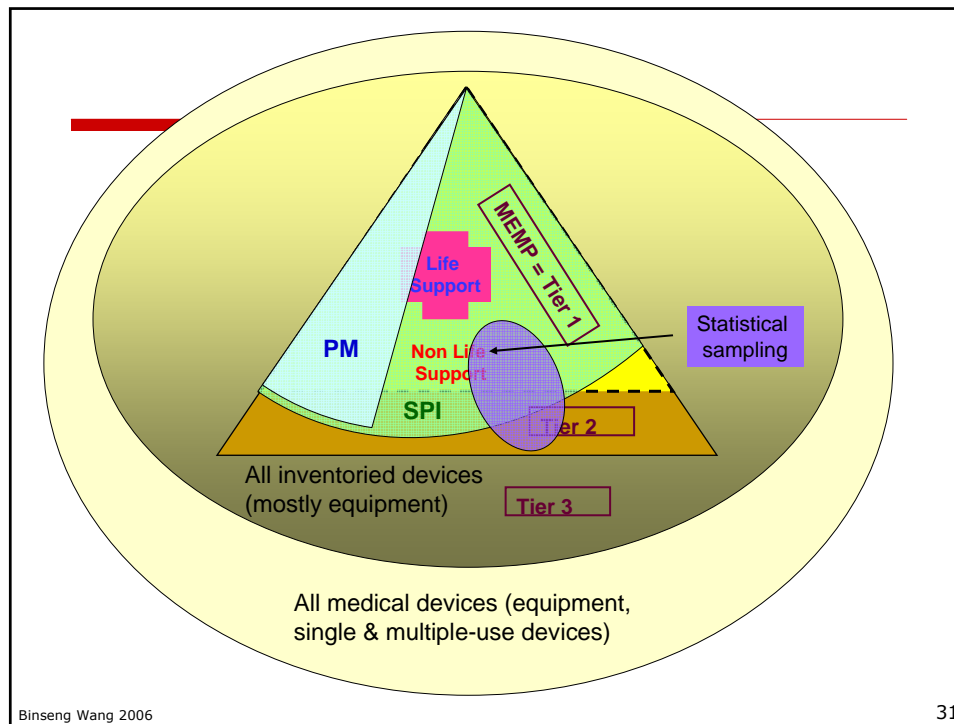
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Nomenclature

- **Preventive maintenance (PM)**: actions, such as replacement of wearable parts after a certain amount of time or hours of use, performed to prevent a predictable failure [*RCM: proactive, scheduled*].
- **Safety and performance inspection (SPI)**: actions performed to verify safe operation and performance according to original specifications, and detect an existing failure or deterioration that requires corrective action [*RCM: on-condition maintenance and failure finding*].

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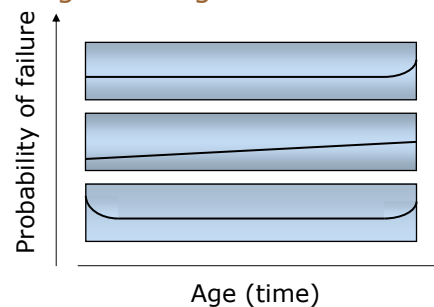
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PM Planning Process

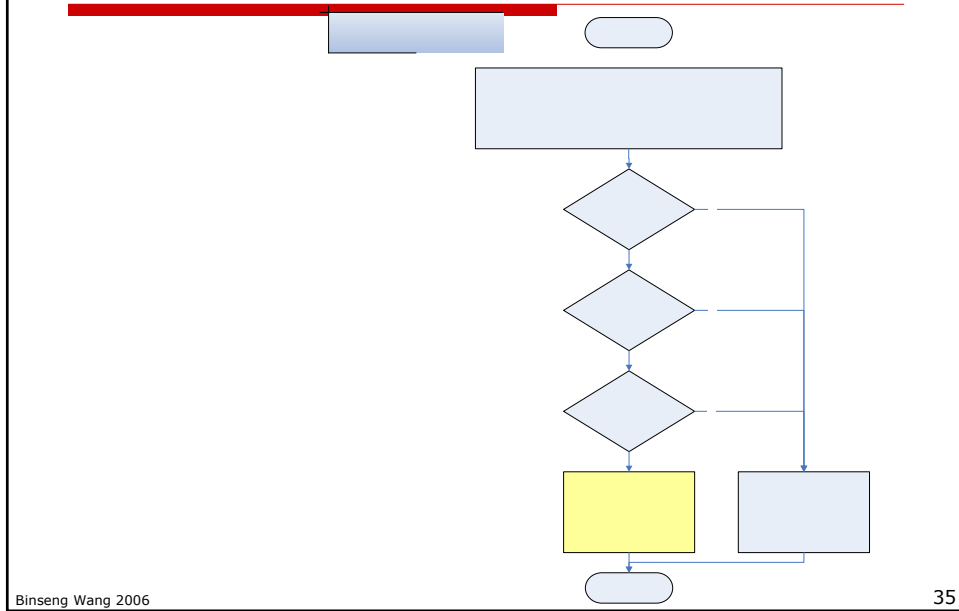
- PM decisions is based on
 - Age-related failure pattern(s) [if OEM cannot provide data, use device construction, OEM recommendations, and collective past experience]
 - *Technical feasibility*
 - *Cost effectiveness* [less weight for high risk devices]



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PM decision tree



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SPI Planning Process

- SPI has “double duty:”
 - “On-condition” (predictive) tasks (*potential failures*)
 - “Failure-finding” (reactive) tasks (*hidden failures*)
- One way to assign SPI is to use a simplified FMEA

		Failure Modes	
		Detectable by user	Not Detectable
Failure Effects (to either patient or mission)	Serious (i.e., mission critical or high risk)	SPI by user and by technician*	SPI by technician
	Not serious	SPI by user	SPI by technician

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Scheduled service frequency

- PM & SPI frequencies: determined individually (i.e., by brand and model) based on MTBF (if available) or alternative methods (construction, expert opinion, OEM recommendations, collective past experience, etc.)
 - PM period \leq MTBF
 - SPI period = $2 \times (1 - \text{availability}) \times \text{MTBF}$
(where availability is measure in %)and **both revised periodically based on experience ("PM yield")**

Continual Improvement

- The afore presented material is intended for "initial" maintenance planning, even though we may use collective experience to "guesstimate" some parameters.
- Each year, **revisions** should be made to the equipment classification, PM and SPI decision, and PM and SPI frequencies, after evaluating the accumulated data for performance, impact, pt incident history, costs, etc.

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Summary of main changes

- Equipment classification: remove maintenance (PM, SPI & repairs) from classification (tiers 1-3). **Classification is defined by mission and risk only** (but "risk" considers all 3 JCAHO requirements: function, physical risk & patient incident history).
- Maintenance decision: distinguish PMs from SPIs and recognize they are **independent but not mutually-exclusive** of each other. Each with a separate decision process (flowchart). **PMs and SPIs are considered only for tiers 1 and 2 devices.**

Summary of main changes₂

- PM & SPI frequencies: can exceed 12 months and independent of equipment tier ranking.
- Statistically sampling: can be used for tiers 1 & 2 devices when they are not high risk and have large "homogeneous" populations [more discussions later]

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Implementation of “New” Maint. Strategy

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Expected impacts and results

- Few, if any, changes at the two extremes of inventory classification (i.e., life support and low risk+low criticality). **Mostly in the “middle.”**
- More attention to mission-critical devices than before -> **increased availability (“uptime”)**
- Less PMs and SPIs when they are not effective (“low yield”) -> **less labor and easier compliance to standards**
- **Initial estimate of labor savings: up to ~25%** (when compared with “traditional” tier thresholds)
- More attention on maintenance data analysis for:
 - Detecting use errors & training opportunities
 - Planning and replacement of equipment

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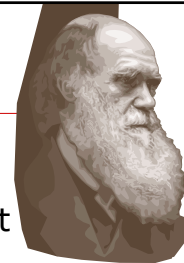


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Discussion

- This is an **evolution** not revolution
 - Follow progress of medical equipment design and manufacturing
 - Incorporate the **mission-critical** concept
 - Adopt the separation of risk and "PM" accepted by JCAHO
 - Learn from Reliability-Centered Maintenance (**RCM**) experience accumulated in industrial maintenance
 - Recent JCAHO root-cause-analysis (RCA) of **10 years of sentinel events** indicate most of them are due to use errors and communication problems



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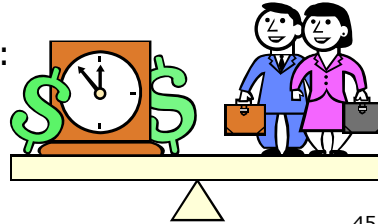
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Discussion₂

- Refocus resources from “scheduled maintenance” (SPIs and PMs) to higher-impact tasks, e.g., use error tracking and user training.
- It is always a balancing act:
 - Needs (mission, safety, revenue, etc.)
 - Re\$ource\$ (human, technical, financial, etc.)

(that's why it is **engineering**: find the best “balanced” solution)



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THANK YOU!

- Please contact us if you have any questions or suggestions
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