



Asia-Pacific
Economic Cooperation

2007/SOM1/MAG/WKSP/004

Medical Device Remanufacturing

Submitted by: GE



Workshop on Remanufacturing
Canberra, Australia
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GE Healthcare

Medical Device Remanufacturing

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January 21, 2007

imagination at work 

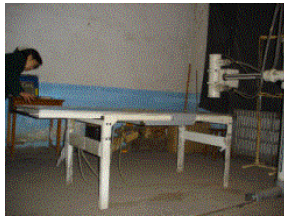
Lost Opportunity

Improving global equity in
health care access



Healthcare in Developing Regions Today X-ray Example

X-Ray Table



Tube Stand



Exposed cable

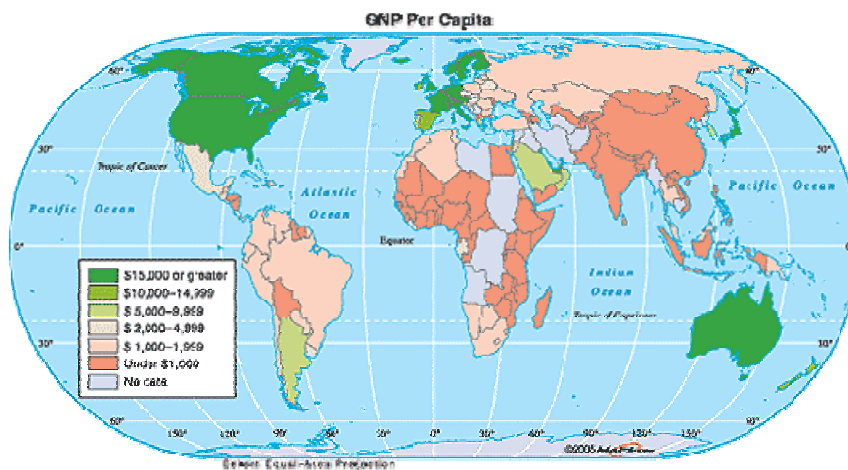


Film



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Underserved Populations



- World population: 6 billion people
- >1.2 billion live on less than \$1 a day. Two billion more people are only marginally better off.
- Development and globalization is driving higher expectations for healthcare access and quality

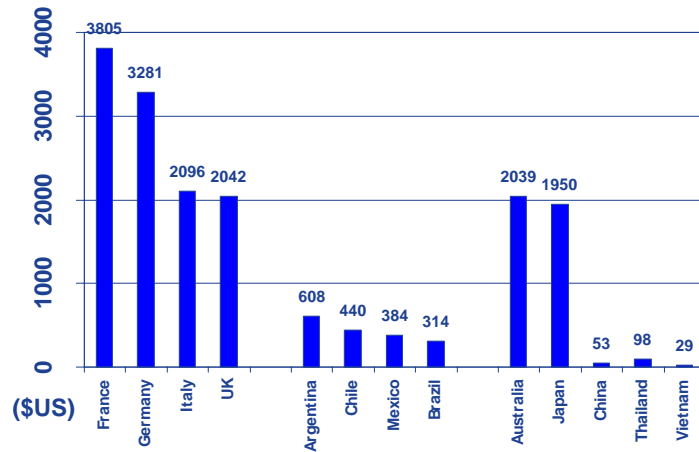


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Significant inequity in health care exists

...

Per Capita Health Care Expenditure, 2006



Source: Espicom



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Also within developing markets ...

Synthetic drug sales in China shows the concentration of healthcare spending in a small number of urban areas



City	US \$ Mill.	Mkt Share
Beijing	969.00	9%
Shanghai	837.00	7.80%
Guangzhou	472.00	4.40%
Hangzhou	268.00	2.50%
Wuhan	216.00	2.01%
Nanjing	208.00	1.93%
Chengdu	201.00	1.87%
Shenyang	199.00	1.85%
Chongqing	185.00	1.72%
Tianjin	181.00	1.68%
Jinan	166.00	1.54%
Xian	161.00	1.50%
Harbin	150.00	1.39%
Zhengzhou	141.00	1.31%
Qingdao	111.00	1.03%
Dalian	102.00	0.95%
Top 16 Cities	4,567.00	42.48%

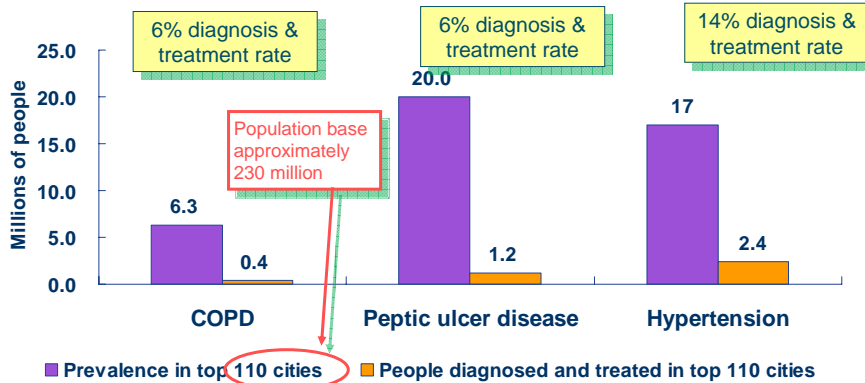


Source: IMS data 2004

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China example ... large areas of unmet need as diagnosis & treatment rates remain low

The combination of poor healthcare access and limited healthcare insurance conspire to restrict diagnosis and treatment of chronic conditions.



Source: China Ministry of Health Information Center; 2003 National Healthcare Development Statistics Report, Boston Consulting Group, Synovate research.



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Vast majority of advanced medical devices concentrated in urban centers

Hospital type (from largest to smallest)	Number of hospitals	Number of medical devices per hospital type by device price		
		<0.5 million RMB (\$65k)	0.5-1 million RMB (\$65-130k)	>1 million RMB (\$130k)
General Hospitals	12,982	789,893	32,347	18,514
Specialist Hospitals	2,682	100,255	4,350	1,938
TCM Hospitals	2,620	103,443	4,000	2,093
Women & Children's Hospitals	3,021	50,596	1,153	415
Community Health Centers	17,128	9,910	281	32
Township Hospitals	40,907	152,611	3,238	491

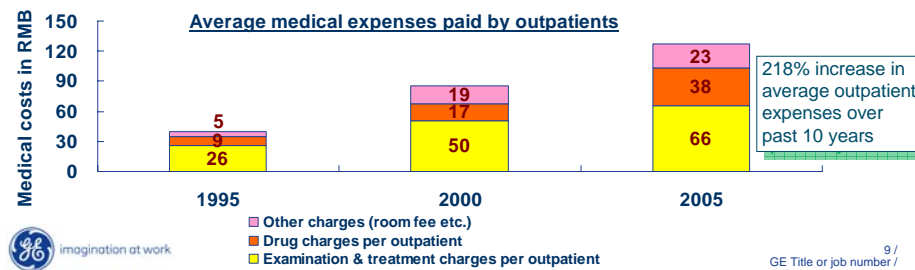
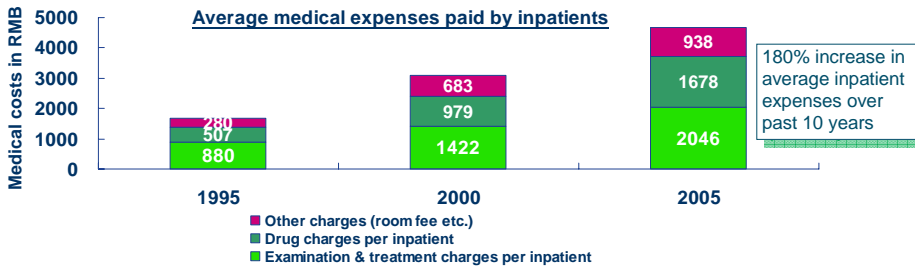


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Source: Ministry of Health 2005 National Statistics Digest

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Privatization and insufficient government funding have led hospitals to significantly increase fees charged to patients

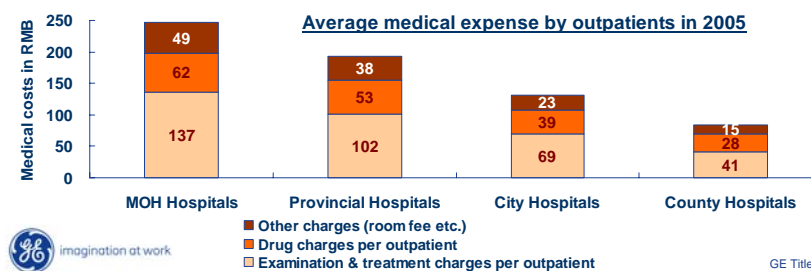
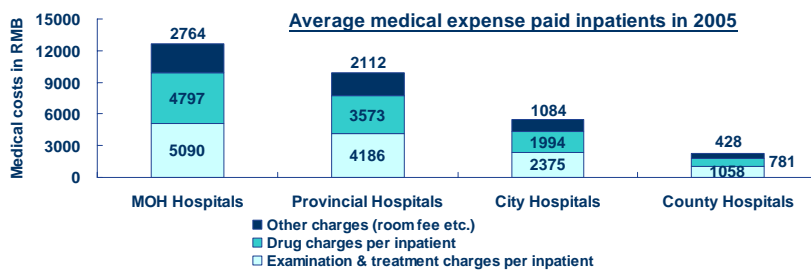


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Source: Ministry of Health 2005 National Statistics Digest

Revenue generated per patient very different between hospital types which exacerbates other funding disparities



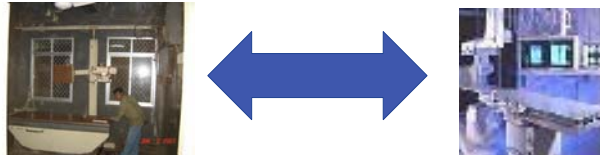
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Source: Ministry of Health 2005 National Statistics Digest

Developing Countries' Problem

As health care capabilities advance, so do costs of technology.



The equity gap in access often gets wider.



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Technology evolution dilemma

Advanced medical devices are designed and built to last 20+ years, with manufacturer support for parts, service, and updates.

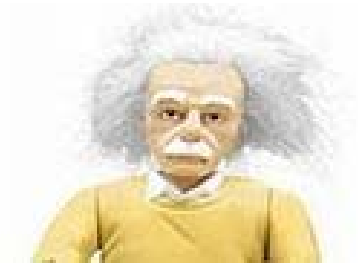
But technology evolves much faster ... leading-edge users want to upgrade to newer products in 2-3 years.



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Remanufacturing solution

- Technology buyers return young devices for trade-in credit and buy “new”
- Equipment makers produce lower cost remanufactured devices for value buyers



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Expanding Healthcare Affordability

Remanufacturing supports technology upgrade and value buyer needs



- ✓ Trade-in Payment Allows Existing Customers to Upgrade
- ✓ Returned system remanufactured and re-certified to current new specification
- ✓ Backed by full service support and new warranty
- ✓ 20-50% Less than new pricing
- ✓ Ecologically Friendly
 - Reduce, Re-Use, Recycle

Quality is Key ... Safety is #1 priority



- Remanufactured medical devices fall under FDA supervision ... as-is used systems do not
- Manufacturers guarantee same quality, warranty, performance as new



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GE Factory Remanufacturing Process

1. Inspection and Selection

- Only certain systems in good condition

2. De-Installation

- GE de-installation team to protect condition

3. Cleaning, Disinfection, Data Removal

4. Consumable/Damaged Part Replacement

5. System update/upgrade installation

6. Quality and Safety Test, Calibration, Certification

- Same as new ... following FDA requirements

7. Shipping and GE Installation – same as new

8. Full GE Warranty – same as new



Standard process to ensure quality and safety ... as Good as New

Why Remanufacture Medical Devices?

Save Money

→ Advanced technology at reduced cost

Save Resources

→ Reduce energy and natural resource usage

→ Minimize disposal and pollution burden

SAVE LIVES

→ Access to life saving technology

Remanufacturing for safe, affordable healthcare

Quality = Safety, Reliability, Efficiency

A Comparison of Alternatives

Value Added	New	OEM Remanufacture	As-Is Used
Price Discount	✗	✓	✓
Manufacturer's Warranty	✓	✓	✗
Assured Parts and Service available	✓	✓	✗
Quality/Safety	✓	✓	?
Patient Data Secure	✓	✓	?
Test to OEM Standards	✓	✓	✗
Update/Upgrade to Latest technology	✓	✓	?
OEM commitment	✓	✓	✗

 **Critical Elements for Medical Devices** 14 / Job number / 1/25/2017

Remanufacturing Summary

Value price with High Quality meets healthcare needs in developed and developing countries

Refurbishing is Eco-Friendly

Quality should be regulated “same as new”

Patient Safety must not be compromised

This is critical life-saving technology

Need non-discriminatory trade treatment ... “same as new”
... with identical quality and safety requirements

Used medical device risks

<u>Issue</u>	<u>“Used”</u>	<u>Remanufactured</u>
No warranty provided	Yes	No
Spare parts unavailable	Yes	No
Untrustworthy seller	Yes	No
Condition hard to ascertain	Yes	No
Safety alerts/recalls unavailable	Yes	No
Technologically obsolete	Yes	No
Potentially unsafe/unreliable	Yes	No

Remanufactured devices are backed by original manufacturer and are FDA-compliant



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Market acceptance and adoption

OEM-remanufactured diagnostic imaging device penetration

USA	>10%
EU	5-8%
Latin America	10-12%



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Saving Lives in Developing Countries

GE Remanufactured Imaging System Installations 2004-2005

	Systems Installed			Patients Treated
	MR	CT	XRay	
India	42	48	3	190,000
Brazil	18	36	8	140,000
Philippines	2	9	4	40,000

Fulfilling a Critical Public and Human Need

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Regulation in major remanufactured medical device markets

USA: *Devices and remanufacturers must be FDA-registered*

EU: *Devices must be CE-marked and meet same requirements as new devices*



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Some countries that prohibit remanufactured medical devices

China: *Imports prohibited from 1998, unclear Domestic trade regulation*

Thailand: *Imports prohibited Domestic resales permitted*

Viet Nam: *Imports restricted*

Egypt: *Imports prohibited*



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History of used medical device bans

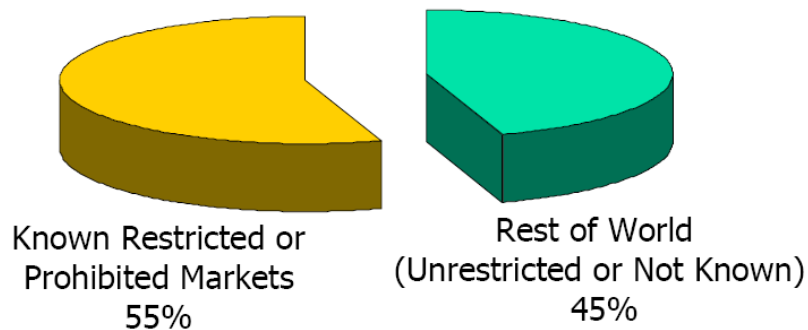
- FDA hasn't actively supervised as-is used trade ... 3000+ independent dealers
- Unethical dealers often look to salvage value from unusable or unsafe devices
- Some countries seek to protect domestic device industry



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Impact of restrictions on access to lower-cost remanufactured devices

Percent of World Population



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Consequences of remanufacturing prohibitions

- Ethical suppliers are blocked
- Non-compliant 3rd parties circumvent rules
- Patients face daunting quality and safety risk
- Access denied to hundreds of millions



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Solution

Devices remanufactured by the original manufacturer should be treated “same as new”, with identical requirements, in all trade policy



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THANK YOU



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