Session 1: Pharmaceutical Products and Under-served Populations

Alan Lyles, Johns Hopkins School of Public Health
Overview of Course Sessions (1)

1. The global context of pharmaceutical products and underserved populations
2. International Policy and Legal framework
3. Drug manufacture, industrial pharmacy considerations, quality assurance and regulation
4. The Drug Management Cycle: Selection
5. Forecasting and Quantification
6. The Drug Management Cycle: Procurement
7. Drug Donations
8. The Drug Management Cycle: Distribution
Overview of Course Sessions (2)

9. The Drug Management Cycle: Use
10. Budgeting and Cost Control
12. Access to Essential Drugs
13. Pharmaceutical Care and Drug Utilization in an HIV/AIDS Clinic
14. Financing and Sustainability
15. Laboratory Exercise on Planning with an Emphasis on Budgets and Sensitivity Analysis
16. Student Presentations
“The right context is worth 50 IQ points.”
-Alan Kay, Inventor of Object Oriented Programming & Laptop Computer Visionary
## World Drug Purchases: Retail Pharmacies

**IMS Health – Retail Drug Monitor: 12 Months to Sept 2005***

<table>
<thead>
<tr>
<th>Region</th>
<th>Sept 2005</th>
<th>Sept 2004</th>
<th>% Growth US$</th>
<th>% Growth Constant Exchange</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selected World</td>
<td>365,348</td>
<td>341,483</td>
<td>7%</td>
<td>5%</td>
</tr>
<tr>
<td>North America</td>
<td>192,649</td>
<td>182,200</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>• USA</td>
<td>180,994</td>
<td>172,182</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>• Canada</td>
<td>11,656</td>
<td>10,017</td>
<td>16%</td>
<td>7%</td>
</tr>
<tr>
<td>Europe</td>
<td>90,685</td>
<td>84,132</td>
<td>8%</td>
<td>3%</td>
</tr>
<tr>
<td>• Germany</td>
<td>27,055</td>
<td>24,281</td>
<td>11%</td>
<td>7%</td>
</tr>
<tr>
<td>• France</td>
<td>22,639</td>
<td>20,641</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>• Italy</td>
<td>14,619</td>
<td>14,249</td>
<td>3%</td>
<td>(2%)</td>
</tr>
<tr>
<td>• UK</td>
<td>15,408</td>
<td>15,083</td>
<td>2%</td>
<td>(1%)</td>
</tr>
<tr>
<td>• Spain</td>
<td>10,965</td>
<td>9,879</td>
<td>11%</td>
<td>6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Region</th>
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<th>% Growth US$</th>
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</thead>
<tbody>
<tr>
<td>Selected World</td>
<td>365,348</td>
<td>341,483</td>
<td>7%</td>
<td>5%</td>
</tr>
<tr>
<td>Japan*</td>
<td>60,820</td>
<td>57,122</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>Latin America†</td>
<td>15,524</td>
<td>13,935</td>
<td>20%</td>
<td>19%</td>
</tr>
<tr>
<td>• Mexico</td>
<td>7,184</td>
<td>6,338</td>
<td>13%</td>
<td>11%</td>
</tr>
<tr>
<td>• Brazil</td>
<td>6,369</td>
<td>4,844</td>
<td>31%</td>
<td>31%</td>
</tr>
<tr>
<td>• Argentina</td>
<td>1,971</td>
<td>1,752</td>
<td>13%</td>
<td>13%</td>
</tr>
<tr>
<td>Australia/NZ</td>
<td>5,670</td>
<td>5,094</td>
<td>11%</td>
<td>5%</td>
</tr>
</tbody>
</table>

*Including hospitals; †Leading three.

Percent of All US Firms Offering Health Benefits: 1996-2005


<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Price</td>
<td>19%</td>
<td>25%</td>
</tr>
<tr>
<td>Rx Type</td>
<td>34%</td>
<td>34%</td>
</tr>
<tr>
<td>Utilization</td>
<td>47%</td>
<td>42%</td>
</tr>
</tbody>
</table>

Adapted from: Kaiser Family Foundation. Trends and Indicators, 2004 Update, Exhibit 1.17.
Access Barriers: Drugs Are Costly

• Major out-of-pocket expense
• Can represent as much as 20 percent of total national health expenditures, 60 percent of total recurrent health expenditures
• Drug expenditures are often second only to personnel salaries and benefits
Many Health Interventions Depend on Pharmaceuticals: Prevention & ACSCs

• Expanded Program on Immunization
• Integrated Management of Childhood Illness
• Directly Observed Treatment, Short-course
• Roll Back Malaria
• HIV prevention (social marketing of condoms)
• AIDS treatment and care
Coverage Distribution

Distribution of Covered U.S. Workers Facing Different Cost Sharing Formulas for Prescription Drug Benefits 2000-2004

- 2000: 49% Two-tier, 27% Same pay for all, 22% Other/DK, 1% Three-tier, 1% Four tier
- 2001: 41% Two-tier, 18% Same pay for all, 13% Other/DK, 1% Three-tier, 1% Four tier
- 2002: 55% Two-tier, 13% Same pay for all, 30% Other/DK, 1% Three-tier, 1% Four tier
- 2003: 63% Two-tier, 13% Same pay for all, 23% Other/DK, 1% Three-tier, 1% Four tier
- 2004: 65% Two-tier, 20% Same pay for all, 10% Other/DK, 1% Three-tier, 3% Four tier

Adapted by CTLT from KFF 2004 Annual Employer Health Benefits Survey, Chart 15
## US Non-compliance from Out-of-Pocket Costs

<table>
<thead>
<tr>
<th>Due to cost:</th>
<th>Base: All Adults</th>
<th>Have Condition for Rx</th>
<th>Out-Of-Pocket</th>
<th>Health Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>$0-$100</td>
<td>$101-$250</td>
<td>$251-$500</td>
</tr>
<tr>
<td>Did not ask MD for an Rx</td>
<td>18%</td>
<td>23%</td>
<td>14%</td>
<td>37%</td>
</tr>
<tr>
<td>Did not fill an Rx</td>
<td>22%</td>
<td>30%</td>
<td>19%</td>
<td>50%</td>
</tr>
<tr>
<td>Used a lower dose to extend Rx</td>
<td>15%</td>
<td>21%</td>
<td>10%</td>
<td>35%</td>
</tr>
<tr>
<td>Used less than Rx'd</td>
<td>18%</td>
<td>25%</td>
<td>13%</td>
<td>45%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Multiple Sclerosis</th>
<th>Hypertension</th>
<th>Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not filled</td>
<td>15%</td>
<td>17%</td>
<td>30%</td>
</tr>
<tr>
<td>Delayed filling</td>
<td>24%</td>
<td>26%</td>
<td>41%</td>
</tr>
<tr>
<td>Taken in lower doses than prescribed</td>
<td>23%</td>
<td>14%</td>
<td>25%</td>
</tr>
<tr>
<td>Taken less often than prescribed</td>
<td>30%</td>
<td>29%</td>
<td>43%</td>
</tr>
<tr>
<td>Discontinued sooner than prescribed</td>
<td>15%</td>
<td>15%</td>
<td>30%</td>
</tr>
</tbody>
</table>

Adapted from: http://www.bcg.com/publications/files/TheHiddenEpidemic_Rpt_HCDec03.pdf
**US Rx Compliance Behaviors & Gender:**
How does female compliance affect household behaviors?

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not filled</td>
<td>21%</td>
<td>15%</td>
</tr>
<tr>
<td>Delayed filling</td>
<td>30%</td>
<td>20%</td>
</tr>
<tr>
<td>Taken in lower doses than prescribed</td>
<td>15%</td>
<td>12%</td>
</tr>
<tr>
<td>Taken less often than prescribed</td>
<td>33%</td>
<td>26%</td>
</tr>
<tr>
<td>Discontinued sooner than prescribed</td>
<td>23%</td>
<td>18%</td>
</tr>
</tbody>
</table>

Adapted from: http://www.bcg.com/publications/files/TheHiddenEpidemic_Rpt_HCDec03.pdf
Drug coverage among Medicare beneficiaries with CHD/MI increases use of lifesaving drugs*

• Medicare beneficiaries with coronary heart disease
  – Statins recommended to lower cholesterol
  – Statins are costly
• 27.4% with coverage used statins
• 4.1% without coverage used statins
What Is Known about Drug Management?

• Effective ambulatory Rx use can reduce morbidity and mortality
• Wise drug selection underlies all other improvements
• Effective management saves money and improves performance
• Rational drug use requires more than drug information
• Systematic assessment and monitoring are essential
Increased Efficiencies: Pooled Procurement

Source: MSH: Management Sciences for Health. Used with permission.
# Pharmaceutical Expenditures

<table>
<thead>
<tr>
<th>Region</th>
<th>Per Capita ($US/yr)</th>
<th>As % of GDP</th>
<th>Private Expenditures as % of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>$8</td>
<td>0.86%</td>
<td>68%</td>
</tr>
<tr>
<td>Asia</td>
<td>$12</td>
<td>0.59%</td>
<td>76%</td>
</tr>
<tr>
<td>LA/C</td>
<td>$31</td>
<td>0.87%</td>
<td>75%</td>
</tr>
<tr>
<td>Developed Economies</td>
<td>$137</td>
<td>0.65%</td>
<td>33%</td>
</tr>
</tbody>
</table>
Geographic Accessibility: Tanzania

Distance to Health Facility

14% >10 km to public facility
6% >10 km to private drug retailer

Source: MSH: Management Sciences for Health. Used with permission.
Affordability: Cambodia, El Salvador, Ghana, India

Number of Days Needed to Pay for Pneumonia Treatment*

<table>
<thead>
<tr>
<th></th>
<th>Cambodia*</th>
<th>El Salvador*</th>
<th>Ghana**</th>
<th>India*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Facilities</td>
<td>2.89</td>
<td>0.45</td>
<td>1.72</td>
<td>0.17</td>
</tr>
<tr>
<td>Private Facilities</td>
<td>0.91</td>
<td>0.28</td>
<td>1.33</td>
<td></td>
</tr>
<tr>
<td>NGO/Mission Facilities</td>
<td>0.75</td>
<td>2.48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private Pharmacies</td>
<td></td>
<td></td>
<td>1.99</td>
<td>0.09</td>
</tr>
</tbody>
</table>

*Child 1-5 years old, co-trimoxazole; **Adult, amoxicillin

Source: MSH: Management Sciences for Health. Used with permission.
Pharmaceutical Management, Access, and Use of Medicines

Source: MSH: Management Sciences for Health. Used with permission.
Pharmaceutical Management Cycle

Source: MSH: Management Sciences for Health. Used with permission.
Dimensions of Access & Potential Barriers
Essential Medicines Definition

Essential medicines are:

– those that satisfy the **priority** health care needs of the **population**

– selected with due regard to **public health relevance**, evidence on efficacy and safety, and **comparative cost-effectiveness**

– intended to be available within the **context of functioning health systems** at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a cost that individuals and the community can **afford**
Substandard Essential Medicines in Developing Countries

Source: MSH: Management Sciences for Health. Used with permission.
Percentage of Medicines Prescribed from Essential Medicines List, by Sector

Source: MSH: Management Sciences for Health. Used with permission.
Understanding and Improving Access to Essential Medicines
Increased Efficiencies: STGs

Total Annual drug costs in a Latin American country for treatments during a cholera epidemic, costs in millions of US$ (1991)

Source: MSH: Management Sciences for Health. Used with permission.
Challenges for Improved Public Drug Supply

• Health reform, equity, and financial sustainability
• Efficiency
• Rational use
• Changing roles of public and private sectors
Essential Medicines
Availability & Dispensing in Dispensaries

Source: MSH: Management Sciences for Health. Used with permission.
Number of Medicines on National Essential Medicines Lists

Source: MSH: Management Sciences for Health. Used with permission.
Goals of a National Drug Policy

Health-Related
• Available essential drugs
• Improve attendance at health facilities
• Safe, affordable, and effective drugs
• Rational use
  • Proper selection of drugs
  • Efficient supply

Economic
• Lower cost of drugs
• Reduce foreign exchange
• Provide jobs
• Improve efficiency and cost-effectiveness

Development
• Human resource development
• Improve infrastructure
• National production of drugs
Components of a National Drug Policy

- Legislative Framework
- Choice of Drugs
- Supply
- Rational Use of Drugs
- Economic Strategies for Drugs
- Human Resources Development
- Monitoring and Evaluation
- Research
- Technical Cooperation Among Countries