Structured Product Labeling (SPL) in the Clinical Environment:

Electronic Health Records (EHR) & Digital Medical References (DMR)

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Co-Founder of Medicos Consultants
Physician, Researcher and former Electrical Engineer with GE & Ford Electronics

1 SPL Clinical Case Studies
2 EHR & DMR Applications
3 Domain Expertise

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Case Study #1

SPL - Use in Enterprise EMR Systems

Evelyn Jordan Center
Outpatient Clinic

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Evelyn Jordan Center Outpatient Clinic

- U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA) Funded
- 1,953 – HIV Patients (FY2009)
- 9,254 Visits (FY2009)
- 16 Physicians (10 ID, 2 Family Practice, 4 Psychiatrists)
- 3 Nurse Practitioners (NPs) and 1 Physician’s Assistant (PA)
- 7 Nurses (HIV Certified and Primary Care)
- 13 Social Work Staff, 1 Dietician, 1 Clinical Therapist, 3 Substance Abuse Specialists, 2 Pharmacists, 8 Administrative Staff
- 6 ID Fellows, Rotating IM Resident and 1 Psychiatry Fellow

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## Baltimore City HIV/AIDS Epidemiological Profile

<table>
<thead>
<tr>
<th>Rank</th>
<th>Metropolitan Area</th>
<th>Number</th>
<th>Rate**</th>
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<tbody>
<tr>
<td>1</td>
<td>Miami, FL</td>
<td></td>
<td>41.9</td>
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<tr>
<td>2</td>
<td>Baltimore-Towson, MD</td>
<td></td>
<td>37.7</td>
</tr>
<tr>
<td>3</td>
<td>Washington, DC-VA-MD-WV</td>
<td></td>
<td>31.8</td>
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<tr>
<td>4</td>
<td>Baton Rouge, LA</td>
<td></td>
<td>30.1</td>
</tr>
<tr>
<td>5</td>
<td>New York, NY-NJ-PA</td>
<td></td>
<td>29.2</td>
</tr>
<tr>
<td>6</td>
<td>Columbia, SC</td>
<td></td>
<td>28.0</td>
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<tr>
<td>7</td>
<td>Memphis, TN-MS-AR</td>
<td></td>
<td>27.1</td>
</tr>
<tr>
<td>8</td>
<td>New Orleans, LA</td>
<td></td>
<td>26.4</td>
</tr>
<tr>
<td>9</td>
<td>Orlando, FL</td>
<td></td>
<td>26.0</td>
</tr>
<tr>
<td>10</td>
<td>Jacksonville, FL</td>
<td></td>
<td>24.6</td>
</tr>
</tbody>
</table>

**Rate defined as HIV/AIDS cases per 100,000 population -> the National Rate was 14.0
**Case Study #1**

**Patient Population**
**CD4 Cell Count**
(EJC Database 2010)

- >500: 33%
- <200: 25%
- 200-500: 42%

**Antiretroviral Therapy**
(EJC Database 2010)

- None: 44%
- HAART: 56%

**HAART** (Highly Active Antiretroviral Therapy) Based on Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents [December 1, 2009] Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC) [http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf](http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf)

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Ambulatory Services

• Primary Care
  – Women’s Health
• Mental Health
  – Psychiatric Care
  – Substance Abuse
• Nutrition
• Laboratory
• Radiology
• Pathology

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Quality Improvement Projects

• Safe Prescription Writing (Top UMMS Priority)
• HIV and Health Maintenance Screening
• Vaccinations (Hep B, Hep A, Pneumovax, etc.)
• Prophylaxis Therapy for Concomitant Dx
• Smoking Cessation Program
• Pain Assessment and Documentation
User Experience Driven by Accessibility and EMR Integration
Patient Health Maintenance Record

### Medications

<table>
<thead>
<tr>
<th>Date</th>
<th>NORVIR</th>
<th>DACTRIM DS D/C 11/23/09</th>
<th>Pravastatin (1 tab daily)</th>
<th>Truvada (1 daily)</th>
<th>Replagene (400mg bid)</th>
<th>Darunavir (300mg 2 bid)</th>
<th>Acetaminophen (pm)</th>
<th>Ibuprofen (600mg, 1 po q 6hrs pm for pain)</th>
<th>Bendadine (150mg hs)</th>
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<tbody>
<tr>
<td>9/13/2010</td>
<td>NORVIR</td>
<td>DACTRIM DS D/C 11/23/09</td>
<td>Pravastatin (1 tab daily)</td>
<td>Truvada (1 daily)</td>
<td>Replagene (400mg bid)</td>
<td>Darunavir (300mg 2 bid)</td>
<td>Acetaminophen (pm)</td>
<td>Ibuprofen (600mg, 1 po q 6hrs pm for pain)</td>
<td>Bendadine (150mg hs)</td>
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<td>9/10/2010</td>
<td>NORVIR</td>
<td>DACTRIM DS D/C 11/23/09</td>
<td>Pravastatin (1 tab daily)</td>
<td>Truvada (1 daily)</td>
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<td>Bendadine (150mg hs)</td>
</tr>
<tr>
<td>8/16/2010</td>
<td>NORVIR</td>
<td>DACTRIM DS D/C 11/23/09</td>
<td>Pravastatin (1 tab daily)</td>
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<td>Bendadine (150mg hs)</td>
</tr>
</tbody>
</table>

### Demographics and Contact Information

- Name: [Redacted]
- DOB: [Redacted]
- Age: [Redacted]
- Gender: [Redacted]
- Race: [Redacted]
- SSN: [Redacted]

- Address: [Redacted]

- Telephone: [Redacted]
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Key EMR Workflow Elements

Progress Note
(Unsigned Note)

Current Medication List
  Name
  Dose
  SPL Look-up

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Case Study #1

Key EMR Workflow Elements

Progress Note
(Signed Note)
Mobile Access

Current Medication List
Name
Dose
SPL Look-up

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Case Study #1

Key EMR Workflow Elements

Monograph Comparison Across Multiple Navigational Fields

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SPL in Safe Prescribing Workflow

1. Health Maintenance Integration: EMR Integration
2. SPL Provides Access to Full Monograph
3. Full-Text Search Makes Information Accessible
4. Navigation by Classification Beneficial for Clinical Workflow
5. Remote Access and Portability
Enterprise SPL Clinical Use

• 100% Staff Compliance – linked to:
  – Billing Performance
  – Individual Workflows Q/A
  – Electronic Prescription Writing

• Improved Access to Full Dosing, Warning, and Contraindications Information

• Adverse Drug Event (ADE) Reporting

• Visual Identification of Rx Products

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CASE STUDY #2

SPL Access through standalone Digital Medical References (DMRs) for use by Healthcare Practitioners
Mobile Prescribing Reference Toolkit: Solo and Small Practice SPL Dataset Integration into a Stand-alone Mobile and Web Application

1. Prescribing Information is the #1 Requested Reference

2. Restricted Internet Access in Many (read “Most”) Networked Clinical Environments

3. Speed and Ease-of-Use are Critical Elements to be workflow compatible

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148,762 Worldwide Users
as of 1-September-2010
User Focus

Structured Product Labeling (SPL) Portal
http://pharmakonalpha.com

User Experience Driven by Accessibility
Search = Fast & Reliable

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User Demographics

- Physician: 41%
- Nurse Practitioner: 15%
- Other: Students, Residents: 15%
- Nurses: 13%
- Physician Assistant: 11%
- Medical Transcriptionist: 8%
- Other: 6%
- Other: 3%
- Other: 4%

Mobile Users: 28%
- Workstation and Web-Service Users: 72%
DMR User Demographics

- Internal Medicine: 26.00%
- Family Practice: 25.00%
- Pediatrics: 14.00%
- OB/Gyn: 10.00%
- Cardiology: 5.00%
- Gastroenterology: 2.00%
- Allergy Specialists: 1.00%
- Other Specialties*: 17.00%

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DMR Metrics and Averages

- Cumulative Number of Drug Searches: 60,052,467
- DMR Uses per Month: > 35 times
- Avg. Time per Search: < 42 ms  (1.8GByte Dataset)
- Avg. Time Using DMRs per Month: 3hrs 50min
SPL Navigation Requirements

1. Full Monograph Searching

2. Navigation by Various Classification Schemas (NLM, FDA, WHO, VA, Proprietary, etc.)

3. Highlight Search Terms

4. Facilitated Monograph Navigation

5. Physical Characteristic Search and Images of Solid Dosage Formulations
User Interface

Full Monograph Searching

Navigation by Categories

Alphabetical Browsing

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• Browse SPL by Classifications (Category)

Drugs by Category

MeSH | VA | WHO | FDA Pharm Class

National Library of Medicine: MeSH Therapeutic Categories (January 2010)

Department of Veterans Affairs: VA National Formulary by Classification (December 2009)

World Health Organization: The Anatomical Therapeutic Chemical Classification System (2009)

Food and Drug Administration: FDA Pharmacological Classifications (February 2010)

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User Interface

Alphabetical Browsing

• Trade & Generic
• Trade
• Generic
• Manufacturer
• Imaged Solid Dosage Formulation

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- Monograph Navigation
- Packaging
- Product Information
- UNII Support (view monographs with related substances)
- Preferred Substance
- Imprint Information
- Product Images
Conclusions
The Rise of Apps Culture: 35% of U.S. adults have cell phones with apps, but only 24% of adults actually use them.

September 15, 2010 - Pew Internet Project and Nielsen Telecom Group

Figure 1: 24% of Adults use cell phone apps

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SPL Applications

SPL: EHR and DMR Applications

- UMMS-Ryan White Clinical System
- Medicos SaaS/ASP Model
- Integrated EHR and Reporting Functionality
- DMR Secure Mobile Access

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Integration of Multiple Datasets to Make SPL Information Clinically Functional

1. Food and Drug Administration (FDA) - Structured Product Labeling (SPL)
2. Food and Drug Administration (FDA) - Substance Registration System (SRS-UNII)
3. Food and Drug Administration (FDA) - National Drug Code Dictionary
4. National Library of Medicine (NLM) - MeSH - Medical Subject Headings
5. National Cancer Institute (NCI) - Thesaurus
6. Logical Observation Identifiers Names and Codes (LOINC®)
7. World Health Organization (WHO) - ATCC (Anatomical Therapeutic Chemical Classification) System
8. Veterans Affairs (VA) - Drug Classification System
9. Veterans Affairs (VA) - National Drug File
10. Proprietary Databases – Licensed Content from Various Publishers
Other SPL Related Work
SPL Imaging Laboratory

- NLM/FDA Imaging Lab

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FDA – Structured Product Labeling (SPL)

- SPL Source Files Contain:

  Data and Validation Inconsistencies

For More Information Please Contact:

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