Medical Tourism: From Idea To Implementation

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Introduction

- An Overview Of Our Program
- What We Will Cover
  - What Is Medical Tourism?
  - The Legal Framework For Employers and Payers – J. Mark Waxman
  - The Quality Challenge – Dr. Dagi, Dr. Helfrick
  - The Medical Provider's Challenge – Fred Entin

Medical Tourism

- Its Scope
  - 750,000 Americans (Deloitte, 2007 Survey)
  - 6 Million by 2010 (Deloitte) representing $16-$19 billion
  - Attracting the uninsured or underinsured and employers seeking to drive down costs (e.g. Hannaford, Serigraph)
- Diversity of Locations and Services
  - India, Thailand and 30 other countries
  - A focus on elective procedures, but cosmetic and dentistry have long histories

It's About The Money

- Sample Costs

Costs	U.S.	India	Thailand
Heart Bypass	$70-$133,000	$7,000	$22,000
Gastric Bypass	$35-52,000	$13,000	$16,500

- (Patients Beyond Borders, 2d. July 2008)

Medical Tourism

- Is It a "Disruptive Innovation"?
- The Key Challenges
  - Quality of Care
  - Defining Covered and Non-Covered Services
  - Expenses (Medicare and Medicaid won't pay for it [42 CFR§411.9(a)]!)
  - Legal Liability Exposure
  - Tax and ERISA Issues

The Players In The Industry

- The Patients
  - Their Families and Support Systems
- The Plans
- The Employers
- The Providers
  - In the US-Outside the US-The Need For Linkage
  - The Accreditors/Inspectors
  - The Affiliates
- The Brokers and Travel Planners

Developing A Legal Framework For Carriers and Employers

- The Benefit To Be Provided
- Establishing An Acceptable Relationship Between All The Players
- The Contractual Framework
  - Who Is Responsible For What
  - Indemnity and Insurance Backdrop
- The Liability Framework To The Patients
- The Promotional Framework

The Benefit To Be Provided

- Pre-Care and Evaluation
  - Full Understanding of the Patient's Condition
  - Is It Safe To Travel?
  - Timing For Care
  - The Informed Consent Process
- Provider Selection
  - The Plan's Role
    - ERISA Plans – The Fiduciary Duty
    - Insurance Plans "Simply" Offering A Reimbursable Benefit
  - Medical Tourism Companies

The Benefit To Be Provided

- Provision of Care
  - The Procedure
  - Follow-Up Care
  - Emergency Care
  - After Care/Follow-Up/Care Coordination
- Care Support
  - Family and Friends
  - Lodging
  - Transportation

The Presentation Of Information About The Benefit

- Member Rights and Responsibilities: NCQA Requirements
- Representations About: Quality, Price, Credentials, Risks
- Documenting The Information Received and the Selection of the Benefit
- Waivers of Liability
  - Scope – What is being waived?
  - What will make the waiver effective?

The Relationship With A Medical Tourism Company

- Separating insurance from the administration of the care benefit outside the United States
- The vendor agreement
- Insurance and indemnity as between the players

What Relationship Is Required With The Provider(s)

- Quality Oriented Issues
  - Follow-Up Information Obligations
  - Records
    - Confidentiality
    - Security
    - Is HIPAA Applicable?
  - Billing
  - Insurance and Indemnity
    - Submission to US Courts?
    - Agreement with respect to dispute resolution process?

The Financial Benefit and Related Issues

- Indemnity vs. Contracted Plans
- Financial Incentives
  - Waiver of Co-Pays and Deductibles
  - Measured By Savings?
  - Fixed Fees?
  - Cash Rebates or Incentives?
  - Can plan assets be spent on non-health care items, such as incentive share of savings?
- Are There Some Tax Issues Here?
  - Amounts paid for medical procedures vs. associated costs of transportation and lodging
  - Non-patient expenses
  - Incentives taxable to the recipient?
  - Costs of prescriptions

Liability Issues

- Misrepresentation theories –
  - Quality?
  - Oversight?
  - Credentials?
  - Follow-up?
  - Costs?
- Lack of informed consent/waiver scope
  - E.g. Espalin v. Children's Medical Center of Dallas 27 S.W. 3d 675 (Tex. Ct. App. 2000)
- Vicarious plan liability
  - Boyd v. Einstein Medical Center, 547 A. 2d. 229 (Pa. Super. Ct 1988)
- See, Note, Medical Malpractice Overseas: The Legal Uncertainty Surrounding Medical Tourism, 70 Law and Contemp. Problems 211, Spring, 2007.

The Legislative Milieu

- Congressional Hearings
- State Legislative Interests
  - West Virginia
  - Colorado
- The West Virginia Incentives Explored –
  - Waiver of all co-payments and deductibles
  - Payment of round trip airfares for covered employee and a companion
  - Lodging expenses for companion for length of treatment or procedure
  - Payment for 7 days sick leave
  - Rebate of up to 20% of costs savings directly to employees

The Legislative Milieu

- What's Next
  - Could a benefit ever become mandatory?
    - Linked network for certain procedures
  - What will the impact of health reform be?
  - Proving quality remains a challenge.

Flat Medicine: The Globalization of Health Care

Dr. John F. Helfrick

Partners Harvard Medical International

Agenda: Globalization of Health Care

The Changing Landscape in International Health Care Development

- Rise of Regional Centers of Excellence
  - Where?
    - Emerging Economies
  - Why ?
    - Rise of the Middle Class
    - Development of the Private Sector in Healthcare and Education
  - Case Studies
    - Dubai, UAE
    - Turkey
    - India

Economic Development:
One size Doesn't Fit All

Least Developed	Emerging Economies	OECD Countries
Afghanistan-Angola-Bangladesh Benin-Bhutan-Burkina Faso-Burundi-Cambodia-Cape Verde-Central African Republic-Chad-Comoros-Congo-Timor-Djibouti-Equatorial-Guinea-Eritrea-Ethiopia Gambia-Guinea-Guinea-Bissau-Haiti-Kiribati-Lao Peoples -Lesotho Liberia-Madagascar-Malawi-Maldives-Mauritania-Mozambique-Myanmar-Mali-Nepal-Niger-Rwanda-Samoa-Sao Tome-Senegal-Sierra Leone Solomon Islands-Somalia-Sudan-Togo-Tuvalu-Uganda Tanzania-Vanuatu-Yemen-Zambia	*111 Countries* *India* *China* *South America* *Central America* *Gulf States* *Middle East* *SE Asia* *Indonesia* *Pakistan* *Russia* *Central Asia* *North Africa*	AUSTRALIA –AUSTRIA BELGIUM -CANADA CZECH REPUBLIC DENMARK –FINLAND FRANCE-GERMANY GREECE-HUNGARY ICELAND-IRELAND ITALY-JAPAN KOREA-LUXEMBOURG MEXICO-NETHERLANDS NEW ZEALAND-NORWAY POLAND-PORTUGAL SLOVAK REPUBLIC SPAIN-SWEDEN SWITZERLAND-TURKEY UNITED KINGDOM UNITED STATES
(0.9 Billion)	*(4.5 Billion)*	*(1.1 Billion)*

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Global Trends: Rise of Quality Hospitals

- Emergence of privately financed, corporate specialty hospitals
  - Focused on serving the needs of the local middle class
  - "Green-field" Development
  - Specialty focused
  - Coexist with public hospitals
  - Capitalize on lower cost labor force
  - Willing and able to institute a culture of quality
  - Expanding regionally
  - Competing globally

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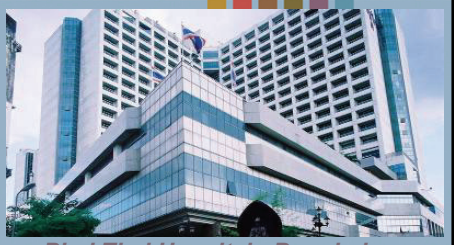
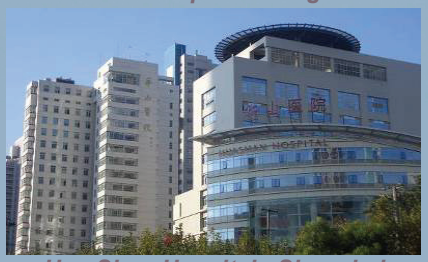
Why are these hospitals more cost effective?

- **Lower facilities construction costs and time**
  - Wockhardt Mulund -18 months from first shovel to first patient
- **Lower labor costs**
  - Nursing, physicians, administration
- **No legacy systems**
  - IT systems from the ground up
  - Clinical Service lines
- **Very low malpractice and liability costs**
- **New "corporate" culture**
  - Better, faster, cheaper, "hungrier"
  - Willing & able to benchmark globally



Phai Thai Hospital - Bangkok



Hua Shan Hospital - Shanghai

Health Care at the Crossroads:

"Medical Tourism"

Vacation, Adventure and Surgery?

- Sept. 4, 2005
- Americans and others are going to exotic locales like India and Thailand for elective surgeries performed by world-class doctors at Third-World prices.
  - (CBS)

Surgical Care vs. Chronic Medical Care

Drivers:

- Cost
- Waiting Lists

Comparative Price List

Surgery	US ($)	India ($)
Hip Replacement	43,000	9,000
Angioplasty	57,000	11,000
Open Heart Surgery (CABG)	130,000	10,000
Spinal Fusion	62,000	5,500
Knee Replacement	40,000	8.500

Source: Patients Beyond Borders Josef Woodman

"Medical Refugees"

- Howard Staab – uninsured
  - Acute mitral valve prolapse
  - $200,000 with 50% deposit
  - Sell family home
  - New Delhi C.V. Surgeons – NYU trained
  - "Credentialed" hospital
  - $6,700 hospital and physician

"America's New Refugees – Seeking Affordable Surgery Offshore." Milstein, A., Smith, M. NEJM Vol.355: 1637-1640 Oct. 19, 2006 Number 16

Most Common Forms of Treatment

- Orthopedics (hip replacement, knee replacement, spinal surgery)
- Cardiovascular Surgery (by-pass surgery, valve replacements)
- Cancer Diagnosis and Management
- Cosmetic Surgery
- Bariatric Surgeries

Waiting Lists

- Changing Healthcare Professionals
  - U.K. 70% Medical Students Female
- Working Time Directives

"Credentialed

"… to assure quality and patient safety

- Accredited
  - Joint Commission International (120 since 2000)
- American and European Trained and Board Certified Physicians
  - Robust Credentialing and Privileging Process

"If you're looking into a treatment that requires hospital care, check to see whether the center is JCI accredited."

Patients Beyond Borders
Everybody's Guide to Affordable, World-Class Medical Tourism
Joseph Woodman
www.patientsbeyondborders.com

What will be the impact on global standards for quality and safety?

Value = Quality / Cost

A Challenge for Physicians and Hospitals in Developed Countries

- Negative impact on revenue
  - Negative impact on manpower

Medical Tourism: The Trends

- 500,000 international patients will travel to India for medical care in 2007
- By 2012, Medical Tourism with infuse $2.2B into India's economy
- Today a $60B global business
- Growing at 20% per year
- The National Coalition of Health Care estimated 500,000 patients left the US for medical treatment last year.

Can US Healthcare Providers Globalize?

- Clone Oneself Internationally
  - Cost
  - Staffing
  - Reputational Risk to Brand at Home
- Buy or Partner with a Successful Regional Provider
  - Local Mission & Non-Profit Structure Challenging
- Create a Consulting/ Management Company
- Franchise Specialty Services
  - Diabetes Care
  - Oncology Services
  - Transplantation
  - Pediatrics

Medical Tourism: A Surgeon's Perspective

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Disclaimer

- The opinions expressed are those of the author and do not necessarily reflect the position of the American College of Surgeons or any other medical or professional organization.

Perspectives

- Patients
- Providers
- Hospitals
- Research Institutions
- Payors

Definition and Setting

- Travel across international borders for the express purpose of receiving medical care
- Commonplace and even expected when patients travel to medical centers of undisputed renown for expert diagnosis and care
- Controversial when motivated by search for unproven therapies, by economic factors, or when mandated in some way

Motivations

- Focus on residents of the US
- Why medical care abroad?
  - Real or perceived lack of services available at home
  - Limitations imposed by payors or regulatory agencies
  - Access to certain specialists, treatment protocols, devices, equipment, services or expertise
  - Long waiting periods
  - Lower costs of care
  - Personal reasons such as a desire to travel, to recover privately after plastic surgery, or to combine medical care with vacation

Details

- Mostly procedure based and surgical
- Increasingly dental
- Some driven by junk science
  - Shark cartilage for cancer
  - Blood replacement therapy for HIV
- Driven by looser indications for surgery
  - Lap band surgery in Argentina
- Driven by unavailability of certain devices
  - Silicone breast implants

Risks

- Variability and differences
  - In training of medical and allied health professionals
  - in standards for medical institutions
  - In interpretation of test results and indications for treatment
- Identity and qualifications of practitioner not always guaranteed
- Lack of support networks, especially with longer term needs

Risks, cont'd

- Differences patient communication
  - Transparency
  - Content
- Accuracy and completeness of medical records
- Lack of follow up care by treating physicians and surgeons
- Exposure to endemic diseases
- Language and cultural barriers
- Bad medical practice (by US standards of care)

Ethical Issues

- We encourage foreign nationals to come to the US: how can we discourage Americans from going abroad?
- Are US trained physicians practicing abroad any less qualified that foreign nationals practicing in the US?
- Duties of American physicians have to patients who ask for assistance in seeking care abroad?
- Duties of American physicians have to provide follow up or remedial care for patients who have been treated abroad?
- What of mandatory treatment abroad driven contractually by insurors and payors?

Protecting the Patient: A Surgeon's Perspective

1. Patients should have the right to seek care of the highest quality and to select their surgeons and healthcare institutions without restriction.
2. Physicians and surgeons should assist their patients in reaching informed decisions concerning medical care, whether at home or abroad.

Protecting the Patient

3. Patients should be advised to consider the medical, social, cultural and legal implications of seeking medical treatment abroad prior to deciding upon a venue of care.
4. In the event of proven medical liability for injury, viable means for the recovery of damages should be in place.

Protecting the Patient

5. Patients should be advised that many legal protections available to citizens in the United States may not be available elsewhere.
6. Patients should be encouraged to seek care at healthcare institutions meeting recognized standards for accreditation such as those conferred by the Joint Commission International (U.S.) and the Trent International Accreditation Scheme (UK).

Protecting the Patient

7. Patients should be advised that standards of medical practice vary greatly around the world, and accreditation standards are not uniform.
8. Patients should be encouraged seek care from surgeons and anesthesiologists certified in their specialties through a process equivalent to that established by the member Boards of the American Board of Medical Specialties.

Protecting the Patient

9. Patients should be encouraged to obtain a complete set of medical records prior to returning home so that the details of their care are immediately available to their physicians and surgeons in the US. Follow-up care at home should be organized prior to travel whenever possible.
10. Patients should be advised of the risks of combining long flights and certain vacation activities with anesthesia and surgery.

Protecting the Patient

11. Insurors should not be permitted to require mandatory referral abroad unless the provisions mandating such referral are stated and explained clearly and explicitly in the insurance contract and freely accepted by the subscriber.
12. Referral abroad for patients with insurance contracts already in force should not be mandated without the subscribers' fully informed consent.

Protecting the Patient

14. Mandatory care abroad should be verifiably equivalent in quality to care available in the United States.
15. Payors referring patients for mandatory treatment abroad should be responsible for the coordination and reimbursement of follow-up care in the United States, including the management of postoperative complications, readmissions, rehabilitation and long term care.

Conclusions

- Medical tourism is a legitimate choice
- Medical tourism carries risks as well as benefits
- Patients should be encouraged to become fully informed before undertaking travel abroad for medical care

Conclusions, cont'd

- The risks and burdens of mandatory referral abroad probably outweigh the benefits
- Mandatory referral must not be imposed without fully informed consent
- Provisions for follow-up care in he US should be in place before travel begins

Global Care for Americans
Legal Issues for an Evolving Industry

Fredric J. Entin
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Business Model is About to Change

- Foreign providers *cannot* ignore the US market
- More US employers are considering inclusion of an insured benefit to travel outside of the US for care
- Meeting the demand of the market will give rise to new issues requiring informed business decisions

Business Decision # 1. Marketing

- Establish US based office, have employees in US, enter into contracts with employers, TPA's or insurers in US?
  - Jurisdiction in the state where have presence
  - May affect jurisdictional analysis by court in another state
  - May want to select site of US presence based on legal environment in particular state
- Greater use Internet to engage with patients
  - Degree of interaction may affect jurisdiction

Implications of Marketing

- Agency-provider is responsible for the acts of its third party marketing agent
  - Must have control over representations
    - Untrue or exaggerated representations of quality, experience and training and those representations were the basis of the decision of the patient to go abroad
    - Vouching for foreign provider without real knowledge of quality, competence or training
    - Failure to explain the risks of going abroad to receive care
- Seek indemnification from agent and proof of insurance to support

Myth of the Waiver of Liability

- Waivers are common and enforceable in ***other*** forms of commercial activity ***but*** in healthcare:
  - Counter to public policy
    - Service of great importance to public
    - Unequal bargaining power
    - Provider holds itself out to public as willing to perform
    - Patient under the control of physician subject to risk of carelessness
- Since 1963 case, *Tunkl v. Regents of University of California*, most judges refuse to enforce
  - Case cited in numerous other state courts

Business Decision # 2. Continuum of Care

- **Network with US based physicians and hospitals?**
  - Employers, TPA's and insurers will expect US care givers before and after travel
  - Will be necessary to improve perceptions of care

Implications of Continuum

- Licensure
  - Internet consultations
  - Where is care delivered
- Privacy
  - Can patient information be legally and securely shared
- Credentialing
  - Who is responsible
  - What are the criteria

Implications of Continuum

- Weakened jurisdictional defenses
- Apparent or ostensible agency-Hospital is responsible for acts of independent practitioners if patient reasonably believes physician held out as agent of hospital; hospital acts to lead patient to believe physician agent of hospital; hospital does nothing to correct mistaken impression
- Liability insurance coverage
  - Will it apply

Business Decision #3. Contract for insured patients

- If with an insurance company-subject to state regulation
- If with a self-insured payer-subject to ERISA
- If part of a network- the provider be subject to regulation as a member of a PPO in some states

Implications of the Contract

- States may impose excessive reserve levels, coverage of procedures or other burdensome regulation
- ERISA plans may encounter fiduciary issues and risks
- Plans designed to cover travel for patient, companion may result in income tax

This is Going to Happen!

1. Someone will be unhappy with the outcome
2. Someone will be shocked by the inadequacy or lack of recourse
3. American lawyers will search for *DEEP POCKET$*
4. American attorneys will attempt to file lawsuits in US courts

Liability is the Threshold Issue

- Current model
  - No physical presence in US
  - Internet contact
  - Medical facilitators
  - Patients are uninsured or under-insured
- Evolving model
  - Marketing, continuum of care and insurance coverage

Business Decision #4. Risk Transfer

- The risks of liability can be addressed but not avoided entirely
- Uncharted territory for US courts
  - It may take years to sort out law
  - Legal fees will be substantial even in victory
- In US each party pays for its attorneys, win or lose
- Insurance covers judgments, settlements and legal fees

Personal Jurisdiction

- Court cannot impose its authority and compel a person or entity do something without personal jurisdiction
  - Doing business in a state confers jurisdiction
    - Office, employees, enter into contracts
  - Affiliate with independent US physicians for continuum of care
    - may affect jurisdictional analysis

Long-Arm Jurisdiction

- What do courts do if defendant has no physical presence in another state, or any state?
  - Defendant has "minimum contacts" with the state
  - Jurisdiction "does not offend traditional notions of fair play and substantial justice"
  - General jurisdiction-"continuous and systematic" activities-personal jurisdiction for all matters
  - Specific jurisdiction-minimum contacts directed at state basis for claim only
- *International Shoe v. Washington* – United States Supreme Court (1945)

Long-Arm Jurisdiction & Internet

- **What if no physical presence in state?**
  - Internet only means to communicate and engage with US patients
- May not be shielded from jurisdiction
  - *Zippo Mfg. Co. v. Zippo Cot Com, Inc.* (1997)
    - Jurisdiction "directly proportionate to the nature and quality of commercial activity that an entity conducts over the Internet"
    - Passive--------virtual admission--------virtual physician

Will Court Exercise Jurisdiction? Is Healthcare Different?

- Even if court finds minimum contacts with forum state, may refuse to exercise personal jurisdiction
  - Courts have treated physicians differently
    - Suit where effects of tort foreseeable is inconsistent with public policy of having care available
    - Fundamentally unfair to permit suit in distant jurisdiction were patient carries consequences of treatment thus offending due process

The New Deep-Pocket Employers

- If care offered to employee as option in employer's health benefit plan, ERISA preemption but –
  - Plan Fiduciary (employer) liability
    - Failure to run plan for benefit of participants
    - Conflict of interest
    - Failure to provide adequate information
    - Failure to exercise care in obtaining provider panel
    - Coercion
    - Elimination of remedy for medical error

Other Potential New Deep Pockets

- Insurance companies
- Third Party Administrators
  - Not a concern within the US because physicians and hospitals have medical liability insurance

What is available today?

- Several companies are offering policies to patients
  - Cover costs of care for complications
  - Cover costs of transportation to obtain necessary follow-up care
  - Additional cost to the patient
- These plans do not insure the provider!

What can be done to manage the risks to foreign providers?

- Self-insurance
- Commercial medical liability insurance
- Captive insurance
- Reinsurance
- Alternative dispute resolution
  - Arbitration
  - Mediation

Questions?

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