Virtual Microscopy-
the view from the reference lab

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Pathology Models

• Introduction
• Current status
• Economic implications
• Manpower implications
• Pressures for implementation
• Barriers to implementation
• Next generation disruptive technologies
Pathology Models

- Pathologists work for the hospital
- Pathologists are a professional corporation that “purchase” technical services from the hospital.
- Pathologists own entire laboratory and all personnel

Cost center model vs Revenue generation model
Basic Business Strategy

• Strategies based on disruptive innovations have the highest chance of creating growth.
• Introduce benefits such as
  • Simplicity
  • Convenience
  • Ease of use
  • Lower price
The Disruptive Playbook

• Scratch an unscratched itch
  • Make it easier to get an important job done
• Make an ugly business attractive
  • Find a way to prosper at the low end of established markets by providing a good enough solution at low prices
    • UNACCEPTABLE TO ME BUT LET THE BUYER BEWARE!
• Democratize a limited market
  • Expand the market by removing barriers such as lack of skills or access
Quick Definitions

1. “Technical component”
   - Relates to medicare billing which separates technical and professional components of billing
   - A laboratory performs the technical work and the pathologist provides a professional interpretation.
   - For some tests, the professional fee includes overall supervision of the technical work
   - Not unlike a typical hospital arrangement with an independent pathology corporation.
Definitions

2. “Reference Laboratory”
   - A laboratory which serves as a referral center for *pathologists* and other *healthcare workers*
   - Usually for profit
   - Usually performs esoteric tests
   - Can be further broken down into
     - horizontal and vertical laboratories
     - Local, regional and national laboratories
Not all reference laboratories are the same

- Publicly traded - Increase shareholder value
  - Pure laboratories
  - Laboratories with a single technology
  - Laboratories (Technology focused)
- Private laboratories
  - Venture backed - Go public or get sold
  - Single/small group owned - No out strategy (mom and pop store)
- Hospital Based
  - Pathologist owned outreach - generate more income, reduce costs
  - Hospital owned outreach - increase referrals, generate more income
Why do physicians use a reference lab?

- **Ease of use**
  - Simple to order
  - Integrated reports
  - Access to knowledgeable pathologists
  - Client support, billing, etc

- **Expert analysis - (Physicians)**
  - Expert opinion
  - Education

- **Technology/Large menu**
  - Access to latest technology
  - Size of menu
History/Current status

- Chromavision and US Labs (now Labcorp) create the concept of technical/professional split billing.
- In 2004, Chromavision and US Labs separate the business arrangement.
- “Virtual IHC” concept was adopted and implemented as a Chromavision replacement at US Labs (Labcorp).
- Competition goes backward and implements an image analysis replacement off of static images.
- Chromavision becomes CLARiENT and implements the old Chromavision/US Labs (now LabCorp) solution in a virtual form.
- CLARiENT offers virtual IHC and creates an infrastructure for virtual consultation.
- Competition places ads for virtual IHC.
Economic implications

- **Make it easier to get an important job done**
  - Quantitative assessment
  - Find rare events
  - Obtain measurements easily
  - Simplify and improve access to second opinions

- **Make an ugly business attractive**
  - Reduce Fed’Ex costs

- **Democratize a limited market**
  - Allow access to complex/difficult immunostains
  - Eliminate the need for clients to obtain space, people and equipment
Manpower/Resource implications

- Shortage of qualified histotechnologists
- Potential shortage of subspecialty Expertise
- High priced equipment without adequate volume – Stepwise growth
- Lack of space
- Competing resources
- More residents being trained in advanced technology but those technologies not available to them in the job market
Consider your unlucky colleagues

- Many board certified pathologists don’t have access to an IHC/ISH lab and thus must send out their samples
  - Loss of revenue
  - Loss of continuity of care
- Each year many graduating pathology fellows could benefit from virtual IHC/ISH by applying for jobs at hospitals sending out IHC/ISH samples
- Many lab can’t staff weekends
- Some labs are closing their IHC/ISH facilities due to lack of personnel, lack of space, decreasing revenues, increasing costs, lack of qualified technicians
Pressures to Implementation

- **Reference Labs/Universities**
  - Improved margins
  - Increased revenue

- **Clients**
  - Improved patient care
  - Increased revenue (participate in professional revenues)
  - Markedly reduced costs
  - Improved turnaround times
  - Improved QA, (measurements, rare events, quantification, virtual multi-headed microscope).

- **Patients**
  - Rapid access to second opinions
Barriers to Implementation

• Change in status quo
• Legal issues
  • Looking at slides on a monitor rather than through a standard microscope
• Billing issues
  • Split billing concerns
• CLIA issues
  • Medical director responsibilities
Potential Problems

Compromises Quality Assurance

The local L.D. should review and agree with the QC plan of the reference laboratory and should review the appropriate metrics. They must not be obligated to send to the reference lab if the QC metrics are inadequate or if the performance is unacceptable.

Compromises Scientific Principles

Positivity threshold, reportable range

Violates CLIA

Must uphold all CLIA regulations; CLIA currently requires a license only for those reporting a test result.

Contrary to Medicare Billing Policies

Not if all applicable rules are followed; similar to hospital and pathology corporation arrangements.
Two problems looking for a solution

Clients
- Access to latest technologies
- Integrated reporting
- Better turnaround
- Education
- Support for tumor conf

Reference laboratory
- Increased revenues
- Higher margins
- New market segment
  (Vertical reference lab)
Virtual Slide
Image Manager
Block Number: J07-18390, Endometrial Curetage Tissue Paraffin Embedded
Stain: H&E
Block Number: J07-18390, Endometrial Curretage Tissue Paraffin Embedded
Stain: CK HMW/LMW Double Stain
What to expect next

- Better
- Faster
- Cheaper

The cell phone example
Predictions

- Virtual programs will allow the latest and greatest will be available to all.
- Multi-headed microscopes will become virtual and instantaneous.
- Textbooks, journals and algorithms will be integrated into the virtual microscope environment.
- Image matching will aid the pathologist in differential diagnosis.
Next-gen technologies
Remember…

• Make it easier to get an important job done
• Find a way to prosper at the low end of established markets by providing a good enough solution at low prices
• Expand the market by removing barriers such as lack of skills or access

Thank you!