



Higher Education and Healthcare Consulting

# Understanding the Financial and Administrative Commitments of Clinical Research

The Second Annual Medical Research Summit  
March 26, 2002

# Agenda

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- Compliance Concerns
- Common Problems
- Communication Issues
- Financial Considerations
- A Potential Answer



# Compliance Concerns in Clinical Research

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- Staff capabilities and workload
- Communication issues
  - patient care / research
  - physician order / charge capture
  - admitting and registration
- Financial considerations and incentives
- Intentional fraud and abuse



## Common Problems

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- Improper planning of financial need
- Limitations on overhead cost recovery
- Historic availability of “other” revenue
- University / Hospital relationship
- Pressure for patents and publications
- Lack of good financial information



## Common Problems: University Mindset

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- Direct v. Indirect Costs
- Federal and non-federal requirements differ, though
  - consider consistency issues
  - consider information maintenance and documentation issues



## Common Problems: Competitive Landscape

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- Jumping off the bridge
- Typical 22% - 25% overhead recovery
  - too low for management
  - too high for the investigator



# Communication in Clinical Research

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- Objective of provided services
  - coverage determination
  - informed consent (ICA)
  - clarification in billing/ financial systems
- Charge capture
  - relative to protocol
  - clerks and nurses
- Admitting and registration procedures
  - information flow-through
  - patient financial accounts
- Decentralization



# Financial Considerations in Clinical Research

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Always consider the incentives for behavior!

- Contract execution
  - payments and perceived inducements for participation
  - use of residual funds
  - classification and categorization of costs
- Data falsification
  - research integrity
  - patient safety





# Financial Considerations in Clinical Research

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- Management and PIs cannot determine financial results of clinical research
  - purely incremental revenue
  - load overhead costs
- Incentives for not charging costs
- Lack of specificity with budgets



# Understanding Clinical Trials Costs

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- Use existing information as a start
  - Medicare Cost Report
  - University F&A rate methodologies
- Evaluate expected outcomes using protocol and standard of care as the guide
  - clinical pathways help here, too!



## Developing Financial Awareness

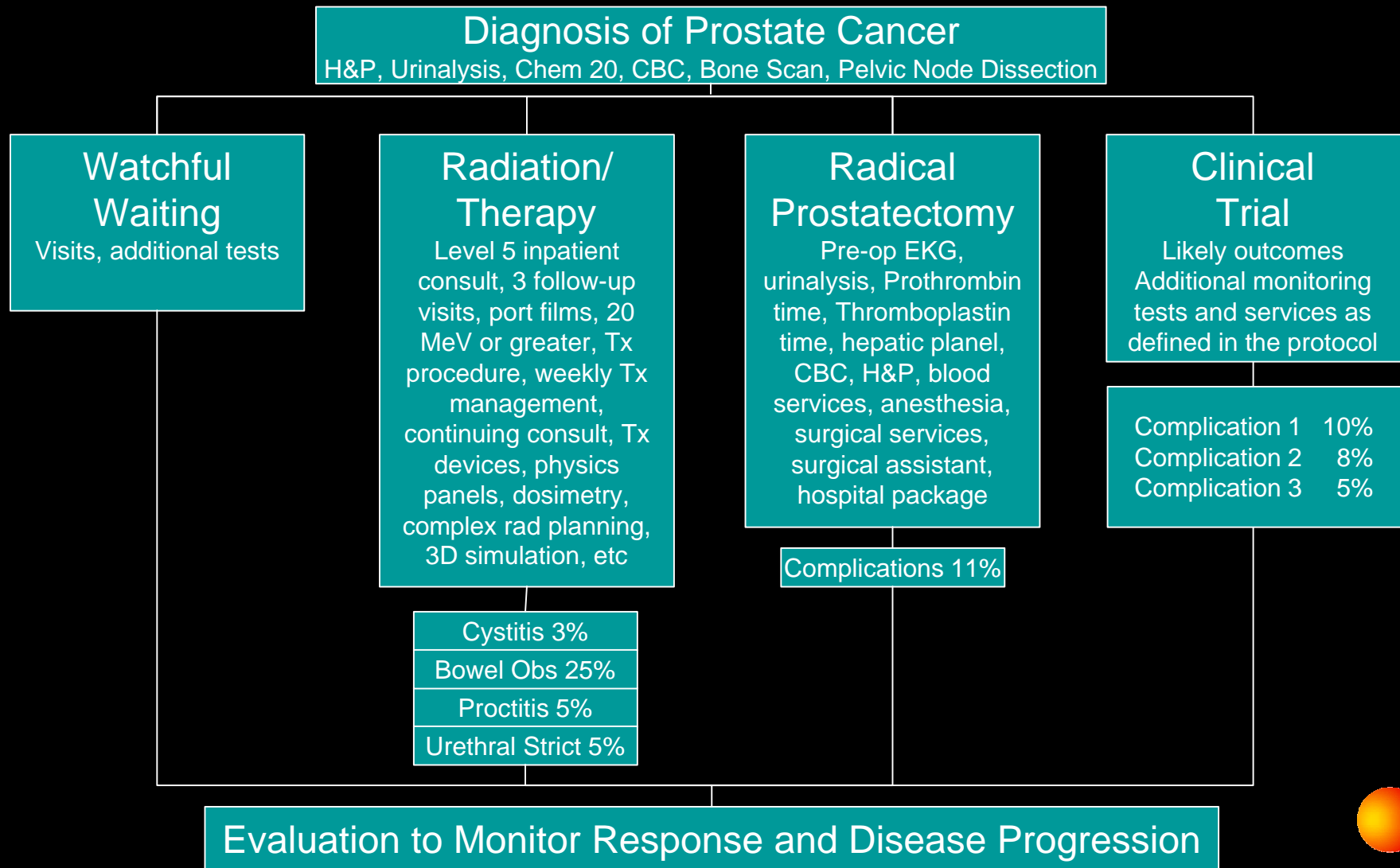
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- Model combined financial, administrative and clinical operations

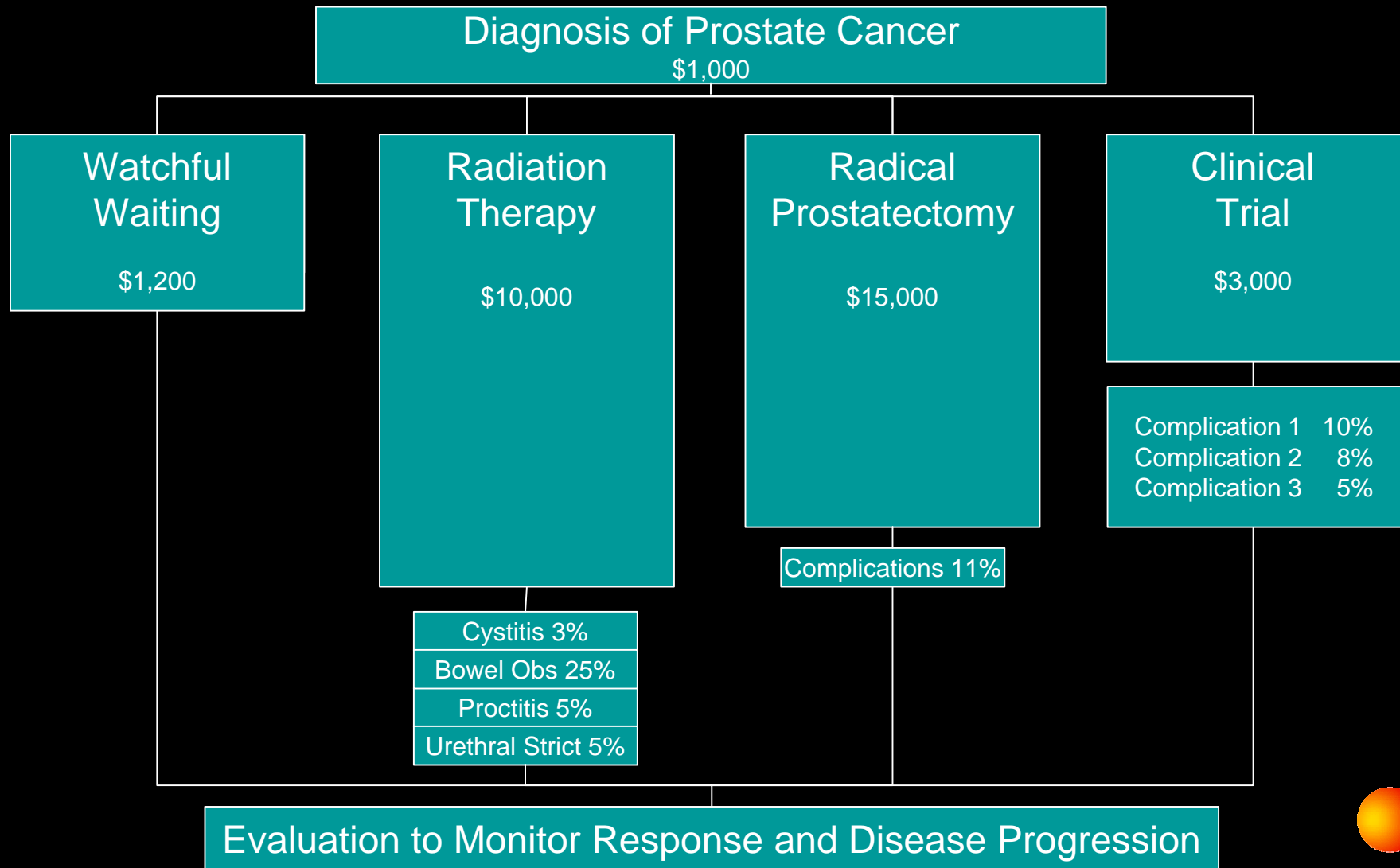
Protocol Pathways



# Protocol Pathway



# Protocol Pathway



## Protocol Pathway: Costs

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- Sum expected costs of treatment:

$$\begin{aligned} & \text{Diagnosis costs} \\ & \text{Protocol costs} \\ & (\text{likelihood} * \text{cost of Watchful Waiting}) \\ & (\text{likelihood} * \text{cost of Radiation Therapy}) \\ & \quad (\text{likelihood} * \text{cost of Cystitis}) \\ & \quad (\text{likelihood} * \text{cost of Proctitis}) \\ & \quad (\text{likelihood} * \text{cost of Bowel Obstruction}) \\ & \quad (\text{likelihood} * \text{cost of Urethral Stricture}) \\ & (\text{likelihood} * \text{cost of Radical Prostatectomy}) \\ & \quad (\text{likelihood} * \text{cost of Complications}) \\ & + (\text{likelihood} * \text{cost of Protocol Complications}) \\ & \hline & \text{TOTAL EXPECTED COSTS OF PROTOCOL} \end{aligned}$$



## Protocol Pathway: Benefits

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- Better information
- Requires planning
- Less reliance on traditional direct v. indirect structure



# Questions

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