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Workshop on Technology and Outcomes Assessment

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BOLD indicates consensus

1. Health Technology Assessment (HTA) – Steve Pearson
 - a. Current HTA in the US
 - i. Poor coordination
 1. no federal role
 2. disparity in standards and quality
 3. confusion for users
 - ii. Weak legitimacy
 1. funding source in question
 2. transparency vs. getting things done
 - iii. Limited usefulness
 1. new technologies take too long to get assessed
 2. cost is not taken into account
 - iv. Incomplete integration
 - b. International Lessons
 - i. NICE, etc.
 1. other countries are centralizing and it works
 - c. Key Recommendation: Congress should create a federal entity to coordinate and conduct tech assessment
 - i. prioritize technologies for assessment
 - ii. review existing evidence on clinical and cost effectiveness
 - iii. fund studies
 - iv. method standards
 - v. disseminate information
 - d. Recommendation 1
 - i. Improve rigor and consistency of nomenclature
 - ii. Example of a Comparative Clinical Effectiveness Matrix that grades potential technologies
 - e. Recommendation 2
 - i. Enhance transparency & stakeholder engagement
 - f. Recommendation 3
 - i. Economic analysis should become a core element of TA

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- g. Recommendations 4&5
 - i. Incorporate TA into benefit design
 - h. Integrated Value Rating (IVR)
 - i. Grade a new technology on an IVR matrix that takes Comparative Clinical Effectiveness with Comparative Value
 - i. Conclusions
 - i. HTA has limits, imperfect
 - ii. It can't function alone
 - iii. It needs economics
2. Israeli Experience
- a. Itemized basket of services that has to be provided to citizens (~3,500 technologies, most of which are pharmaceuticals)
 - b. Mechanism for updated basket
 - i. Identify new technologies
 - ii. Quick assessment (<1 year)
 - iii. Comprehensive clinical/epidemiological/economic analysis
 - iv. Priority setting by the Ministry of Health with input from 3 groups
 - v. Public Committee of which stakeholders are a part
 - vi. Government approval and legislation
 - vii. Implementation
 - c. Lessons learned
 - i. TA is highly dependent on budget fluctuations
 - 1. high degree of variability year to year in the amount of money available to new technologies
 - ii. Importance of a centralized process
 - iii. Stakeholder involvement is critical and feasible
 - 1. key: access is not equal, different groups get different levels of access
 - 2. problems w/ stakeholders:
 - a. conflicts of interest
 - b. appeals are still made
 - iv. Transparency creates legitimacy but the Israeli experience is not fully legitimate
 - v. Evaluation timetables
 - 1. depth vs. time
 - 2. short timetable is good

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- 3. long timetable → creates a vacuum that can lead to political intervention
- vi. Assessment methods
 - 1. decision modeling is sufficient for most technologies
 - 2. comparable to NICE
- vii. International cooperation
 - 1. similar TAs are being conducted elsewhere → data sharing
- viii. Direct link between TA and coverage decisions
- d. Specific Israeli Issues
 - i. Can't legally remove technologies once they are in the basket
 - ii. Have a problem conditionally using technologies
- 3. Kaiser perspective
 - a. Kaiser's framework
 - i. By law Kaiser can't say "no" nor can it raise taxes
 - ii. Has state specific oversight
 - 1. self-insurance is done at federal level
 - iii. Guerilla cost effectiveness
 - 1. because Kaiser is prohibited by law from using cost-effectiveness in decision making it has to do so surreptitiously
 - b. Comments
 - i. Creation of a federal entity is critical because on a local/HMO level, TA is not legitimate
 - ii. There is a need for interoperability and standardization
 - iii. Campaign finance reform is critical
 - 1. too much PhRMA influence throughout the process
 - iv. Delivery system reform
 - 1. make physicians account for value and not only quality
 - v. TA needs to be current
 - 1. need to be able to revisit decisions
 - 2. this is integral to legitimacy, as doctors will trust if it is current
 - vi. Need a mechanism for changing consumers' perceptions of technologies
- 4. NICE perspective
 - a. Coverage decisions are taken at two levels: local and NICE

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- b. System of mandatory guidance for the NHS
 - c. Manufacturers submit data but otherwise sit on the sidelines
 - i. Though, reps of industry sit on committee
 - d. Fast Track
 - i. Allows for quicker consideration but also relies solely upon manufacturer supplied data
 - e. Big question: what is TA trying to achieve?
 - i. Efficiency
 - ii. Coverage
 - iii. Equity
 - f. Comments on paper
 - i. Rec. 2
 - 1. there should be input into analysis and not a seat at the table
 - ii. Rec. 3
 - 1. doesn't think QALY should be sacrificed
 - 2. too much emphasis on manufacturers
 - iii. Rec. 6
 - 1. federal entity is appealing but there is something already in place (AHRQ) that could do the job
5. General Commentary
- a. Federalizing TA
 - i. "The discussion is naïve w.r.t. a monolithic federal agency;" there isn't political appetite for this type of an entity
 - ii. AHRQ
 - 1. Existing structure is receptive to more TA
 - 2. There is something to be gained from some redundancy
 - b. Implementation
 - i. Waste will still exist because a lot of technologies will pass TA but have issues at the patient level
 - ii. TA needs to incorporate how a technology will be used**
 - 1. this could lead to inflexibility
 - iii. Link to coverage, P4P, etc.
 - 1. Difficulties in administration
 - 2. Implementation should be decentralized**
 - 3. Will depend on the nature of the delivery system**
 - c. Impact of TA on future technology development

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- i. Technology development allows expensive tech. to become cheaper
- ii. We need to send the right “price signals” with TA
 - 1. if technologies are constrained by cost effectiveness this could mean that fewer resources are allocated in the future to an area of research
 - 2. static vs. dynamic pricing
 - a. prices today affect tech. decisions tomorrow
- iii. Lots of disagreement as to how TA would impact future innovation
- d. PhRMA & TA
 - i. some said PhRMA sees centralized TA as one of its biggest risks
 - 1. PhRMA has a divide and conquer strategy where a single decision won’t kill a company
 - ii. others saw TA as providing PhRMA clear guidelines and eliminating uncertainty of whether particular tech. will be paid for
- e. What type of information?
 - i. **Same treatment class is an easy case**
 - 1. Have head-to-head clinical trials → same outcomes → choose the cheaper technology
 - ii. **Look at existing information but also fund your own new research**
 - iii. **Need both speed and thoroughness**
 - 1. err on the side of thorough
 - 2. interim reports
 - a. they work in drug trials
 - 3. need things out in 90 days for HMOs
- f. Structure of TA agency
 - i. TA agency should just provide information and let others sort through it and do the cost effectiveness work
 - 1. with no decision making power, the entity has more credibility
 - a. but you could mandate a “basic” benefits package without sacrificing credibility

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- 2. others thought that structure does not influence legitimacy
- ii. 1 decision maker → too much authority, destroys usefulness of TA
 - 1. need to keep decision making power at state level
- iii. Federal Reserve Model for independence
 - 1. realistic? TA can't print its own money
- iv. Funding
 - 1. "fees" and not "taxes"
 - 2. involve manufacturers without giving them too much input (realistic?)
 - 3. combination of public and private dollars**
 - a. large disagreement as to whether to take PhRMA dollars
- v. **Needs to be centralized and not diffuse**
- vi. **Coordinate on an international scale**
- vii. **Cost**
 - 1. **\$5-6 billion** (made up number)
 - 2. need it to cost money in order for it to be legitimate
 - 3. research will cost money
- g. Consumers
 - i. Consumers don't pay for the decisions they make right now, arming them with information is pointless
 - ii. Consumers are not willing to address tradeoffs
 - iii. Not a good idea to provide information to patients because they are sick/irrational when they are making healthcare decisions
 - 1. Docs make better choices for patients
 - 2. But what about preventive/consumable healthcare decisions?
- h. Incentives
 - i. TA provides accountability and incentives for health care system
 - 1. TA done by HMOs works and is beneficial
- i. Diagnostics vs. Treatment
 - i. TA is needed in both

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1. Outcomes Assessment (OA)– Jon Skinner
 - a. Effectively same objective as TA
 - b. Outcomes depend on:
 - i. Who does the procedure
 - ii. On which patient
 - iii. And a “black box” of unobservables
 - c. Observations
 - i. Geographic variation in expenditure on Medicare
 - ii. Costs driven by end of life treatments
 - iii. Comparison of four hospitals and treatment options for heart disease
 1. treatments chosen and costs varies across hospitals
 2. generated quite a bit of disagreement as to what the “takeaway” was
 - iv. LA hospitals have a great deal of variability in costs
 1. again lots of disagreement as to what the chart really meant
 - d. What is needed
 - i. Accountable health organizations
 - ii. Measurement
 - iii. Mechanisms to improve the low performing hospitals
 - iv. Incentives to reward or punish based on accurately measure outcomes and costs
2. Goldman presentation
 - a. [not sure how this fit into Skinner’s paper]
 - b. Value of a human life
 - i. It is difficult to estimate the value of a human life
 - ii. Studies vary quite a bit
 - iii. Some doctors in the audience were skeptical of methods
 - c. Limitations of technology assessments
 - i. Work well when given a budget
 - ii. Don’t work as well allocating between care elements
 - d. Society may not want cost effective health care
 - i. Nordhaus studies showing people choosing cost ineffective policies
 - ii. Goldman believes this is because social values are missing
 1. there is a social value to health improvements, in addition to value to the individual

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2. people value taking care of others
3. end of life care is particularly problematic because offering hope has value
- e. Dynamic vs. Static Efficiency
 - i. Need to consider lifetime effects of spending \$1 on health care
 1. spillover effects / innovation elasticity
 2. small providers shouldn't care about this, but a monolithic agency (i.e. Medicare) should
 - f. Dark matter view of health care
 - i. Need better information
 - g. Need to account for personal behavior in outcomes assessment
 - h. TA is not good enough to make "upstream rationing decisions"
 - i. OA needs more investment
 - j. Suggests a 10 year public-private investment in an institute of clinical excellence
 - i. Temporary so that it must prove results
 - ii. Medicare linked so that it matters
 - iii. Well-funded so that it works
3. Stirling's comments
 - a. Takeaways from Skinner's paper
 - i. Emphasis on healthcare as a "local event"
 - ii. Clinical trial results break down at the level of service delivery
 - iii. TA progress has been slow
 - b. US and limit setting
 - i. Tough to do here in the US
 - ii. Should study the VA medical system more because they are able to do it
 - iii. The public may not be that unwilling to accept considering costs in health care decision making
 - c. OA methodological weaknesses
 - i. Lack of generalisability of clinical trials to the real world
 - ii. Where benefits are uncertain, which seems to be in most cases, OA might not be as informative
4. Discussion
 - a. Big fight over semantics: TA vs. OA
 - i. TA is in the lab / OA is in practice
 - ii. TA does look practical applications

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- iii. TA starts with technology, OA start with groups of patients and how things work over time
- iv. OA is a subset of TA
- v. Link between clinical effectiveness and implementation
- vi. OA creates a demand for TA
- vii. Need to get the science right and not just look at outcomes
 - 1. this shouldn't be an either or proposition
 - 2. in some cases need better evidence, in others it is about practices
- b. Management
 - i. OA is shaped by behavior/social sciences/management; how providers are organized
- c. OA evidence
 - i. Difficult to determine what kind of evidence needs to be developed for OA
 - ii. Do you go for all of the data or do you just target particular areas?
 - iii. Observation may not be sufficient, may need clinical trials in some cases**
- d. System
 - i. FDA process of narrow approval and the off-label use generated a lot of discussion
 - ii. Registration and assessment creates a barrier to this kind of a system
 - iii. Need something in-between "Cowboy" method of any use and on-label only**
 - iv. Want to collect data on all use (on and off label)**
 - 1. this gives more accurate information
 - 2. doctors won't have incentives to lie in order to get treatment for patient
 - 3. this could speed implementation
 - 4. also could result in less off-label use
 - v. Difficulty in implementing OA with rewards in existing system
- e. Costs
 - i. Existing registries are low cost**
- f. Best Practice Assessment (BPA)
 - i. OA feeds BPA

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- ii. In some cases need to look at variation in outcome and look back to see what is driving the disparities
- iii. This contributed to the confusion of OA v. TA discussion
- g. OA incentive structures
 - i. Reward good care / penalize bad
 - 1. question as to what is “good” or “bad”
 - ii. Problems with solo / small practices
 - iii. Need to reward improvements AND levels**
 - iv. Process vs. Outcome rewards
 - 1. understand the process/outcome relationship
 - 2. system wide rewards on outcomes
 - 3. clinician rewards on process
 - 4. Reward process care because outcomes are noisy
 - v. Reward
 - 1. don’t need lots of money to create effective incentives**
 - 2. “bulletin board” system, just need to show doctors performance metric
 - a. Intrinsic rewards
 - vi. Hard to assign responsibility in ambulatory care system with multiple doctors responsible for outcomes
 - vii. Need a new payment system
 - 1. encourage cooperation among doctors (management)
 - 2. incentives for improvement
 - viii. Take into account possible “gaming” of system
 - ix. Political dimension
 - 1. people want evaluation of doctors
 - x. Regional rewards as opposed to individuals
 - 1. disputed effectiveness
- h. International perspective
 - i. UK
 - 1. less focused on outcome
 - 2. incentives have worked too well: too many docs responding to incentives
 - ii. Israel
 - 1. Ministry doesn’t look at outcomes normally
 - 2. Health funds do look at outcomes