Washington State Health Care Authority

Emerging Therapies Workgroup Agenda

October 18, 2019 8:30 AM-12:30 PM
HCA – Sue Crystal 106 A & B

Attendees:					
☐	Cody Gillenwater	☐	Ken West	☐	Jean-Baptiste Roullet
☐	Carly Rodriguez	☐	Carolyn Parsey	☐	Sean Sullivan
☐	Bruce Wilson	☐	Stephanie Simpson	☐	Monica Thakar
☐	Shawn Akavan	☐	Melissa Tribelhorn	☐	Donna Sullivan
☐	Petra Eichelsdoerfer	☐	Jonathan Espenschied	☐	Robyn Williams
☐	Shea Wilson	☐	Armen Khatchatourian	☐	Judy Zerzan
☐	Kerrie Fowler	☐	Thomas May	☐	Wylie Burke
☐	Yusuf Rashid	☐	Rebecca Owen	☐	Emily Transue
☐	Marco Mielcarek	☐	Mike Bonetto	☐	

No	Agenda Items	Time	Lead	Summary Meeting Notes
1.	Welcome / Introductions	20 min	Judy Zerzan	
2.	Workgroup expectations/answers to survey questions	10 min	Judy Zerzan	
3.	Recap of June 18th meeting.	5 min	Mike Bonetto	
4.	Patient advocate presentations: • Melissa Tribelhorn, Parkinson's Disease • Stephanie Simpson, Hemophilia • Ken West, Sickle Cell	40 min	Mike Bonetto	
5.	**BREAK**	10 min		
6.	Perspectives on educating and guiding patients to treatment decisions: • Monica Thakar, pediatric cancer specialist • Marco Mielcarek, Oncologist specialized in blood & marrow (stem cell) transplantation • Emily Transue, patient decision aid specialist-slides	60 min	Mike Bonetto	
7.	**BREAK**	10 min		
8.	Wylie Burke, Medical Ethics	60 min	Wylie Burke	
9.	Next steps	25 min	Mike Bonetto	

	Action Items/Decisions				
#	Action Item	Assigned To:	Date Assigned:	Date Due:	Status

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Emerging Therapies Workgroup Roster

Employee and Retiree Benefit (ERB) Plans

- Cody Gillenwater, MD, Regence, Associate Medical Director
- Carly Rodriguez, PharmD, Moda Health, Pharmacy Director, Clinical Innovation
- Bruce Wilson, MD, Kaiser P&T Committee Chair

Medicaid Managed Care Organizations (MCO)

- Shawn Akavan, MD, Amerigroup
- Petra Eichelsdoerfer, RPh, MS, ND, UnitedHealthCare, Pharmacist Account Manager
- Kerrie Fowler, PharmD, Coordinated Care, Senior Pharmacy Director
- Yusuf Rashid, RPh, Community Health Plan of Washington, Vice President of Pharmacy and Vendor Relationship Management
- Shea Wilson, PharmD, Molina Healthcare of Washington

Patient Advocates

- Dawn Sanderson, Susan G. Koman
- Stephanie Simpson, Bleeding Disorder Foundation of WA
- Melissa Tribelhorn, NW Parkinson's Foundation, Executive Director
- Foxy Williams, Seattle Sickle Cell Task Force

Subject Matter Experts (SME)

- Jonathan Espenschied, MD, WA State University, Associate Dean, GME and CME, Physician
- Armen Khatchatourian, PharmD, MBA, HEOR, OptumRx, Senior Director, Industry Relations & Formulary Consulting, Pharmacist
- Thomas May, PhD, WA State University, Medical Ethicist
- Rebecca Owen, FSA MAAA, HCA Solutions, Pharmacy Actuary
- Carolyn Parsey, PhD, UW Assistant Professor Dept. of Neurology, Clinical Neuropsychologist
- Jean-Baptiste Roullet, PhD, WA State University, Rare Disease Researcher
- Sean Sullivan, PhD, University of WA, Dean, School of Pharmacy, Healthcare Economics
- Monica Thakar, MD, Fred Hutchinson, Gene-based Therapy

WA State Agencies Representatives

- Donna Sullivan, PharmD, MS, Health Care Authority, Chief Pharmacy Officer
- Robyn Williams, Office of Financial Management, Budget Analyst
- Judy Zerzan, MD, MPH, Health Care Authority, Chief Medical Director

Emerging Therapies Workgroup

October 18, 2019

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Review of Agenda

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Agenda

- Welcome and Introductions
- Workgroup expectations/answers to survey
- Recap of June 18th meeting
- Patient advocate presentations
- Perspectives on educating and guiding patients to treatment decisions
- Medical ethics
- Next steps

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Welcome and Introductions

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Workgroup Expectations/Answers to Survey Questions

- On a scale of 1-5 (with 5 being excellent), please rate your overall assessment of the June 18th meeting in Spokane
  - 54% - Above average
  - 46% - Excellent
- What was most valuable to you at the June meeting?
  - Good level-setting and background
  - Understanding different perspectives
- What was least valuable to you at the June meeting?
  - Travel time to Spokane
  - Focusing on reactionary actions

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Workgroup Expectations/Answers to Survey Questions (cont.)

- Do you have additional comments from the June meeting topics that you would like to share?
  - Better breakdown on the annual growth in specialty drug costs from 2008-17
  - More information on how Pharma sets prices
- What, if any, changes would you recommend for the October 2019 meeting?
  - Clear understanding of end goal
  - Limit participation to one representative from each organization

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Workgroup Expectations/Answers to Survey Questions (cont.)

- Are there topics not in the charter, that you think pertains to emerging therapies, that the workgroup should address?
  - State budgetary constraints and trade-offs

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Recap of June 18th Meeting

Mike Bonetto, Ph.D., MPH, MS

Center for Evidence-based Policy, OHSU

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Workgroup's Scope

Issues related to Emerging Therapies:

- Long-term funding
- Quality oversight and outcome tracking
- Management of patients eligible for emerging therapies
- Potential improvements to health outcomes and quality of life
- Potential long-term savings or expenditures to the state
- Metrics that could be used to measure the fiscal and health impacts

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Schedule

- **June 18, 2019 – Spokane**
  - Overview of new therapies coming to market
  - Private sector perspective on managing emerging therapies
  - HCA/Medicaid perspective on managing emerging therapies
  - Current financing
- **October 18, 2019- Olympia**
  - Patient decision aids
  - Patient experience
  - Patient advocates present
- **February 19, 2020- SeaTac**
  - Long-term funding for emerging therapies
  - Potential funding options between manufacturers and the state
  - Different payment options between the state and managed care organizations
- **April 15, 2020 – SeaTac**
  - Potential improvements and harms to health outcomes and quality of life for patients
  - Quality oversight and outcome tracking of providers and facilities administering emerging therapies
  - Metrics that could be used to measure the fiscal and health impacts of emerging therapies
  - Potential long-term savings and expenditures to the state

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Growth in Specialty Drugs

2008	2017
About 10 years ago, specialty medicines accounted for **24.7%** of total pharmacy spending	Today, they contribute to **46.5%** of total pharmacy spending, but only **~2% of prescriptions**

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Pipeline

- Breakthrough specialty drugs
  - Certain types of cancer
  - Cystic Fibrosis
  - Duchenne Muscular Dystrophy
  - Spinal Muscular Atrophy
  - Nonalcoholic Steatohepatitis
  - Blindness (neovascular age-related macular degeneration)
  - Hemophilia
  - Alzheimer's disease
  - Certain neurologic diseases

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Pipeline (cont.)

- Of the drugs now in Phase III trials…
  - 60% are specialty drugs
  - 33% are orphan drugs
  - 13% are considered breakthrough therapies
  - Only 8% are biosimilars
- Of the applications submitted to the FDA…
  - 25% of new drug applications submitted to the FDA have been granted "priority review"

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Current Approaches to Determining Coverage

Similarities between Commercial Insurers and WA Health Care Authority:

- Evaluation of evidence
- Budget/Financial impact analysis
- Development of clinical criteria
- Tracking outcomes

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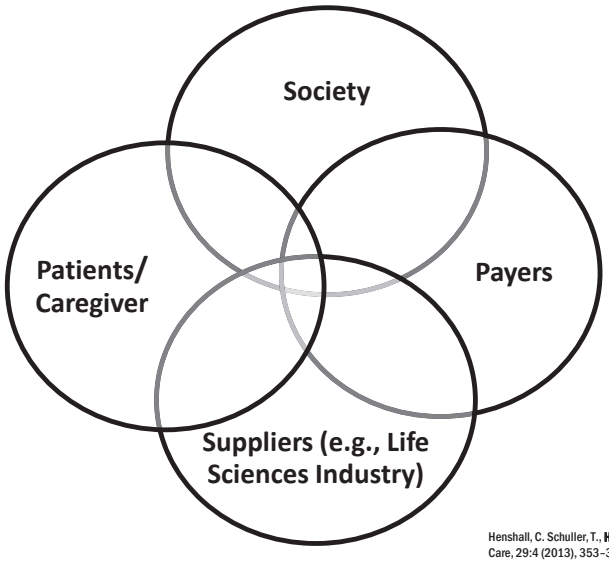
Decisions are Complex and Affected by Perspective



- What the decision-makers value and how they value it is a complex inter-relationship of what matters within the organization and who they serve.
- The decision-making criteria are shared though elements of it may be weighted or valued differently.

Henshall, C. Schuller, T., **Health Technology Assessment, Value-based Decision Making and Innovation.**, International Journal of Technology Assessment in Health Care, 29:4 (2013), 353–359.

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Workgroup's Discussion

- **Cost, Quality & Access**
  - What are the levers we have?
  - Reinsurance options with orphan drugs
  - Best price implications
  - Societal impact
  - Outcome-based contracts
  - Long term side-effects
  - Cure vs. maintenance (patient perspective -- disease by disease)
  - Patient decision aids
  - Outcome registry
  - Provider education
  - Informed consent
  - Alternative treatments

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NORTHWEST PARKINSON'S FOUNDATION

Melissa Tribelhorn, MPA

Executive Director

Overview of Parkinson's

- 1% of the population over age 65*
  - 1 million in U.S., 18,000 estimated in WA, 33,000 pwp + cp in NW Park's database
- 13-20% of people with Parkinson's are diagnosed before age 65
- Symptoms & treatments are unique to each individual
- Carbidopa/levodopa still major medication, been using since 1960s
  - Dopamine agonists, surgical options (DBS) & other add-on treatments have come on the market since, but the major medication has not changed
- End-stage progression – what this means for whole family system

*Michaeljfox.org

Helping patients self-advocate

Micro	Mezzo	Macro

• Education around comprehensive care & palliative care
• Making the most of your visit
  • Medication management
  • Questions for providers
  • Bring a friend
  • Tracking symptoms
  • Tracking medication side effects
• Understanding coverage
	• Educational programming on disease state, treatment options, research updates
	• Increase Access to specialty care
	• Promote TeleHealth programs
	• Rural provider support
		• State & federal level policy advocacy
		• Collaborate with national & regional orgs
		• Utilizing data to demonstrate need

The Parkinson's Experience

- Experience of Americans with Parkinson's over 1 year
  - 54% are chronic and managed on an out-patient basis*
  - 11% spend year in an institution
  - 23% are chronic, non-institutionalized, and experience an acute event
  - 12% die (mortality is 3 times greater for people w/ Parkinson's than general population^)

*O'Brien, J, A Ward, S Michels, and S Tzivelekis. 2009. Economic Burden Associated with Parkinson Disease. Drug Benefit Trends 21(6):179.
^Hamilton, J, The Michael J. Fox Foundation for Parkinson's Research; W Yang, The Lewin Group; et al. 2019. The Economic Burden of Parkinson's Disease. Manuscript in Preparation.

The Parkinson's Experience

- 60% of people with Parkinson's disease report at least one fall and recurrent fallers report 4.7 to 67.6 falls per year*
- The risk of suffering a fracture is 2x HIGHER in people with Parkinson's disease, and the risk of a hip fracture is >3x HIGHER**
- DEMENTIA is NEARLY INEVITABLE for people with Parkinson's disease — affecting MORE THAN 80% of people followed for >20 YEARS after disease onset***

* Allen, N, A Schwarzel, and C Canning. 2013. Recurrent Falls in Parkinson's Disease: A systemic review. Parkinsons Dis doi: 10.1155/2013/906274.
** Melton, L, C Leibson, S Achenbach, J Bower, D Maraganore, et al. 2006. Fracture Risk After Diagnosis of Parkinson's Disease: Influence of concomitant dementia. Mov Disorders 21(9):1361-7.
*** Biundo, R, L Weis, and A Antonini. 2016. Cognitive Decline in Parkinson's Disease: The complex picture. NPJ Parkinsons Dis 2:16018; doi: 10.1038/npjparkd.2016.18.

Economic Burden of Parkinson's

Total annual cost of Parkinson's in the U.S. = $51.9 billion*

- **Direct Medical Costs** = $25.4 billion
  - Hospital Inpatient
  - Outpatient
  - Physician Office
  - Durable Medical Equipment
  - Rx
  - Non-acute Institutional Care
- **Indirect Medical Costs** = $26.5 billion
  - Disability Income
  - Indirect Costs
    - Attributable death
    - Reduced employment
    - Absenteeism
    - Social productivity loss

    (Includes cost to patient $7.7 bil & cost to primary and secondary carepartners $6.5 bil)
  - Other non-medical costs

* Hamilton, J, The Michael J. Fox Foundation for Parkinson's Research; W Yang, The Lewin Group; et al. 2019. The Economic Burden of Parkinson's Disease. Manuscript in Preparation.

Value of Innovation

- Gene Therapy: Putanimal AADC
  - an enzyme allowing better communication between cells in the nervous system, was found in early stage clinical trials to REDUCE THE AMOUNT OF LEVODOPA the subject needed to take — up to 42% less in the highest dose group*
- Gene Therapy: AXO-Lenti-PD
  - encodes for the three critical enzymes required for dopamine production, was found in early stage clinical trials to produce a 42% improvement in UPDRS OFF scores and improvements in activities of daily living, 3 months after treatment**
- Stem Cell Therapy: Bone Marrow-Derived Allogeneic Mesenchymal Stem Cells Infused Intravenously
  - found improved motor function in Parkinson's subjects with mild to moderate disease***

*Christine, C, K Bankiewicz, A Van Laar, R Richardson, B Ravina, et al. 2019. Magnetic Resonance Imaging-Guided Phase 1 Trial of Putanimal AADC Gene Therapy for Parkinson's Disease. Ann Neurol 85(5):704-14.
**Lopes, JM. 2019. AXO-Lenti-PD Gene Therapy Shows Benefits in 2 Advanced Parkinson's Patients in Phase 1/2 Trial. Parkinson's News Today. Available at https://parkinsonsnewstoday.com/2019/03/14/axo-lenti-pd-gene-therapyshows-benefits-2-patients-phase-1-2-trial/. Last updated March 14, 2019.
***Scheiss, M, J Suescun, T Ellmore, M-F Doursout, E Furr-Stimming, et al. 2019. Preliminary Report on the Safety and Tolerability of Bone Marrow-Derived Allogeneic Mesenchymal Stem Cells Infused Intravenously in Parkinson's Disease Patients. Available at http://indexsmart.mirasmart.com/AAN2019/PDFfiles/AAN2019-003060.pdf. Last accessed on May 13, 2019.

Value of Innovation

"Cure" vs. Treatment

If Parkinson's disease progression was*:

Slowed by 20%

- Savings of $75, 891 per person
  - Medical costs savings of $37,927
  - Lost income $15,325

$1,366,038,000 in WA State

Halted

- Savings of $442,429 per person

$7,963,722,000 in WA State

*Johnson, S, M Diener, A Kaltenboeck, H Birnbaum, and A Siderowf. 2013. An Economic Model of Parkinson's Disease: Implications for slowing progression in the United States. Mov Disorders 28(3):319-26.

Bleeding Disorder Foundation of Washington

Emerging Therapies for Bleeding Disorders

Emerging Treatments for Bleeding Disorders

The Bleeding Disorder Foundation of Washington is monitoring all emerging and gene therapy treatments for hemophilia.

- Gene therapy trials for both Hemophilia A & B there are a number of extended factor treatments.
- Extend factor treatments for Hemophilia A & B
- Subcutaneous treatments for Hemophilia A & B
- Novel treatments is pre-clinical

Treatments outside of bleeding disorder

Treatments that have been approved or will be approved:

- Luxturna
- Zolgemsma
- Any other treatments that may be approved

Why we are monitoring:

- Understand the concerns of the patients
- Reaction of the payer
- Lessons learned
- ICERS role
- Challenges of patients after treatment
- Education needed for patients

How & why we monitor emerging treatments

- For many, these treatments provide significant improved quality of life
- To evaluate, how the role of the patient can improve as new treatments are approved
- To help patients understand new treatments

How do patients define cure?

As treatments have improved for patients I have seen the definition of the word cure evolve:

- Improved experience with treatment
- Less invasive treatment
- Treatments makes condition less impactful
- Treatment reduces severity
- Treatment may mean every 7 years
- Treatment may mean I don't have the condition

Cure changes with hope.
Hope evolves with treatment options

What do patients need?

How can the patient community help?

- Education on what is gene therapy
- Education on emerging treatments
- What is needed for the success of the treatment
- What happens if your condition doesn't impact you daily, weekly or yearly
- What are long term outcomes of these treatments

What the BDFW provides?

- Educational meetings on new treatments
- Presentations from local providers
- Workshops on how to have successful appointments with providers
- How to work with your insurance company
- Self advocacy
- State advocacy
- Peers to work with on concerns and thoughts

Additional things to think about?

- How do patients adjust to a new way of life?
- Unknown consequences of treatment?
- Care for patients if the disease has caused long term impact that gene therapy will not fix?
- Mental health impact
- What is needed to empower patients to be successful after treatment

METROPOLITANSEATTLE SickleCell TASKFORCE

New Drugs

2017-Endari (L-glutamine oral powder)

1998-Hydroxyurea

METROPOLITANSEATTLE SickleCell TASKFORCE

- How new drugs are evaluated
  - NWSCC
  - FDA site
  - Clinical Trial site

METROPOLITANSEATTLE SickleCell TASKFORCE

- A cure
  - Available to all of the SC population

METROPOLITANSEATTLE SickleCell TASKFORCE

- Education
  - Lunch n Learn sessions
  - Sickle Cell Camp
  - Sickle Cell Walk
  - Newsletter
  - Website
  - Phone calls
  - Social Media

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Shared Decision Making:
Potential Role in Emerging Therapies

Emily Transue, MD, MHA, FACP
Associate Medical Director

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What is Shared Decision Making?

A process in which clinicians and patients work together to make decisions and select tests, treatments and care plans based on clinical evidence that balances risks and expected outcomes with patient preferences and values.

–National Learning Consortium, HealthIT.gov, 2013

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How is SDM different from informed consent and other communication?

- Most providers think they "already do" SDM
- Informed consent, motivational interviewing, and other techniques for high quality provider-patient communication have significant overlap, including active listening and understanding patient goals
- SDM is a structured process for supporting patient decisions around preference sensitive conditions (see below)

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Preference-Sensitive Conditions

- Shared Decision Making applies specifically to situations where:
  - There is clinical equipoise (more than one comparably appropriate option) or high clinical uncertainty about the risks/benefits of one or more options; AND
  - The options have different implications for patient-specific goals and values (pain relief vs procedural risk, length vs quality of life, etc)
- In these settings, helping the patient make a values-congruent choice is critical

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Components of SDM

- Ensuring patient understanding of:
  - The medical condition under discussion
  - All appropriate options for treatment or testing
  - Risks and benefits/pros and cons of each option
- Elicitation of patient values and exploration of the impact of options relative to values
- Shared decision between provider and patient
- Confirmation of decision, addressing questions, and documentation

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SDM: Examples

- Procedures: TJR, spine surgery
- Medications: statins, etc.
- Prostate cancer screening and treatment
- End of life care

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Why is SDM important?

- Systematic use of shared decision making can:
  - Improve patient experience
  - Improve health outcomes
  - Reduce variation and health disparities
  - Improve appropriateness of utilization and spending
  - Support value based care and population health strategies
- Most SDM studies involve use of a Patient Decision Aid (PDA) to support high quality SDM
- PDAs come in many forms , but serve to provide accurate information, elicit values, and structure the patient conversation

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Shared Decision Making in Washington

- State and HCA role:
  - Foundational legislation to support SDM
  - Certification of patient decision aids (PDAs) by HCA
  - Promotion of SDM and PDA use in HCA's role as purchaser (1.8M Medicaid lives, 200K PEB)
- Implementations by Group Health/Kaiser for 10+ yrs
- Many engaged stakeholders:
  - Providers, plans, malpractice carriers, PDA developers, etc
  - Bree SDM implementation workgroup 2019

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Opportunity: SDM in Emerging Therapies

- Many emerging therapies involve a high degree of clinical uncertainty
  - How many patient benefit and how big is the impact?
  - How long will effects last?
  - What are the short- and long-term risks?
- Core patient values are often in play
  - Both potential risks and potential benefits are often high
  - Some therapies may prolong life in a setting where quality of life is poor
  - "Financial toxicity" may be high

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Opportunity: SDM in Emerging Therapies

- Patients/advocates have expressed concern about being pressured both toward emerging therapies (since a "cure" might save money in the long term, even if safety is unclear) and away from them (due to high up-front costs)
- Costs are high, so the importance of ensuring appropriate utilization is heightened
- All of these conditions make this an appropriate topic for a shared decision making approach
- Other states are interested in following our lead

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Challenges: SDM in Emerging Therapies

- PDAs are important to the consistency and fidelity of the SDM process
- PDAs are expensive to develop, and are therefore generally proprietary and only developed for higher-volume conditions where developers can recoup their costs
- Alternatives to the usual process of commercial development could be considered

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Challenges: SDM in Emerging Therapies

- Most PDAs are developed for conditions with clinical equipoise but large evidence base
  - Approach would be someone different for emerging therapies where clinical uncertainty is high and evidence often limited
- If SDM were a requirement for coverage, would need to address how this would be implemented (standards, documentation, etc)

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Questions?

More Information:
www.hca.wa.gov/about-hca/healthier-Washington/shared-decision-making

Emily Transue, MD, MHA, FACP
Associate Medical Director
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Ethical Considerations for Emerging Therapies

Wylie Burke MD PhD

Department of Bioethics and Humanities

Two types of decisions

- Policy decisions
  - Should this therapy be approved for use?
  - Should this therapy be covered by health payer?
- Personal decisions
  - Should I accept this therapy?

Health care coverage policies

- Involve the use of shared resources
  - A "medical commons" - Resources that provide health care for all those covered under a particular group plan
- Have a specific goal – provision of beneficial and appropriate health care

"Medical necessity"

- "Services or supplies that are needed for the diagnosis or treatment of your medical condition and meet accepted standards of medical practice." (Medicare, cms.com)
- "Health care services that a physician, exercising prudent clinical judgment, would provide to a patient." (Cigna, cigna.com)

Standards for process of health care decision-making

- Readily accessible explanations for decisions
- Moral justification for decisions
- Alternative views respected
- Decisions revisable with new evidence

Gutmann & Thompson. Just deliberation about health care, in Ethical Dimensions of Health Policy. Oxford 2002

The importance of communication

- Readily accessible explanations
  - Group members should know what is covered, what is not covered, and why
- Alternative views respected
  - Decision-making process should include opportunities for stakeholders to voice full range of views about appropriate coverage
  - Decisions should acknowledge opposing views

Decisions revisable with new evidence

- Central role of evidence in determining benefits and harms of medical interventions
- Need to define methods used for identification and review of evidence
- Need to acknowledge judgements involved
  - What counts as evidence?
  - How are different types of evidence weighed?
  - What is the decision-making process?

Moral justification for coverage decisions

- Valid procedures for assessment of therapy
- Coverage provided when assessment indicates:
  - Benefit outweighs harm
  - Coverage provides fair distribution of benefits and burdens

Coverage not necessarily all or nothing

- Identification of suitable candidates for therapy may be appropriate
  - For example, if evidence indicates differences in efficacy based on patient status
- Decisions about candidates for therapy should also be morally justified
  - Based on goals and outcomes of therapy

Threats to decision-making process

- Faulty process
  - Is process for analysis of evidence and decision-making clear?
  - Do all stakeholders agree the process is fair?
- Misrepresentation of problem
  - Are all relevant facts & circumstances accurately presented?
- Unequal representation
  - Are perspectives missing or over-represented?
    - Health disparities
    - Minority perspectives (e.g., rare disorders)

The "wicked problem" posed by many emerging therapies

- Average benefit may be small, with wide range
- Often, no clear basis on which to distinguish those patients who will benefit from those who will not, creating a "ragged edge"

But if all have access to growing numbers of therapies with incremental effects, care becomes unsustainable

Fleck. New Biotechnology 2012; 29:757

Continued growth in national health expenditures (NHE)

In 2017

- NHE grew 3.9%: $3.5 trillion, $10,739 per person
- Out of pocket grew 2.6%: $365.5 billion, 10% of NHE

Projections for 2018-27

- NHE expected to grow 5.5% per year: $6 trillion by 2027
- Prices expected to grow 2.5% per year (compared to 1.1% for 2014-7)

Centers for Medicare & Medicaid Services. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html

Personal decisions about emerging therapy

- Cannot occur if therapy is not approved by FDA for use
- Likely to be influenced by whether or not health payer coverage is provided
- Potentially limited by capacity of available health care system

Moral considerations in personal decision-making

- Patient and family must have ready access to information about benefits and harms of treatment and any other relevant information (e.g., out of pocket cost)
- Autonomy of competent patient is absolute- Patient has right to decide whether or not to seek or accept treatment