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Role of HEOR in Decision Making: Global Knowledge for Local Application

September 20, 2018

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CENTER FOR HEALTH OUTCOMES & PHARMACOECONOMIC RESEARCH
COLLEGE OF PHARMACY

United States Pharmaceutical Value Frameworks

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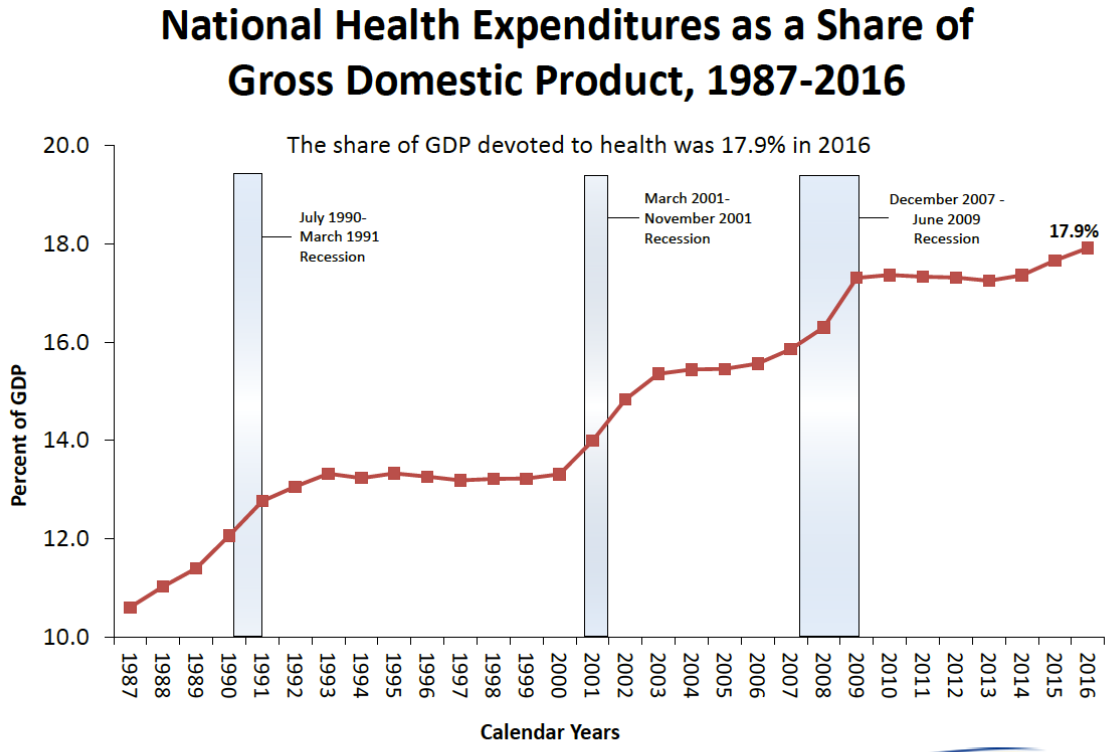
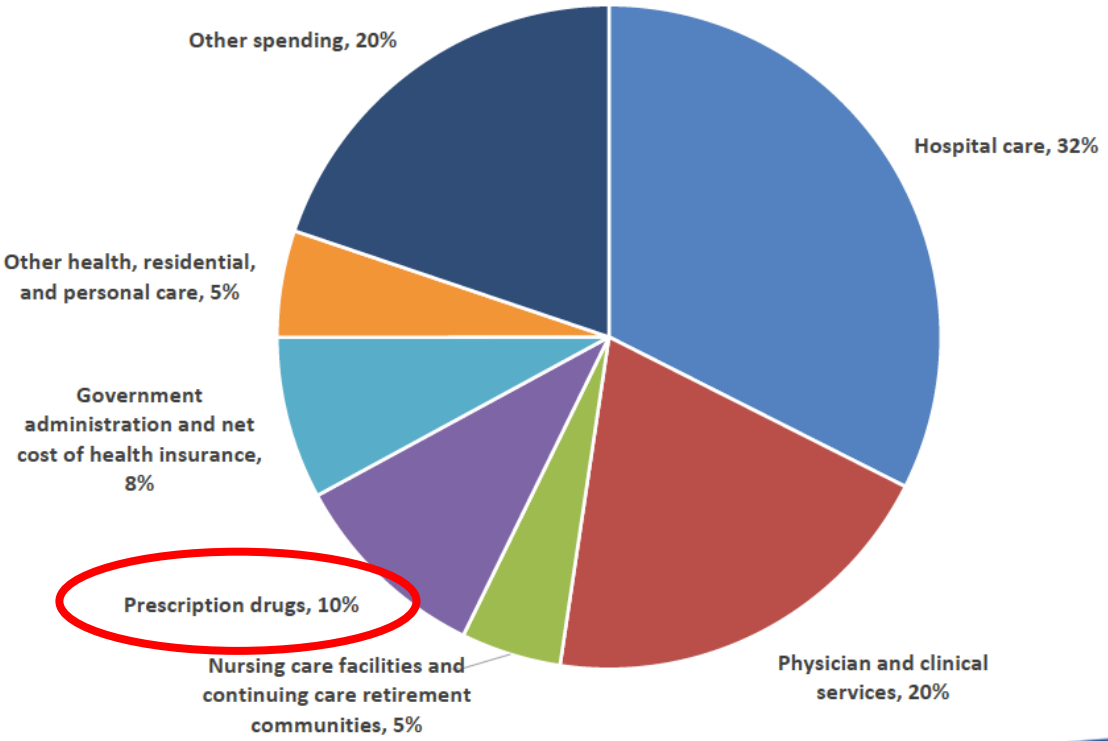
United States Healthcare Spending



SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group; U.S. Department of Commerce, Bureau of Economic Analysis and National Bureau of Economic Research, Inc.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF THE ACTUARY

The Nation's Health Dollar, Calendar Year 2016: Where It Went



NOTE: "Other spending" includes Dental services, Other professional services, Home health care, Durable medical equipment, Other nondurable medical products, Government public health activities, and Investment.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

CMS
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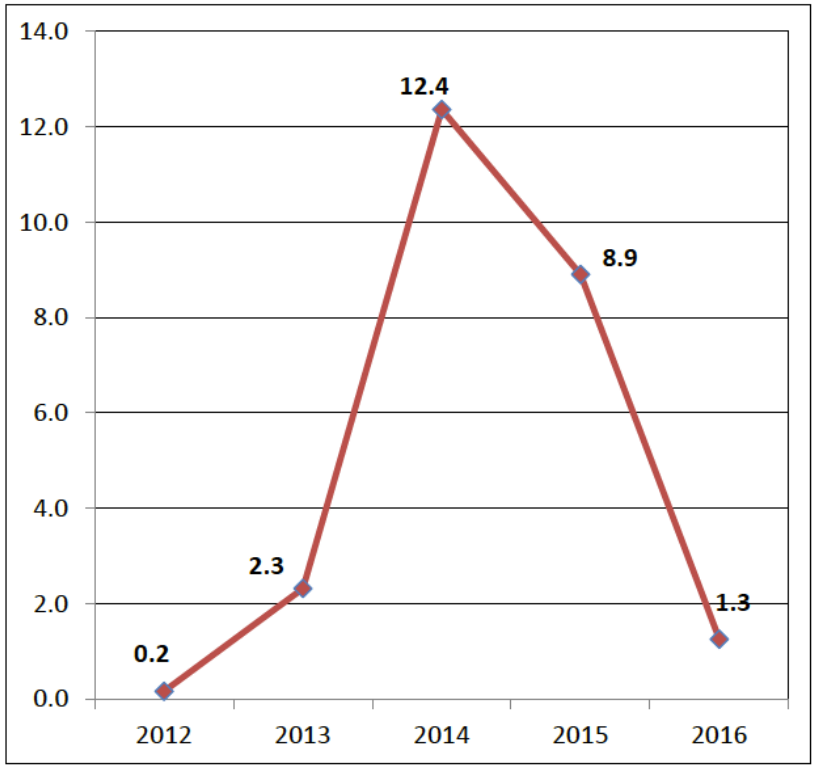
Annual Growth in Retail Prescription Drug Spending, 2012-2016



2016 highlights:

- Total spending = $328.6 billion
- Spending increased 1.3%
- Slower growth in 2016:
  - Fewer new drugs approved
  - Slower growth in brand name drugs
    - Decline in spending for hepatitis C drugs

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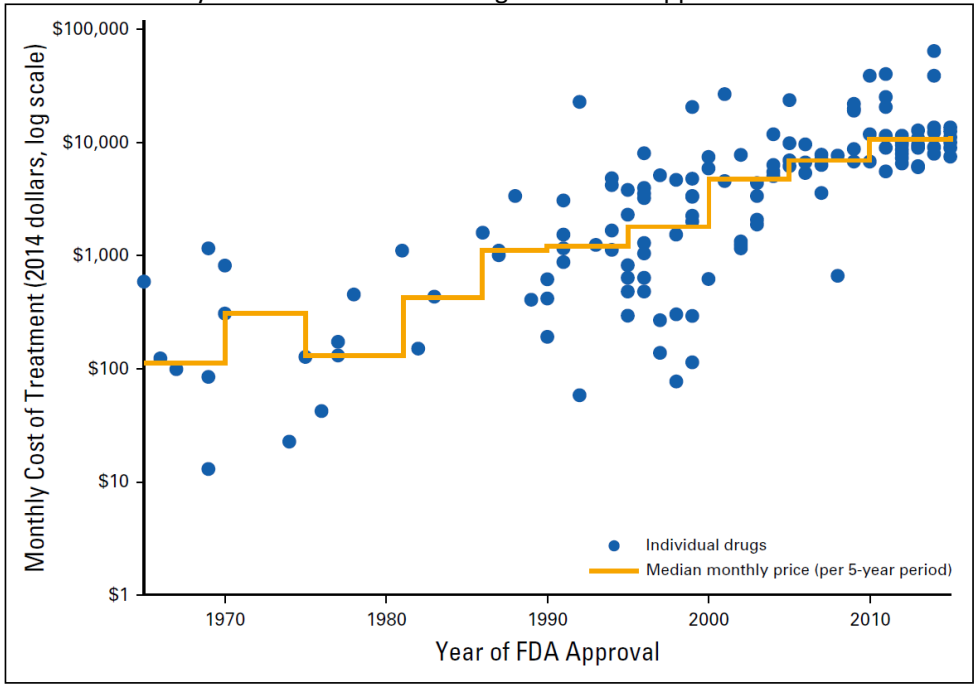
SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

High Costs of Oncology Drugs

In 2015, growth in oncology expenditures was 23.7% due to increases in utilization (9.3%) and unit costs (14.4%)[1]

Median Monthly Cost for New Cancer Drugs at Time of Approval[2]



COMMENTARY

3 MAYO CLINIC

In Support of a Patient-Driven Initiative and Petition to Lower the High Price of Cancer Drugs

Ayalew Tefferi, MD; Hagop Kantarjian, MD; S. Vincent Rajkumar, MD; Lawrence H. Baker, DO; Jan L. Abkowitz, MD; John W. Adamson, MD; Ranjana Hira Advani, MD; James Allison, MD; Karen H. Antman, MD; Robert C. Bast Jr, MD; John M. Bennett, MD; Edward J. Benz Jr, MD; Nancy Berliner, MD; Joseph Bertino, MD; Ravi Bhatia, MD; Smita Bhatia, MD; Deepa Bhojwani, MD; Charles D. Blanke, MD; Clara D. Bloomfield, MD; Linda Bosserman, MD; Hal E. Broxmeyer, PhD; John C. Byrd, MD; Fernando Cabanillas, MD; George Peter Canellos, MD; Bruce A. Chabner, MD; Asher Chanan-Khan, MD; Bruce Cheson, MD; Bayard Clarkson, MD; Susan L. Cohn, MD; Gerardo Colon-Otero, MD; Jorge Cortes, MD; Steven Coutre, MD; Massimo Cristofanilli, MD; Walter J. Curran Jr, MD; George Q. Daley, MD, PhD; Daniel J. DeAngelo, MD, PhD; H. Joachim Deeg, MD; Lawrence H. Einhorn, MD; Harry P. Erba, MD, PhD; Francisco J. Esteva, MD, PhD; Elihu Estey, MD; Isaiah J. Fidler, DVM, PhD; James Foran, MD; Stephen Forman, MD; Emil Freireich, MD; Charles Fuchs, MD, MPH; James N. George, MD; Morie A. Gertz, MD; Sergio Giralt, MD; Harvey Golomb, MD; Peter Greenberg, MD; Jordan Gutterman, MD; Robert I. Handin, MD; Samuel Hellman, MD; Paulo Marcelo Hoff, MD; Ronald Hoffman, MD; Waun Ki Hong, MD; Mary Horowitz, MD, MS; Gabriel N. Hortobagyi, MD; Clifford Hudis, MD; Jean Pierre Issa, MD; Bruce Evan Johnson, MD; Philip W. Kantoff, MD; Kenneth Kaushansky, MD; David Khayat, MD, PhD; Fadlo R. Khuri, MD; Thomas J. Kipps, MD, PhD; Margaret Kripke, PhD; Robert A. Kyle, MD; Richard A. Larson, MD; Theodore S. Lawrence, MD, PhD; Ross Levine, MD; Michael P. Link, MD; Scott M. Lippman, MD; Sagar Lonial, MD; Gary H. Lyman, MD, MPH; Maurie Markman, MD; John Mendelsohn, MD; Neal J. Meropol, MD; Yoav Messinger, MD; Therese M. Mulvey, MD; Susan O'Brien, MD; Roman Perez-Soler, MD; Raphael Pollock, MD, PhD; Josef Prchal, MD; Oliver Press, MD, PhD; Jerald Radich, MD; Kanti Rai, MD; Saul A. Rosenberg, MD; Jacob M. Rowe, MD; Hope Rugo, MD; Carolyn D. Runowicz, MD; Brenda M. Sandmaier, MD; Alan Saven, MD; Andrew I. Schafer, MD; Charles Schiffer, MD; Mikkael A. Sekeres, MD, MS; Richard T. Silver, MD; Lillian L. Siu, MD; David P. Steensma, MD; F. Marc Stewart, MD; Wendy Stock, MD, MA; Richard Stone, MD; Rainer Storb, MD; Louise C. Strong, MD; Martin S. Tallman, MD; Michael Thompson, MD, PhD; Naoto T. Ueno, MD, PhD; Richard A. Van Etten, MD, PhD; Julie M. Vose, MD, MBA; Peter H. Wiernik, MD; Eric P. Winer, MD; Anas Younes, MD; Andrew D. Zelenetz, MD, PhD; and Charles A. LeMaistre, MD

1. Express Scripts. 2015 Drug Trend Report, March 2016. http://lab.express-scripts.com/lab/drug-trend-report.
2. ASCO. The State of Cancer Care in America, 2016: A Report by the American Society of Clinical Oncology. *Journal of Oncology Practice.* 2016;12(4):339-383.
3. Tefferi A, et al. *Mayo Clin Proc.* 2015;90(8):996-1000.

Can we afford drugs for rare diseases?

Harvard Business Review

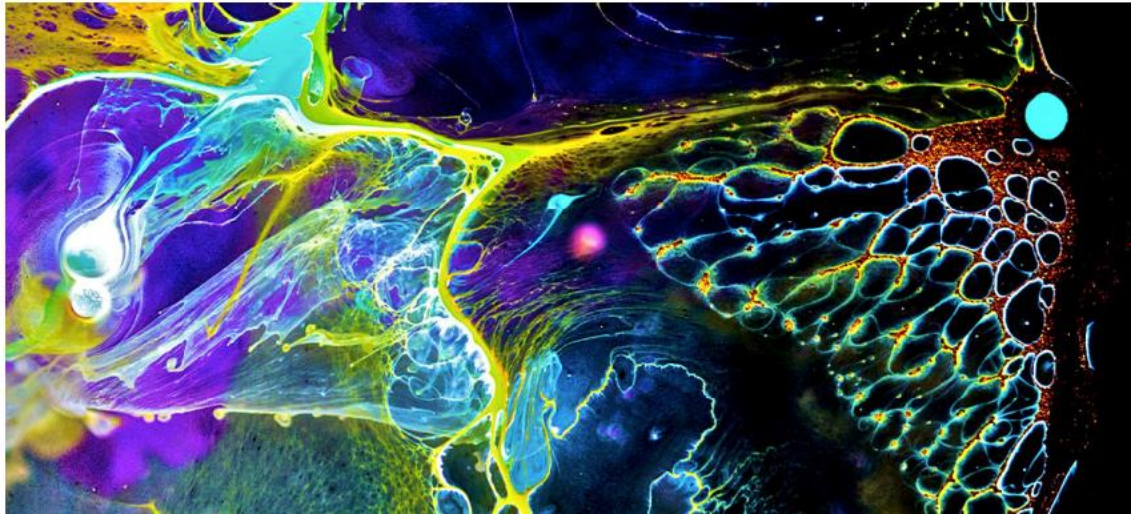
$750,000 per year for SMA treatment

POLICY

The Cost of Drugs for Rare Diseases Is Threatening the U.S. Health Care System

by A. Gordon Smith

APRIL 07, 2017



United States Pharmaceutical Value Frameworks

- American Society for Clinical Oncology (ASCO)
- Memorial Sloan Kettering Cancer Center (MSKCC) DrugAbacus
- National Comprehensive Cancer Network (NCCN) Evidence Blocks
- Institute for Clinical and Economic Review (ICER)
- American College of Cardiology / American Heart Association

ACC/AHA Framework

Journal of the American College of Cardiology
© 2014 by the American College of Cardiology Foundation and the American Heart Association, Inc.
Published by Elsevier Inc.
Vol. 63, No. 21, 2014
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2014.03.016

PERFORMANCE MEASURES

ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures

A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines

Label	Thresholds	Qualifying Statements
High	< $50,000 / QALY gained	Better outcomes at lower cost (dominant) or threshold value
Intermediate	$50,000 to $150,000 / QALY gained	
Low	> $150,000 / QALY gained	
Uncertain		Insufficient data to draw conclusions
Not assessed		Value not assessed by guideline committee

Source: Journal of the American College of Cardiology 2014; 63(21):2305-2322

ACC/AHA Framework

- Association developed framework
- Focusses on guidelines to drive physician/patient decision making
- Limited to cardiovascular conditions
  - Not drug specific

American Society of Clinical Oncology (ASCO) Framework – Version 2.0

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

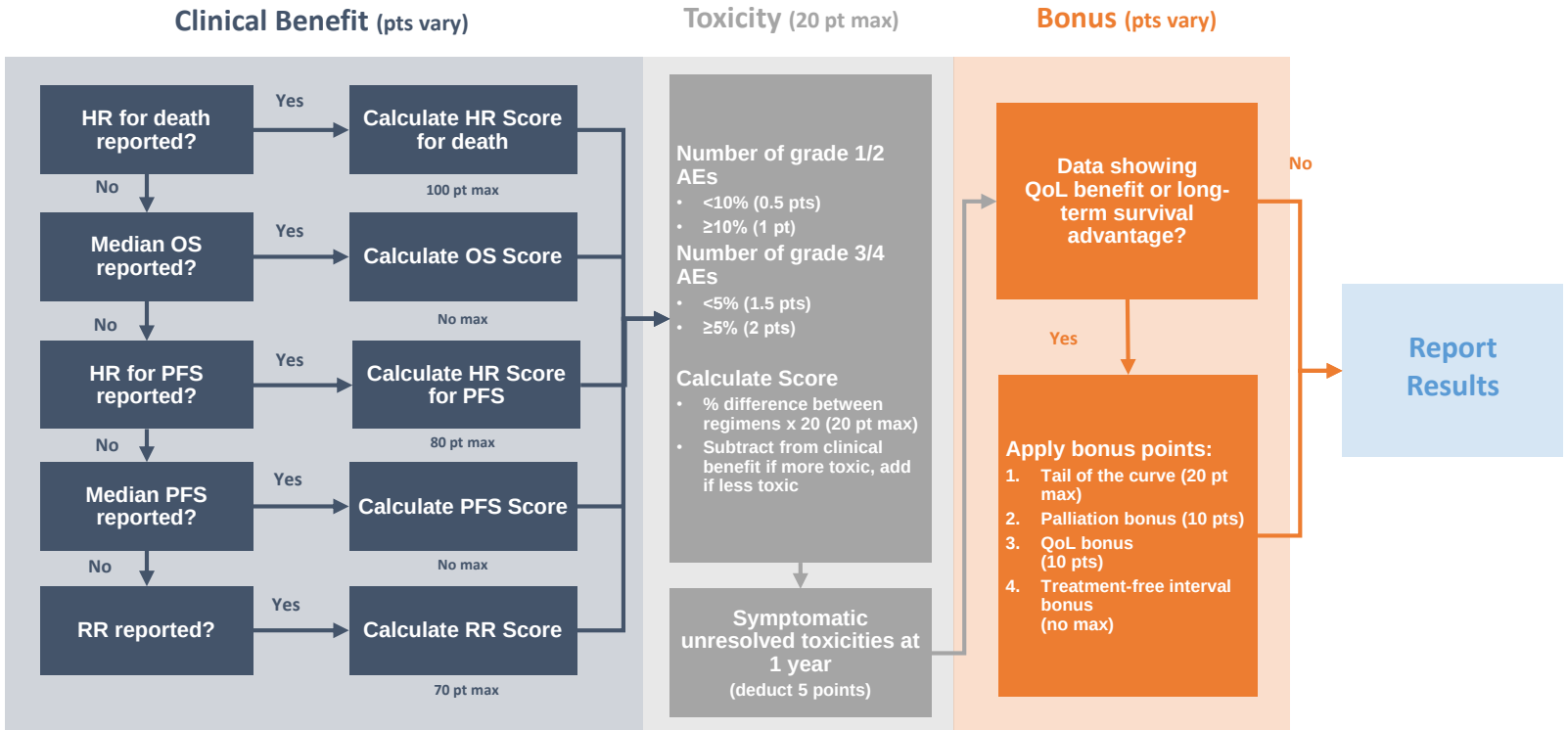
Updating the American Society of Clinical Oncology Value Framework: Revisions and Reflections in Response to Comments Received

Lowell E. Schnipper, Nancy E. Davidson, Dana S. Wollins, Douglas W. Blayney, Adam P. Dicker, Patricia A. Ganz, J. Russell Hoverman, Robert Langdon, Gary H. Lyman, Neal J. Meropol, Therese Mulvey, Lee Newcomer, Jeffrey Peppercorn, Blase Polite, Derek Raghavan, Gregory Rossi, Leonard Saltz, Deborah Schrag, Thomas J. Smith, Peter P. Yu, Clifford A. Hudis, Julie M. Vose, and Richard L. Schilsky

Source: Journal of Clinical Oncology:
Published Ahead of Print on May 31, 2016 as 10.1200/JCO.2016.68.2518

ASCO Value Framework: Summary

Advanced disease scoring schematic



AE = adverse event; OS = overall survival; PFS = progression-free survival; RR = response rate.

Schematic based on Schnipper LE, et al. *J Clin Oncol.* 2016;10.1200/JCO.2016.68.2518.

ASCO Framework

- Focus on Provider – Patient decision process
- Goal:
  - “standardized approach to assist physicians and patients in assessing value of a new drug treatment for cancer as compared to one or several prevailing standards of care”
- Limited to oncology directed treatments (“pharmaceuticals”)
- Sophisticated algorithm to calculate “net health benefit score”

Source: Journal of Clinical Oncology:
Published Ahead of Print on May 31, 2016 as 10.1200/JCO.2016.68.2518

ASCO Frameworks

- Net Health Benefits (Advanced Cancer)
  - Clinical benefits
    - Hazard ratio for death
    - Median overall survival
    - Hazard ratio for progression-free survival
    - Median progression-free survival
    - Response rate
  - Toxicity
  - Bonus points
    - Tail of the curve
    - Palliation of symptoms
    - Quality of Life
    - Treatment-free interval
- Cost

- Net Health Benefits (Adjuvant Cancer)
  - Clinical benefits
    - Hazard ratio for death
    - Median overall survival
    - Hazard ratio for disease-free survival
    - Median disease-free survival
  - Toxicity
  - Bonus points
    - Tail of the curve
- Cost

Clinical Benefits (Advanced Disease)

Outcome	Calculation method
Hazard ratio for death	1-HR X 100
Overall survival (OS)	Difference in percentage survival X 100
Hazard ratio for progression-free survival (PFS)	1-HR X 100 X 0.8
Median progression-free survival (PFS)	Difference in percentage PFS X 100 X 0.8
Response rate (complete response + partial response)	RR X 100 X 0.7

Note: Only one attribute is allowed

Source: Journal of Clinical Oncology:
Published Ahead of Print on May 31, 2016 as 10.1200/JCO.2016.68.2518

Toxicity

Calculate toxicity for each relevant adverse event from clinical trial experience

	Grade 1 or 2 Toxicity		Grade 3 or 4 Toxicity	
Frequency	< 10%	≥ 10%	< 5%	≥ 5%
Points	0.5 points	1.0 points	1.5 points	2.0 points

- Sum all toxicity scores across the events for each treatment arm
- Toxicity score = Difference in toxicity scores X 20
- If treatment is more toxic than comparator – subtract score from clinical benefit score
- If treatment is less toxic than comparator – add score to clinical benefit score

Source: Journal of Clinical Oncology:
Published Ahead of Print on May 31, 2016 as 10.1200/JCO.2016.68.2518

Tail of the Curve Bonus Points (Advanced Disease)

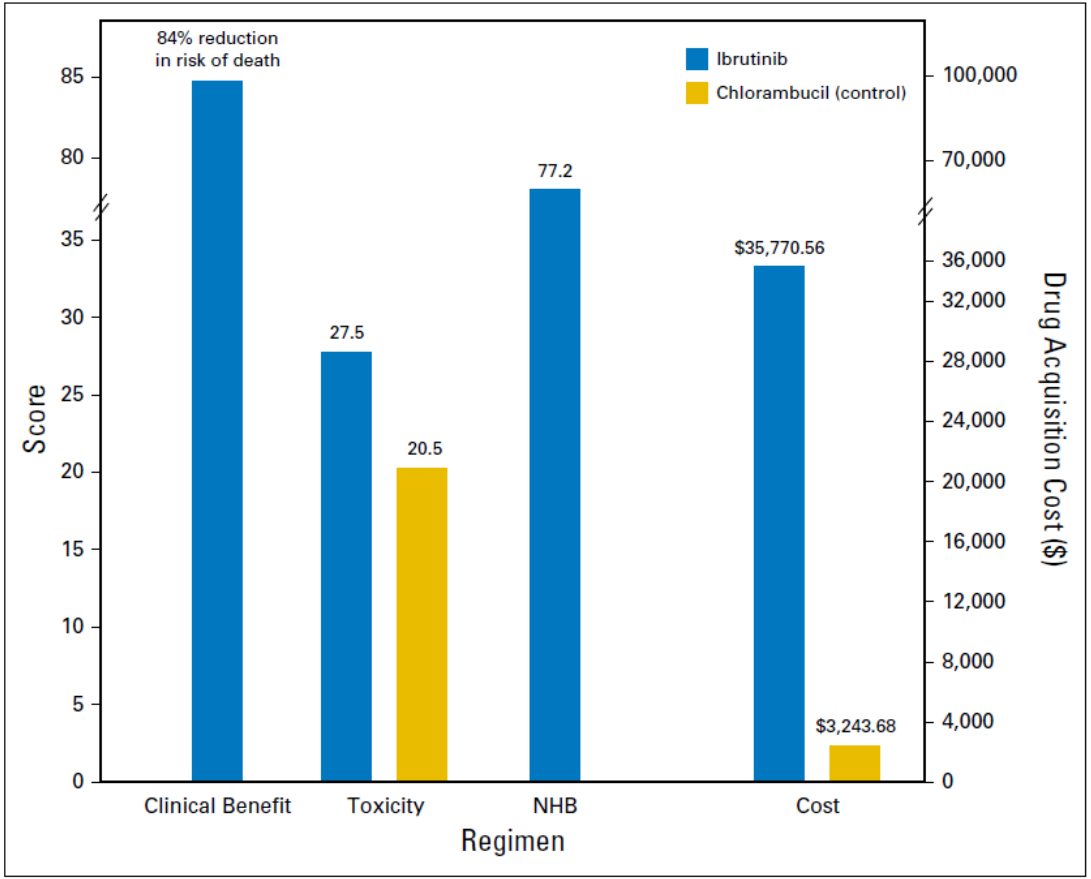
- Identify the time point on the survival curve that is 2X the median OS or PFS of the comparator regimen.
  - If ≥50% improvement in patients alive at this time point
    - Assuming ≥ 20% survival with comparator
  - + 20 points if Overall Survival (OS)
  - + 16 points if Progression-Free Survival (PFS)

Source: Journal of Clinical Oncology:
Published Ahead of Print on May 31, 2016 as 10.1200/JCO.2016.68.2518

ASCO Value Framework: Presentation of Results

ASCO results reflect a cost-consequence analysis

- Results
  - Clinical benefit, not score
  - Toxicity (points for each regimen), not score
  - Net Health Benefit (NHB) score
  - Bonus points are not included
  - Cost (for each regimen)
  - There is no single measure of value (eg, value-based price, ICER)



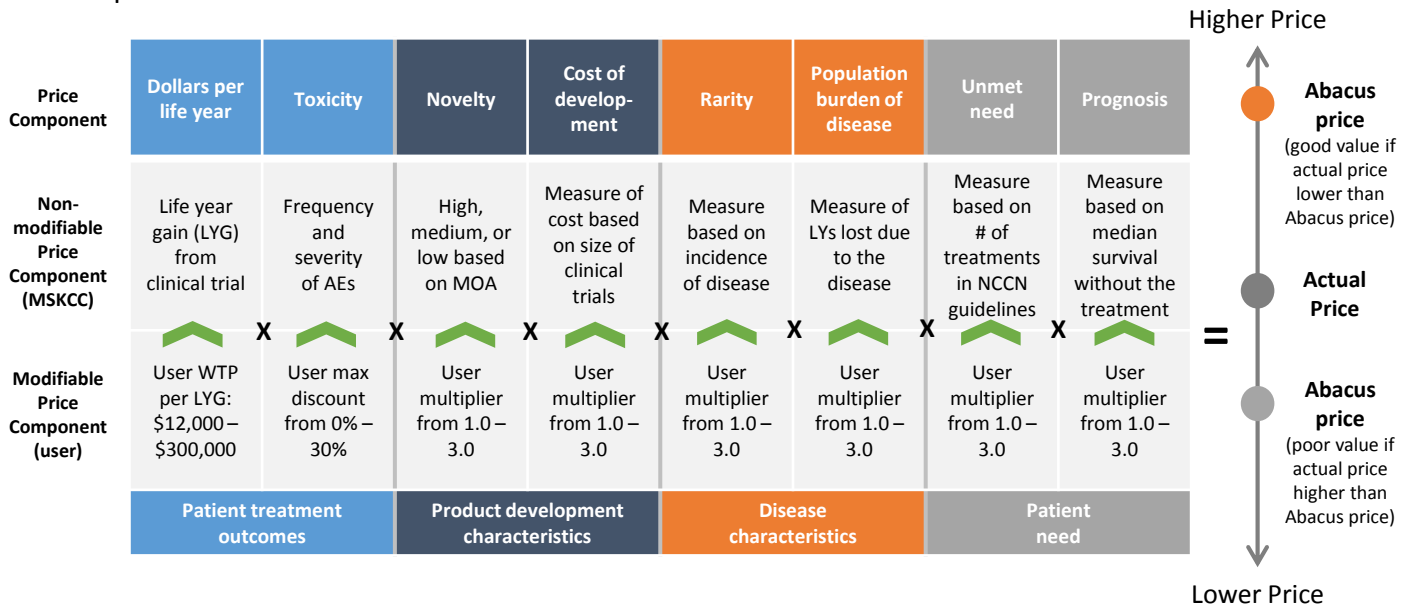
Schnipper LE, et al. *J Clin Oncol.* 2016;10.1200/JCO.2016.68.2518.

ASCO Value Framework: Pros and Cons

☑ Pros	☒ Cons
• Methodological transparency, algorithm available • User can conduct own analysis, not reliant upon framework developer • May encourage cost discussion between providers and patients • Includes points for patient QOL • Includes patient out-of-pocket costs (in addition to total acquisition costs)	• Calculator not yet available (only score sheet, which is more challenging to use) • Trial comparator and endpoints can have a significant impact on clinical benefit score • NHB score not meaningful by itself and cannot be compared across drugs • Toxicity points may not capture value • Does not include medical costs • Difficult to use with single-arm trials

MSKCC DrugAbacus: Summary

The DrugAbacus price is a value-based price based on the user's preferences regarding the price components



MSKCC DrugAbacus: Pros and Cons

Pros	Cons
• Online availability and easy-to-use user-friendly tool • Focus on value-based price potentially useful to payers and policymakers • Wide range of value metrics included in the tool, captures broader societal perspective • Allows users to conduct an analysis reflective of their own preferences regarding the value metrics	• Lack of methodological transparency, not easy to replicate analyses • Not up to date, new drugs on market have not been incorporated • Toxicities are underweighted • Does not include QOL • Does not include full regimen costs (only costs of listed drug) • User preferences can be modified to justify almost any price

ICER – Institute for Clinical and Economic Review

A non-profit organization that evaluates evidence on the value of medical tests, treatments and delivery system innovations and moves that evidence into action to improve the health care system.

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Source: https://icer-review.org/

ICER's Evaluation Process

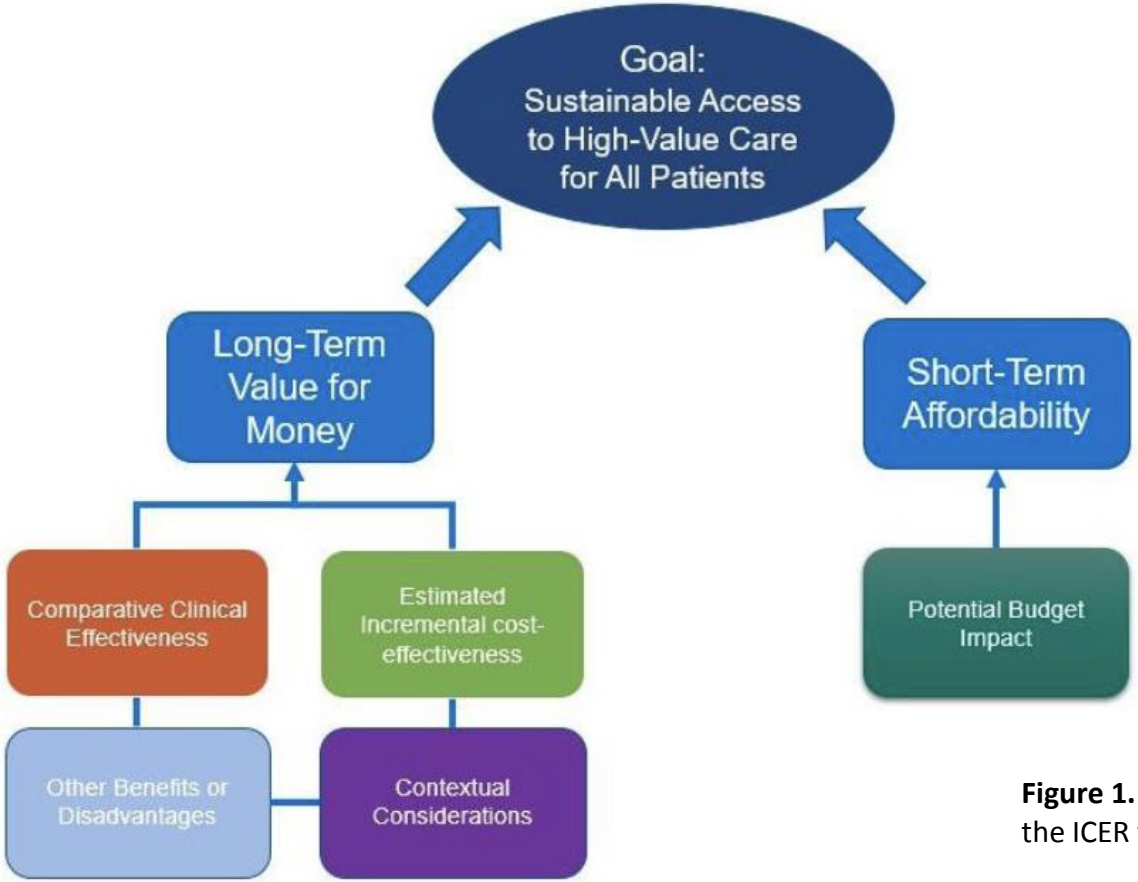


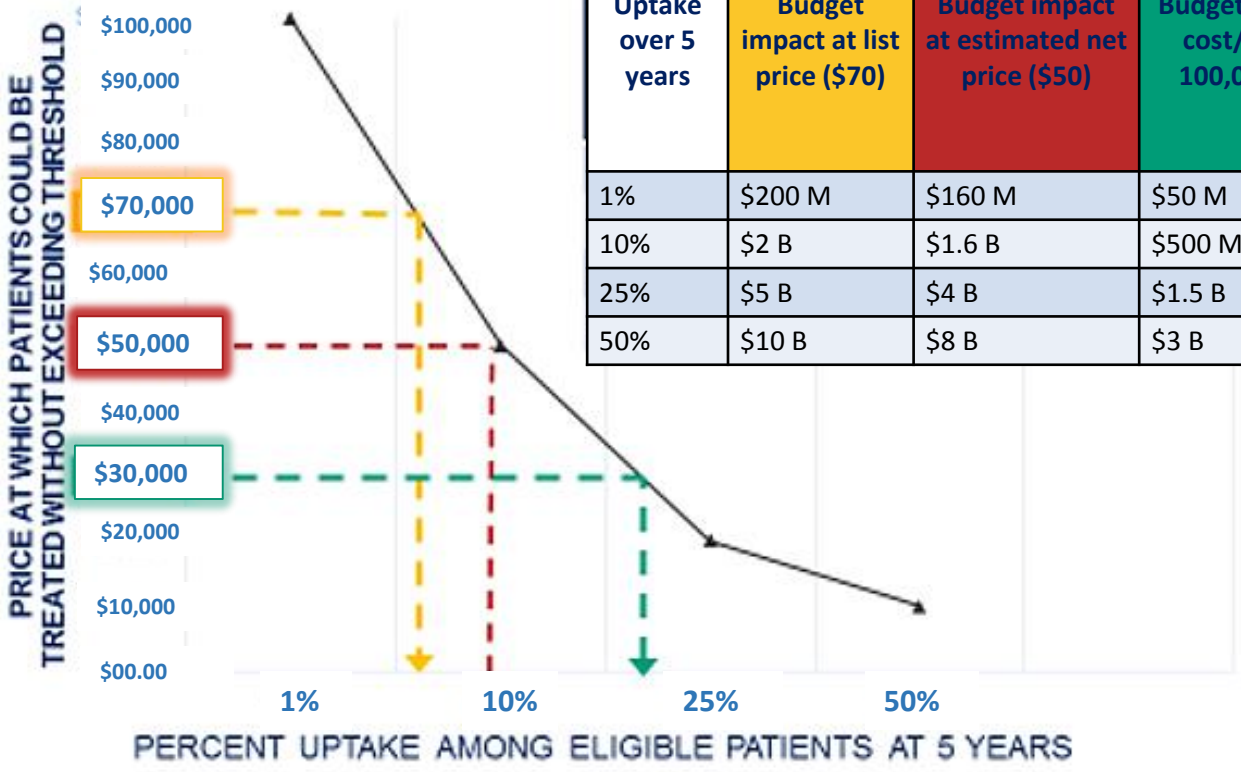
Figure 1. New Conceptual structure of the ICER value assessment framework

Specifics of ICER's Methods

- Replacement of "care value" with "long-term value for money"
- Incremental cost-effectiveness ratios
  - Threshold values
    - $50,000 to $150,000 / QALY
  - Based on:
    - 1-3x GDP
    - Similar to ACC/AHA stated thresholds
    - Willingness to pay studies suggest $90,000 / QALY

Budget Impact Analysis

POTENTIAL BUDGET IMPACT SCENARIOS



Uptake over 5 years	Budget impact at list price ($70)	Budget impact at estimated net price ($50)	Budget impact at cost/QALY of 100,000 ($30)
1%	$200 M	$160 M	$50 M
10%	$2 B	$1.6 B	$500 M
25%	$5 B	$4 B	$1.5 B
50%	$10 B	$8 B	$3 B

ICER

ICER Evaluation of PCSK9 Cholesterol Lowering Agents

	Person-years of treatment (millions)	Total MACE averted	NNT_5†	QALYs gained^	Incremental Drug Costs^ (million $)	Incremental Costs, Other CV Care^ (million $)	ICER ($/QALY)
Statin§	*comparator*						
Statin + Ezetimibe‖,¶	22.3	115,900	77	250,600	$40,359	-$6,632	$135,000
Statin + PCSK9 inhibitor**,¶	23.7	324,200	28	665,200	$210,516	-$17,304	$290,000

Source: https://icer-review.org/materials/ - PCSK9 Final report

Benchmark Price for Evolocumab

Table 6. Value-based Benchmark Prices* for Evolocumab Among Patients with a History of ASCVD, an LDL-C of ≥70 mg/dL, and Current Use of Statins.

Agent	WAC*	Cost to achieve $100k/QALY*	Cost to achieve $150K/QALY*	Discount from WAC to reach threshold*	Current net price discount sufficient?
Evolocumab	$14,523	$1,725	$2,242	85% to 88%	No

QALY: quality-adjusted life year, WAC: wholesale acquisition cost

*Annual prices

Evolocumab for Treatment of High Cholesterol: Effectiveness and Value, September 11, 2017

Comparisons Across Frameworks – Methods

Attribute	ACC-AHA	ASCO 2.0	DrugAbacus	ICER	NCCN
Type of method	Cost-utility analysis	New – multiple criteria	New – multiple criteria	Cost-effectiveness / budget impact	New
Evidence provided by manufacturer	No – preference for published studies	No	No	No	Yes
Discussion /inclusion of sensitivity analysis	No	No	No	Yes – depends on analysis	No

Comparisons Across Frameworks – Costs

Attribute	ACC-AHA	ASCO 2.0	DrugAbacus	ICER	NCCN
Is cost included?	Yes-part of cost-effectiveness	Yes – reported separately	Yes – user determines "weight" of cost	Yes – part of cost-effectiveness analysis	Yes – reported separately
How to value technology cost	Not discussed	Acquisition cost /patient cost sharing	Medicare fee schedule/cost	Not specified – market price /fee schedules	Ordinal scale (1-5) rated by members
Other costs included/ allowed?	Yes	No	No	Yes	No

Summary

- Numerous ”Value-Frameworks”
- High cost of medications driving the desire to use value frameworks
- Some managed care organizations “love” the ICER work
  - CVS supports ICER’s approach @ $100,000 / QALY
- Numerous issues with the existing value frameworks
- Defining ”value” is challenging

Role of HEOR in Decision Making: Global Knowledge for Local Application

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Role of HEOR in Decisions – a UK Perspective

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UK structure

- The United Kingdom has a population of 66.57million (2018) and consists of England, Scotland, Wales and Northern Ireland
- The National Health Service (NHS) provides the majority of health services throughout the UK, and each country has its own structure and budget for organising the NHS
- The National Institute for Health and Care Excellence (NICE) was established in legislation during the late-1990s.
- NICE guidance is officially England-only. However, there are agreements to provide certain NICE products and services to Wales, Scotland and Northern Ireland.
- Decisions on how NICE guidance applies in these countries are made by the devolved administrations, who are often involved and consulted with in the development of NICE guidance.

NHS in ENGLAND

- Almost all NHS revenue comes from taxes, with a small proportion from charges for prescriptions
- Population of England = 55.33million (2018).
- The government spent about £122 billion on health in England in 2017/18, or roughly £2,200 per person. About £108 billion was spent on the day-to-day running of the NHS. Estimated total NHS spending on medicines in England has grown from £13 billion in 2010/11 to £17.4 billion in 2016/17 (an average growth of around 5 per cent a year).
- Much of the recent growth in medicines spending has been in the hospital sector, where estimated costs have grown at around 12 per cent a year on average since 2010/11. Today hospitals account for nearly half of total NHS spending on medicines.
- In primary care, spending growth has been much lower. Although the volume of prescription items provided to patients increased by almost half in the decade to 2016 (to 1.1 billion items), which was offset by a reduction of nearly a quarter in the average cost per prescription item (to £8.34).

NHS in SCOTLAND

- Health spending in Scotland was about £13.2 billion in 2017/18, or around £2,500 per person.
- Population: 5.4million (2018).
- The Scottish Medicines Consortium (SMC) decides whether new medicines should be routinely available for prescribing by the NHS in Scotland based on its assessment of the value for money of those new medicines.

NHS in WALES

- Almost all from Welsh government . No charges for prescription but they are charges for dentist and opticians
- Population: 3.1million 2018
- Health spending in Wales is planned to be £7.3 billion in 2017/18, or roughly £2,300 per person. Like Scotland, this includes some money for sport as well as health
- The Welsh Assembly Government has an agreement in place with NICE covering the Institute's technology appraisals, clinical guidelines and interventional procedure guidance, which all continue to apply in Wales.

NHS in NORTHERN IRELAND

- NORTHERN IRELAND In Northern Ireland the NHS is referred to as the Health and Social Care Service (HSC) and includes hospitals, GP services, and community health and social services.

- Population: 1.8million

- Health spending in Northern Ireland in 2016/17 was £5 billion, or roughly £2,700 per person.

HTA in UK

- National Institute for Health and Care Excellence (NICE) in England
- Scottish Medicines Consortium (SMC) in Scotland
- All Wales Medicines Strategy Group (AWMSG) in Wales.
- There is no separate Health Technology Appraisal (HTA) body in Northern Ireland that assesses medicines for use within the HSC. Northern Ireland essentially adopts NICE guidance

NICE's role

To improve outcomes for people using the NHS and other public health and social care services by:

- Producing evidence-based guidance and advice for health, public health and social care practitioners.
- Developing quality standards and performance metrics for those providing and commissioning health, public health and social care services.
- Providing a range of information services for commissioners, practitioners and managers across the spectrum of health and social care.

Bournemouth University

nice.org.uk

Our guidance takes several forms:

NICE guidelines make evidence-based recommendations on a wide range of topics, from preventing and managing specific conditions, improving health and managing medicines in different settings, to providing social care to adults and children, and planning broader services and interventions to improve the health of communities. These aim to promote integrated care where appropriate, for example, by covering transitions between children's and adult services and between health and social care.

Technology appraisals guidance assess the clinical and cost effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, but also include procedures, devices and diagnostic agents. This is to ensure that all NHS patients have equitable access to the most clinically - and cost-effective treatments that are viable.

Our medical technologies and diagnostics guidance help to ensure that the NHS is able to adopt clinically and cost effective technologies rapidly and consistently.

Interventional procedures guidance recommends whether interventional procedures, such as laser treatments for eye problems or deep brain stimulation for chronic pain are effective and safe enough for use in the NHS.

NICE processes

Technology appraisals take one of three forms:

- A **single technology appraisal (STA)** which covers a single technology for a single indication.
- A **fast track appraisal (FTA)** which also covers a single technology for a single indication but with a shorter process time to speed up access to the most cost-effective new treatments.
- A **multiple technology appraisal (MTA)** which normally covers more than one technology, or one technology for more than one indication.

On 3 April 2018 we published an updated technology appraisals process guide which covers the single technology appraisal and fast track appraisal processes, as well as including processes for the Cancer Drugs Fund and assessing budget impact. The process for multiple technology appraisal can be found in the process guide published in September 2014.

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Section V.

Health Research

Health Research in UK

- Each UK nation has its own government department that oversees health and care research:
- The *National Institute for Social Care and Health Research* (NISCHR) is the Welsh Government body that develops strategy and policy for research in the NHS and social care in Wales.
- The *Chief Scientist Office* (CSO), part of the Scottish Government's Health and Social Care Directorate, supports and promotes high quality research aimed at improving the quality and cost-effectiveness of services offered by NHS Scotland and securing lasting improvements to the health of the people of Scotland.
- The *Health and Social Care Public Health Agency* (HSC PHA) is the major regional organisation for health protection wit in Northern Ireland, with a mandate to protect public health, improve public health and social wellbeing, and reduce inequalities in health and social wellbeing.
- The *Department of Health and Social Care* in England funds a Policy Research Programme to provide the evidence-base for robust policy development, as well as funding health and care research through the National Institute for Health Research.

National Institute for Health Research (NIHR)

The NIHR funds health and care research and translate discoveries into practical products, treatments, devices and procedures, involving patients and the public in all their work.

The NIHR has a central role in England's health and care research landscape.

The body has several research funding streams related to developing and evaluating new technologies and health service delivery.

Key messages

1. Formal HTA is often treated as a “one-off”, summative evaluation of new technologies
2. UK’s NHS has many institutional mechanisms for promoting cost-effective, affordable service provision
3. There is a growing need for formative, continual processes for supporting NHS decisions

Role of HEOR in Decision Making: Global Knowledge for Local Application

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Improving healthcare decisions

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Role of HEOR in Decision-Making: Global Knowledge for Local Application in Egypt

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syreon
Research Institute

Starting points

- HTA was introduced in high income countries
- HTA implementation requires investment
- How to transfer knowledge form high income countries?

Middle income countries (Egypt)

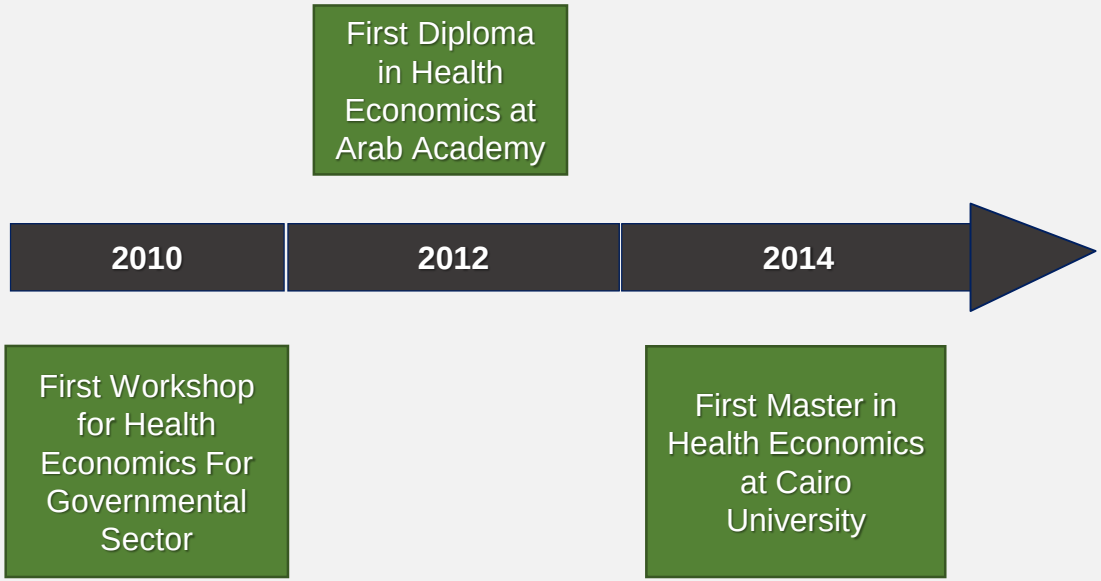
- Compared to high income countries
  - worse health status
  - even more limited health care resources

- Middle income countries need HEOR more than high income countries.

Investment needed for implementation

- Human capacities
- Financial resources
- Local data (IT infrastructure; patient registries)
- Political commitment
- Consistency in implementation

Development Of Health Economics Education in Egypt



Recent Health Economics Education and Activities in Cairo

ISPOR Egypt 2nd Annual Conference 2017

ISPOR Egypt 2nd Annual Conference 2017

Community Health Workers Program 2018

Community Health Workers Program 2018

HTA Summit 2018

Health Insurance Organization 3 days workshop 2018

Pharmaco-Economic Unit

5- years in Egypt

Vision:

Provide scientific guidance of the value of drugs in delivering expected outcomes to decision makers, health professionals and the public.

Pharmaco-Economic Unit cont.

5- years in Egypt

Mission

- Evaluate economic studies of both new and existing pharmaceutical products and medical devices.
- Conduct economic studies for products selected in Tender List, Essential Medicine List and Hospital Formulary.
- Provide education and training programs to build capacities.

Source:Elsisi Gihan

Pharmaco-Economic Unit cont.

5- years in Egypt

Objectives

- Lowering the pharmaceutical expenditure .
- Improvement in accessibility of patients to medicines.

Source:Elsisi Gihan

Recommendations for Reporting Pharmacoeconomic Evaluation in Egypt

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/vhri

CONCEPTUAL PAPER

Recommendations for Reporting Pharmacoeconomic Evaluations in Egypt

Gihan H. Elsisi, MSc[1,*], Zoltán Kaló, MSc, MD, PhD[2], Randa Eldessouki, MSc, MD[3,4], Mahmoud D. Elmahdawy, PharmD[5,6], Amr Saad, MSc, PhD[7], Samah Ragab, MPA[8], Amr M. Elshalakani, MD, MBA[9], Sherif Abaza, MBA[10]

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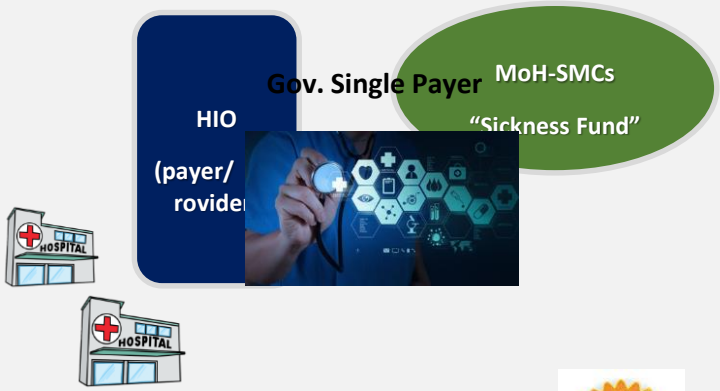
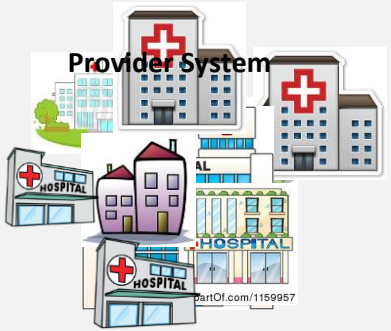
Future: Moving towards Universal Health Care Coverage (SHI)





Public Hospitals & Private Hospitals

Accreditation Body

(Regulator)

Law was published in Jan 2018 and implementation plan on May 2018
New SHI law include creation of HTA department
within payer body

THANK YOU

Role of HEOR in Decision Making: Global Knowledge for Local Application

Ola Ghaleb Al Ahdab, PhD
Ministry of Health and Prevention
United Arab Emirates

ISPOR United Arab Emirates Chapter

Health Economics & Outcomes Research(HEOR) In The UAE: Current Challenges And Potential Opportunities

Ola Ghaleb Al Ahdab, PhD.

- Pharmaceutical Advisor, Drug Department, MOHAP, UAE
- President, ISPOR United Arab Emirates Chapter
- President, ISPOR Arabic Network
- Adjunct Assistant Professor, Colleges of Pharmacy, UAE
- Vice-President FIP Social & Administrative Pharmacy Section
- Vice-President for Pharmacy Society, EMA

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AGENDA

- INTRODUCTION
- THE UAE FACTS & FIGURES
- CURRENT STATUS & CHALLENGES
- PROPOSED PLANS &RECOMMENDATIONS
- SUMMARY

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Introduction: Access to Medicines

- **Innovation & Pre-Registration**
  - Pre-clinical testing: Lab or Animal
  - Clinical testing in Human: (3 Phases)

    1: volunteers, 2 patients, 3 multi-centre
- **Registration/Market Authorization**
  - Safety, Quality & Efficacy, **Affordability**
- **Post registration**
  - **Outcomes Research**
  - PV Reporting/ Post Marketing Surveillance/ Good Pharmacovigilance Practices

PharmacoEconomic (PE) HealthEconomic (HE)

INTRO: Current Status Development in the UAE

- Pharmacoeconomics applications do not compromise clinical care.
- Using economic evaluation methods as decision making tools shall support rational Health Care (HC) spending and promoting/facilitating patient's access to HC services/ pharmacotherapy.
- Expensive health care is not always the best health care
- CEA, CUA, CBA, Budget Impact Analysis, and Risk sharing agreement are an example for HEOR methodologies that promote rational patient access to medicines
- The ISPOR UAE Chapter team provides PE /HEOR Education for UG/PG in Academia
- The ISPOR UAE Chapter start providing HEOR Training
- Few Pharma Industry start to bring expert speakers with HEOR

OECD's Health at a Glance

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Introduction: ISPOR ARABIC NETWORKS

Available Chapters

1. Algeria
2. Egypt
3. Jordan
4. Kuwait
5. Qatar
6. Lebanon
7. Saudi Arabia
8. **United Arab Emirates**

Coming Shortly

- Oman
- Sudan
- Iraq

Key Achievements

- ISPOR Arabic Network established = 2014
- ISPOR Arabic Network: 6 forums in ISPOR Meetings
- ISPOR BOT Arabic translation
- ERP publication with CEE*
- Wrote Chapter IV in Book**

* Zoltán Kaló, Ibrahim Alabbadi, Ola Ghaleb Al Ahdab, Maryam Alowayesh, Mahmoud Elmahdawy, Abdulaziz H Al-Saggabi, Vito Luigi Tanzi, Daoud Al-Badriyeh, Hamad S Alsultan, Faleh Mohamed Hussain Ali, Gihan H Elsisi, Kasem S Akhras, Zoltán Vokóa & Panos Kanavos (June/2015). Implications of external price referencing of pharmaceuticals in Middle East countries. Expert Review of Pharmacoeconomics & Outcomes Research. DOI:10.1586/14737167.2015.1048227

**Güvenç Koçkaya, Albert Wertheimer; Ola Al Ahdab & et al. Pharmaceutical Market Access in Emerging Markets book, (Chapter 6: Market Access in the United Arab Emirates and selected Middle Eastern Countries -Pages 129-162)

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Key Information About The UAE

- Population: 9.12 million population (Dec 2016)
- Total GDP $bn379 (2016 : 2nd in GCC (<KSA) 3rd in MENA region
- Total life expectancy at birth = 76.9 years
- Industry is fuelled with latest technology
- International service providers manage many facilities in the UAE with high standards
- MOHAP has mandated all facilities to achieve International accreditation by 2021.
- Health Insurance models becoming the dominant way of health funding.

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UAE 7th most competitive in the world
Jump from Position 10 to Position 7 in 2018

IMD | IMD WORLD COMPETITIVENESS CENTER

The 2018 IMD World Competitiveness Ranking
One year change

2018	Country	2017	Change
1	USA	4	+3
2	Hong Kong SAR	1	-1
3	Singapore	3	-
4	Netherlands	5	+1
5	Switzerland	2	-3
7	UAE	10	+3
8	Norway	11	+3
9	Sweden	9	-
10	Canada	12	+2
11	Luxembourg	8	-3
12	Ireland	6	-6
13	China Mainland	18	+5
14	Qatar	17	+3
15	Germany	13	-2
16	Finland	15	-1
17	Taiwan	14	-3
18	Austria	25	+7
19	Australia	21	+2
20	United Kingdom	19	-1
21	Israel	22	+1
22	Malaysia	24	+2
23	New Zealand	16	-7
24	Iceland	20	-4
25	Japan	26	+1
26	Belgium	23	-3
27	Korea Rep.	29	+2
28	France	31	+3
29	Czech Republic	28	-1
30	Thailand	27	-3
31	Estonia	30	-1
32	Lithuania	33	+1

2018	Country	2017	Change
33	Portugal	39	+6
34	Poland	38	+4
35	Chile	35	-
36	Spain	34	-2
37	Slovenia	43	+6
38	Kazakhstan	32	-6
39	Saudi Arabia	36	-3
40	Latvia	40	-
41	Cyprus	37	-4
42	Italy	44	+2
43	Indonesia	42	-1
44	India	45	+1
45	Russia	46	+1
46	Turkey	47	+1
47	Hungary	52	+5
48	Bulgaria	49	+1
49	Romania	50	+1
50	Philippines	41	-9
51	Mexico	48	-3
52	Jordan	56	+4
53	South Africa	53	-
54	Peru	55	+1
55	Slovak Republic	51	-4
56	Argentina	58	+2
57	Greece	57	-
58	Colombia	54	-4
59	Ukraine	60	+1
60	Brazil	61	+1
61	Croatia	59	-2
62	Mongolia	62	-
63	Venezuela	63	-

https://www.imd.org/wcc/world-competitiveness-center-rankings/world-competitiveness-ranking-2018

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Pharma-Regulatory Culture

- The Intellectual Property Protection in the UAE considered strong (UAE is WTO member and signatory to TRIPS)
- ≈ 85% of pharmaceuticals are imported
- MOHAP regulates Conventional & Complementary Medicines ; Medical Devices and Veterinary Medicines
- MOHAP regulates Drug Price
- Fast Track: Accelerated Approval and Availability of life saving and innovative drugs in the UAE.
- PV/ Risk management plan for each registered medicine mandatory within registration process
- GCC Price Dollarization and CIF Unification rational and promote patient access to innovative drugs in the GCC.
- Quality healthcare services, Quality Education and capacity building are at the top of the UAE government agenda & 2021 Vision.

*MOHAP (Ministry of Health and Prevention)

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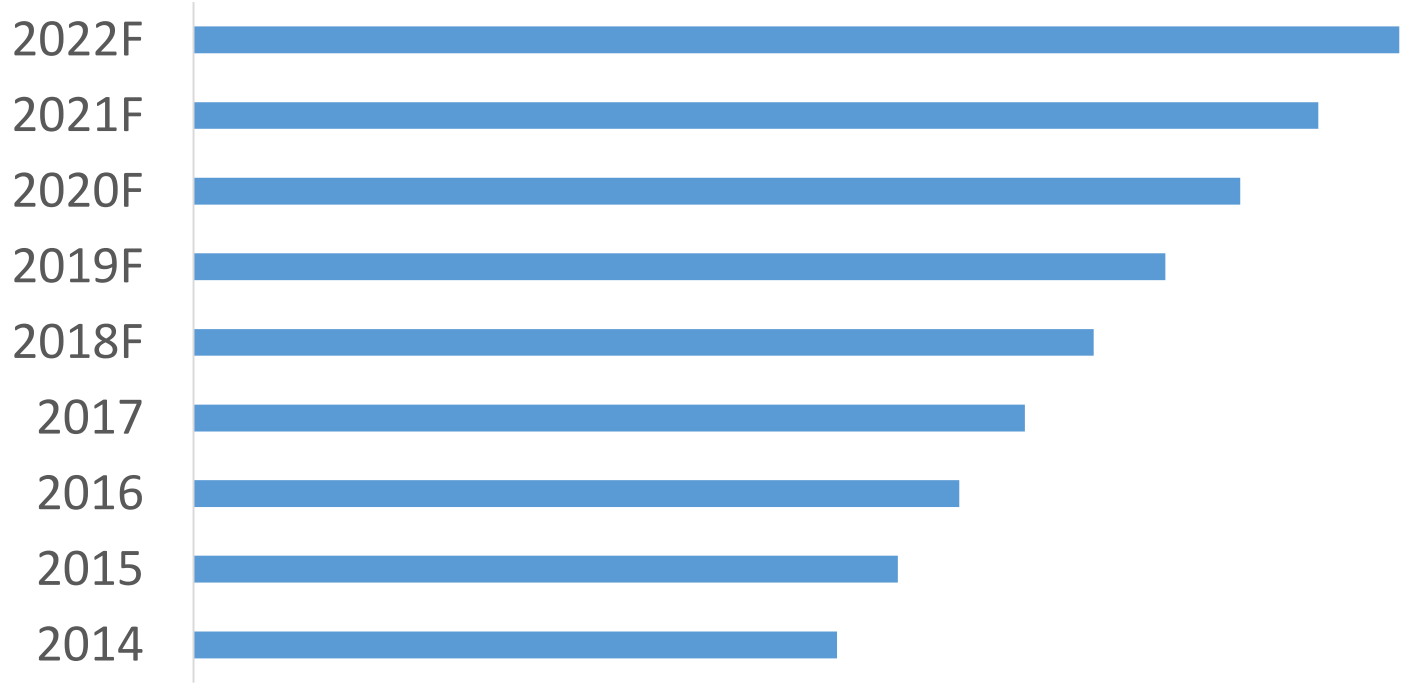
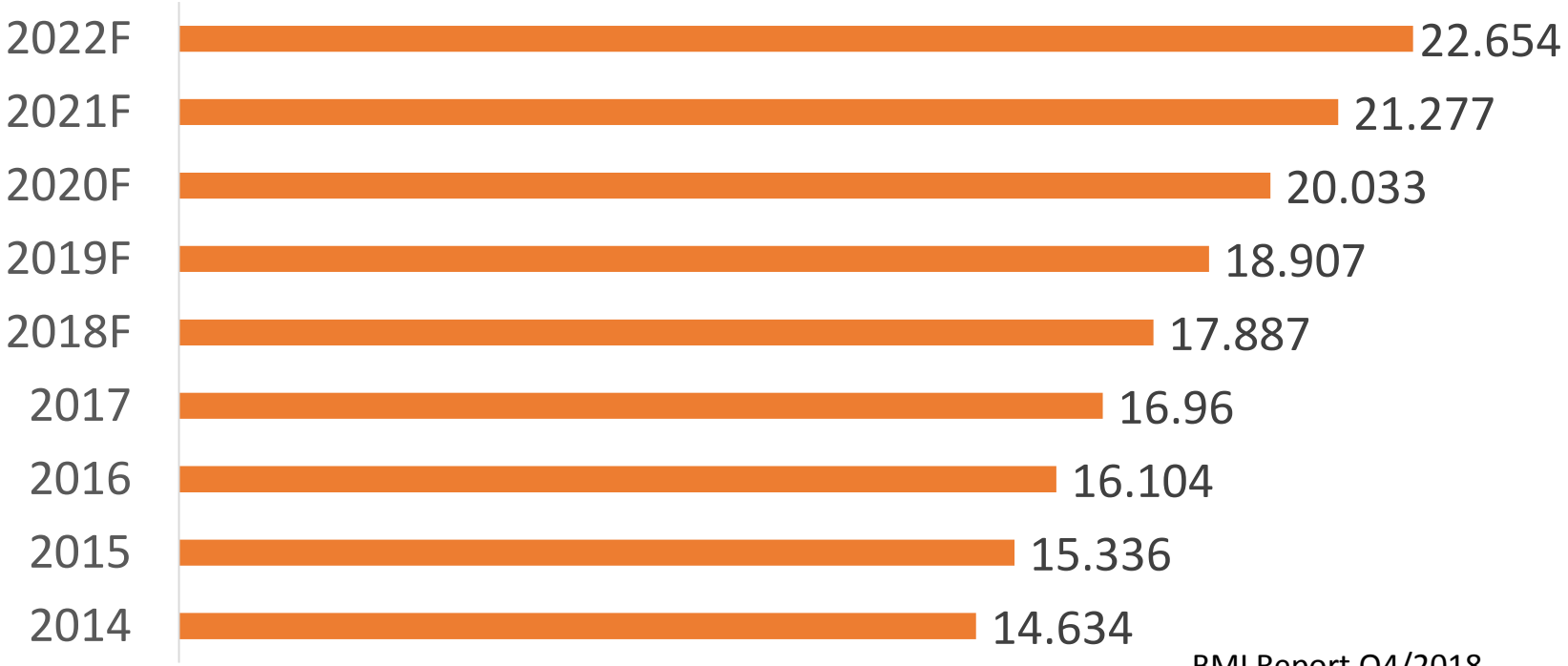
Pharmaceutical Sales Data in the UAE in USDbn (Historical & Forecast)



BMI Report Q4/2018

ISPOR United Arab Emirates Chapter

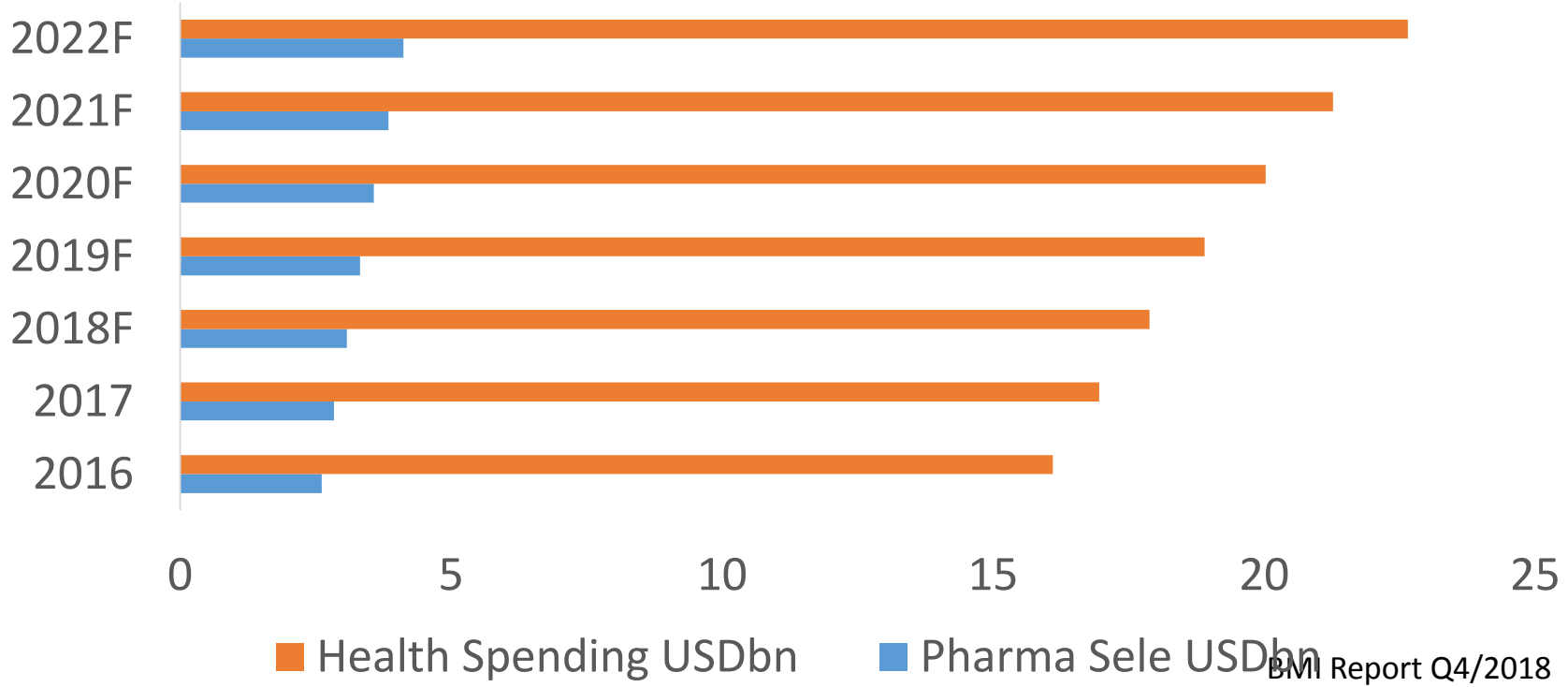
Health Expenditure Data in the UAE in USDbn (Historical & Forecast)



BMI Report Q4/2018

ISPOR United Arab Emirates Chapter

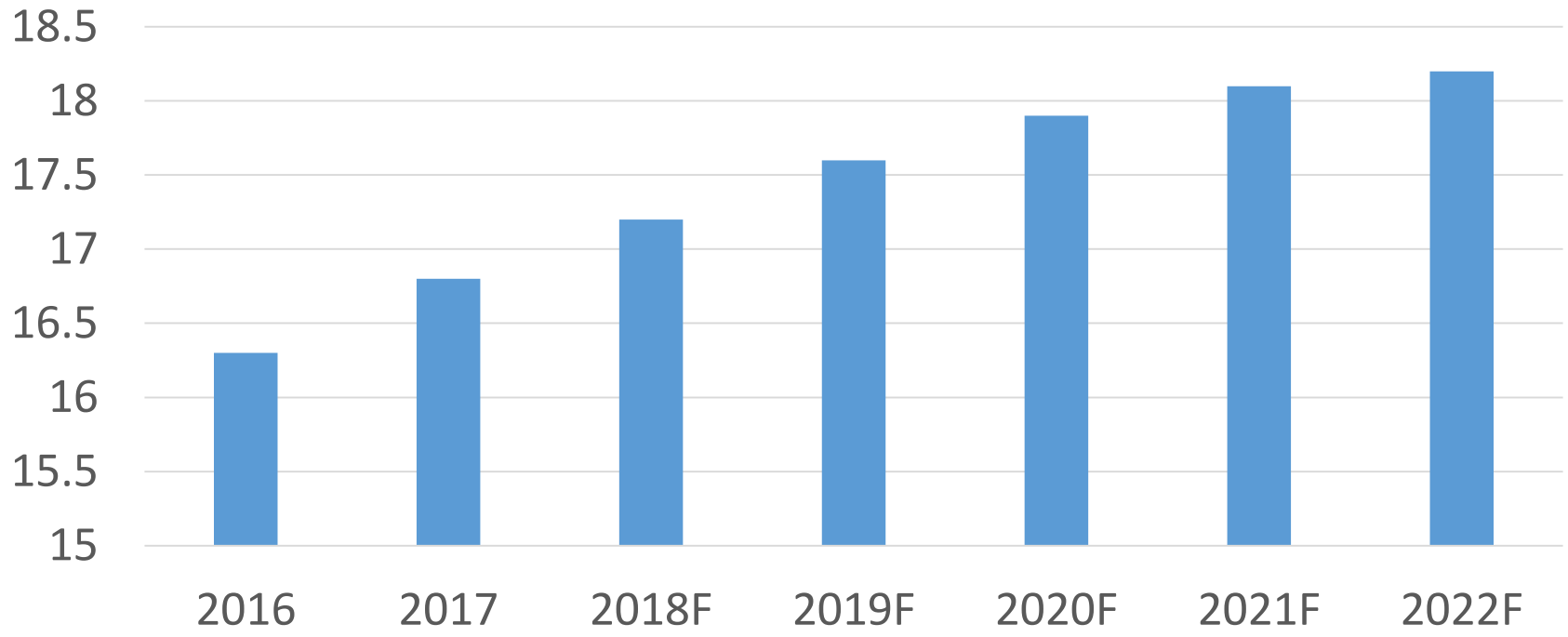
Pharma& Healthcare Expenditure $bn



BMI Report Q4/2018

ISPOR United Arab Emirates Chapter

Pharmaceutical Sale % of Health Expenditure



BMI Report Q4/2018

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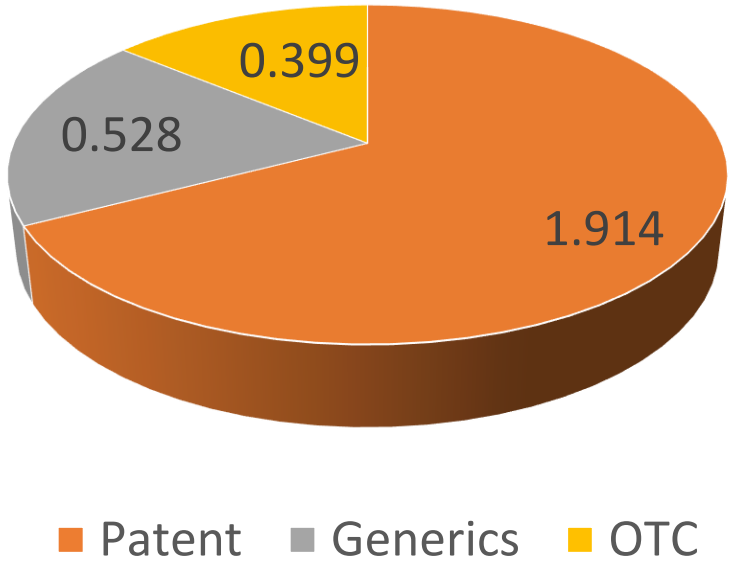
Pharmaceutical Market Sale (2017 2.841 USDbn) By Sub Sector

Patent 67%
Generics 19%
OTC 14%



BMI Q4-2018

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MOHAP Milestones For Pricing Medicines

SN	Initiatives	Year
1	1st Pricing system: Total margin = 70% of CIF price (27.5% local agent and 42.5% Pharmacy) followed by 2 changes 2004 & 2005 affecting local margins	1985
2	Complains published in the media about high prices of medicines in the UAE	2009
3	**CIF Price comparison study (MOH study)**	**2010**
4	**As a result of the above study MOH start Price Reduction waves initiatives from 2011-2017 (7 waves)**	**2011**
5	**Current Pricing System-Key Changes (June 2013)**	**2013**
6	MENA External Price Referencing (EPR) Survey, conducted by ISPOR Regional Chapters in the region	2014
7	GCC Price Harmonization: Dollarization & CIF Unification	2015

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Current Pricing System-Key Changes (June 2013)

1.CIF Prices in USD*

2.Medicines are categorized in 3 categories as per CIF in AED

A	B	C
CIF ≤ 250 AED/ ≈ 68$	CIF >250 to 500 AED/≈136$	CIF >500 AED/ >136$
Pharmacy Margin from WSP		
24%	20%	17%

3.New Profit Margins:

- **Total Margin = 35-43% from CIF to RP/PP**
- **Wholesaler margin: 15% of CIF** (11% of WSP)
- **Pharmacy margins** : **17-24% of WSP =** (20-28% from CIF)
- **Total Margin from CIF** to RP/PP range from 35-43%

The Ex-Factory price in AED for local companies will substitute for the CIF import price AED

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MENA Region : An Overview

- Pricing medication is controlled by government
- Public Pharmaceutical market procured by tendering
- >140 pharmaceutical factories operating across the region
- Local production dominated by Generic Manufacturers
- Strong dependence on imported finished products
- Strong dependence on imported raw materials
- There is a slowdown in the GDP growth as a result of low oil prices (regional challenges)

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Are We Ready: For Using Economic Evaluation Formally?

- Cost Effective Analysis (CEA); Budget Impact Analysis (BIA); HTA; Value Based Pricing & Pay for Performance/Managed Entry Agreement (MEAs) are an example for decision making tools that promote rational access to innovated medicines and facilitate the rational reimbursement decision
- However, Middle East countries & the UAE are relatively underdeveloped in applying PE/HE & HTA for formulary inclusion and reimbursement decisions
- **Barriers to the use of economic evaluation are existing**

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The Situation In The UAE

- HCPs from around the world & mix education background
- High potential for irrational use & wastage of HC resources
- Lack of updated Standard Treatment Guidelines for many diseases
- Lack of appropriate service training and education
- Gaps in academic syllabus and the practice needs
- Lack of valid willingness to pay per QALY
- Lack of active communications between partners & Stakeholders
- Relatively new health insurance & reimbursement system
- Lack of related regulations and mandates
- Lack of healthcare data base
- Lack of related drug use study and outcomes research
- Lack of HE, PE & HTA infrastructure
- Lack of experts in HE, PE and Health Technology Assessment

Challenges Towards Implementing HEOR, PE/HE & HTA

Major challenges need to get the right strong recommendations are:

1. Lack of data & Lack of publication
2. Lack of professional manpower
3. Budget impact analysis may provide more useful tool, needs how could promoted for use
4. Availability of HTA is long term objectives that need a strong infrastructure
5. Quality healthcare services, Quality Education and capacity building are at the top of the UAE government agenda in order to be among top countries as per UAE vision 2021
6. Value Assessment in Hospital Based-Formulary Management; within this, issues such as the following may be elicited:
   - Multiple decision makers in these hospitals/Healthcare organisations may have different evidence needs.
   - How could Rapid Review of evidence provide timely decision making in a dynamic environment, yet relevant to all decision makers.

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What We Need ?

1. Active communication/collaboration
2. Appropriate education for decision makers, healthcare professionals and the public
3. HE, PE & HTA infrastructure:
    - Independent HTA Agency
    - Related regulations and mandates
    - Pharmaceutical/ HCS Database
    - Implemented PE/HE Guideline
    - Valid willing to pay value per QALY/LYG
    - Related studies & outcomes research
    - Dynamic Clinical Guideline(s)
    - Education and training for decision makers, healthcare professionals and the public
    - Develop UAE patients advocate

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Proposed Strategic Plan: Implementing PE/HTA

I. Short Term Plan (1-5 years)

II. Long Term Plan (>5years)

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Summary

- PE/HE& HTA are needed and the future's decision making tools for formulary and re-imbursement process in the UAE and the region.
- Joint efforts & collaboration among partners & stakeholders are the key driver to have sustainable health care system and in developing & implementing the HE, PE & HTA in the UAE&MENA
- Barriers to the use of economic evaluation are existing
- Regulators, academia & ISPOR regional Chapters have an important role to overcome current challenges, in capacity building, providing appropriate training & education and in developing and implementing HE, PE & HTA in the UAE
- **High level governmental support is an essential requirement to facilitate the development and implementation of PE/HE&HTA**

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The Way Forward: UAE VISION 2021

We want to be among the best countries in the world by 2021

"With our Citizens at the heart of development, we strive to become one of the most competitive countries in the world"

His Highness Sheikh Mohammed Bin Rashid Al Maktoom

ISPOR
United Arab Emirates Chapter

22-26 Sep 2019
FIP Congress in ABU Dhabi

79th FIP World Congress of Pharmacy and Pharmaceutical Sciences

Abu Dhabi,
United Arab Emirates
22 - 26 September 2019

SAVE THIS DAYS

New horizons for Pharmacy – Navigating winds of change

ISPOR United Arab Emirates Chapter

Key Resources

- Ministry of Economy www.economy.gov.ae
- UAE Statistics www.uaestatistics.gov.ae
- BMI Q4-2018 report
- MOHAP Data www.mohap.gov.ae
- World Bank Reports www.worldbank.org
- The IMD World Competitiveness Centre https://www.imd.org/wcc/world-competitiveness-center-rankings/world-competitiveness-ranking-2018
- www.ispor.org

- Jomkwan Yothasamut, Sripen Tantivess, Yot Teerawattananon. Using Economic Evaluation in Policy Decision-Making in Asian Countries: Mission Impossible or Mission Probable? (ISPOR) 1098-3015/09/S26
- Güvenç Koçkaya, Albert Wertheimer; Ola Al Ahdab & et al. Pharmaceutical Market Access in Emerging Markets book, (Chapter 6: Market Access in the United Arab Emirates and selected Middle Eastern Countries -Pages 129-162)
- Al Ahdab, O. (2008). Role of Pharmacoeconomics in Clinical Pharmacy Service Development. PhD thesis, Queen's University, School of Pharmacy.

Q&A

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Thank you

Role of HEOR in Decision Making: Global Knowledge for Local Application

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