Applied Pharmacoeconomics

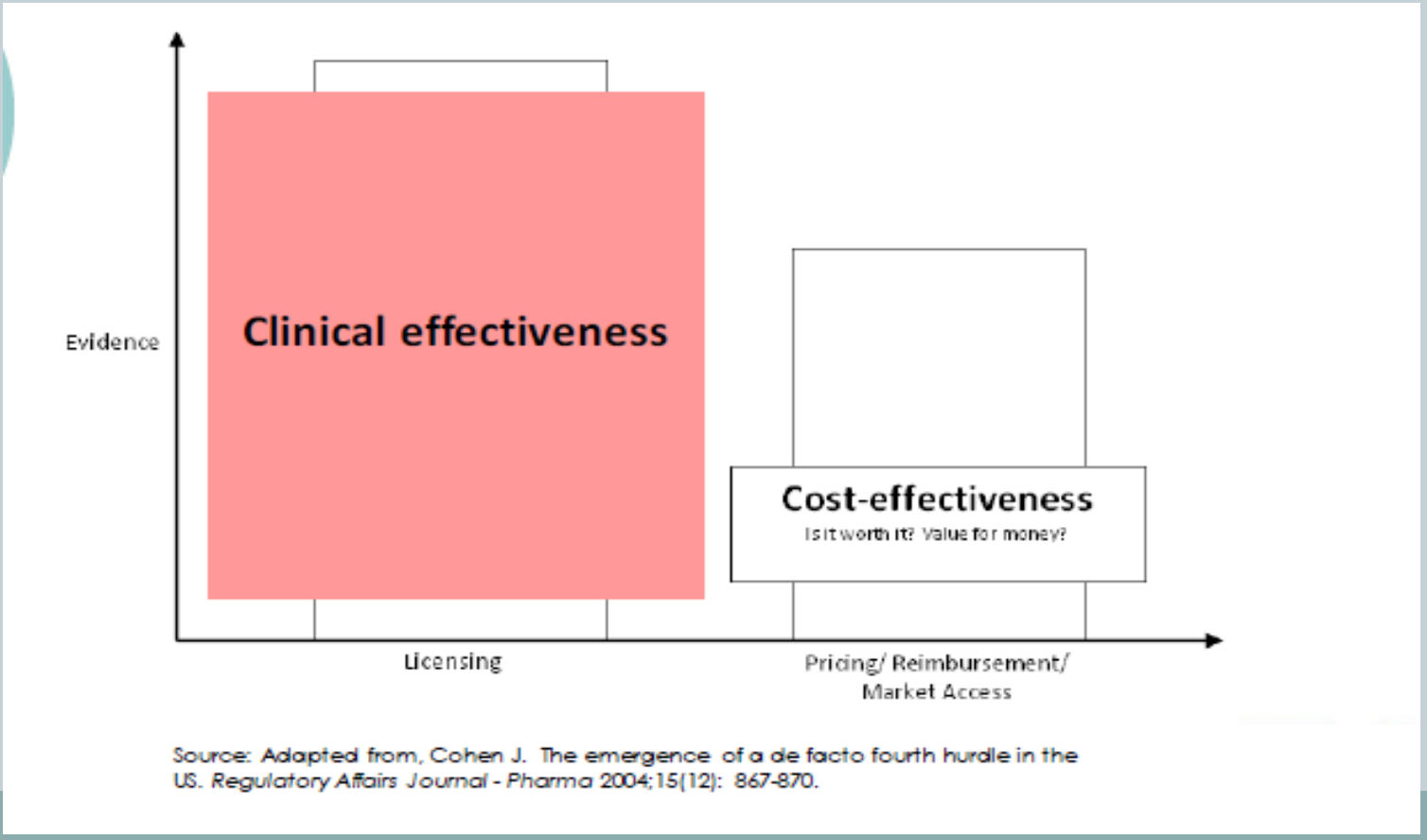
DR EMAN A. HAMMAD
DR. RIMAL MOUSA

Assistant professor of Clinical Pharmacy and Health Economics

Lecture Outline

- This is the last topic in our course and we will be talking about:
  - The use of Pharmacoeconomic in policy making and informing health decision
  - Pharmacoeconomics Guidelines
  - Jordan drug pricing system
  - Challenges of Pharmacoeconomic Research and practice (areas you might find yourself after graduation)

- Pharmaceutical industry spends billions of dollars annually for development of new drugs.



Source: Adapted from, Cohen J. The emergence of a de facto fourth hurdle in the US. *Regulatory Affairs Journal - Pharma* 2004;15(12): 867-870.

Uses of economic evaluation

- Development of public reimbursement lists
  - In Australia, since 1993 it has become mandatory for industry to submit economic evidence to the Pharmaceutical Benefit Advisory Committee (PBAC) if they want their products to be in the Pharmaceutical Benefit Scheme, which is subsidized by the government
- Price negotiation

The development of clinical practice guidelines, and communicating with prescribers

- In England and Wales, the National Institute for Health and Clinical Excellence (NICE) considered economic evaluation to be a significant input for developing practice guidelines intended to influence health service delivery throughout the country . Same in Sweden

Pharmacoeconomics Guidelines

Researchers and evaluators continue to develop and refine guidelines for pharmacoeconomic analysis.

The International Society for Pharmacoeconomics and Outcomes Research

- The International Society for Pharmacoeconomics and Outcomes Research is an international organization promoting the science of pharmacoeconomics and health outcomes research.
- The International Society is organized to act as a scientific leader relevant to research in pharmacoeconomics, health outcomes assessment, and related issues of public policy.

http://www.ispor.org/RegionalChapters/Jordan

COUNTRY-SPECIFIC PHARMACOECONOMIC GUIDELINES

	Published PE Recommendations	PE Guidelines	Submission Guidelines
Africa	South Africa	Egypt	
America- Centre and South		Brazil Cuba México	
America-North	United States	Canada	
Asia	China Mainland	Taiwan South Korea Malaysia	Thailand
Europe	Austria Denmark Hungary Italy Russian Federation Spain Croatia	Baltic (Latvia, Lithuania, Estonia) Belgium France Germany Ireland The Netherlands Norway Portugal Slovak Republic Slovenia Sweden	England & Wales Finland Poland Scotland
Oceania		New Zealand	Australia

Published PE Recommendations: they are country-specific economic evaluation guidelines or recommendations published by experts in the field but are not "officially" recognized or required by the healthcare decision making bodies/entities in this country/region for reimbursement.

PE Guidelines: they are country-specific "official" guidelines or policies concerning economic evaluation that are recognized or required by the healthcare decision making bodies/entities in this country/region for reimbursement.

Submission Guidelines: they are country-specific "official" guidelines or policies concerning drug submission requirements with an **economic evaluation part/section** and are required by the healthcare decision making bodies/entities in this country/region for reimbursement .

Worldwide guidelines

- Australia was the first country that required pharmaceutical companies, seeking a national formulary listing (registration), to provide a detailed economic analysis to support their case….1993

- Canada and New Zealand (1993-4): Guidelines for Economic Evaluation of Pharmaceuticals

- Australian guidelines have received considerable publicity and have proven to be a catalyst in the development of both guidelines and standards-related documents in countries such as Canada, New Zealand, and United Kingdom (UK).

The UK experience

- British government is encouraging the use of economic evaluation of new drug products, by agreeing voluntary "guidelines for the economic evaluation of pharmaceuticals" with the Association of the British Pharmaceutical Industry (1996).

- National Health Services (NHS) reforms increase the potential for the use of economic evaluation, but that there was a need to increase decision makers' awareness of economic evaluation (1997).

- The National Institute for Health and Clinical Excellence (NICE; a special health authority1999): Although therapeutic benefit is the most important consideration, guidance on cost-effectiveness by NICE influences prescribing.

Source: National Institute for Health and Care Excellence. Guide to the methods of technology appraisal 2013. London: National Institute for Health and Care Excellence, 2013. http://www.nice.org.uk/media/D45/1E/GuideToMethodsTechnologyAppraisal2013.pdf

Health Technology Assessment (HTA)

- **Health Technology Assessment (HTA)**
- A form of policy research that examines short- and long-term consequences of the application of a health care technology.
- –Generally comprised of **Systematic Evidence Reviews and Health Economic Assessments such as CEA; Used to inform evidence based decision making (EBDM).**

Countries adapting different perspectives

- Guidelines (non-societal)
  - e.g. UK NICE: reference case analysis, “the perspective adopted on costs should be that of the NHS (National Health Service) and PSS (Personal Social Services)” (NICE 2008)

- E.g. CADTH (Canada): perspective of the publicly funded health care system should be used in the reference case.
  - Other costs may be considered where it is likely that they have a substantial impact on results.

- Guidelines (societal)
  - e.g. The Swedish Dental and Pharmaceutical Benefits agency recommends a societal perspective
  - Accordingly, the inclusion of costs of loss of production, informal care (unpaid carers) and mortality are recommended

- **USA**
  - The payer perspective is recommended for the primary analysis, with optional perspectives (i.e., societal, employer) conducted as secondary evaluations.

Jordan Pricing system

- JDFA has a published officinal guide on pricing drugs
- It is not intended to you to memorise these. But here to highlight some of the main points and that evidence of cost-effectiveness is required to add in some decisions

المادة ٥:

أولا

يحدد سعر الدواء الأصيل للجمهور الأردني بأقل سعر ينتج عن تطبيق إحدى الآليات التالية:

أ. **السعر محسوبا من تطبيق المادة (٢) .**

ب. **السعر محسوبا من تطبيق المادة (٣) .**

ج. **.وسيط (median)السعر الناتج عن أسعار الجمهور في الدول التالية: (بريطانيا، فرنسا، إسبانيا، إيطاليا، بلجيكا، اليونان، هولندا، استراليا، قبرص، هنغاريا، إيرلندا، نيوزيلندا، البرتغال، التشيك، كرواتيا والنمسا) محسوبا من تطبيق المادة (٣) من هذه الأسس على أن لا يقل عدد الدول عن أربعة .**

د. السعر محسوبا من سعر تصدير الدواء (المستورد للأردن) للسوق الدوائي السعودي أما المستحضرات غير المسجلة في السعودية فيتم إعادة النظر في سعرها في الأردن حال تسجيلها هناك ويلتزم الوكيل بتزويد المؤسسة بسعر التصدير للسعودية خلال مدة لا تزيد عن أربعة أشهر من تاريخ تسعيره هناك

ه. إذا لم يكن الدواء مسجلا ومسعرا إلا في بلد المنشأ وثلاث دول (أي أن الدواء مسجل في ثلاث دول أو أقل من الدول الواردة في الفقرة (ج) من هذه المادة) يسعر على المتوسط الحسابي لهذه الدول وعلى دراسة الجدوى الاقتصادية (Cost-effectiveness) أيهما أقل.

المادة ٨ :

يحدد سعر الدواء المحتوى على أكثر من مادة فعالة بتطبيق المادة ٥ أو٦ من هذه الأسس مع مراعاة الآليات التالية (أيهما أقل):

١- الدواء الجديد في حالة إضافة مادة فعالة جديدة من نفس الشركة يعطى سعر الدواء الجديد الأول مضافاً له سعر الدواء الجديد الثاني ويخصم ١٠% من المجموع.

٢- الدواء الجديد في حالة اضافة مادة فعالة أخرى من مصدر آخر يعطى سعر الدواء الجديد مضافاً له سعر المتوسط الحسابي لأسعار الأدوية الجنيسة المسجلة من المادة المضافة ويخصم ١٠% من المجموع.

٣- الدواء الذي له مثيل مسجل في حالة اضافة مادة فعالة أخرى يعطى سعر الدواء الذي له مثيل مسجل مضاف له سعر المتوسط الحسابي لأسعار الأدوية الجنيسة المسجلة من المادة المضافة ويخصم ١٠% من المجموع.

المادة ٩ :

بالرغم مما ورد في المواد(٧,٨) أعلاه يتم اعطاء ميزة سعرية للدواء الذي يحتوي على مادة إضافية أو ميزة تقنية تزيد من فعالية الدواء أو تضفي ميزات علاجية عليه بناء على دراسة Cost-Effectiveness مقدمة من الشركة.

There are problems that limit our use of health economics in practice in Jordan

- The whole process may be open to bias:
  - In the choice of comparator drug, the assumptions made, or in the selective reporting of results.
  - This suspicion arises because most studies are conducted or funded by pharmaceutical companies

- What is the most appropriate perspective to take when valuing costs and consequences?

Final note on the course

- Finally, health economics and pharmacoeconomics is a young science and is slowly developing and testing its methodologies.
- We do not have space to address and develop the potential use of PE
- There have been many guidelines developed for the conduct of economic evaluation; there must be a need to develop and mandate the use of such in Jordan.

Hopes and goodbye ☺

- Hope you enjoyed the course
- Hope you will find it useful
  in your future venture

- Hope not to see you again, re-doing the course next semester