근거중심보건의료정책

- 잉글랜드의 HTA제도를 중심으로 -

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근거중심 보건의료정책의 도입배경

- 1988년 영국 과학기술관련 상원특별위원회

  (House of Lords Select Committee on Science and Technology)

  의학연구의 우선순위(Priorities in Medical Research) 보고서

- 주요내용

  NHS는 연구의 필요성을 명백히 해야 하며, 관련 연구성과가 체계적이고 효과적으로 의료서비스에 반영되도록 보장하는 체계가 부족하다고 질타

- 1991년 4월 NHS내 연구개발(R&D) 전략이 시작

  보건의료의 질, 유효성과 서비스 비용에 대한 평가가 강조

  보건성(DOH)에서는 총 지출의 1.5%를 R&D 예산으로 산정

의료기술평가의 발전과정

- HTA관련업무는 단일기관에서 수행하기보다는 대학이나 연구기관에서 모두 조화로운 역할을 수행

- UK Cochrane Centre in Oxford

  1992년 설립, RCT에 대한 체계적 문헌고찰의 지원과 유지를 촉진하고 통합하는 역할 수행, 코크란 도서관과 DB 지원

- NHS Centre for Reviews and Dissemination

  1994년 1월 시술의 효과에 대해 연구중심의 정보를 제공하기 위한 목적으로 요크대학교에 설립, 3가지 주요한 DB로 구성, 효과성(DARE), 경제성(NHS EED) 및 HTA

- National Coordinating Centre for HTA(NCCHTA)

  1996년 사우스햄튼 대학교에 설립, R&D 프로그램을 관리하고 지원하는 역할 담당

- National Coordinating Centre for Service Delivery and Organisation(SDO)

  2000년 3월 보건의료서비스 조직과 관리 및 전달체계에 있어 근거중심적 강화와 개발을 위한 목적으로 런던 위생 열대 의학대학원에 설립, SDO R&D 프로그램을 관리하고 지원

- Department of Health's National Research Register

  재정지원을 받았거나 NHS에서 관심있는 주제 중 진행중이거나 완료된 연구결과를 등록하는 DB, 연구자료 등록기관은 350개

- New & Emerging Application of Technology(NEAT)

  건강과 간호 또는 질병의 예방 및 치료를 위해 개발된 신제품과 시술에 관한 기초 지식과 기술에 있어 최신성을 적용하는 일을 지원, 재정적 차이의 분석업무를 수행

- National Horizon Scanning Centre(NHSC)

  1998년 버밍엄대학교에 설립, 새로운 및 신흥 의료기술을 주로 선택하여 이에 대한 정보를 사전에 알려줌으로 적절히 대처하기 위한 목적으로 버밍엄대학교에 설립

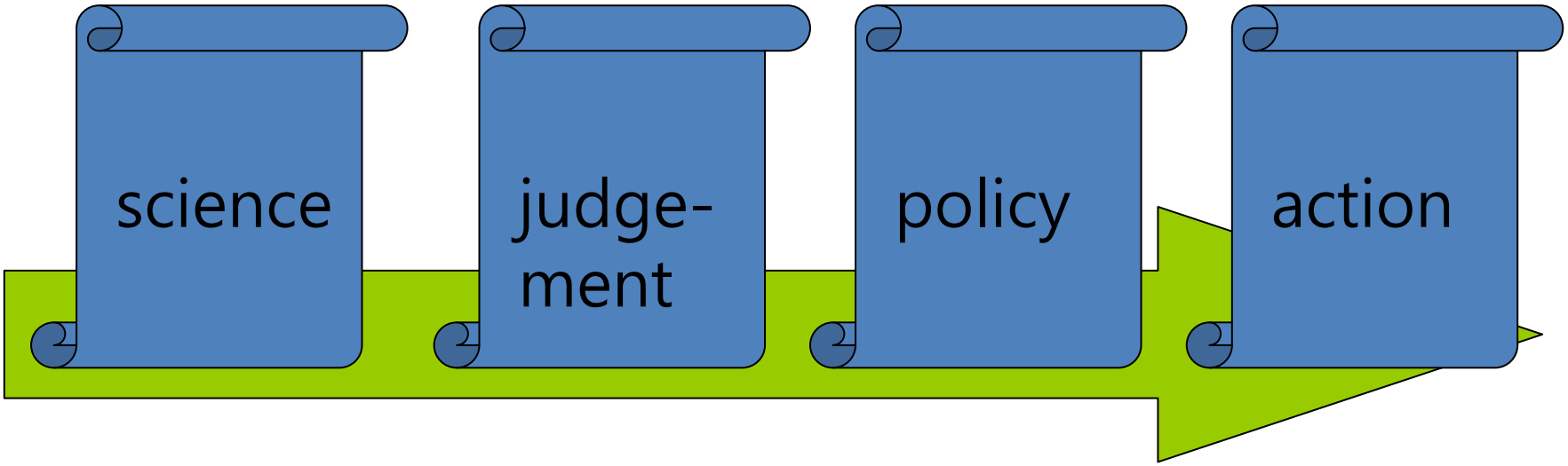
- Critical Appraisal Skills Program

  다양한 교육과 훈련을 지원

잉글랜드의 HTA 관점

- 다양한 기구에서 각자 주어진 역할에 따라 HTA 수행
- HTA는 안전성과 효능에 초점을 맞누는 제품 개발 또는 규제적 허가와는 구별, 해당기술의 임상적, 경제적 측면에만 초점을 맞춤
- 이후 평가와 구별되는 가치평가(Appraisal)이라고 불리는 다음 단계에서 윤리적, 조직적, 정치적, 거시 경제적 및 사회적 영향과 기술의 다른 함의를 다룸(우선순위, 형평성, 수용성 및 실현가능성에 대한 보다 넓은 관점을 반영)
- 다른 나라에서는 이를 별도의 단계로 구분하지 않고 의료기술평가의 통합된 부분으로 형성

From HTA to decision – UK NHS



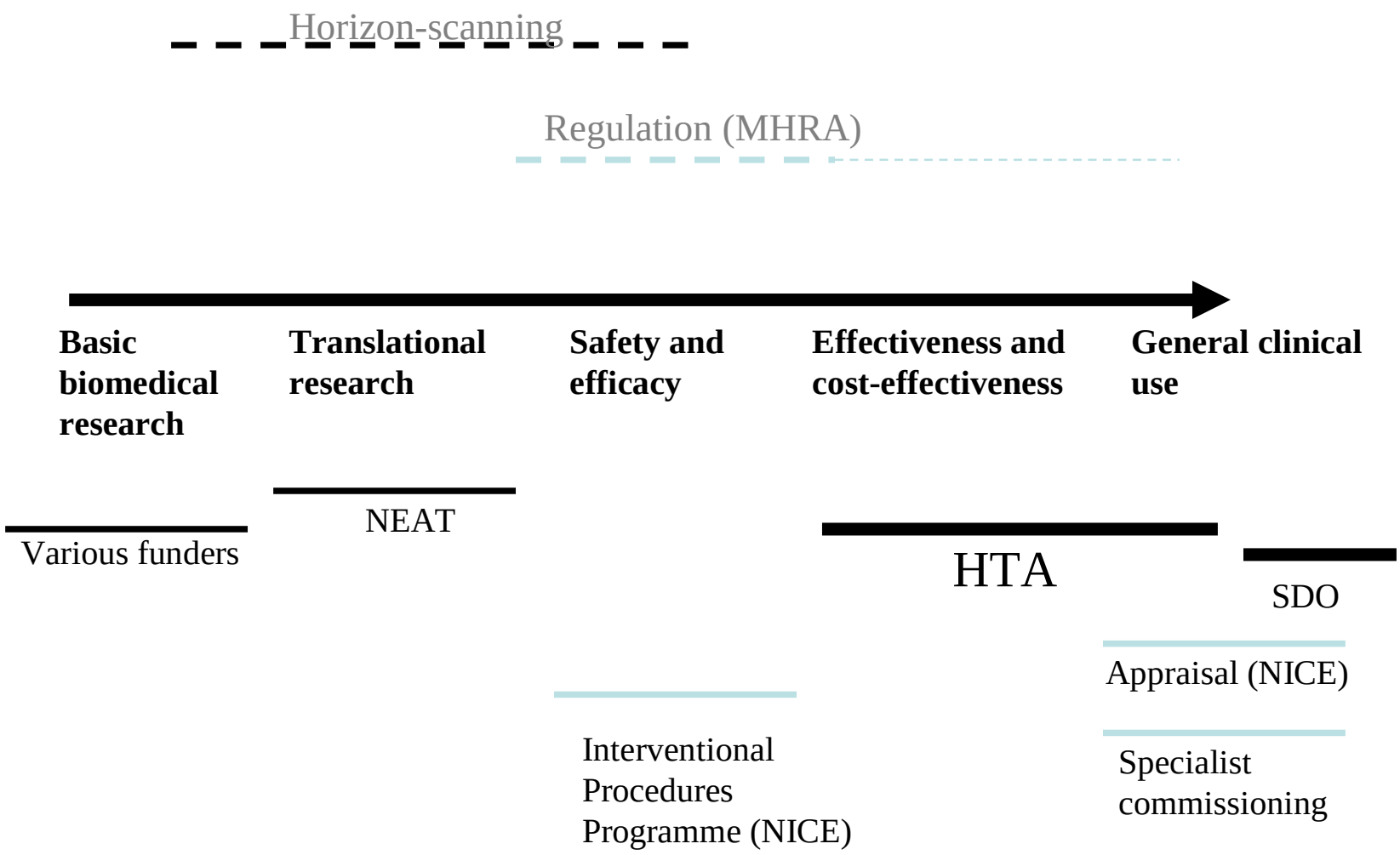
HTA

Assessment → Appraisal → Decision

기술개발에서 실무 적용까지

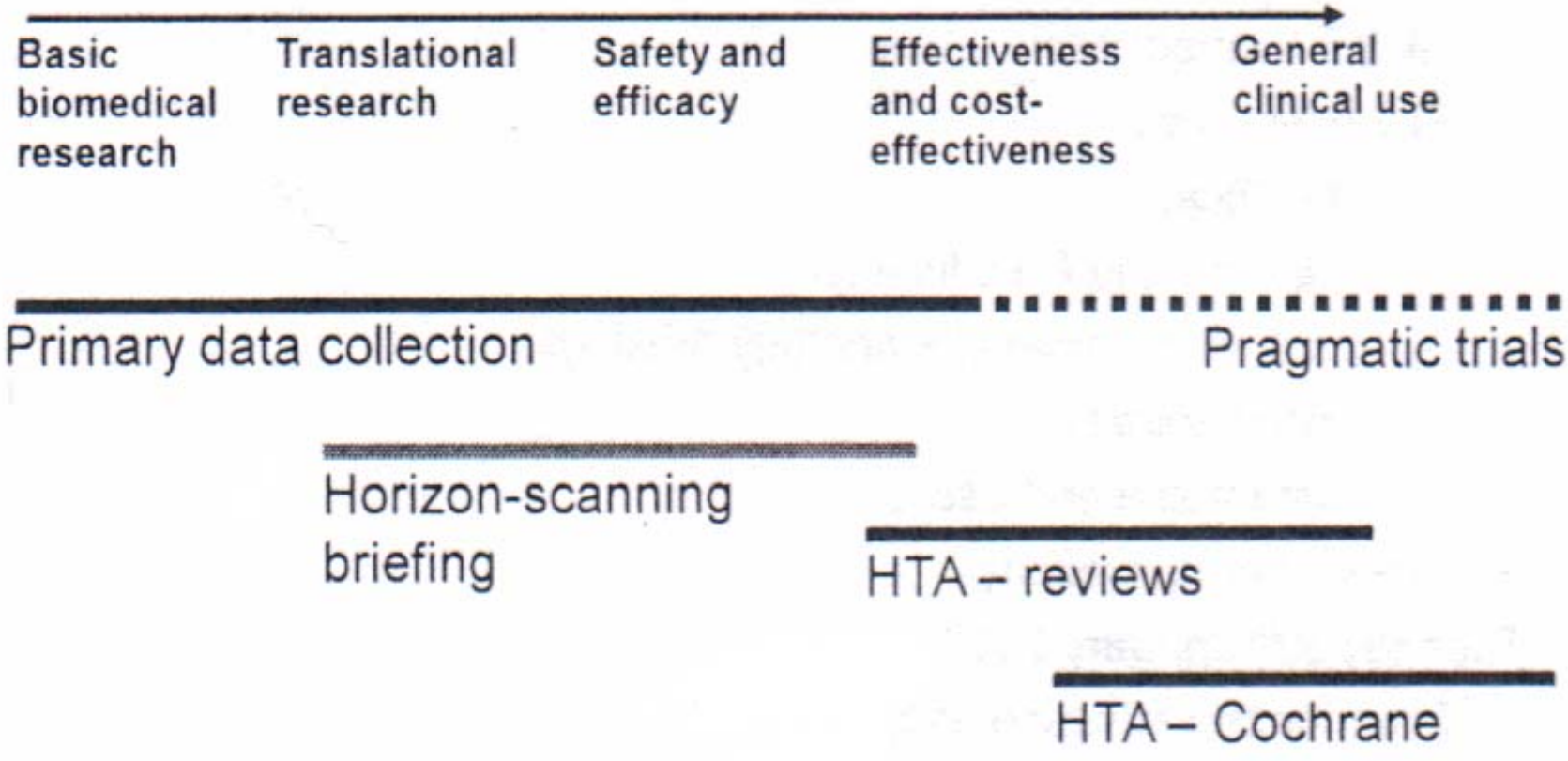
- 다양한 기초 생의학 연구에 의해 어떤 기술이 개발
- 이 기술이 임상에 적용할 수 있는지에 대한 translational research가 진행
- 안전성과 이상적 상태에서 해당기술에 대한 효능에 대한 검증이 시도
- 안전성과 효능이 있는 경우 이를 실제 임상에 적용했을 때의 실제 효과(유효성)와 비용-효과성을 분석
- 일반 임상에서 사용할 수 있도록 하는 확산과정

Getting Innovation Into Practice (UK)



The HTA sequence

NHS
National Institute for Health Research



국가조기기술통보센터(NHSC)

- 년 540억원의 재정 지원
- 주요목표

  긴급한 평가가 필요할 것으로 판단되는 임상적 및 비용의 영향, 또는 임상지침의 변경이 고려되는 새로운 및 신흥의료기술(기존 의료기술의 적응증과 사용의 변화를 포함)을 주로 선택하여 이를 사전에 알려줌으로 적절히 대처하기 위함

- 주요대상

  의약품, 의료기기, 진단검사와 시술, 외과 및 기타 중재법, 재활과 치료, 공중보건과 건강증진 활동 등이 모두 포함

조기기술통보의 대상

- NHS에 도입되기 전 단계로 그간 5년 이상 개발되어 온 기술이 주요 대상이 되며, 이는 초점화된 정규검토와 특별 연구프로그램으로 구성
- Focused Routine Scanning
- 임상적 특수성에 관계없이 긴급성이 있다고 판단되는 기술이 설계
- 의약품의 경우 중요한 제약회사에서 시행하는 제2상 및 3상 시험이 진행되어 개발 경과를 거치는 단계가 해당
- 우선순위가 높은 임상시험과 허가단계를 통해 추적
- 연구소나 상업적 개발자의 네트워크에 의하거나 일반적으로 의학 및 약학 문헌, 뉴스, 재정보고서와 허가기관 및 선택된 웹사이트 등의 다양한 1,2,3차 정보를 이용하여 선정

- Specialty-based work Programme
- 모든 임상 신제품과 기술유형이 새로운 개발을 위한 투자를 위해 시간을 투자했다면 이를 보장하기 위한 목적으로 수행
- 왕립대학과 다른 전문기관과 함께 연계하여 인식단계에서의 어떤 차이를 확인하거나 특정 의료기술의 우선순위 결정을 지원

- 기술의 여과와 우선순위
- 3년 안에 NHS에 적용될 것으로 보이는 신흥의료기술
- 신의료기술
- 기존 의료기술의 적응증 또는 사용이 유의하게 변경된 경우
- 개발된 의료기술의 일부분이 전체에 유의한 영향을 줄 경우

조기통보의 관점

- 만약 해당 기술이 광범위하게 채택될 경우 유의한 건강에의 유익성
- 만약 해당 의료기술이 확산될 경우 주 비용의 영향(환자의 수, 서비스 재편성의 여부, 훈련여부 등)
- 의료기술의 확산속도가 부적절한 경우
- 해당 의료기술의 사용에 있어 이와 관련된 중요한 윤리적, 사회적, 정치적 또는 법적 이슈나 기타 다른 문제들
- 만약 해당기술이 채택될 경우 현재 임상지침과 규범이 유의한 영향을 받게 되는지 여부

조기기술평가의 보고내용

- 해당 기술에 대한 요약보고 형태로 제공(약 4-5쪽)
- 해당 의료기술에 대한 설명
- 대상 환자그룹(환자수를 포함)
- 현재 진단법이나 대체 치료법
- 기술에 소요되는 비용
- 현재 연구된 임상적 및 비용효과성에 대한 근거
- 진행 중이거나 관련된 연구활동에 대한 자세한 조사
- 추정된 임상서비스 및 재정적 영향이 미치는 효과

▷이를 통해 밝혀진 몇 개 만이 HTA로 연결, 주요 의료기술에 대한 정책적 의사결정에 도움을 주는 활력소

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NHS National Institute for Health Research

Horizon Scanning - Inputs

Where do we get information from?

- Industry
- Commercial news
- Journals
- Medical media
- Clinical experts
- Other Horizon Scanning/ HTA agencies
- Licensing agencies

What topics are the NHSC interested in?

New & emerging health technologies

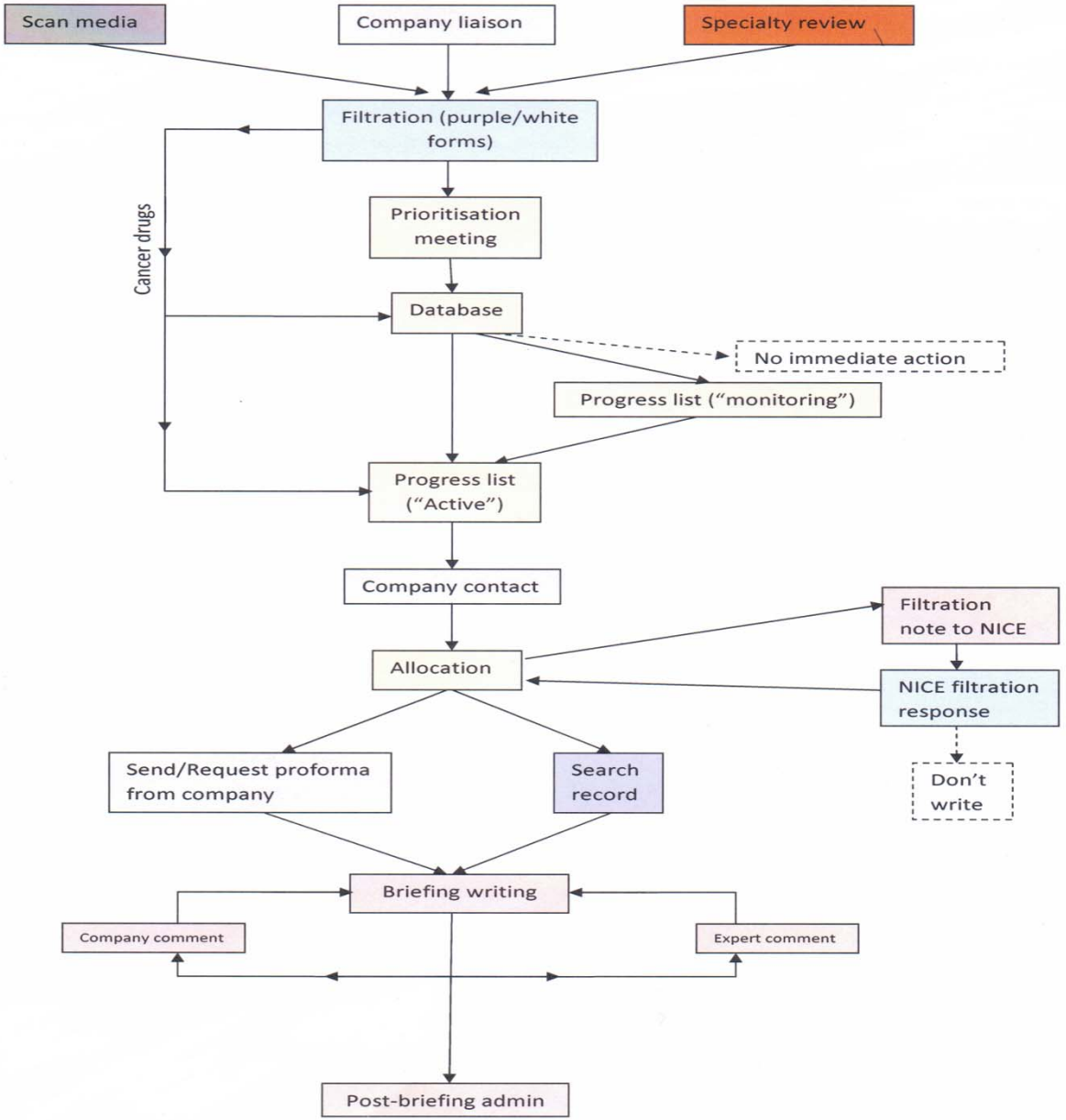
Potential for significant impact on health services

- Drugs
- Devices
- Diagnostics
- Procedures
- Rehabilitation aids
- Public health interventions

How can I suggest a topic? Complete our form at:
www.haps.bham.ac.uk/publichealth/horizon

Briefing work breakdown structure

NHSC National Horizon Scanning Centre



National Horizon Scanning Centre
News on emerging technologies in healthcare

Drug filtration form

Name of Technology for indication xxxx

Date: xxxxxxx		Information source	Confidential information
Company			
Drug name			
Patient group and/or indication including stage of disease and targeted patient sub-groups.			
What is its place in the treatment pathway (e.g. first-line, second-line)?			
What class of drug or pharmacological action is the product?			
Is it a new class of drug?			
What is its route of administration e.g. oral, subcutaneous, intravenous (short or infusion)?			
What is the treatment schedule and /or combination (e.g. once a day, twice a day, days 1-5 in a 28 day cycle)?			
What trial phase is the drug in?			
What are the licensing, launch or marketing plans for England and Wales?			
What is the patient group number for the indication specified for England and Wales?			

FILTRATION STEPS

LEAD:_____

HS_No.:_____

Filtration Step One

*Fields marked with an asterix must be completed

***Technology name:**

***Patient group:**

Indication subgroup:

Stage of disease:

Place in treatment:

***New/emerging technology:**

Emerging or new
Old
Old with new indication
Other

***Tech area type:**

***Tech type:**

Diagnostics & imaging
Devices & biotechnology
Drugs
Non-surgical therapy
Procedures
Screening & Immunisation Programmes
Settings & Organisational Programmes
Transplantation

***Original Source:**

Source Details:

Key references:

***Status:**

Available but not fully diffused
In clinical trials
Pre-registration in EU
Licensed (approved) in EU
Other

Status Details:

***Company/Developer:**

***Specialty One:**

***Date entered:**

NHSC work programme: past

Start date	Regular Review	Occasional Review	DoH / TAG Review or briefing
February 2000	• Haematology & blood products (inc leukaemia) • Genetics & gene therapy • Laboratory services • Endocrine & diabetes	• Anaesthetics • Rehabilitation & physiotherapy • Dental health	Goserelin Antigastrin Artificial oxygen carriers Artificial pancreas Drugs for stroke
August 2000	• Cardiology & cardiovascular disease • Respiratory disease • Transplantation • Orthopaedics & rheumatology • Oncology	• Urology (inc oncology) & GUM • Renal medicine	Boron capture neutron therapy Coronary MR angiography
February 2001	• Gastroenterology (inc colorectal cancer) • Infectious disease • Neurological disease (inc brain tumour) • Radiology, imaging & nuclear medicine	• Dermatology • Palliative care	HIV therapy triple vs quadruple Azimilide
August 2001	• Biomaterials & tissue engineering • Genetics & gene therapy • Paediatrics & neonatology • Women's health, breast care, obstetrics & gynaecology	• Accident & Emergency • Ophthalmology & ENT	Robots in surgery. Inhaled and oral insulin. Neonatal cooling Artificial oxygen carriers.
February 2002	• Haematology & blood products (inc leukaemia) • Endocrine & diabetes • Oncology	• Nursing services	Anegrelide for thromobcythaemia. Oral heparin. Continuous glucose monitors, non-invasive glucose monitors, artificial pancreas.
August 2002	• Cardiology & cardiovascular disease • Respiratory disease • Transplantation • Orthopaedics & rheumatology	• Complementary care	Cardiac imaging, New revascularisation techniques, brachytherapy. Statins for osteoporosis. Needle free technologies

NHSC Staged Search Record

Date: _____

Intervention: _____ **Company:** _____

Synonyms, codes names etc _____

Patient group: _____ **NHSC lead:** _____

Commercial developer contact Proforma received Yes ☐ Date: Note of other information received e.g. clinical trial protocols	**Commercial developer - contact name, phone number and email**
Company comments on draft technology summary Draft briefing sent Yes ☐ Date: Deadline: Comments received Yes ☐ Date:	**Other contact with company (e.g. telephone calls, chasing emails) – Keep a note on the company record sheet.**

EuroScan database entry Yes ☐ Date: Not suitable ☐ **(Do not add confidential information)** NHSC files sorted Yes ☐ Date: Time Log Yes ☐ Date: Information on diseases – specialty files Information from company – company files	Updated Technology Database Yes ☐ date: Updated Expert Database Yes ☐ date: Updated Company Contacts Database Yes ☐ date: (including date of data protection agreement on proforma) Google News Alerts set up Yes ☐ date:

Experts Used: Yes ☐ No ☐

NHSC Scanning Sources – December 2008

Source	Claire	Sue	Ali	Sara T	Luan	Jo	Matt	Janette	Ash	Simon	Zaheda
Newspapers Journals	BMJ Future Prescriber Gene Therapy Advisory Group (annual)		Clinica Radio 4 Today & World Tonight Saturday Times		Lancet NEJM JAMA Pharmaceutical Marketing Live		Scrip Scrip Magazine				
Email Alerts	Presswatch UK daily news alert		HES Newsletter		Dr's Guide	ECRI monthly newsletter Clinica Daily Alert	Scrip Daily Alert	UKMI New Product Evaluations (monthly)	NeL for Medicines Headlines		PharmaTimes
Internet		EuroScan		MEDICA Clinica Diagnostics IVT Tech	Clinica Diagnostics	Californian technology assessment forum International Hospital Eqpt & solutions	Formulary Journal	EMEA (orphan drugs) Company pipeline (with Simon and Ash): Elan; Lundbeck; Schwartz; Genentech; sanofi-aventis	Company pipeline (with Janette and Simon): Amgen; Biogen Idec; Leo Pharma; Medimmune; Antisoma;	CADTH (non drug) ANZHSN Medgadget Company pipeline (with Janette and Ash): Merck Serono International; Novo Nordisk; Schering Plough; Shire; Millenium pharmaceuticals; Antigenics	

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NHSC Customer Relationships

- National Institute for Health and Clinical Excellence (NICE)
- Centre for Evidence Based Purchasing (CEP) at PASA
- Department of Health policy teams
- National Screening Committee (NSC)
- National Specialised Commissioning Group (NSCG)
- Interventional Procedures Programme (IPP) at NICE
- Rapid Review Panel at Health Protection Agency
- NIHR Health Technology Assessment Programme
- Joint Committee on Vaccination and Immunisation (JCVI)

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Horizon Scanning - Outputs

What does the NHSC produce?

Technology Briefings
- Time-limited information
- 4-5 pages

→ NICE Topic Consideration Panels & other customers

Filtration Forms
- Allows customers to assess their requirement for a technology briefing
- 1-2 pages

→ NICE & other customers

Intelligence Email
- Early alert
- Assesses customer interest in health technology
- 1-2 paragraphs

→ CEP at PASA & other customers

National Horizon Scanning Centre
Department of Public Health & Epidemiology, University of Birmingham
Workshop on Identification, Filtration and Prioritisation
of New and Emerging Health Technologies
20th January 2009
Exercises

Exercise 1 - New & Emerging Health Technologies: Information provision and customers

- Why do health systems want or need information on emerging health technologies?
- Who might want or need to receive this information?
- When would you need this information?

Exercise 2- Filtration

You will be provided with typical information on a selection of new and emerging health technologies. Using this information:

1. Select the health technologies that may be of interest to your health service.
2. List the criteria you used to select the technologies.
3. What other information would you need to know?

Exercise 3 - Prioritisation

For the technologies that you selected in the previous exercise as being potentially of interest to your health service:

1. Fill in the prioritisation grid for 3-4 of the selected technologies. The information provided may not be enough for you to complete all boxes - in these cases either use prior knowledge or internet sources to complete the grid.
2. Discuss whether some criteria are more important than others.
3. Use the completed prioritisation grid to select **1** technology that you would prioritise to investigate further.

	Technology	Patient group size ○ Major ○ Minor ○ Moderate	Potential for health benefit ○ Major ○ Minor ○ Moderate	Costs/ Savings ○ Major ○ Minor ○ Moderate	Service impact ○ Major ○ Minor ○ Moderate	Patient acceptability ○ Major ○ Minor ○ Moderate	Potential for inappropriate diffusion ○ Major ○ Minor ○ Moderate	Innovative ○ Yes ○ No ○ Don't know
10	Light therapy for cancer							
11	Ibuprofen for parkinsons							
12	Etanercept for plaque psoriasis							
13	Acam-flu-A							
14	Blood test for alzheimers							
15	Stellaris machine							

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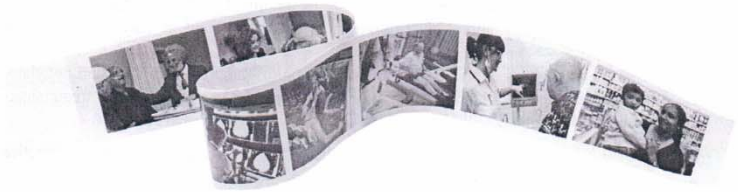
Entecavir (Baraclude) for chronic hepatitis B with associated decompensated liver disease

August 2008



The National Horizon Scanning Centre Research Programme is part of the National Institute for Health Research

Entecavir (Baraclude) for chronic hepatitis B with associated decompensated liver disease

Target group

- Adults with chronic hepatitis B infection and decompensated liver disease.

Technology description

Entecavir (Baraclude) is an oral nucleoside analogue with selective activity against hepatitis B virus (HBV). Entecavir inhibits DNA synthesis in HBV infected cells in three steps: the priming of the polymerase, the reverse transcription of the pregenomic messenger RNA and the synthesis of the positive strand of HBV DNA. Entecavir effectively reduces viral load and disease burden in infected patients. Entecavir is administered at 0.5mg once daily for previously untreated adults and at 1.0mg daily for those receiving lamivudine or with known lamivudine resistance mutations.

Entecavir is already licensed for chronic hepatitis B in adults with compensated liver disease.

Innovation and/or advantages

Entecavir represents a new treatment option for this indication (which is associated with poor prognosis) and has the potential for less treatment resistance and prolonged survival, compared to lamivudine.

Developer

Bristol Myers Squibb.

Availability, launch or marketing dates, and licensing plans:

In phase III clinical trials.

Relevant guidance

NICE has not issued specific guidance in decompensated liver disease for hepatitis B patients. Other relevant guidance includes:

- NICE technology appraisal in development. Tenofovir disoproxil fumarate for the treatment of chronic hepatitis B. Expected May 2009[1].
- NICE technology appraisal. Entecavir for the treatment of chronic hepatitis B. 2008[2].
- NICE technology appraisal. Telbivudine for the treatment of chronic hepatitis B. 2008[3].
- NICE technology appraisal. Hepatitis B (chronic) - adefovir dipivoxil and pegylated interferon alpha-2a adefovir dipivoxil and peginterferon alfa-2a for the treatment of chronic hepatitis B. 2006[4].
- British HIV Association (BHIVA) guideline. HIV and chronic hepatitis: co-infection with HIV and hepatitis B virus infection. 2004[5].

Clinical need and burden of disease

Chronic hepatitis B is defined as persistence of HBV infection for more than six months[6]. The World Health Organization (WHO) estimates that in the UK the prevalence of chronic hepatitis B infection is 0.3% of the general population (an estimated 160,200 cases in England and Wales)[7,8]. It is estimated that there are between 7,000 and 7,700 new cases of chronic hepatitis B in England and Wales each year[4,9].

Approximately 20% of untreated patients with chronic hepatitis B with compensated liver disease will decompensate over 5 years[10]. If untreated, the survival of decompensated cirrhosis is poor (15% at 5 years). The extent of HBV replication, as assessed by serum HBV-DNA level, is a strong predictor of the risk of disease progression and hepatocellular carcinoma[11].

Existing comparators and treatments

The current treatment options for HBV associated decompensated liver disease are:

- Lamivudine, an oral nucleoside analogue reverse transcriptase inhibitor.
- Adefovir dipivoxil, an oral nucleotide reverse transcriptase inhibitor (effective in lamivudine-resistant, and IFNα/pegIFNα-resistant chronic hepatitis B).
- Liver transplantation.

Efficacy and safety

Trial code	NCT00663182[12]: decompensated HBV-related cirrhosis; phase IV.	NCT00298363[13]: decompensated HBV-related cirrhosis; entecavir vs tenofovir; phase III.	NCT00065507[14]: HBV; hepatic decompensation; entecavir vs adefovir; phase IIIb.
Sponsor	Shanghai Changzheng Hospital.	Gilead Sciences.	Bristol-Myers Squibb.
Status	Ongoing	Ongoing	Ongoing
Location	China	US, Canada, Europe, Singapore, Taiwan.	USA, Canada, Brazil, Europe, Asia, Russia, South Africa.
Design	Randomised, controlled.	Randomised, double-blind, controlled.	Randomised, controlled.
Participants in trial	n=200 (planned); ≥16 years; decompensated HBV-related cirrhosis. Randomised to: entecavir 0.5mg daily or untreated.	n=100; 18-69 years; previously untreated decompensated HBV-related cirrhosis. Randomised to: 1. tenofovir 300mg, 2. emtricitabine and tenofoir 200mg or 300mg or, 3. entecavir 0.5mg or 1mg.	n=400; adults ≥16 years; chronic HBV with hepatic decompensation. Randomised to entecavir 1.0 mg vs. adefovir 10 mg.
Follow-up	2 years.	48 weeks.	96 weeks.
Primary outcome	Liver histology; undetectable HBV DNA (<300 copies/mL).	Safety and efficacy.	Mean serum HBV DNA PCR adjusted for baseline.
Secondary outcomes	Disease progression, hepatocellular carcinoma, Child-Pugh score, mortality.	-	Discontinuation due to adverse effect or lab abnormality, confirmed nephrotoxicity[a].
Expected reporting date	Study started Jan 2008. Expected to complete in Dec 2012.	Study started March 2006. Expected to complete in Dec 2010.	Study started August 2003. Expected to complete in May 2013.

Estimated cost and cost impact

The monthly cost per patient of entecavir 0.5-1mg is £378. The monthly cost of current alternative treatments for chronic HBV infection is[b]:

[a] Defined as < or equal to mg/dL increase in serum creatinine compared with baseline
[b] British National Formulary No.55, March 2008.

Drug	Brand name	Dose	Approximate monthly cost per patient
Lamivudine	Zeffix (GSK)	100mg daily	£78
Adefovir	Hepsera (Gilead)	10mg daily	£315
Interferon alpha (SC)	IntronA (Schering-Plough)	5-10 million IU 3 times per week	£259-£518
	Roferon-A (Roche)	2.5-5 million IU/m^2 3 times per week	£271-£542
PegInterferon alpha (SC)	Pegasys (Roche)	180 µg once weekly	£528

Potential or intended impact – speculative

Patients

- ☑ Reduced morbidity
- ☐ Quicker, earlier or more accurate diagnosis or identification of disease
- ☑ Reduced mortality or increased survival
- ☑ Other: reduction of progression to transplantation
- ☑ Improved quality of life for patients and/or carers
- ☐ None identified

Services

- ☐ Increased use
- ☐ Decreased use
- ☐ Service reorganisation required
- ☐ Other:
- ☐ Staff or training required
- ☑ None identified

Costs

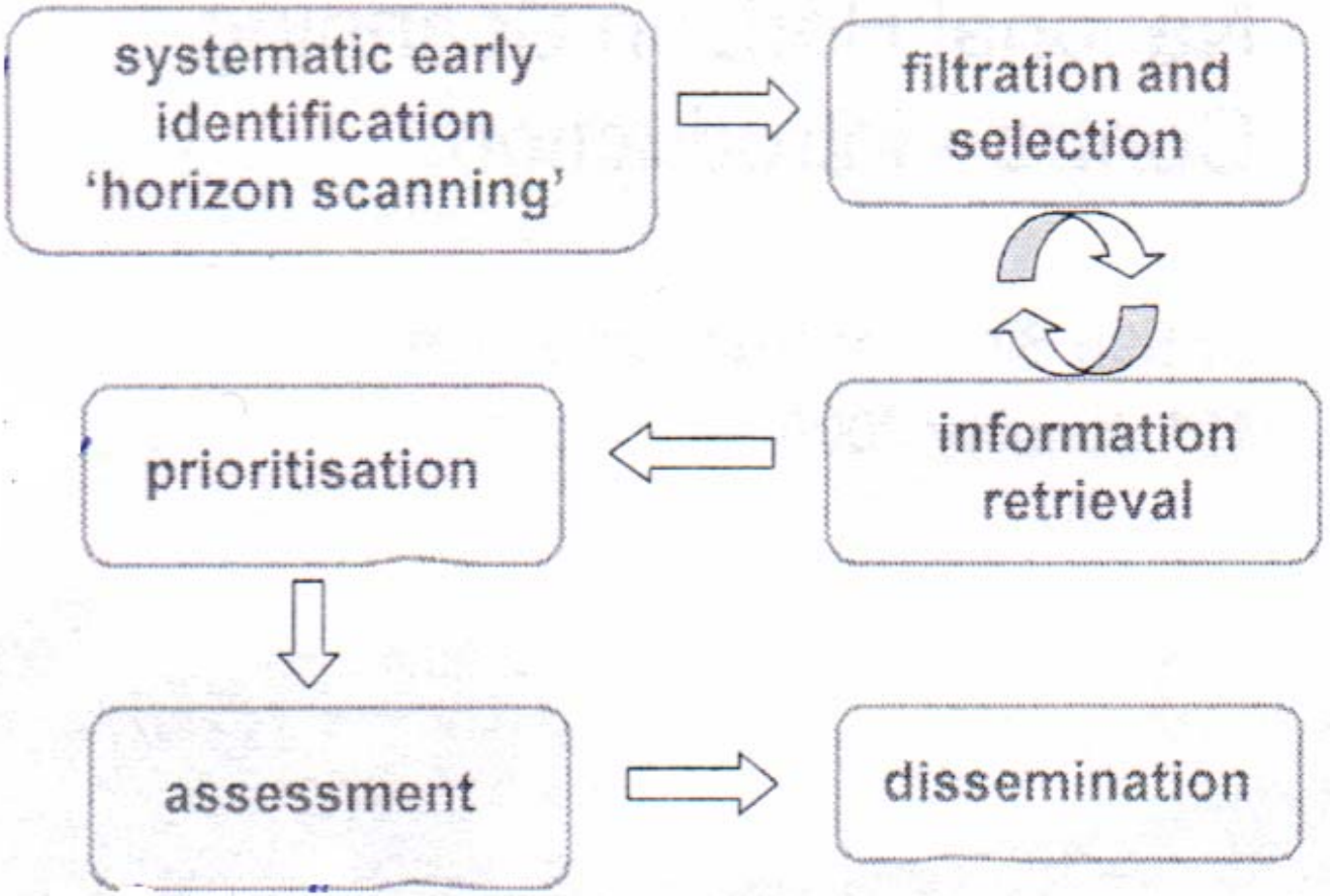
- ☐ Increased unit cost compared to alternative
- ☐ New costs:
- ☑ Increased costs: may be additive therapy rather than alternative.
- ☑ Savings: may reduce need for transplantation.
- ☐ Increased costs: capital investment needed
- ☐ Other:

References

[1] National Institute for Health and Clinical Excellence. Tenofovir disoproxil fumarate for the treatment of chronic hepatitis B. Technology appraisal in development. Expected May 2009.
[2] National Institute for Health and Clinical Excellence. Entecavir for the treatment of chronic hepatitis B. Technology appraisal TA153. August 2008.
[3] National Institute for Health and Clinical Excellence. Telbivudine for the treatment of chronic hepatitis B. Technology appraisal TA154. August 2008
[4] National Institute for Health and Clinical Excellence. Hepatitis B (chronic) - adefovir dipivoxil and pegylated interferon alpha-2a adefovir dipivoxil and peginterferon alfa-2a for the treatment of chronic hepatitis B. Technology Appraisal TA096, February 2006.
[5] British HIV Association (BHIVA) Guideline. HIV and chronic hepatitis: Co-infection with HIV and hepatitis B virus infection. October 2004. Available at: http://www.bhiva.org/cms1191559.aspx (accessed 16.6.08).
[6] Merck Manual online. Chronic hepatitis. Available at: http://www.merck.com/mmpe/sec03/ch027/ch027c.html?qt=hepatitis%20b&alt=sh (accessed 16.6.08).
[7] Department of Health. Children in need and bloodborne viruses: HIV and hepatitis. November 2004.
[8] Health Protection Agency. General information on hepatitis B. Available from: http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1195733758963?p=1191942171120 (accessed 6.8.08).
[9] Shepherd J, Jones J, Takeda A, Price A. Adefovir dipivoxil and pegylated interferon alfa-2a for the treatment of chronic hepatitis B - a systematic review and economic evaluation. Technology assessment report commissioned by the HTA Programme on behalf of The National Institute for Health and Clinical Excellence. Southampton Health Technology Assessment Centre, May 2005.
[10] Hache C and Villeneuve JP. Lamivudine treatment in patients with chronic hepatitis B and cirrhosis. Expert Opinion on Pharmacotherapy. 2006; 7(13): 1835-43.

Early warning systems

NHS
National Institute for
Health Research



Thank you for your attention

Getting Value for Money in Healthcare

2010.05.24

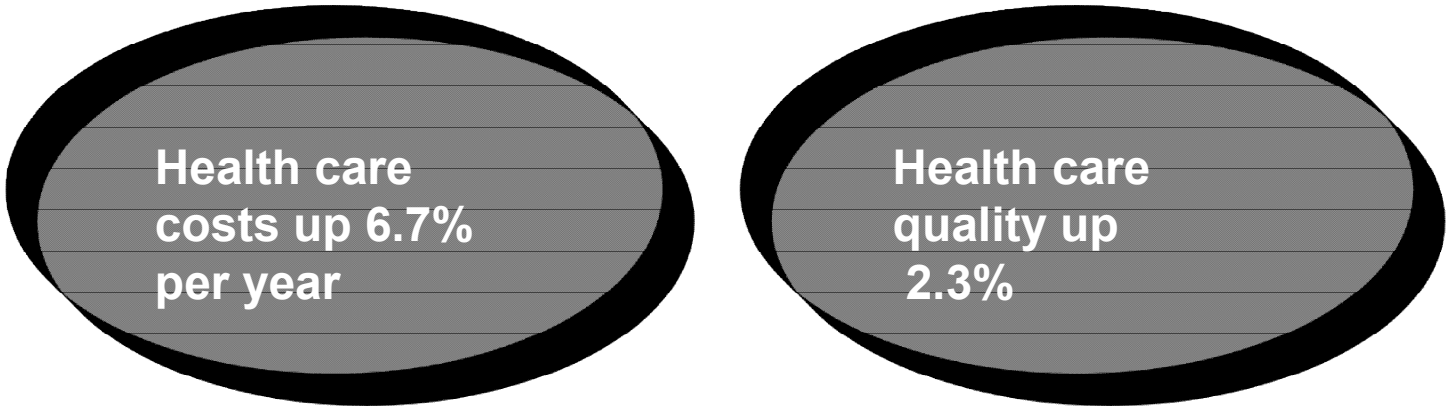
한국보건의료연구원 이 희 영

The Effective Health Care Challenge

What Is Quality?

- The Right Care
- For The Right Person
- At The Right Time

A Quality Disconnect



February 2009

Value for Money: Making Canadian Health Care Stronger

www.CanadaValuesHealth.ca

FIGURE 6

Should value-for-money questions drive the system?

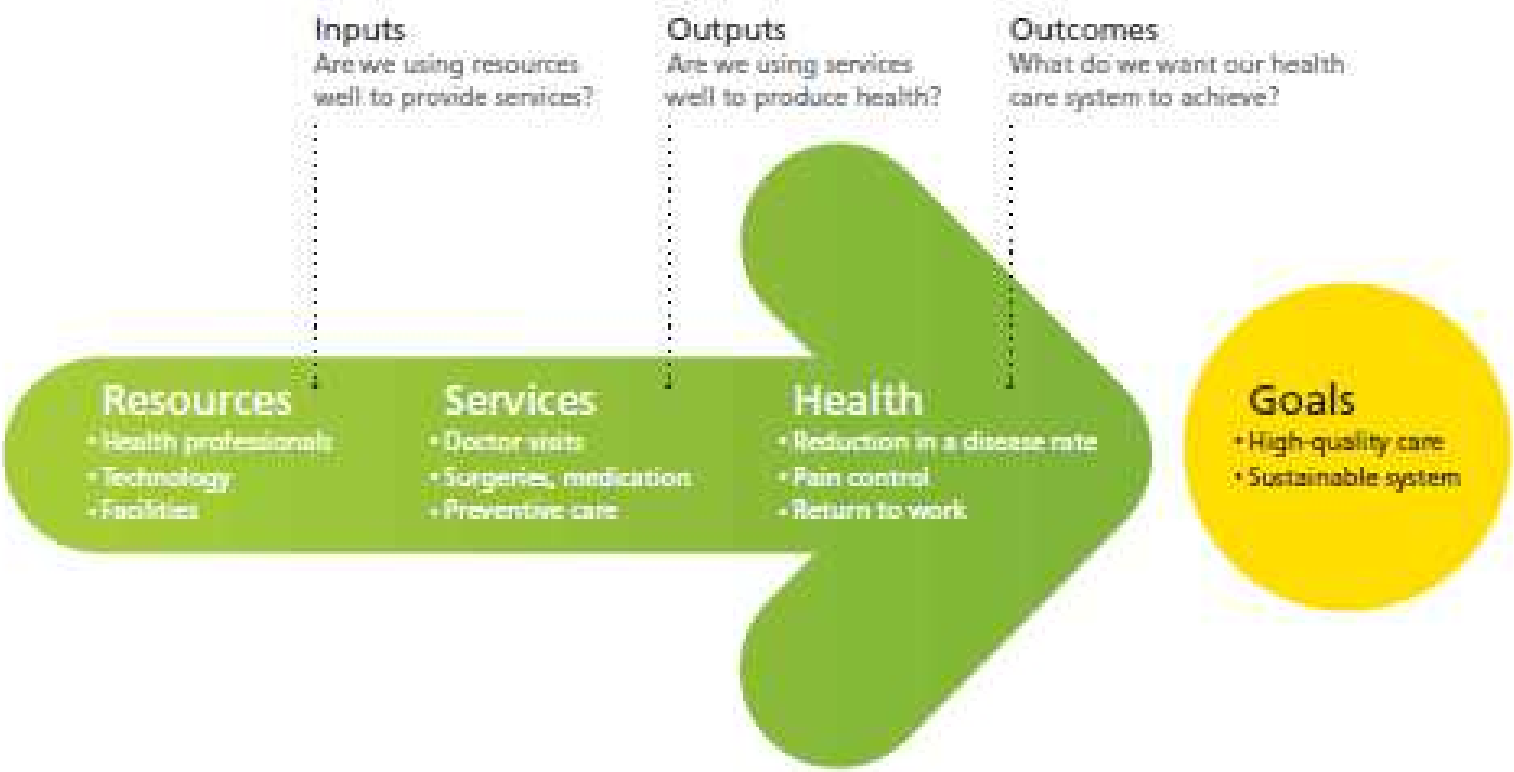


FIGURE 7

Not all care is good value for money

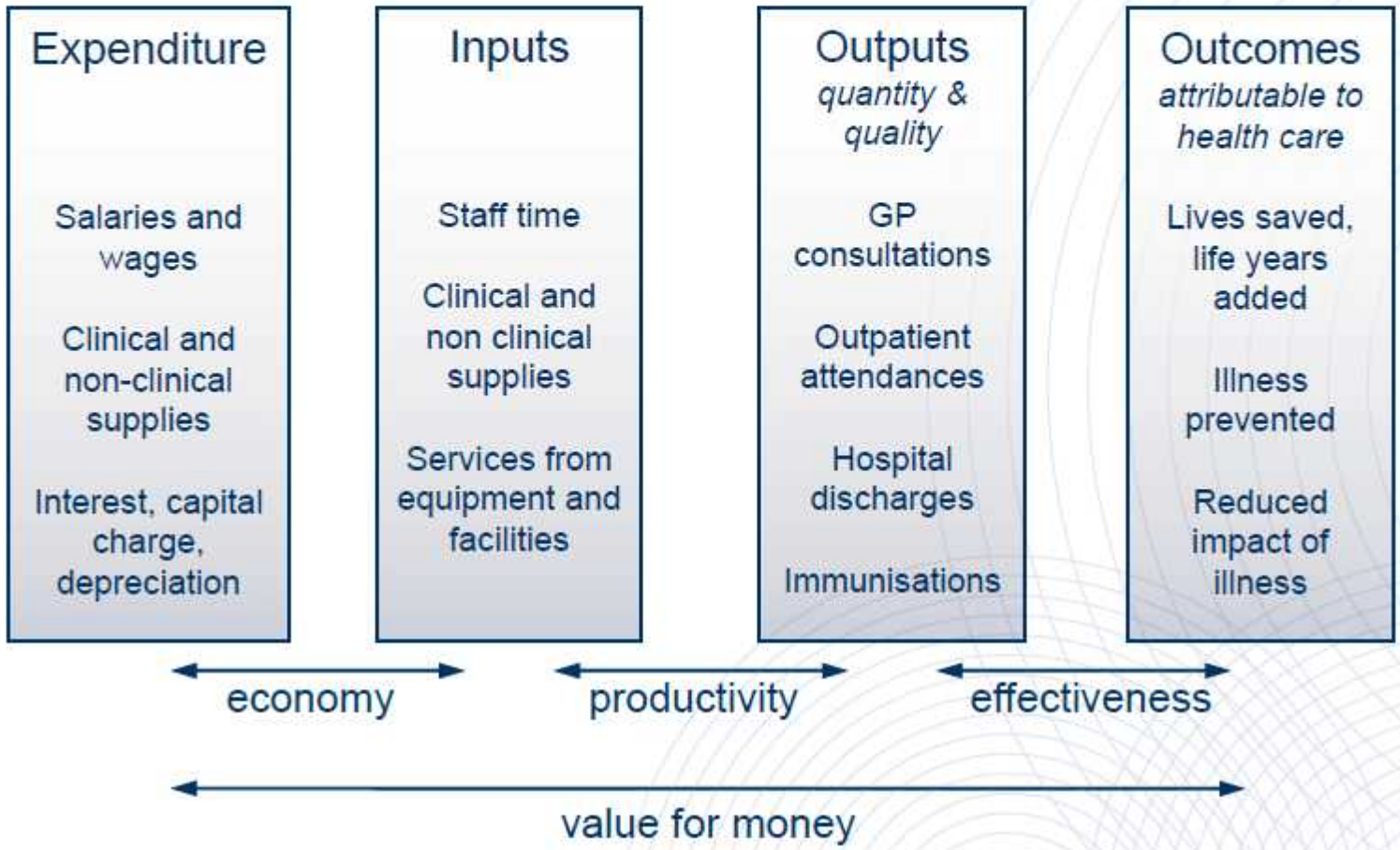
한정된 자원에 대한 Rationing필요

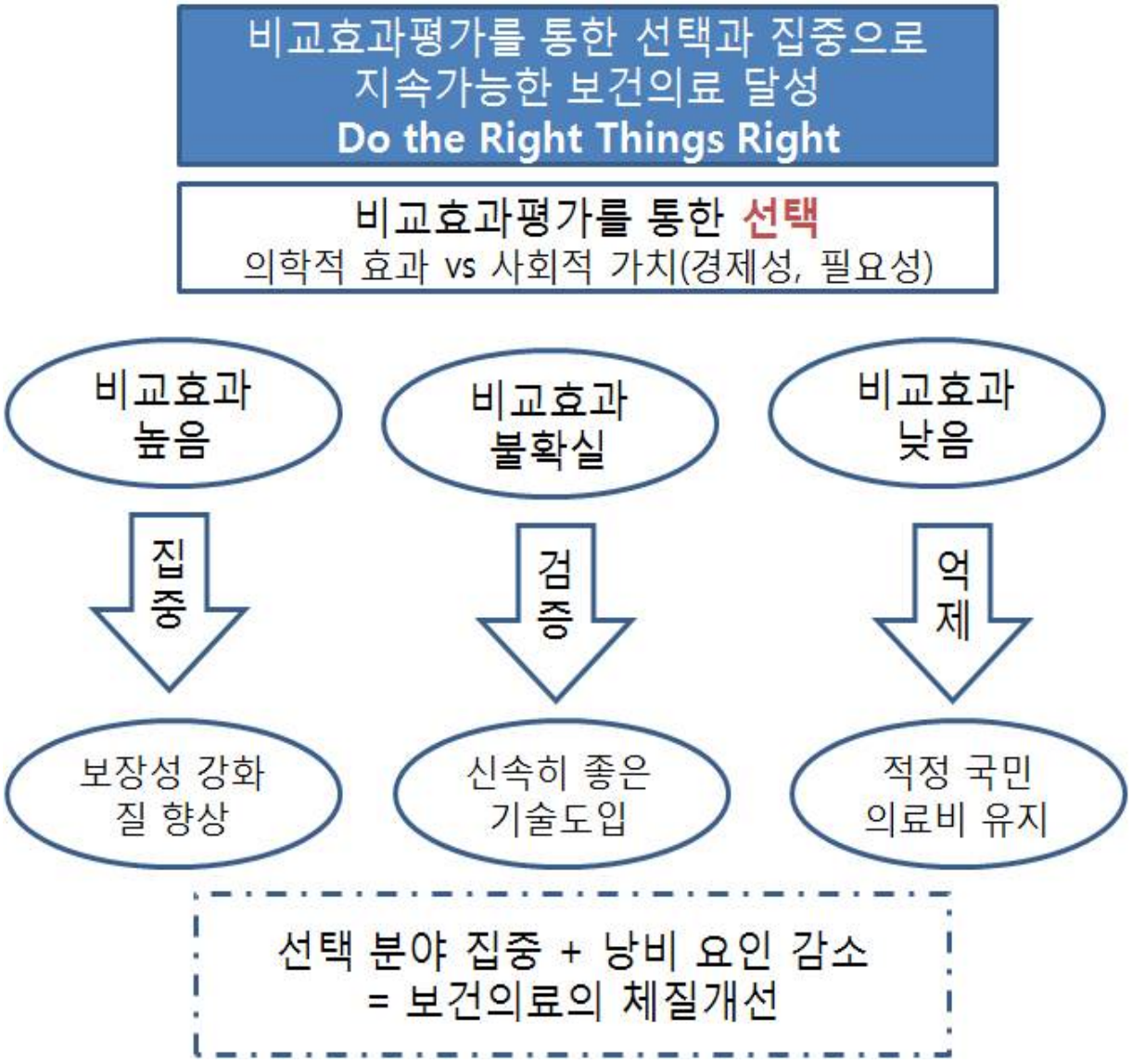
- Rationing : Value for Money
  - 자원배분(Resource Allocation)
  - 우선순위설정(Priority Setting)

- 전략의 예
  - Evaluation Research : HTA, CER etc
  - Access with Evidence Generation
  - Pay for Performance(P4P)

Unpacking VFM

Components of value for money – *a framework*




비교효과평가를 통한 선택과 집중으로
지속가능한 보건의료 달성
Do the Right Things Right
비교효과평가를 통한 선택
의학적 효과 vs 사회적 가치(경제성, 필요성)
비교효과 높음
비교효과 불확실
비교효과 낮음
집중
검증
억제
보장성 강화
질 향상
신속히 좋은
기술도입
적정 국민
의료비 유지
선택 분야 집중 + 낭비 요인 감소
= 보건의료의 체질개선

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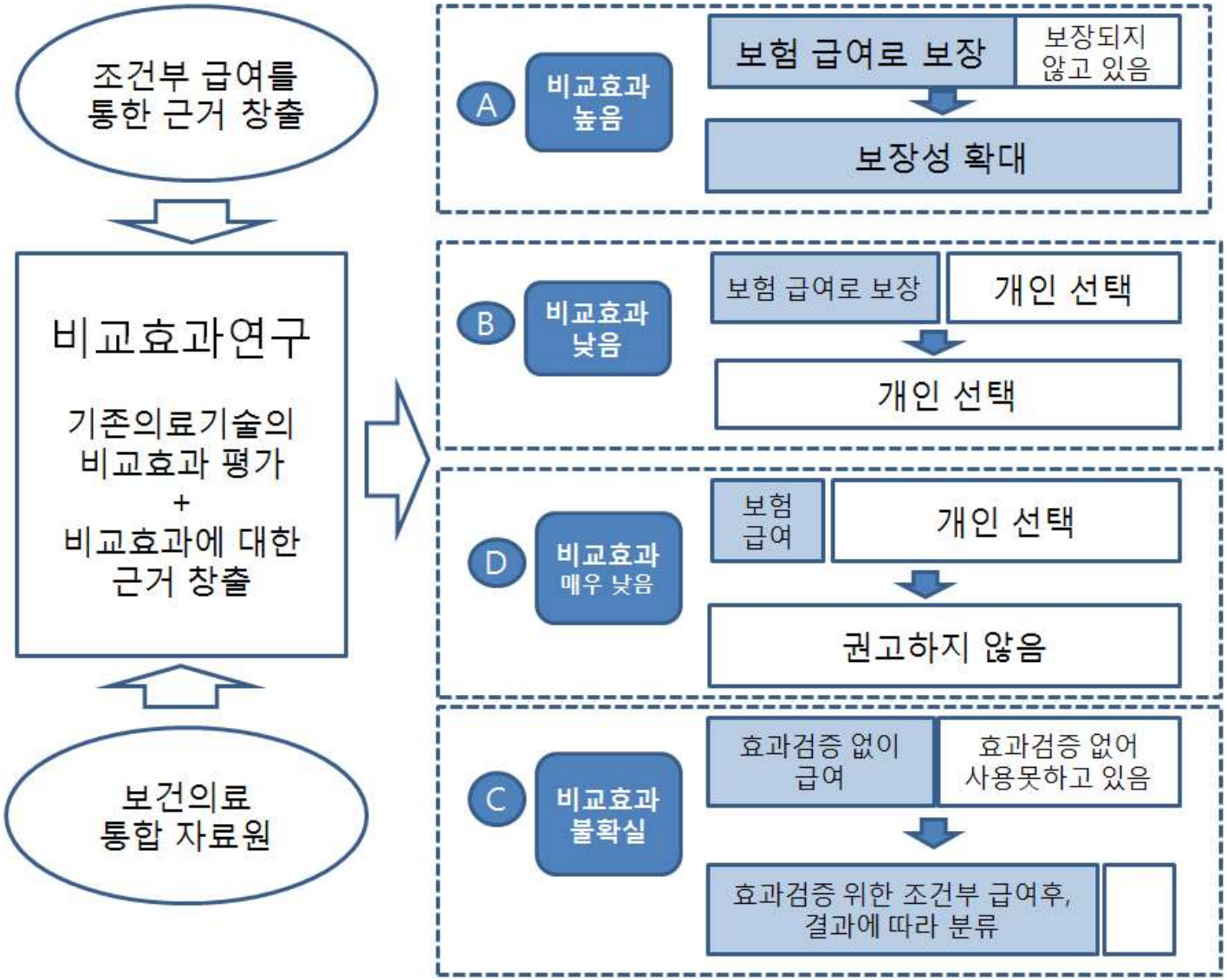
<tr><td>High</td><td>Low</td></tr>
<tr><td rowspan="2">사회적가치
(경제성,
필수여부)</td><td>High</td><td>A 비교효과 높음
⇩
필수의료로 보험 급여</td><td>C 비교효과 불확실
⇩
근거창출을 위한 조건부 급여</td></tr>
<tr><td>Low</td><td>B 비교효과 낮음
⇩
선택의료</td><td>D 비교효과 매우 낮음
⇩
권고하지 않음</td></tr>
</table>


조건부 급여를
통한 근거 창출
비교효과연구
기존의료기술의
비교효과 평가
+
비교효과에 대한
근거 창출
보건의료
통합 자료원
A
비교효과
높음
보험 급여로 보장
보장되지
않고 있음
보장성 확대
B
비교효과
낮음
보험 급여로 보장
개인 선택
개인 선택
D
비교효과
매우 낮음
보험
급여
개인 선택
권고하지 않음
C
비교효과
불확실
효과검증 없이
급여
효과검증 없어
사용못하고 있음
효과검증 위한 조건부 급여후,
결과에 따라 분류

Comparative Effectiveness research

The IOM Committee's working definition of CER

The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition, or to improve the delivery of care.

The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

Other Definitions

- Congressional Budget Office(2007)
- IOM Roundtable on Evidence-Based Medicine(2007)
- American College of Physicians(2008)
- IOM Committee on Reviewing Evidence to Identify Highly Effective Clinical Services(2008)
- Medicare Payment Advisory Commission(2008)
- Agency for Healthcare Research and Quality(2009)

Agency for Healthcare Research and Quality(2009)

- A type of health care research that compares the results of one approach for managing a disease to the results of other approaches.
- Comparative effectiveness usually compares two or more types of treatment, such as different drugs, for the same disease. Comparative effectiveness also can compare types of surgery or other kinds of medical procedures and tests
- The results often are summarized in a systematic review.
- The direct comparison of existing health care interventions to determine which work best for which patients and which pose the greatest benefits and harms . . . . the core question of comparative effectivenes research (is) which treatment works best, for whom, and under what circumstances.

Evaluation research in Health

- HTA – Health Technology Assessment
- HSR – Health Services Research
- CER – Comparative Effectiveness Research
- EBM – Evidence based medicines

	Main audience	Typical object of study	Central idea
HTA	Policy maker/public	Device or drug	Comprehensive
HSR	Manager/professional	Management options	Pragmatic
CER	Clinician/patients	Clinical alternatives	Comparative
EBM	Clinician/patients	Clinical intervention	Well-founded

	Health	Economic	Ethical/Social
HTA	+++	+++	+++
HSR	+++	++	++
CER	+++	+++/−−	+/−
EBM	+++	+/−	+/−

CER vs HTA

- Health Technology Assessment (HTA)

  Multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner.

- Assessment includes:
  - Identifying evidence, or lack of evidence, on the benefits and costs of health interventions
  - Synthesising health research findings about the effectiveness of different health interventions
  - Evaluating the economic implications and analysing cost and cost–effectiveness
  - Appraising social and ethical implications of the diffusion and use of health technologies as well as their organisational implications
  - The HTA process helps identify best practices in health care, thereby enhancing safety, improving quality and saving costs.

CER and EBHP

Comparative Effectiveness Research and Evidence-Based Health Policy: Experience from Four Countries

KALIPSO CHALKIDOU, SEAN TUNIS, RUTH LOPERT, LISE ROCHAIX, PETER T. SAWICKI, MONA NASSER, and BERTRAND XERRI

National Institute for Health and Clinical Excellence (UK); Center for Medical Technology Policy (USA); Department of Health and Ageing (Australia); Haute Autorité de Santé (France); Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Germany)

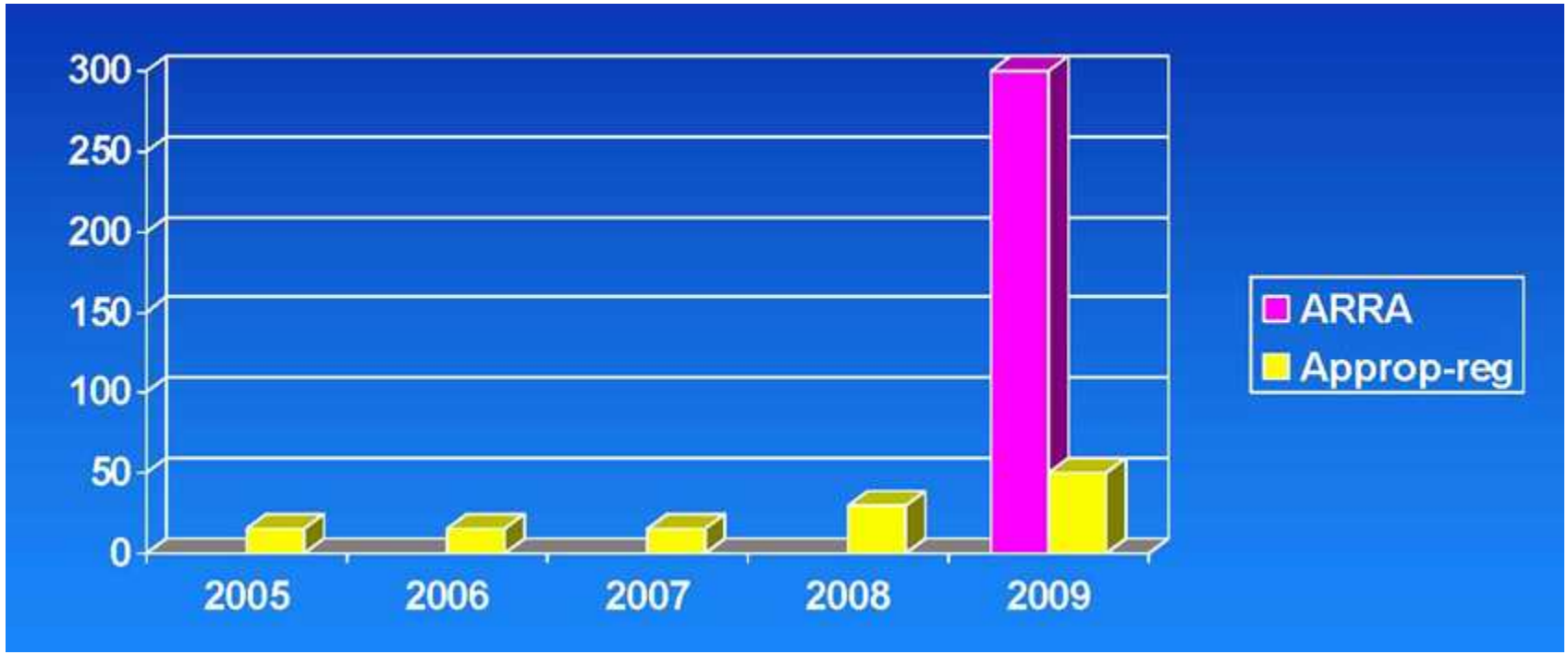
TABLE 1
Key Attributes across CER Entities

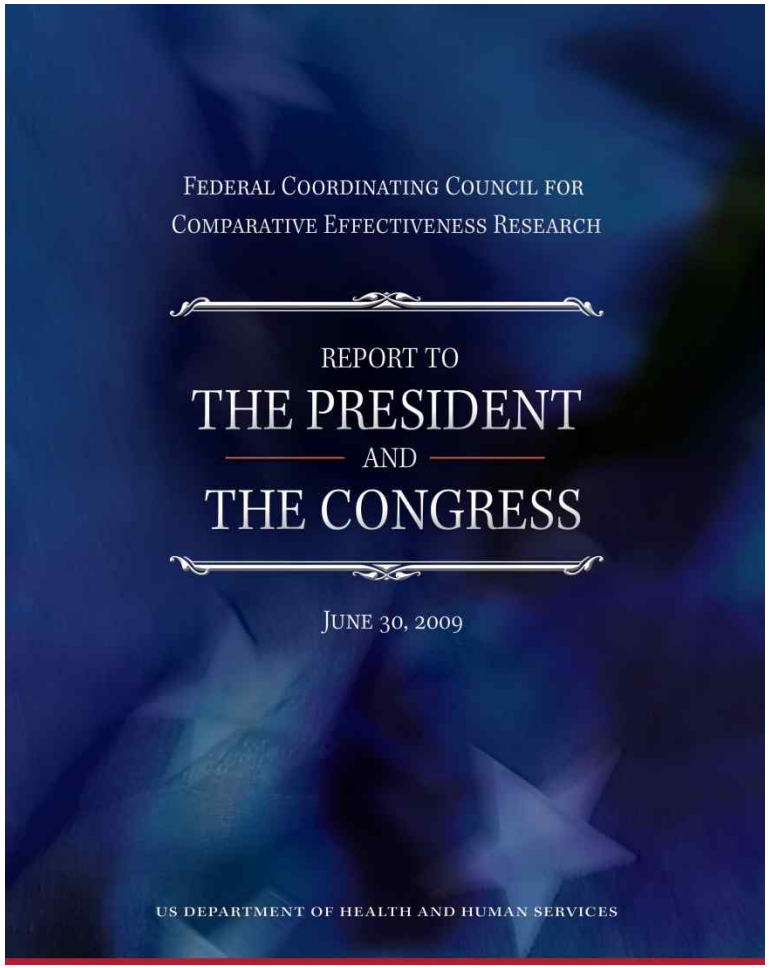
Attributes	NICE	HAS	IQWiG	PBS
1. Stated objective and purpose	Reduce variation in practice; accelerate uptake of new technologies; set quality standards and improve efficiency.	Improve the quality of health care services through hospital accreditation, best care standards, and continuous professional development; evaluation of medical effectiveness, public health impact, and health technology assessments (new and within the existing formulary).	(1) Search for, assessment, and presentation of current scientific evidence on diagnostic and therapeutic procedures for specific diseases; (2) Preparation of scientific reports and expert opinions on quality and efficiency issues of Statutory Health Insurance fund, taking age, gender, and personal circumstances into account; (3) Appraisal of evidence-based clinical practice guidelines on epidemiologically most important diseases; (4) Development of recommendations on disease management programs; (5) Provision of understandable evidence-based information for patients and public.	(To support) timely access to the medicines that Australians need, at a cost that individuals and the community can afford.

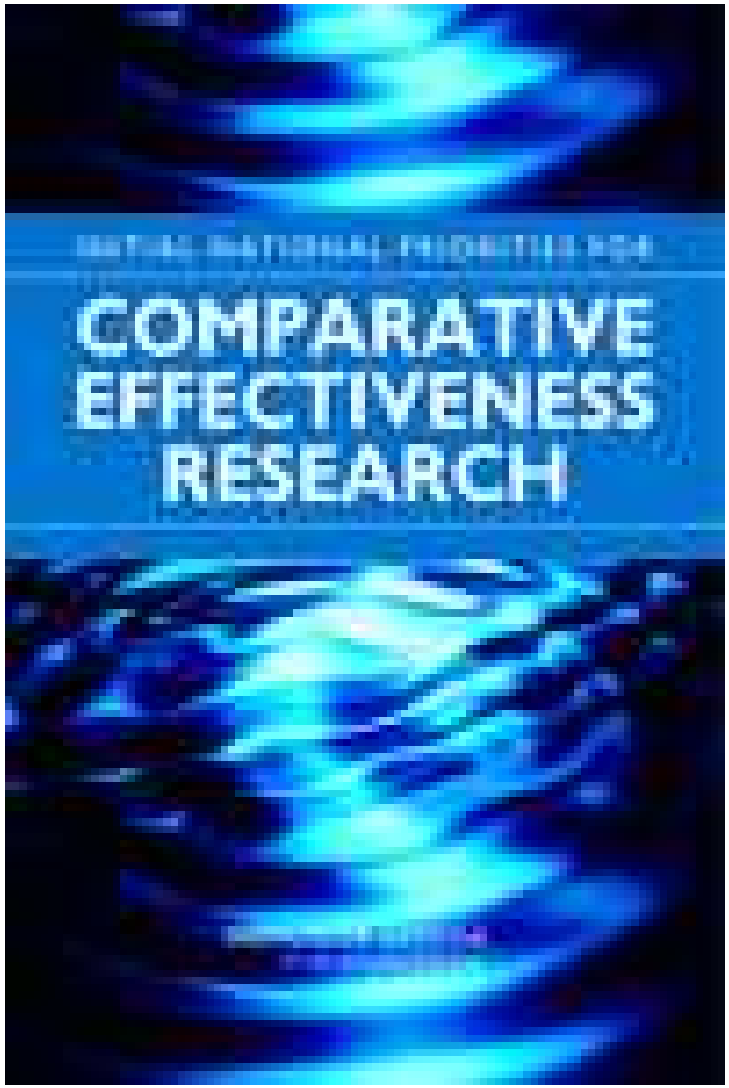
Health Reform Elements

Major Policy Area	Critical Value Policies
Coverage expansion and Financing	1. Align public and private policies 2. Connector or Exchange promoting value
Benefits	3. Assure core benefits promote affordable "right care"
System Reforms	4. Full measures and public reporting (including release Medicare data) 5. Promote wellness 6. Consumer and provider incentives for shared decisions 7. Payment reform – Change payments AND the decision process
Infrastructure	8. Patient-centered comparative effectiveness 9. HIT that promotes better care 10. Foster innovation

Targeted Money(million) for CER in AHRQ




FEDERAL COORDINATING COUNCIL FOR
COMPARATIVE EFFECTIVENESS RESEARCH
REPORT TO
THE PRESIDENT
AND
THE CONGRESS
JUNE 30, 2009
US DEPARTMENT OF HEALTH AND HUMAN SERVICES


COMPARATIVE
EFFECTIVENESS
RESEARCH

IOM's 100 Priority Topics

- *Initial National Priorities for Comparative Effectiveness Research (June 20, 2009)*

TABLE 4-1 Portfolio and Priorities Criteria

Portfolio Criteria	Condition-Level Criteria	Priority Topic-Level Criteria
• Research area • Population to be studied • Interventions • Proposed methodology	• Prevalence • Mortality • Morbidity • Cost • Variability	• Appropriateness of topic for CER • Information gaps and duplication • Gaps in translation

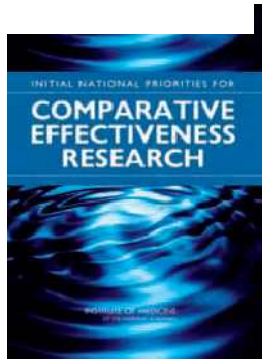
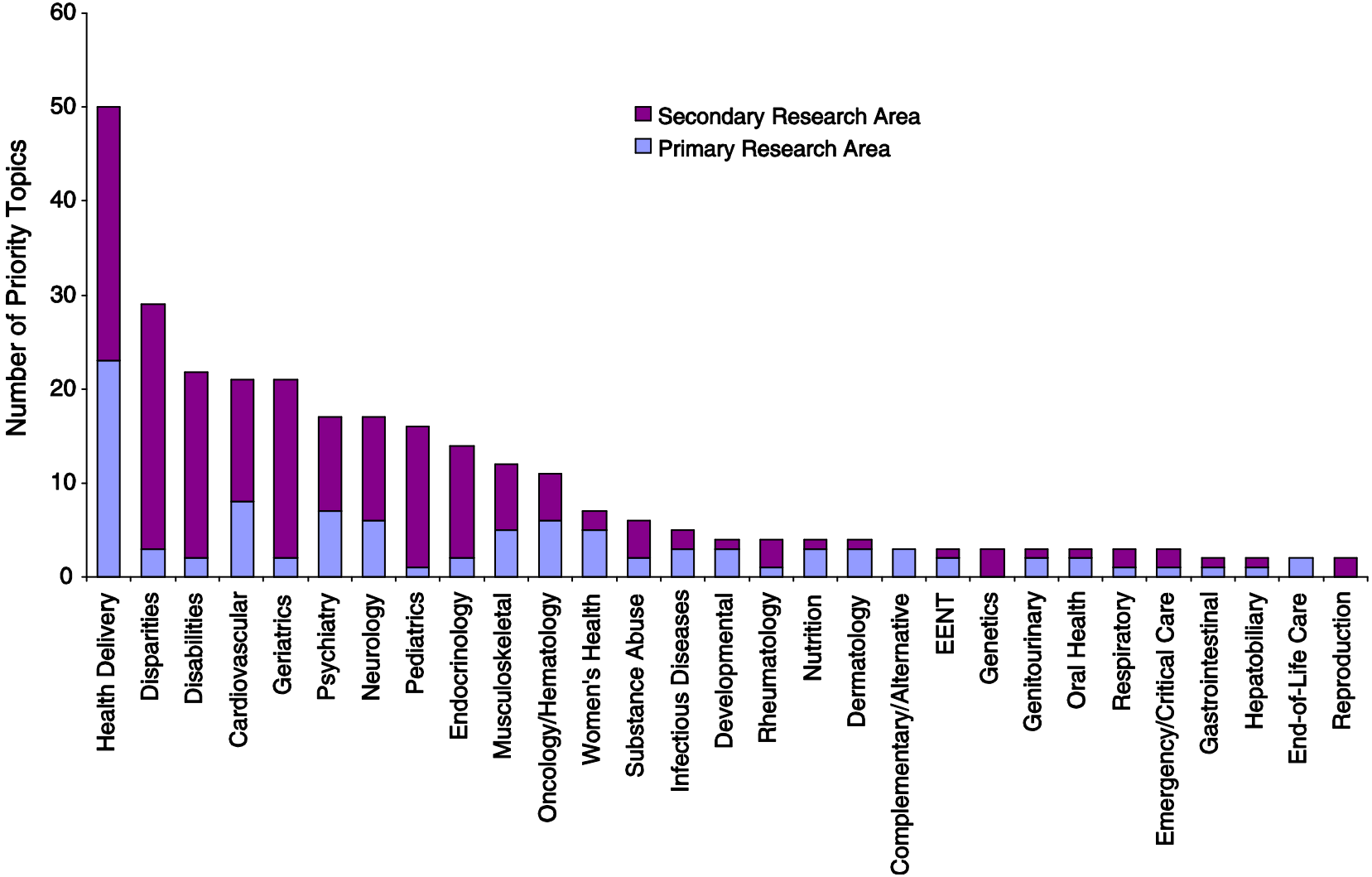
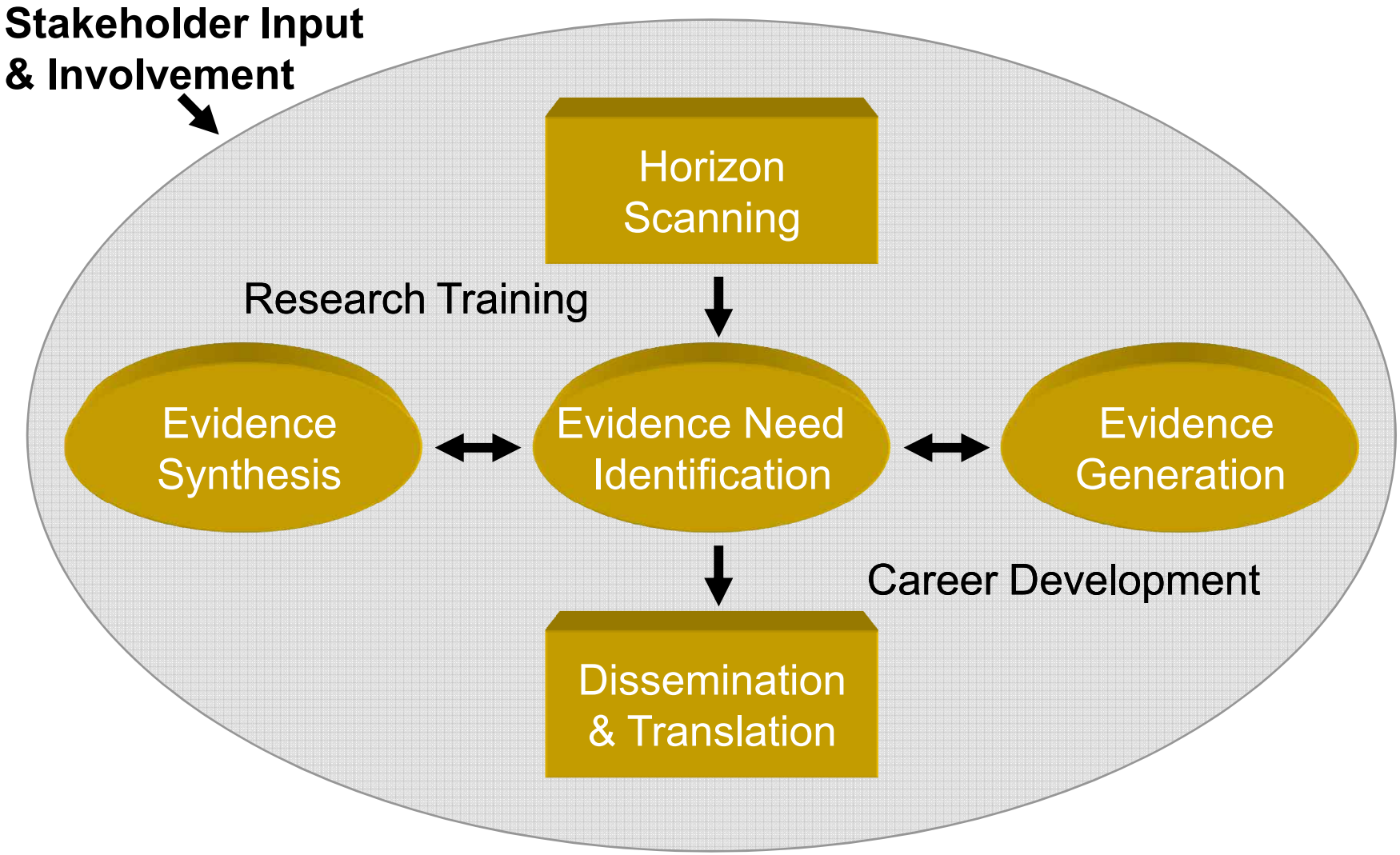


Figure 5.1 Distribution of the recommended research priorities b y primary and secondary research areas



Conceptual Framework of CER in AHRQ

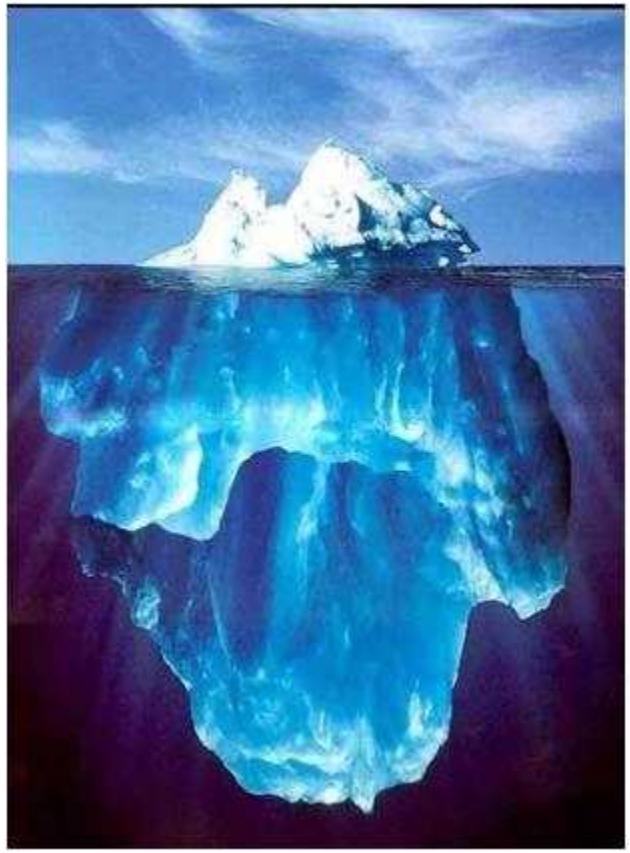


Institute for CER

	하원 통과 법안	상원에서 논의 중인 법안
기관명칭	Center for Comparative Effectiveness Research	Patient-Centered Outcomes Research Institute
소속	AHRQ내에 설립함	비영리 독립 기관 (정부 기관이나 정부관련 연구기관 아님)
목적 및 역할	1. 예방, 진단, 치료와 관련한 모든 보건의료 서비스와 의료시술에 대한 결과연구, 비교효과연구, 적절성 평가연구를 직접 수행하거나 지원하는 역할 2. 연구 범위는 모든 약물, 의료기기, 내과 및 외과적 시술을 모두 포함함	하원 통과 법안과 유사하나 환자, 의료인, 정책 결정자가 올바른 결정을 내릴 수 있도록 도와주는 역할을 명시하고 있음
주요 권한	미국 내 모든 정부기관에 정보를 요청하여 직접 이용할 수 있음	하원 법안과 비슷함
자문기구	1. 독립적인 CER 위원회 설립 2. 역할: 연구우선 순위 설정과 관련한 자문 제공, CERTF 재원을 제대로 사용했는지 모니터링, 센터가 고려해야 할 연구방법론 및 근거의 기준을 제공 등	1. 자문위원회를 둘 수 있으나 하원 법안과 같이 항시적인 운영기구 아님 2. 역할은 하원 법안과 비슷함
재원 조달	CER Trust Fund 설립 (CERTF) 2010: 9천만 달러 2011: 1억 달러 2012: 1억 천만 달러 2013 이후: 추후 조정	Patient-Centered Outcomes Research Trust Fund 설립 (PCORTF) 2010: 1천만 달러 2011: 5천만 달러 2012: 1억 5천만 달러 2013 이후: 최소 1억 5천만 달러 이상

Issues on CER

- What really affects costs?
  - After billions spend on 'War on Cancer', recent data suggest very little reduction in overall mortality (age-adjusted, etc.)
    - Cancer biology is very complex (only understand the very tip of the iceberg)
    - Solutions are largely empiric
  - Same goes with our complex health care system
    - Health care reform solutions offered in 2009 are largely empiric

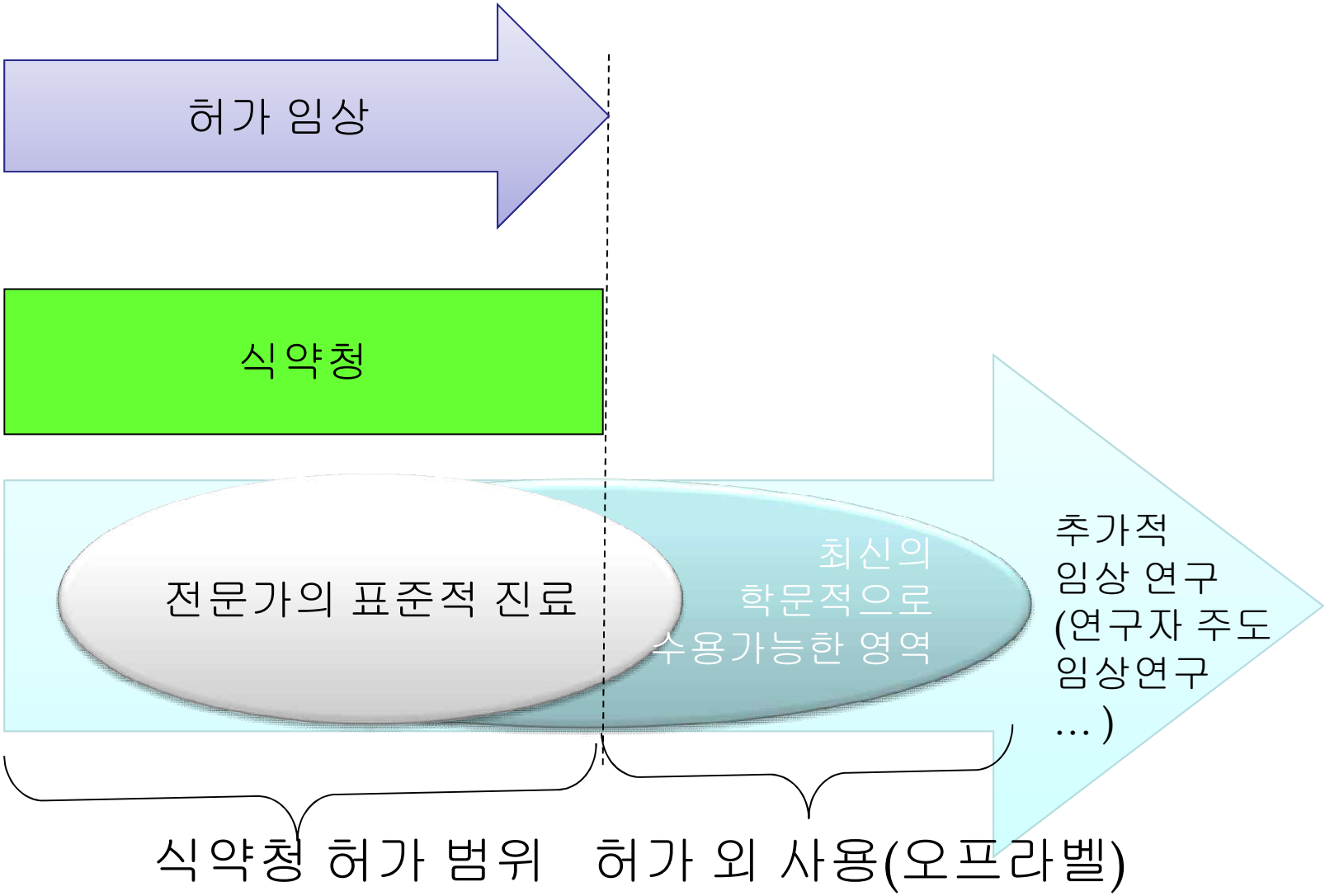


Issues on CER

- Individualized Care vs. One–size Fits All
- Ensuring Disparities Are Not Exacerbated (or ignored)
- Common Conditions vs. Rare Diseases
- Inclusion of Cost and/or Cost–Effectiveness
- Paying for Unproven Care vs. "Rationing" or Denial of Coverage
- Rewarding What Works vs. Stifling of Innovation
- Rigor of Scientific Evidence
- Who Decides – what to research; what to do with the results

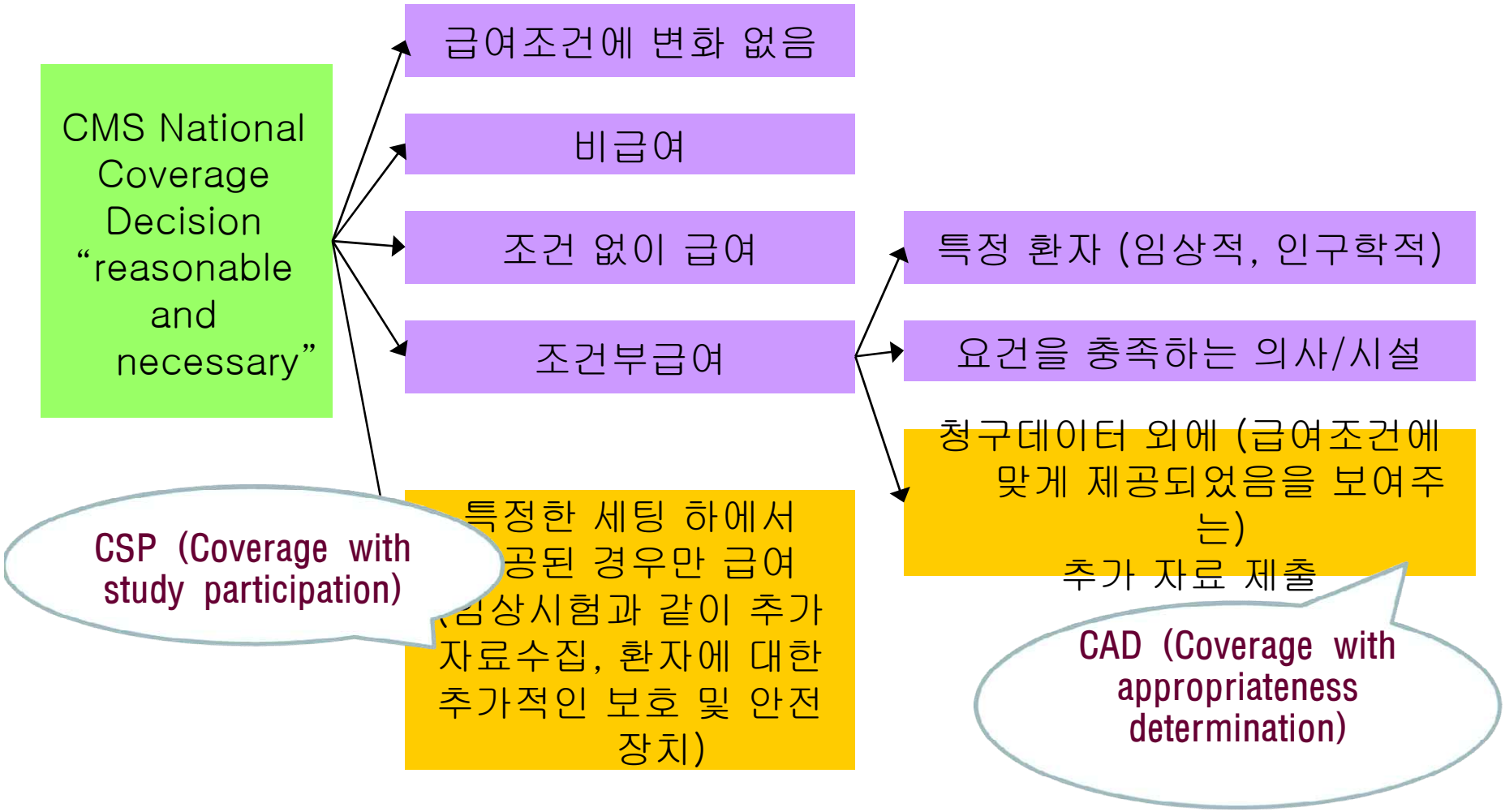
Access with Evidence Generation(AEG)

의료기술에서 근거의 생성 발전



근거 생산 조건부 급여

- 미국의 CED(Coverage with evidence development)



근거 생산 조건부 급여

- 영국의 OIR(Only in research)

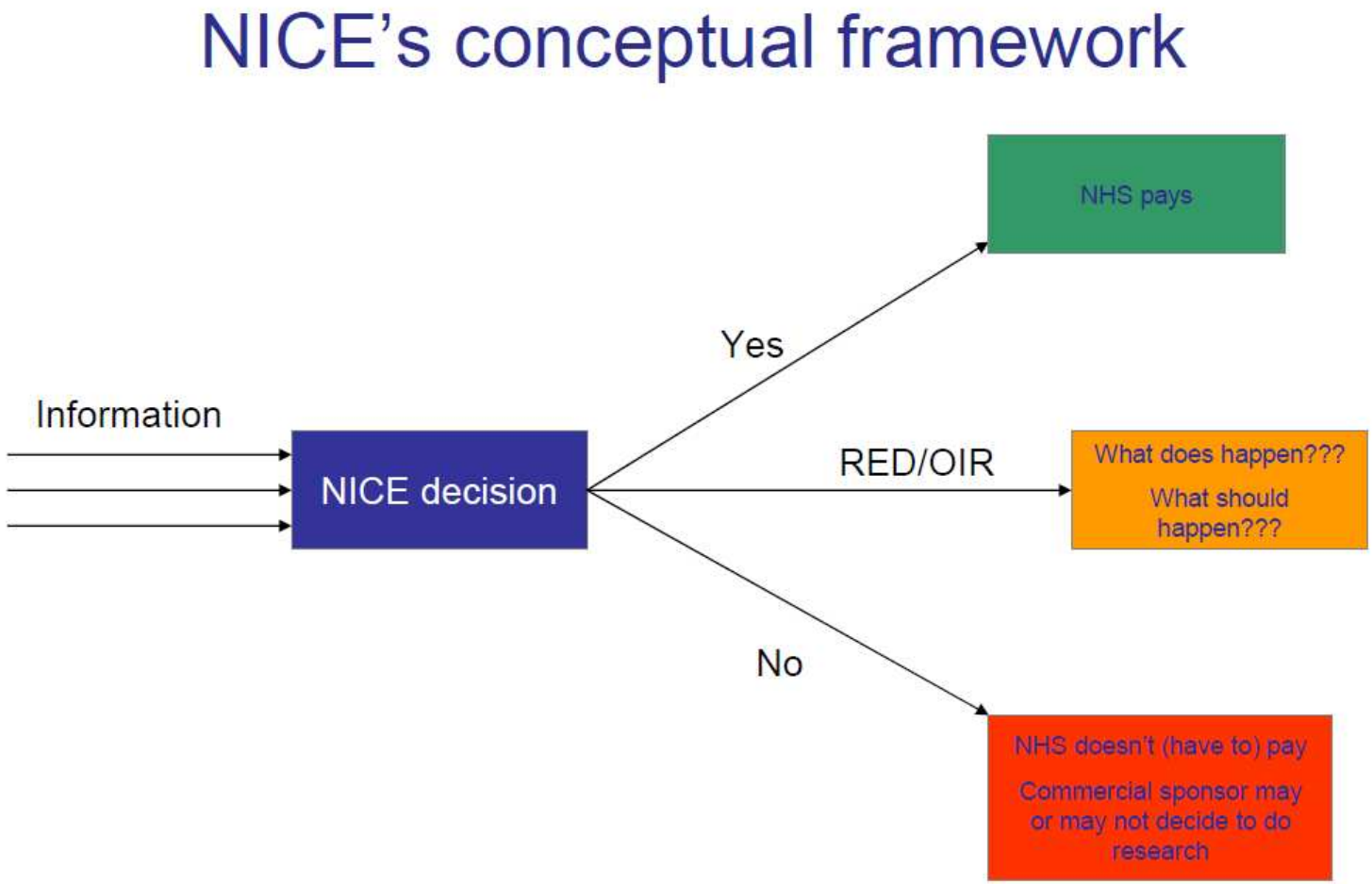


Table 4. Degree of Implementation of AEG Mechanisms by Various Countries

	Marketing approval		Coverage decision		
Country	Medicine	Medical device	Medicine	Medical device	Procedure
Canada (Ontario)	+++[N]	+++	+++	+++	+++
Spain	+++[E,N]	+++	+++	+++	+++
Australia	+++[N]	+++	+++/++	+++	+++
US	+++[N]	+++	+++	+++	+++
England/Wales	+++[E,N]	++	+++	+++	+++
France	+++[E,N]	++	+++	+++	++/+
Germany	+++[E,N]	++	++	+++/++	++
Sweden	+++[E]	−	+++	++	++
Belgium	+++[E,N]	−	−	+++	−
Italy	+++[E,N]	−	+++/++	+/−	+/−
Netherlands	+++[E,N]	−	+++/−	−	−
Switzerland	−	+++	−	−	+++/−
Austria	+++[E]	−	++	++	++
Denmark	+++[E,N]	−	++	++	++
Latvia	+++[E,N]	+++	−	−	−
Portugal	+++[E,N]	−	−	−	−
Finland	+++[E,N]	−	−	−	−
Poland	+++[E]	−	−	−	−
Ireland	+++[E]	−	−	−	−
Estonia	+++[E]	−	−	−	−
Slovenia	+++[E]	−	−	−	−
Cyprus	+++[E]	−	−	−	−
Norway	−	−	−	−	−

Note. +++, full AEG; ++, partial AEG; +, passive AEG; −, No AEG. [E], AEG implemented by EMEA and applicable in European Countries; [N], country-specific AEG implemented at national level.

Pay for Performance(P4P)

P4P Definition

"The use of incentives to encourage and reinforce the delivery of evidence-based practices and health care system transformation that promote better outcomes as efficiently as possible."

Outcomes-Based Compensation:
Pay-For-Performance Design
4th Annual Disease

Principles
Management Outcomes Summit
Johns Hopkins / American Healthways, Nov. 2004

Example of P4P: US

- Process Measures:
  - Diabetes
  - Asthma
  - Child and Adolescent well care
  - Cardiovascular Conditions
  - Appropriate testing for children with pharyngitis
- Outcome Measures:
  - Diabetes
  - Cardiovascular Conditions
  - Childhood & Adolescent Immunizations
- Technology Adoption (EMR, EHR, eRX, Electronic disease registry adoption or AQI Portal use)
- Generic pharmacy utilization Measure

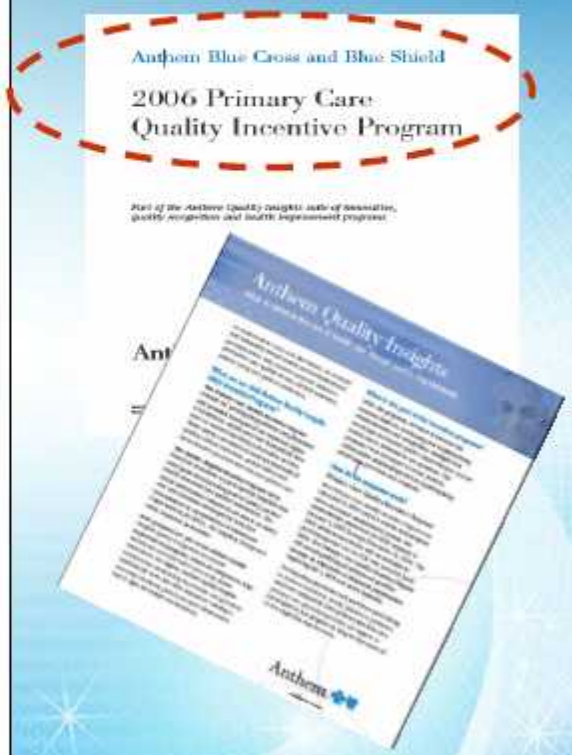


Table. Examples of Some of the Largest Pay-for-Performance Initiatives to Date

Program	Participant	Sponsor	Target	Results
Hospital Quality Improvement Demonstration Project	230 Acute care hospitals in the United States	Center for Medicare & Medicaid Services	Process measures for heart failure, acute myocardial infarction, pneumonia, hip replacement, coronary artery bypass grafting surgery	Modest improvements in process performance, no identifiable impact on outcomes
Quality and Outcomes Framework/General Practitioner Pay-for-Performance contract	42 Family practices in England	National Health Service	146 Indicators related to chronic disease and patient experience	Short-term improvements in care which slowed once performance targets were reached
Integrated Healthcare Association Pay-for-Performance Program[10]	225 Physician groups in California	8 Health plans in California representing 10.5 million patients	Multiple, including clinical process measures, patient experiences of care, adoption of information technology	Modest improvements in targeted areas of care
Bridges to Excellence[11]	Multiple provider groups operating in 13 states	Collaborative effort among large employers, including General Electric and Verizon Communications	Includes excellence programs in diabetes, cardiac, spine, and depression	Cost savings in diabetes care, achievement of performance thresholds in diabetes and cardiac care
Hill Physicians Medical Group[12]	2200 Physicians in North Carolina	Hill Physicians Medical Group serving 332,000 patients in 7 HMOs	Resource utilization, clinical performance (cancer, diabetes, low back pain, immunization), patient experience, up to 15% of compensation to quality performance	Improvement in threshold diabetes care by 42% and cholesterol levels by 32%
Hawaii Medical Service Association Practitioner and Hospital Quality and Service Recognition Programs[13]	More than 2500 physicians in its preferred provider plan, 17 hospitals	Blue Cross Blue Shield of Hawaii	Patient safety, adherence to evidence-based guidelines, patient satisfaction	Significant improvements in adherence to clinical measures in a number of areas, including cancer screening, immunization, and heart failure

HMO indicates health maintenance organization.

P4P Potential BENEFITS Summary

1. Finances quality improvement projects
2. Aligns goals of care with payment
3. Encourages more standardized care
4. Healthy patients = health care savings

P4P Potential BURDEN Summary

1. Quality data collection is burdensome
2. Up front investment is large and risky
3. May erode medical professionalism
4. Altered physician–patient relationship
5. May discourage clinical judgment
6. Sicker patients may get worse care
7. May increase health care disparities
8. May slow integration of new evidence

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감사합니다