

HTA TO INFORM BENEFITS PACKAGE DESIGN AND REIMBURSEMENT DECISIONS: THE EXPERIENCE OF NICE AND BEYOND

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Commitment to

Universal Coverage



General Assembly GA/11326

Sixty-seventh General Assembly Plenary 53rd Meeting (AM)

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UN adopts 'momentous' resolution on universal healthcare

General assembly urges countries to launch affordable healthcare systems that cover all their citizens

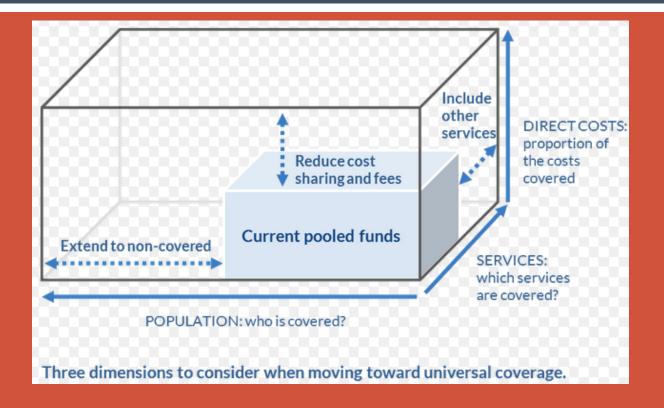
Mark Tran

guardian.co.uk, Thursday 13 December 2012 13.26 GMT



How much is enough?





UNIVERSAL COVERAGE OF WHAT AND FOR WHOM?

What's the problem? Distorted priorities cost lives

Colombia

- Avastin paid for for all indications (incl FDA unlicensed ones)
- Regional variation in immunisation with parts of the country with <50% coverage

Kyrgyzstan

- >50% of insulin budget goes to analogues
- Switching to human insulin can double the number of patients on treatment

HIV

- 40-50% of eligible patients NOT on treatment in Africa
- 2nd and 3rd line ART for <5% of patients, consumes one fifth of the total ART budget

UK

- Cancer Drugs Fund spends £300m pa on non-cost effective drugs
- 14,400 QALYs lost across the NHS due to displacement of other needed, cost-effective care



World Health Assembly resolution on Health Intervention and Technology Assessment, 2014

"to integrate health intervention and technology assessment concepts and principles into relevant strategies and areas...including, but not limited to, universal health coverage, health financing, access to and rational use of quality-assured medicines, vaccines and other health technologies, the prevention and management of non-communicable and communicable diseases, mother and child care, and the formulation of evidence-based health policy"

NICE: EXPERIENCE IN THE TIME OF PLENTY

NICE....what is it now?

The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care

We do this 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.

Core principles of NICE's work

- Based on the best evidence available
- Expert input
- Patient and carer involvement
- Independent advisory committees
- Genuine consultation
- Regular review
- Open and transparent process
- Social values and equity considerations

Cost effectiveness –

Incremental cost-effectiveness ratio (ICER):

health gain_{new} – health gain_{current}

At NICE, health gain is expressed as quality adjusted life years (QALYs) which allows us to calculate the **cost per QALY** for any technology under consideration

Application of 'special circumstances'

Table 1

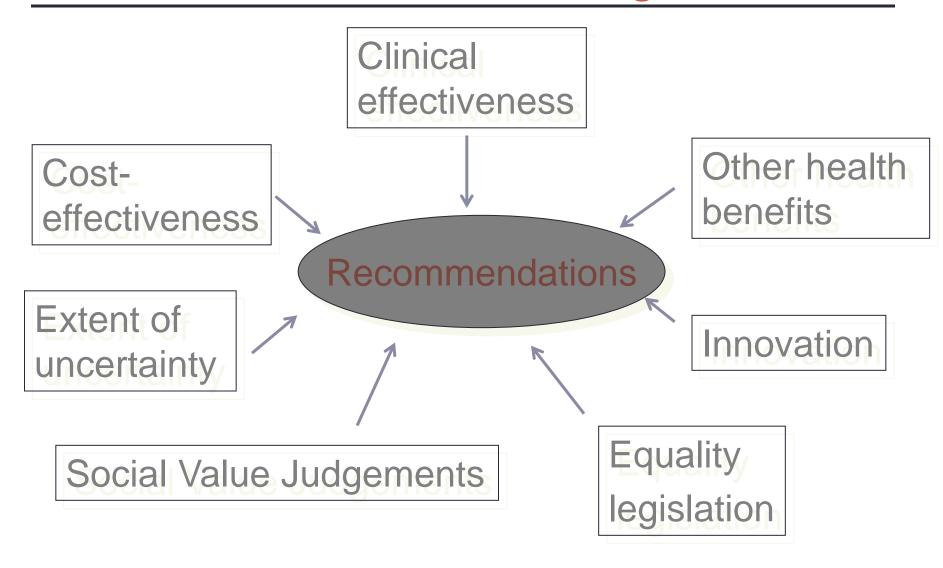
Application of 'special circumstances' in the appraisal of some products with incremental cost-effectiveness above £30 000 per quality adjusted life yea

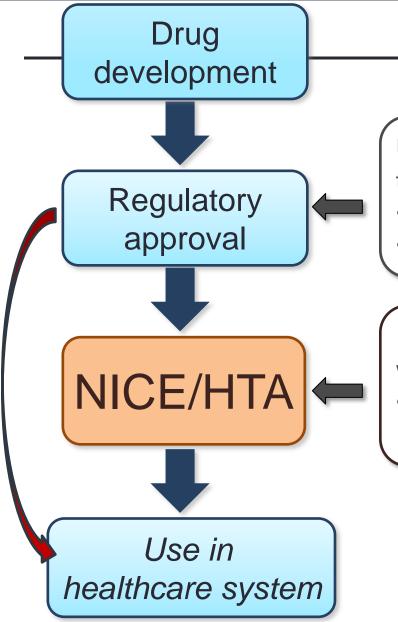
Topic	ICER ('000s)	Severity	End of life*	Stakeholder persuasion	Significant innovation	Disadvantaged population	Children
Riluzole (motor neurone disease)	38–42	/	✓	✓			
Trastuzumab (advanced breast cancer)	37.5	✓			✓		
Imatinib (chronic myeloid leukaemia)	36-65	✓			/		
Imatinib (gastrointestinal stromal tumour)		✓	✓		✓		
Pemetrexed (malignant mesothelioma)	34.5	✓	✓			✓	
Ranizumab (age-related macular degeneration)	>>30			✓	✓		
Omalizumab (severe asthma)	>30	✓		✓	/		
Sunitinib (advanced renal cancer)	50	✓	✓	✓	✓		
Lenalidomide (multiple myeloma)	43	✓	/		/		
Somatotropin (growth hormone deficiency)	n/a			✓	✓		✓
Chronic subcutaneous insulin infusion (childhood Type 1 diabetes)	n/a			✓			✓

^{*}End-of-life considerations have only been explicitly taken into account since January 2009 on the basis of supplementary advice from the Institute to the Appraisals Committee. ICER, incremental cost-effectiveness ratio (£ per quality-adjusted life year).

Rawlins, Barnett, Stevens Br J Clin Pharmacol 2010

Committee decision making





Under controlled conditions and compared to placebo:

- Is the drug safe?
- Does the drug do more good than harm?

In routine clinical practice and compared with existing treatments:

 Do the additional clinical benefits justify the expected additional cost?

Incorporating consideration of relevant social value judgements

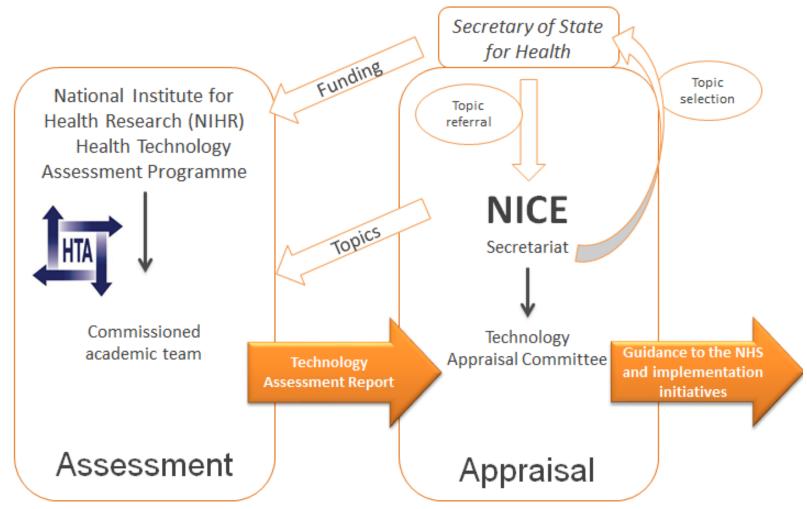


NICE: a negative list for technologies

TA007	2000	MTA	Rabeprazole	Dyspepsia	Recommended	Guidance has been incorporated in CG17. Recommendation in line with marketing authorisation.
TA008	2000	MTA	Digital hearing aids	Deafness	Not Recommended	The Department of Health made digital hearing aid technology available across the NHS after TA008 was published which made guidance obsolete. Guidance withdrawn from May 2003.
TA008	2000	MTA	Analogue hearing aids	Deafness	Recommended	The Department of Health made digital hearing aid technology available across the NHS after TA008 was published which made guidance obsolete. Guidance withdrawn from May 2003.
TA009	2000	MTA	Rosiglitazone	Type 2 diabetes	Recommended	Guidance has been replaced by TA63 and incorporated in CG66. Recommendation in line with marketing authorisation.
TA010	2000	MTA	Dry powder inhalers (DPI)	Asthma (children under 5 years)	Recommended	Recommendation in line with marketing authorisation.
TA010	2000	MTA	Nebulised therapy	Asthma (children under 5 years)	Recommended	Recommendation in line with marketing authorisation.
TA010	2000	MTA	Pressurised metered dose inhalers (pMDI) and spacer system	Asthma (children under 5 years)	Recommended	Recommendation in line with marketing authorisation.
TA011	2000	MTA	Implantable cardioverter defibrillators (ICDs)	Arrhythmias	Recommended	Guidance has been replaced by TA95. Recommendation in line with clinical practice.
TA012	2000	MTA	Abciximab (intravenous)	Acute coronary syndromes	Recommended	Guidance has been replaced by TA47. Recommendation in line with marketing authorisation.

 Positive guidance: 3-month directive for funding and legal entitlement to access drug – new NICE compliance regime announced in Dec 2011 for automatic inclusion in local formularies

NICE appraisal vs assessment



Adapted from Walley, T. (2007) MJA; Overview of Health technology assessment in England: assessment and appraisal 187: 283–285



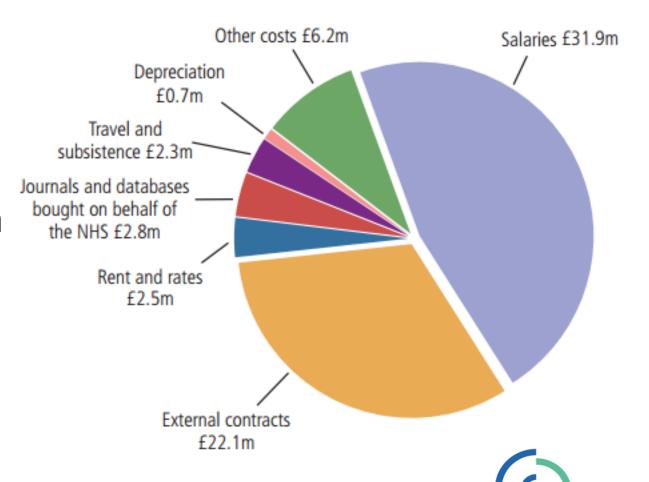
Groups involved in an appraisal





This is how funding was spent 13/14

This is how NICE spent £68.5 million in 2013/14



Lessons from the 'NICE way'

- Good governance structures can significantly increase the legitimacy (in the eyes of the law and of the public) of priority setting decisions, but:
- · The process needs a degree of flexibility to avoid being too rigid
- The system needs to be responsive and be able to adapt to changing needs
- Importance of reviewing processes/methods
- An inclusive, multidisciplinary approach can improve both the quality and legitimacy of decisions made
- BUT...



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The adoption of ex

other kinds of heal

The report said that £10m spent on a new drug approved at Nice's February 19, 2015 12:00 current upper threshold would produce 333 extra quality-adjusted life years for patients who received the treatment but cause the loss of 773 to patients denied other forms of care because of Andrew Ward, Pharminsufficient resources.

An example of this might be money spent on a cancer drug that earlier diagnosis or surgery and radiotherapy.

good, according to Prof Claxton: "There has to be some honesty and accountability if, companies are pai for political reasons, we are prepared to pay half a million pounds for [a drug] that is not very effective and, as a result, these people Research by the Ulover here are going to suffer from increased mortality and a diminished becaus reduced quality of life."

Affordability matters more than ever!

Revamped Cancer Drugs Fund

Highly Specialised Technologie s proposal

Accelerated
Access
Review
proposal

- NHS England, the NHS executive with budgetary responsibilities, is becoming a decision maker
- NICE must consider budget impact in decisions or...phased adoption and delays in access
- What does this mean for Cost Effectiveness and Value for Money?
- Who should worry about budgets? NHS England or the government?

Accelerated Access Review - Nov 2016

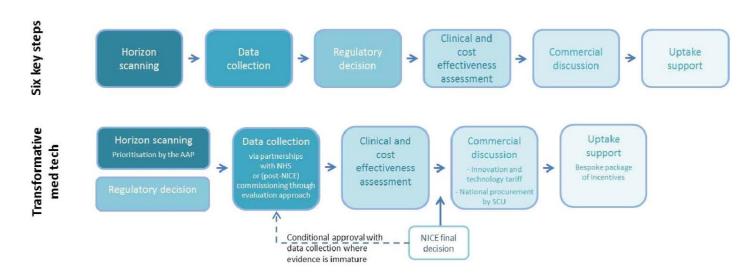


Figure 11: The sequencing of the Accelerated Access Pathway for strategically important medical technologies

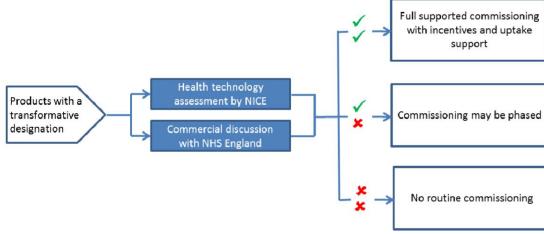


Figure 10: Products that reach a commercial deal will move swiftly to reimbursement

Highly Specialised Technologies – joint NHS England – NICE proposal

- Introduce a 'fast track' NICE technology appraisal process for the most promising new technologies, which fall below an incremental cost-effectiveness ratio of £10,000 per QALY (quality adjusted life year), to get these treatments to patients more quickly.
- Operate a 'budget impact threshold' of £20 million, set by NHS England, to signal the
 need for a dialogue with companies to agree special arrangements to better manage the
 introduction of new technologies recommended by NICE. This would apply to a small
 number of technologies that, once determined as cost effective by NICE, would have a
 significant impact on the NHS budget.
- Vary the timescale for the funding requirement when the budget impact threshold is reached or exceeded, and there is therefore
 WHERE BUSINESS MEETS POLICY -
- Automatically fund, from routine commis conditions (highly specialised technologisthan the lower end of NICE's standard the treatments above this range to be consider prioritising other highly specialised technologisth.

the new technology would risk disruption



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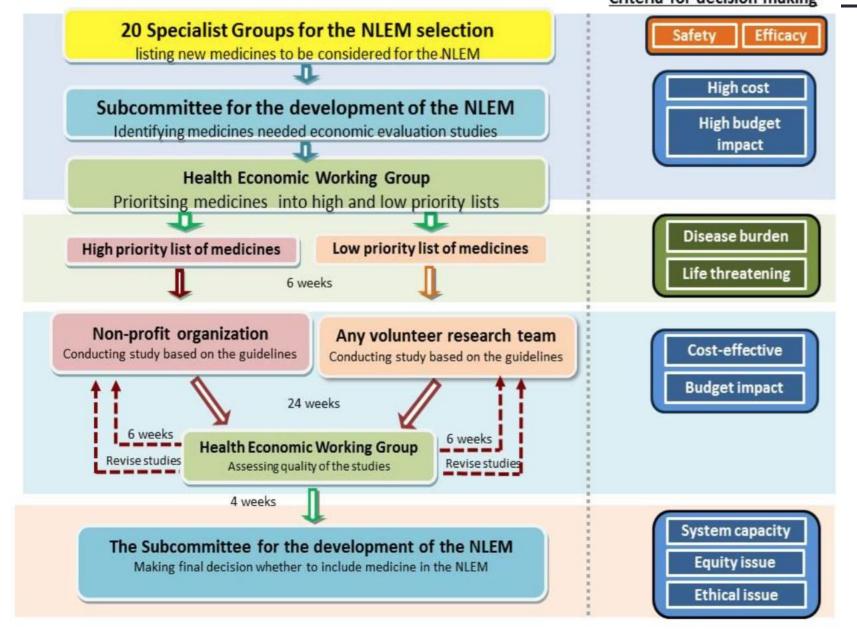
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Deal or Delay: NICE's New Negotiating Chip

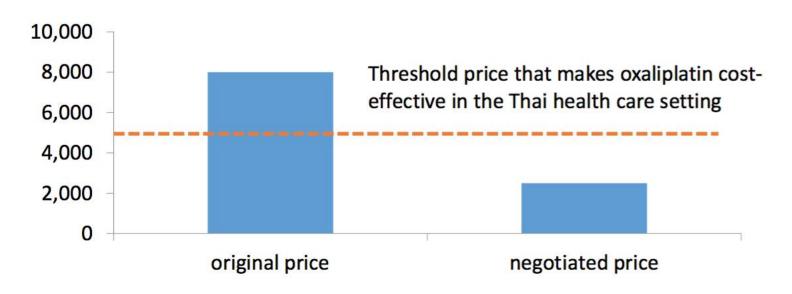
Oct 20, 2016 By Leela Barham

WHAT ENGLAND IS MISSING: THE ABILITY TO NEGOTIATE PRICES AND THE CASE OF THAILAND

Enhances value for money: Thailand's HTA-informed essential medicines list



Threshold analysis for price of oxaliplatin

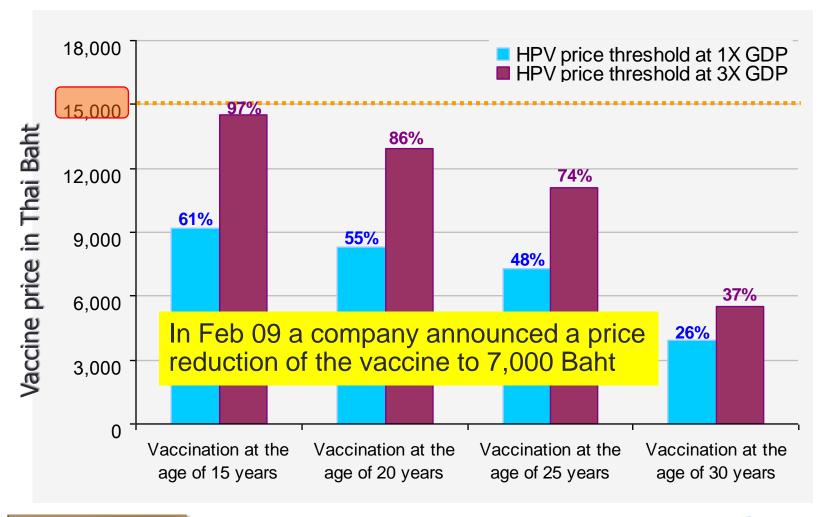


Use of HITA information in price negotiation

Medicine	Original price (THB)	Reduced price (THB)	Potential saving (THB per year)
Tenofovir	43	12	375 million
Pegylate interferon alpha-2a (180 mcg)	9,241	3,150	600 million
Oxaliplatin (injection 50 mg/25 ml)	8,000	2,500	152 million

Example of using HTA in price negotiation

the analysis of pricing threshold of the HPV vaccine against the WTP threshold



Source: HITAP

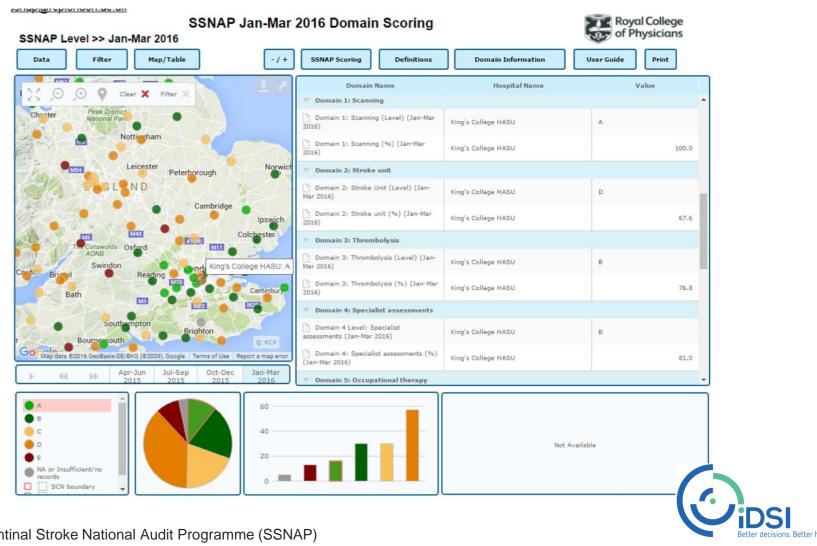


DATA MATTER

Auditing and benchmarking of providers against national standards for stroke care

		Over	all SSNAP level:								
AMZ	P Domains and Key Indicators										
JUINA	P Domains and Key malcators										
					2014		2015				2016
1.	Scanning		Time Period	Apr-Jun 2014	Jul-Sep 2014	Oct-Dec 2014	Jan-Mar 2015	2015	Jul-Sep 2015	Oct-Dec 2015	2016
1.1 Propor	rtion of patients scanned within 1 hour of clock start	07L	Barking and Dagenham CCG	С	В	В	В	В	В	В	
	rtion of patients scanned within 12 hours of clock start	07M 07N	Barnet CCG Bexley CCG	B B	В	B B	B B	B B	B A	B B	E
	n time between clock start and scan (hours:mins)	07P	Brent CCG	A	A	A	A	A	A	A	
1.3 Mediai	n time between clock start and scan (nours:mins)	07Q	Bromley CCG	В	В	Α	В	В	Α	A	E
2.	Stroke unit	07R	Camden CCG	С	D	С	С	В	Х	С	C
	Stroke diffe	09A	Central London (Westminster) CCG	В	С	В	С	В	С	В	E
2.1 Propor	rtion of patients directly admitted to a stroke unit within 4 hours	07T	City and Hackney CCG	Х	Х	В	Х	В	В	Х)
2.2 Media	n time between clock start and arrival on stroke unit (hours:mins	07V 07W	Croydon CCG	В	A A	B A	B A	В Д	A A	B A	E
		07W	Ealing CCG Enfield CCG	C	X	X	X	В	C	C	(
 2.3 Proportion of patients who spent at least 90% of their stay on strol Thrombolvsis 		08A	Greenwich CCG	В	В	В	В	В	A	В	
	Thrombolysis	08C	Hammersmith and Fulham CCG	В	В	В	В	В	В	В	
Briefstone (Briefstone Court State Court S		08D	Haringey CCG	Х	Х				Х	С	- (
3.1 Propor	rtion of <u>all</u> stroke patients given thrombolysis (all stroke types)	08E	Harrow CCG	Α	Α	Α	Α	Α	Α	Α	
3.2 Proportion of <u>eligible</u> patients (according to the RCP guideline minimur- thrombolysis		08F	Havering CCG	С	В	В	В	В	В	В	
		08G 07Y	Hillingdon CCG	A B	A B	A B	A B	A B	A B	A B	
3.3 Propor	rtion of patients who were thrombolysed within 1 hour of clock s	07Y 08H	Hounslow CCG Islington CCG	С	D	С	С	В	D	С	
		08J	Kingston CCG	В	A	В	В	В	A	В	
3.4 Proportion of applicable patients directly admitted to a stroke unit with		08K	Lambeth CCG	В	Α	Α	В	В	Α	Α	
	r receive thrombolysis or have a pre-specified justifiable reason	08L	Lewisham CCG	В	В	В	В	В	Α	В	ا
be given		08R	Merton CCG	В	Α	В	В	В	Α	В	
3.5 Media	n time between clock start and thrombolysis (hours:mins)	08M	Newham CCG	С	В	В	В	В	В	В	
4	Consistint assessment	08N	Redbridge CCG	В	B	B B	B B	B B	B B	B A	
4. Specialist assessment		08P 08Q	Richmond CCG Southwark CCG	В	B	Δ	В	В	A	Δ	
1.1 Propor	rtion of patients assessed by a stroke specialist consultant physic	08Q 08T	Sutton CCG	В	A	В	В	В	A	A	
	n time between clock start and being assessed by stroke consult	08V	Tower Hamlets CCG	С	A	Α	В	В	Х	С	
		08W	Waltham Forest CCG	Х	Х	В	В	В	В	С	
1	rtion of patients who were assessed by a nurse trained in stroke	08X	Wandsworth CCG	В	Α	В	В				
clock start		08Y	West London CCG	В	В	В	Х				
		03V	Corby CCG	С	В	В	С				

Auditing and benchmarking of providers against national standards for stroke care



Conditions for success

"Successful development depends to a large extent on a government's capacity to implement its policies and manage public resources through its own institutions and systems" The Paris Declaration on Aid Effectiveness (2005) and the Accra Agenda for Action (2008)

sustained financial investment

Local Institutions
Local Information
Local Experts

sustained political backing



WORKING IN CHINA

Who we are





International Decision Support Initiative: 50 FTEs with active links to policy makers in over 20 countries and a track record of delivery in China with CNHDRC - our long term partners

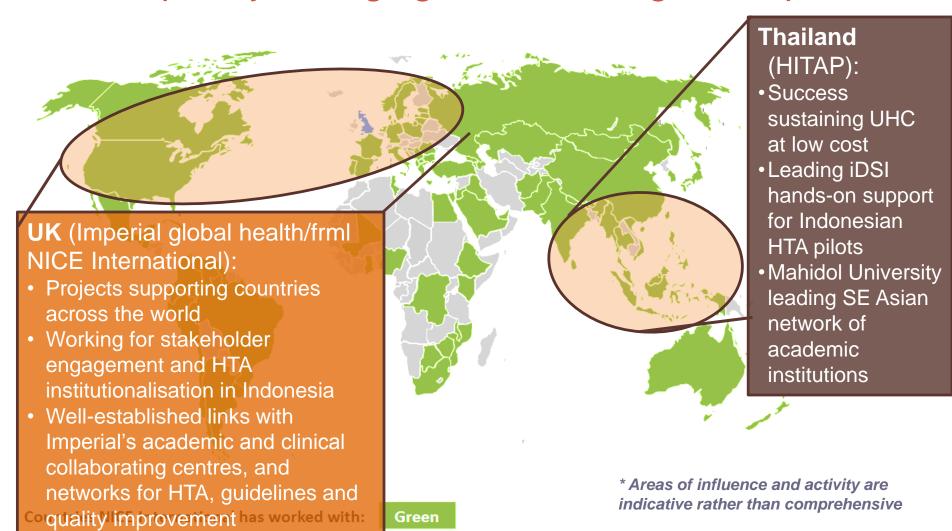
Global Health & Development Group @ Imperial – Lord Darzi – Institute for Global Health Innovation

London Academic Health Science Networks incl. Imperial and King's Health Partners

World leading academic and professional networks from UK and abroad with applied health economics and quality expertise

Health and development policy think tanks from UK and beyond incl. Centre for Global Development and the Nuffield Trust

The institutions co-leading iDSI are embedded in national priority-setting agencies with a global reputation



iDSI regional hubs will provide a responsive, sustainable mechanism for delivering practical support

South Africa (PRICELESS-SA, Wits University):

- Technical resource within South Africa
- Entry point for practical support in Sub-Saharan African countries
- Links to CABRI, AfHEA and related initiatives

China (CNHDRC):

- Technical resource on HTA and best practice for 33 provinces
- Entry point for supporting prioritysetting in countries under 'One Belt One Road' strategy
- Participation in HTAsiaLink and related networks

* Areas of influence and activity are indicative rather than comprehensive

Countries NICE International has worked with:

Green

Our work in China

Joint pilots: clinical pathways and payment reform

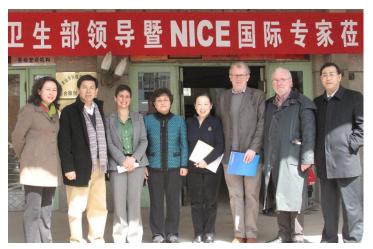
Phase I (2009-2012)

'Simple' pathways for selected surgeries

Phase II (2012-)

Stroke + COPD pathways in four counties

- Projects strengthen rural health system, including promoting effective use of medicines and medical devices, and treatment in community
- Payment reforms applied in over 1,000 counties
- CNHDRC increasingly active as a source of priority-setting expertise





CNHDRC and **NICE**: continued collaboration

areas of collaboration

Sustained support to **public hospital reforms** and strengthening community
care facilities (building on existing clinical
pathway and payment reform projects)

Imperial

iDSI

CNHDRC

NHFPC

Roadmap for institutionalizing evidenceinformed priority-setting methods as the basis for spending decisions and CNHDRC **HTA Hub**

Joint **UK Research Council and FCO** applications incl recent to Engineering and Physical Sciences Research Council

Regional and South-South support to priority-setting in other countries in the region

expected outcome

Progress in institutionalising explicit and evidence-informed priority-setting (including health technology assessment) which considers economic evidence and local values



A China Hub for HTA linking academe to government and the healthcare delivery system

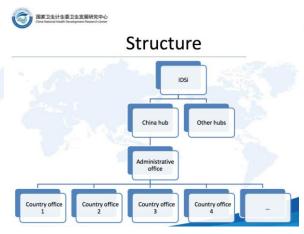


Appendix three: FCO project

国家卫生计生委卫生发展研究中心

Evidence-based integrated care pathway of chronic disease management

China National Health Development Research Center 2016, March



Purpose

国家卫生计生委卫生发展研究中心

 The project aims to influence both central and local health delivery policies by evaluating and strengthening evidence-based clinical guidance, quality control, and coordinated care through the use of quality standard and care pathways in chronic disease management.



Vision and Mission

- Vision: An dedicated center on knowledge translation, supporting evidence-based decision-making(EBDM) for one belt one road countries.
- · Mission:
 - 1. Promote HTA
 - 2. Promote evidence use in decision-making
 - 3. Facilitate collaborations



Project organization



