

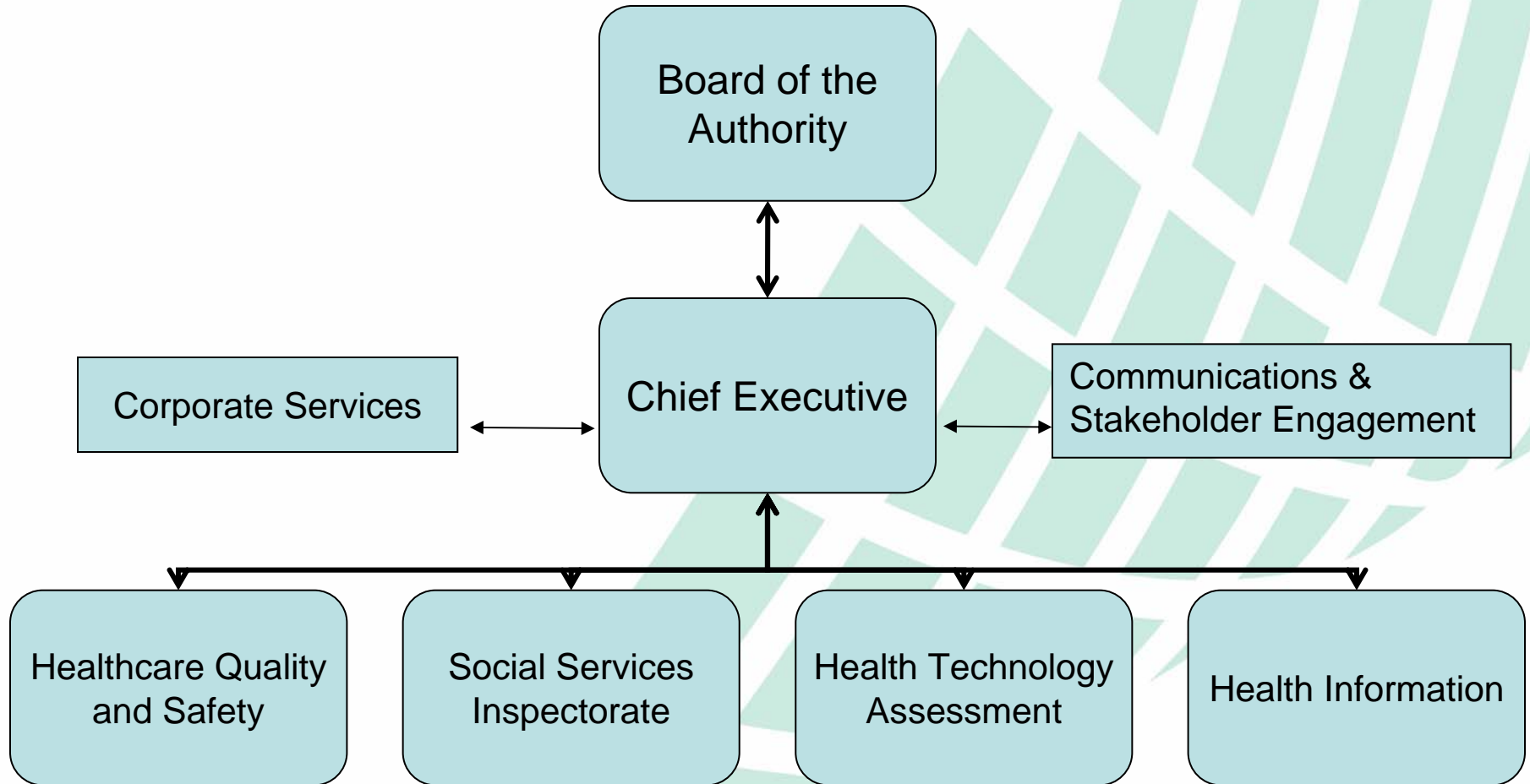


HIQA and Health Technology Assessment in Ireland

Trish Harrington
Acting Director of
HTA

Health Information
and Quality Authority

HIQA Organisational Structure



Healthcare Quality and Safety

- Framework for continuous quality improvement - standards for clinical and corporate governance
- Assure the **minimum quality** of service, mandatory reviews of organisations
- Provide programme of 'accreditation' to enable demonstrable **move towards excellence**
- Undertake condition/service-specific system reviews
- Investigate serious concerns

Social Services Inspectorate

Monitor, register and inspect residential services for:

- Dependent older people
- People with disabilities
- Children in need of care and protection
- Setting standards for assessment of need under the Education for Persons with Special Educational Needs (EPSEN) and Disability Acts

Health Information

- Identifying and advising on health information deficiencies
- Setting standards for health information systems
- Establishing an information governance framework
- Evaluating and providing accurate health information
- Establishing an eHealth information portal for the public

Health Technology Assessment



Perceptions

Putting a price on a life

A new state body will analyse how cost-effective drug treatments are. A similar body in Britain has made for some frightening headlines



Susan Mitchell

What is a year of healthy life worth? That is one of the many difficult questions facing the country's new health regulator.

The Health Information and Quality Authority (HIQA) will be given statutory authority under legislation currently before the Dáil.

Its remit includes managing all reviews of drugs, medical devices and health promotion

effectiveness will have an increasingly important role to play in public healthcare.

Advocates of cost containment believe the dilemma is simple: do you spend more on saving a few patients, or sacrifice them to help many others?

A number of doctors, together with some pharmaceutical companies, have expressed concern about the greater emphasis cost-effectiveness appears to be playing in Irish healthcare.

They believe the system is beginning to adopt a more heavy-handed approach when it comes to sanctioning the use of innovative, but costly, medicines.

Sources in the pharmaceutical sector said there was a fear that HIQA would emulate the National Institute for Health and Clinical Excellence in Britain. Known by the friendly-sounding acronym: Nice, it effectively decides whether patients will get treatment which is potentially life-saving.

Nice has been described as the scourge of the pharma sec-

court action from the makers of an Alzheimer's drug that it refused to fund.

The crux of the issue is how you value a 'healthy' year. What health economists call a quality-adjusted life year, or QALY, is priceless, many would say. Nice puts the value at about €45,000. Very roughly, if a new treatment to give one good year of health costs more than that, there have to be exceptional circumstances for Nice to approve it.

So what lies ahead for Ireland? Brian Murphy, commercial affairs manager at the Irish Pharmaceutical Healthcare Association (IPHA), said the pharma sector was concerned that "some of these health technology assessments may purely focus on costs, as opposed to benefits. But we shouldn't fear the state wanting to get value for money".

At present, the National Centre for Pharmacoeconomics carries out health technology assessments in Ireland. Murphy said that it takes account of the quality-adjusted life year, but also looks at the

it is now."

Dr Tracey Cooper, who is heading HIQA, said there was "no intention of lifting methodology for health technology assessments from another jurisdiction. Because I'm from Britain, people think I'm bringing in Nice, but that is not the case. We will cherry-pick what is right for us."

Cooper said the guidelines for health technology assessments would be set after consultation with various stakeholders. "It will be about quality, safety, outcomes, quality-of-life and quality of end-of-life," she said.

Cost, she added, "will obviously be a factor".

Sanctioning the use of effective – yet expensive – medicines and new technologies could be a dangerous policy that would bankrupt the health system. But refusing them to chronically sick patients will prove highly contentious.

So does Cooper expect to be hit with a wave of negative headlines if HIQA refuses a so-called wonder drug due to its cost?

Sunday
Business
Post

February
2007

Drug schemes put pressure on HSE budgets

The HSE's 2006 Annual Report will be remembered for its €97.7m underspend. Julie-Anne Barnes takes a look at some of the other figures

The HSE has indicated that a principal risk for the organisation surrounds the annual increase in the costs of demand-led schemes, such as the Long Term Illness Scheme and the Drug Payments Scheme. The schemes come within the Primary Care Reimbursement Service and Medical Card Schemes.

According to the HSE, by their nature, the demand for these schemes is unpredictable and this, along with price increase

has led to budgetary pressure year on year.

In 2006 payment for pharmaceutical services amounted to €1.654 billion, an increase of €235 million over the 2005 spend on the same services.

The HSE also said the capitation payments for older persons increased from €420 million in 2005 to €485 million in 2006, a 15.48 per cent increase.

"While the HSE attempts to minimise the adverse financial effects of these schemes,

through stringent monitoring and control procedures, there is no doubt that increased demand volume and rising costs represent a significant challenge to the organisation in delivering on its accountability responsibilities," the HSE said.

The annual report outlines developments for 2006 which included the extension of the CIDR (Computerised Infectious Disease Reporting system) to cover more than 85 per cent of the country.

The report said norovirus infection outbreaks in acute hospitals and community facilities were responsible for 147 outbreaks and active control measures were put in place in all health care settings to minimise the impact of these outbreaks.

According to HSE Chief Executive Prof Brendan Drumm, 2006 was the year "the HSE started to introduce greater consistency and accountability and thanks to the tremendous com-

mitment and efforts of thousands of staff, we provided many excellent services. Many services have improved and others will continue to get better".

The underspend of €97.7 million drew particular criticism last week and the HSE said the underspend was partially due to the "lack of anticipated progress on a number of major projects, e.g., the Mater Misericordiae Hospital project and the National Rehabilitation Project".

In addition, the HSE said the capital expenditure process is now being actively managed by a newly established Estate Directorate as well as the Primary Community and Continuing Care programme (PCCC) and the National Hospitals Office capital steering committees.

Explaining the underspend the HSE said that the Department of Finance sanctioned approval for the HSE to move €71 million from its capital surplus to revenue (day-to-day spending) in 2006, in order to address core service delivery issues such as the cost of additional beds in the community, to support hospital services.

"The HSE, therefore, had a surplus of €25 million and can,

The report also highlights the work done towards rolling out primary care teams.

In terms of consultant staffing, the report notes that on December 31, 2006, there were 2,144 approved permanent consultant posts in the public sector in Ireland and during 2006 the HSE approved a total of 188 consultant posts.

Of these 125 were new posts and 63 were replacement posts.

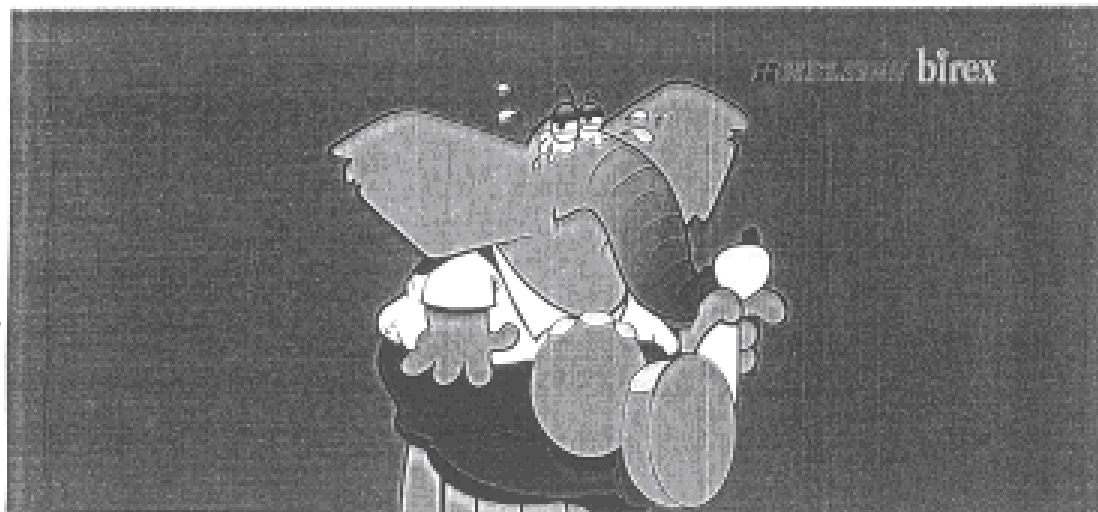
According to the HSE, the 125 posts represent the largest number of additional consultant posts ever approved in the Irish health services in one year.

Of the 188 posts approved, 12 were approved as Category two posts and 176 were approved as Category one posts.

The annual report said the HSE had some 106,000 staff on its payroll at the end of 2006.

New consultant posts approved by speciality in 2006

| | |
|------------------------|----|
| Anaesthesia | 13 |
| Medicine | 27 |
| Obstetrics/gynaecology | 11 |
| Pathology | 11 |
| Paediatrics | 7 |
| Psychiatry | 31 |
| Radiology | 13 |



HSE freeze 'will harm patients'

Frontline service will be crippled, warn hospital consultants

Health service jobs freeze blamed on drug refunds

Sticking to budget is top HSE priority for 2008

GP says patients will bear brunt of fallout from new HSE staff freeze

Money-saving measure to have 'pronounced effect' on services within two weeks

HSE jobs freeze to continue

HSE to reduce wholesale mark-up on medicines

Stricter controls on drugs

HSE cutbacks triggered by €350m shortfall

Health Technology Assessment



Objective:

To inform safe and effective health policies that are patient focussed and achieve best value

Why carry out HTA?

- Introduce technologies speedily with proven, significant health benefits,
- Prevent the introduction of technologies which fail to meet the requirements of evidence-based analysis, and
- Continuously monitor the effectiveness of technologies after their introduction.

Quality & Fairness

National Health Strategy 2001

Health Act 2007

The functions of the Authority are as follows....

To evaluate the clinical and cost-effectiveness of health technologies including drugs and provide advice arising out of the evaluation to the Minister and the Executive

HTA

- HTA is a multidisciplinary process that summarises information about:

- Medical
- Social
- Economic (VFM)
- Organisational
- Ethical
- Medicolegal issues

related to the diffusion and use of a health technology in a systematic, transparent, unbiased and robust manner

Health Technologies

- Includes a wide range of interventions used in healthcare and health promotion
 - Pharmaceuticals (Drugs)
 - Medical Devices
 - Diagnostics
 - Medical and surgical procedures
 - Public health activities
- Includes the systems within which health is protected and maintained

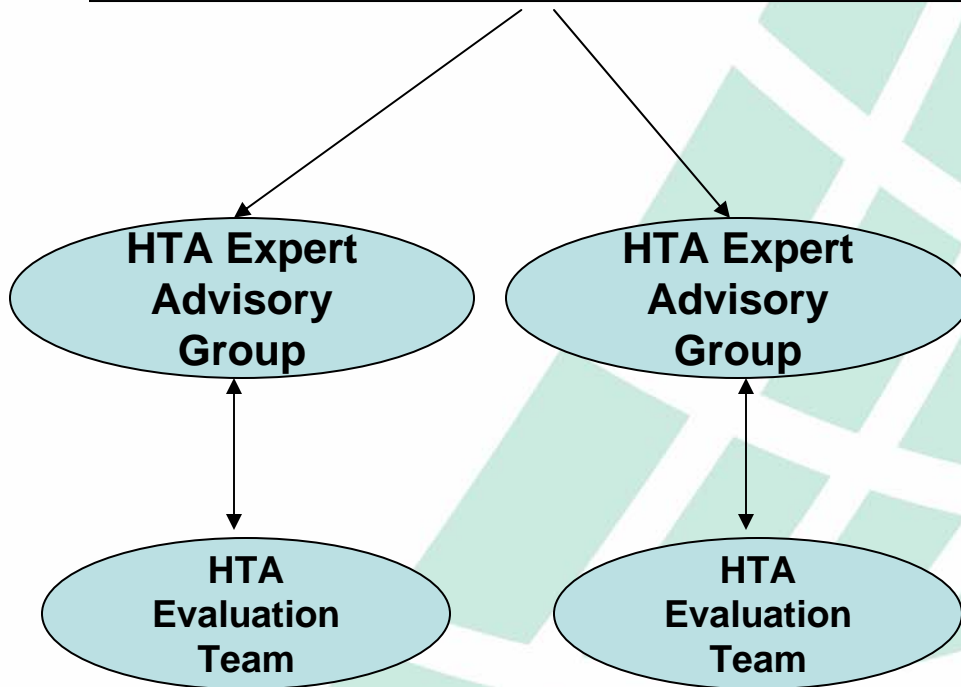
HTA Directorate Objectives

- **Establish a Quality Framework for HTA**
- Promote conduct of high quality HTAs
- Independent conduct of HTAs with national significance
- Develop HTA capacity

Quality Framework

H
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Q
A

Programme Advisory Group
Scientific Advisory Group



DoHC
HSE

Quality Framework

Opportunities

- Stakeholder Engagement
- National guidelines
- Best practice from other jurisdictions
 - International networks
 - Strategic Partnerships
 - Collaborative Approach (Horizon Scanning, Core HTAs, Research)

Quality Framework

Stakeholder engagement

- **Patients/Service Users**
 - Programme Ad Group, Scientific Ad Group, Expert Ad Groups
 - Focus Groups
- **Decision Makers**
 - Programme Ad Group, Scientific Ad Group, Expert Ad Groups
 - Key to successful implementation
- **Industry**
 - Programme Ad Group, Scientific Ad Group
 - IPHA Agreement
- **Academics/Clinicians**
 - Programme Ad Group, Scientific Ad Group, Expert Ad Groups
 - Evaluation Teams
 - Foster HTA expertise and quality practice

Quality Framework

National Guidelines

- Guidelines for the Economic Evaluation of Health Technologies
 - Work with Scientific Advisory Group
 - Planned broader consultation process
 - Guidelines increasing prescriptive – establish 'Reference Case' or preferred set of standards for use in the 'Base Case' analysis
 - Focus on the publicly funded healthcare system in Reference Case
 - Reflect international trends in economic analysis
- Planned additional sections
 - Procedures and processes of the Authority for the identification, prioritisation and selection of topics for assessment
 - Sections on the social, ethical and organisational aspects of HTA
 - Budget impact analysis
 - Recommended reporting formats

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Promote Conduct of Quality HTA

Types of HTA conducted in Ireland:

- HTAs of national significance by HIQA
 - use of independent economic models
- 'Rapid HTA': under HSE/IPHA agreement
 - new pharmaceuticals on Community Drugs Schemes
 - review of company submissions
- 'Mini-HTA': to inform local level decision-making
 - technologies including drugs at local hospital level
 - non-pharmaceuticals through PCCC, e.g., CF Physiotherapy Vest

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- Establish a Quality Framework for HTA
- Promote conduct of high quality HTAs
- **Independent conduct of HTAs with national significance**
- Develop HTA capacity

HIQA HTA Process: Prioritisation

- Priority Diseases
 - High budget
 - Safety concerns
 - Organisational issues
 - Horizon Scanning
 - National impact (public and private)
- 

HTA Directorate Objectives

- Establish a Quality Framework for HTA
- Promote conduct of high quality HTAs
- Independent conduct of HTAs with national significance
- **Develop HTA capacity**

Develop HTA Capacity

- HTA Capacity Building
 - Synergistic relationships
 - Adequate remuneration, Multi-annual funding
 - Post-graduate fellowships
 - NCI / HRB PhD programme
 - Ad hoc training
 - HTA Forum

HTA: Challenges

- Quality of HTAs
 - Different levels of expertise, experience and skills
 - HTA Capacity Building
 - Communications
 - Implementation
- 
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Implementation of HTA: Enhancing Factors

- Prioritisation by decision makers
- Culture of HTA
- Scientific reputation and credibility of HTA agency
- High quality HTA
- Compact user-friendly presentation
- Pharmaceuticals versus other technologies

Implementation of HTA: Hindering Factors

- Strong influence of stakeholders
- Long standing beliefs
- Recommendations differ from experience of clinicians
- Technology introduced pre-HTA

Issues for Conduct of HTA

- Skill sets:
 - Clinical evaluation, systematic review, biostatistics, mathematical programming, health economics, health services research, ethical and legal expertise
- Cost data
- HTA guidelines

The Role of Human Papillomavirus Vaccines in Reducing the Risk of Cervical Cancer in Ireland

A Health Technology Assessment

25th February 2008

1st HTA Undertaken

Objective:

To estimate the cost-effectiveness of a combined national HPV vaccination and cervical screening programme compared to a screening programme alone in the prevention of cervical dysplasia and cervical cancer due to HPV types 16 and 18 in Ireland

Human Papillomavirus (HPV)

- More than 100 different types of HPV infection have been characterised:

- High risk – most common are HPV 16, 18, 45 and 31.

- Low risk- include HPV types 6, 11.

Cause ~ 90%
of anogenital
warts

Cause ~70% of
cervical cancers

Human Papillomavirus (HPV) Vaccine

- Two vaccines currently developed:
 1. **Gardasil**[®] – protects against HPV types 16, 18, 6 and 11.
 2. **Cervarix**[®] – protects against HPV types 16 and 18.
- Efficacy demonstrated for up to 5.5 years after vaccination.
- Requirement for booster dose at later time not established.
- Routine cytology screening still required, as vaccines do not protect against all oncogenic types of HPV.

Methods

- Adaptation of an independently developed dynamic model
- Herd immunity is reflected in the model
- HPV type 16 and 18 infection only
- Outcome measure: Life Years Gained
- Comparator: Population-based cervical cancer screening programme
- Perspective: Healthcare payer i.e., HSE

Data Inputs

- Duration of protection: lifelong
- Vaccine efficacy: 95% in HPV-naïve ITT population
0% in HPV-exposed individuals
- Delivery of the vaccination programme:
 - School-based programme (12-19 year olds)
 - GP administration (19 - 26 year olds)

Vaccination Scenarios

| Scenarios | Vaccine coverage |
|--|--------------------------|
| 1. Annual vaccination of 12-year old girls | 80% |
| 2. Annual vaccination of 12-year old girls with catch-up to 15 years in 1 st vaccination year | 80% |
| 3. Annual vaccination of 12-year old girls with catch-up to 17 years in 1 st vaccination year | 80% |
| 4. Annual vaccination of 12-year old girls with catch-up to 19 years in 1 st vaccination year | 80% |
| 5. Annual vaccination of 12-year old girls with catch-up to 26 years in 1 st vaccination year | 80% (school) 30% (GP) |

Cost of Vaccination

- Ex factory price per dose:
€100 (€80-€120)
- Cost of administration:
 - School based programme cost per dose:
€30 (€15-€45)
 - GP administration fee: cost per dose:
€58 (€50-€67)
- Sensitivity analysis:
One booster dose after 10 years

Results

Compared to a screening programme alone,
combined vaccination plus screening:

ICER: 12-year-old girls
€17,383 / LYG

Cost: €9.7 million per annum

Catch-up: 13-15-year-old girls (one-off)
Marginally cost-effective
Cost €29.2 million

Health Technologies

Colorectal Cancer Screening

- To evaluate the clinical and cost-effectiveness, resource implications and ethical considerations of a population-based colorectal cancer screening programme

Vision

HTA programme which contributes substantially to improving patient outcomes by supporting investment in effective, efficient technologies



Quality Framework

- National Guidelines
- International peer review

Stakeholder engagement:

- Patients / Service users
- Decision Makers
- Service Providers
- Technology Industry
- Academic Groups



Thank You