



Department  
of Health

# Emerging Science and Bioethics Advisory Committee (ESBAC)

## Forum

Monday 13 May 2013

# Agenda

- 10:00 Welcome and introduction
- 10:10 ESBAC: background, role and where are we now?
- 10:20 ESBAC's Horizon Scanning function
- 10:40 Keynote speech
- 10:55 Q&A Panel session
- 11:10: Tea/coffee break
- 11:30 ESBAC's emerging work strands: Focus Group proposals (Q&A/discussion after each presentation)
- 13:00 Closing comments from the Chair

Buffet lunch

# ESBAC: background, role and where are we now?

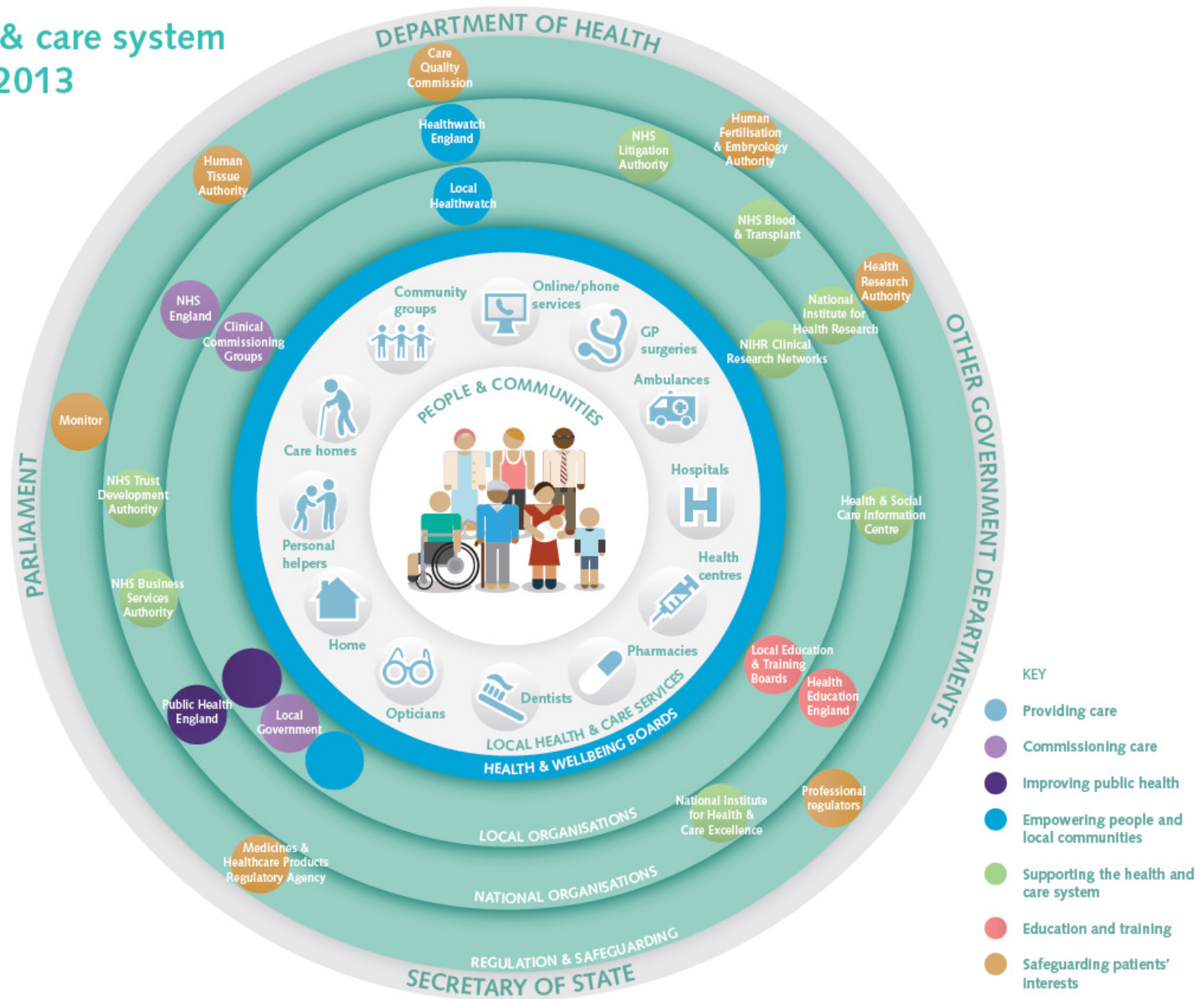
Dr Mark Bale

Director of Health Science and Bioethics  
Department of Health

# Background

- ESBAC established as an expert advisory committee in 2012 (first meeting July 2012)
- Following the 2010 review of Advisory Non-Departmental Public Bodies (Human Genetics Commission disbanded)
- ESBAC – wider remit to include new scientific developments
- Wider context – new health & care system and new DH

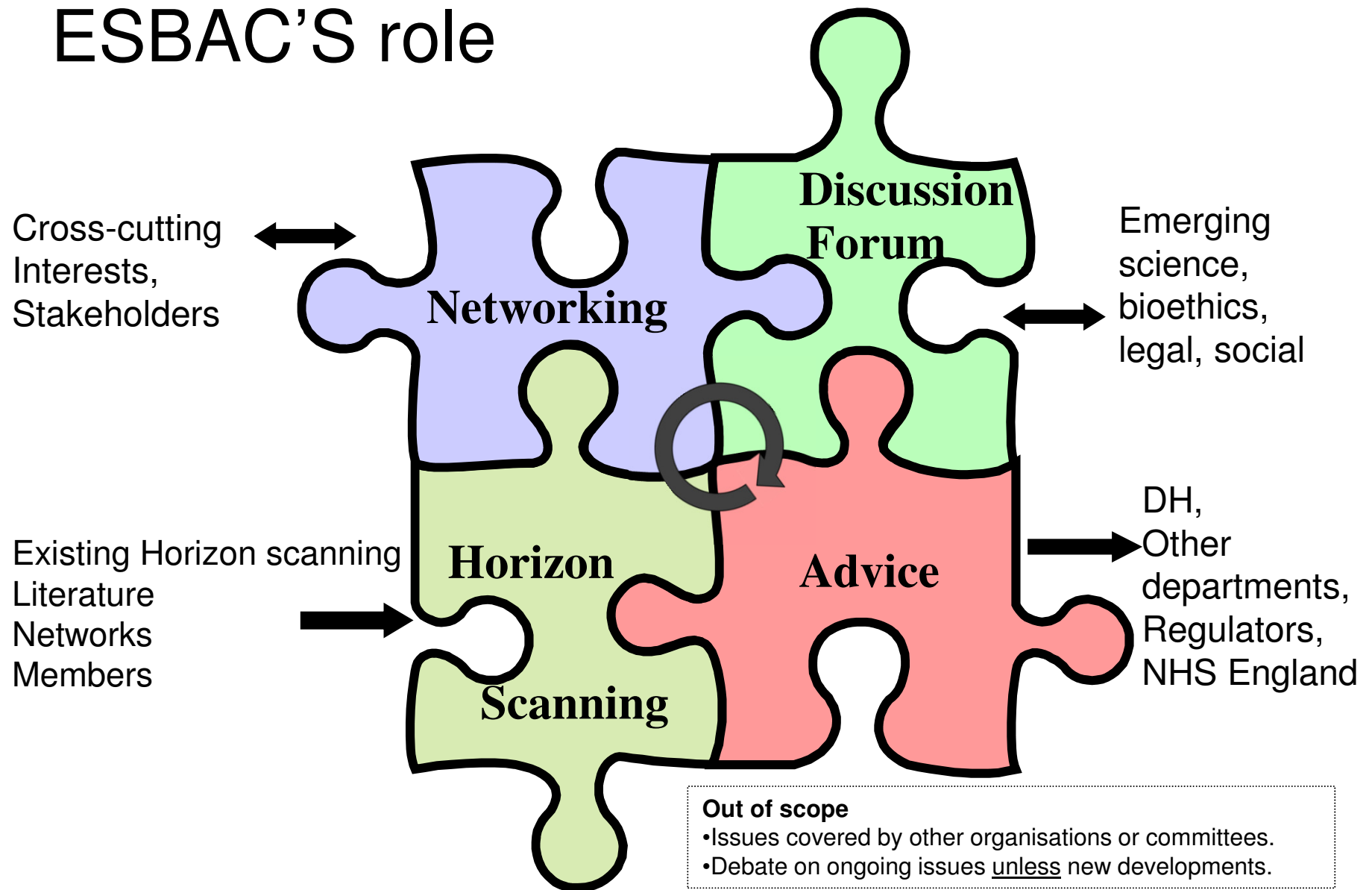
# The health & care system from April 2013



# Role and Membership

- Main UK advisory body on emerging healthcare scientific developments and their ethical, legal, social and economic implications. ESBAC's purpose is to provide expert advice to support policy development and priority setting in healthcare science
- Sponsored by the CMO (DH, England)
- Broad membership (including social sciences, humanities, economics, law, industry, science in society, biosciences and biotechnology)
- 29 Members, including ex-officios and representation from all UK Health Departments

# ESBAC'S role



# ESBAC topic selection criteria

**Relevant:** proposed work should fit with ESBAC's terms of reference and as such: involve a new advance in health-related science and/or clinical application and; raise a relevant ethical, legal, social or economic issue.

**Applicable to policy:** proposed work should be relevant to the statutory remits and priorities of DH and other government departments.

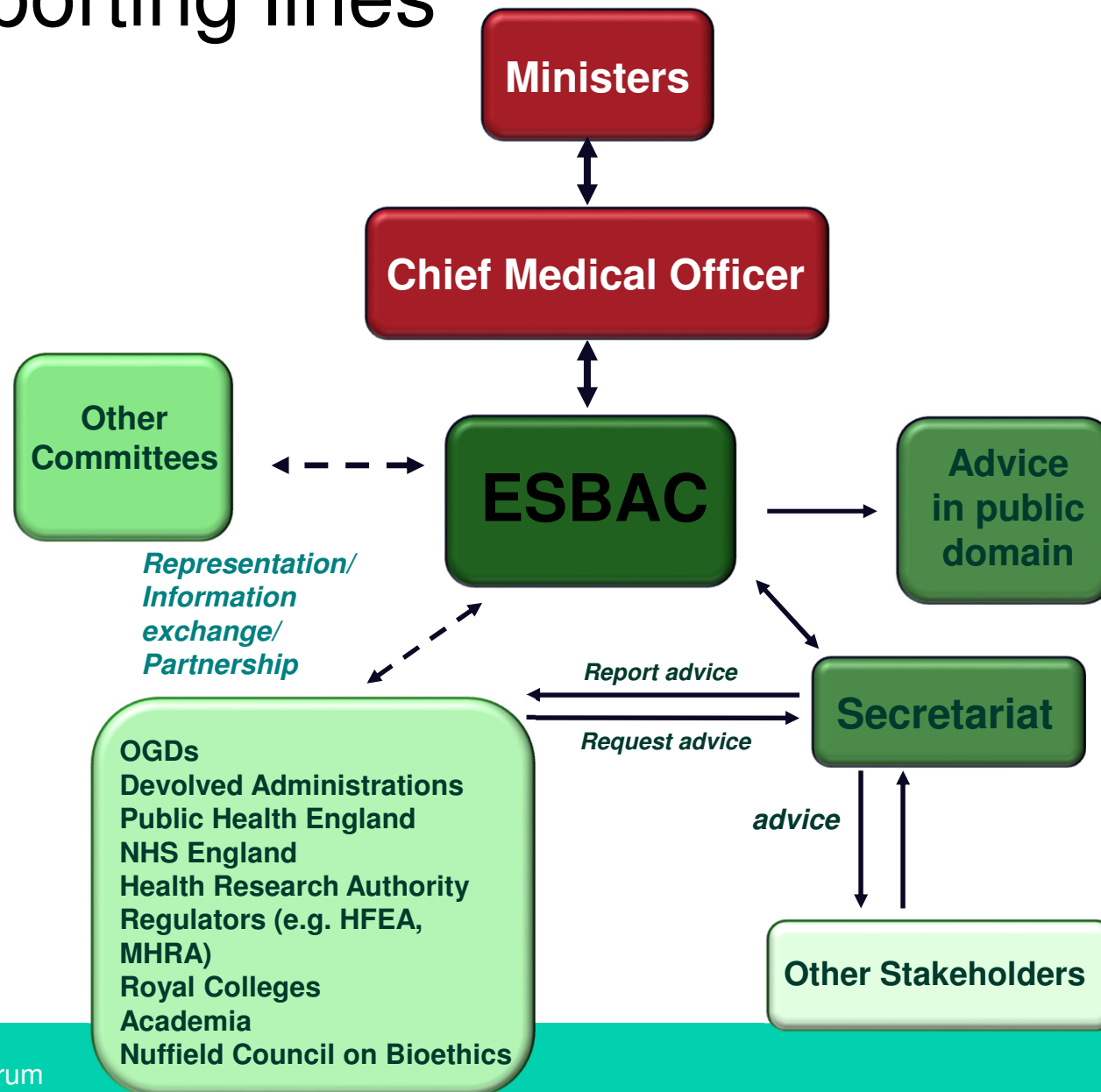
**Timely:** proposed work should make an authoritative and timely contribution to policy debate and have a realistic opportunity of having a significant and positive influence.

**Realistic:** proposed work should be achievable within resource constraints (taking into account any expectation of additional/external support) and have a clearly defined deliverable.

**Unique:** the work must not be already being carried out elsewhere or must not fall within other organisations statutory remit. If it does, ESBAC may wish to consider waiting for the work to be completed or engage in partnership(s) if appropriate.



# Reporting lines



# ESBAC to date

- Three Committee meetings held to date:

July & September 2012

- ESBAC's Code of Practice
- Agreed ESBAC's topic selection criteria
- Developed an approach to horizon scanning (Horizon Scanning Steering Group set-up)
- Discussed and identified topics to be scoped further
- Four focus groups set up (genomics, innovative governance, technologies to optimise treatment, dementia)

(Focus group meetings in-between to scope topics)

January 2013

- Proposals from three focus groups presented to main Committee (genomics on hold)
- Proposal from Horizon Scanning Steering Group (pro-forma)

# ESBAC to date

- Post-January meeting
  - Fine-tuning of proposals following January Committee meeting
- Now
  - Forum opportunity to ‘sense-check’ the proposals with stakeholders and for you to provide feedback
  - Stakeholders as ‘horizon scanners’ – referring issues to ESBAC
  - Seek your expertise in work going forward (what can be achieved collectively and collaboratively?)

# ESBAC's Horizon Scanning function

Peter Littlejohns

(ESBAC Member and Chair of the Horizon Scanning Steering Group)

James Peach

(ESBAC Member, Horizon Scanning Steering Group Member)

# What is Horizon Scanning ?

*“the systematic examination of potential threats, opportunities and likely developments including but not restricted to those at the margins of current thinking and planning. Horizon scanning may explore novel and unexpected issues as well as persistent problems or trends.”*

The definition of horizon scanning is taken from the Chief Scientists Advisory Committee for horizon scanning

# Role of Horizon Scanning Steering Group

The role is to gather evidence, detect signals, cross cutting scientific issues and general trends and consider their implications in healthcare science to advise ESBAC on emerging developments and their ethical, legal, social and economic implications, relevant to ESBAC's remit. This will provide strategic early warning to ESBAC, that will challenge and test current policy thinking by acknowledging future uncertainties.

# Horizon Scanning Steering Group Membership

- Professor Peter Littlejohns (Chair and ESBAC Member)
- Professor Sir Alasdair Breckenridge (ESBAC Chair)
- Mr James Peach (ESBAC Member)
- Professor Joyce Tait (ESBAC Member)
- Professor Joyce Tait (ESBAC Member)
- Dr Rachel Quinn (Academy of Medical Sciences)
- Dr Peter Mills (Nuffield Council on Bioethics)
- Mr Oliver Grant (Foresight Centre)
- Dr Claire Packer/ Dr Sue Simpson (NIHR Horizon Scanning Centre and EUROSCAN)
- Dr Neil Ebenezer (MHRA)
- Paul Mason (TSB)
- PHE (to be confirmed)
- Ideally each area of interest could be championed by a Member or external person e.g. stems cells, legal framework, etc.
- International – (to be confirmed)

# Method of Working

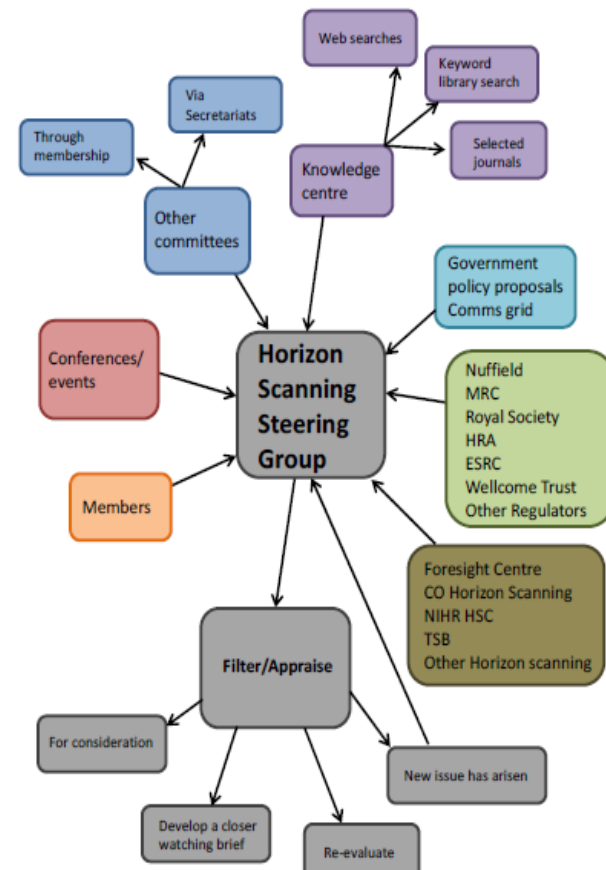
Acting as a receiver of referrals rather than “another “ horizon scanner

Seek referrals from key organisations and ESBAC members

Work through the completion of a pro-forma

Compare referrals against ToR of ESBAC

Present to ESBAC with a recommendation to monitor, ask for more information, take forward





# Pro-forma for Horizon Scanning (i)

This “Horizon-scanning pro-forma” is designed to enable organisations and individuals to submit emerging healthcare scientific developments for consideration by the Emerging Science and Bioethics Advisory Committee (ESBAC).

ESBAC is keen to know about all relevant healthcare scientific developments, and that UK individuals and organisations are able to bring particular developments to our attention. Areas identified should :

- (1) involve a new advance in health-related science and/or clinical application
- (2) raise a relevant ethical, legal, social or economic issue as set out in the ESBAC terms of reference and
- (3) be applicable to policy-making. They could be seen as opportunities or threats, as long as the implications are significant. Developments that affect healthcare regulation are in scope.

New advance			
Issue raised			
Likelihood of impact	%	Timing of impact	(in 1, 2-5, 5-10, 10+yrs)
Impact if nothing is done			
Suggested policy actions now			
Source	Name, email, organisation		
Further details			
Uniqueness			
Resources			
Please return the completed pro-forma to the ESBAC secretariat by email ( <a href="mailto:esbac@dh.gsi.gov.uk">esbac@dh.gsi.gov.uk</a> )			

# Pro-forma for Horizon Scanning (ii)

## Notes to completing the ESBAC Horizon-Scanning Pro-forma

**New Advance:** This should be no more than 20 words long and should identify the area in which the change is happening (e.g. genetics, stem cells etc.), and what the change is (e.g. routine assessment of germline DNA, extraction and storage of pluripotent cells). It should make clear what the relevance is to the ESBAC terms of reference, if this is in doubt.

**Issue raised:** This should be no more than 30 words long and should identify the main area in which the issue is raised (e.g. ethical, legal, social or economic) and what the main issue is expected to be.

**Likelihood of impact:** A % figure estimating to the nearest 20% how likely the impact is to happen, in the absence of any action from ESBAC on this topic

**Timing of impact:** Will this impact happen in the: next year, 1-2 years, 2-5 years, 5-10 years?

**Impact if nothing is done:** No more than 20 words outlining: what the impact is, any organisations or groups that are particularly affected, and any idea of scale (e.g. number of people/patients). Impact can be positive or negative, as well as direct or indirect. This should be the impact in the absence of intervention by ESBAC.

**Suggested policy actions now:** No more than 20 words recommending what ESBAC could recommend to policymakers to maximise benefit and minimize risk from this issue. It should make clear what the relevance is to policy, if this is in doubt.

**Source:** Name and contact details (email or phone) of source (organisation, individual, ESBAC member)

**Further details:** Up to 100 words of extra information that would help an ESBAC member understand the issue – including website links if appropriate.

**Uniqueness:** Details of on-going work already answering this question (with contacts), or other organisations whose statutory remit this falls under.

**Resources:** An idea of the work required to assess or review this issue and recommend a policy response. If this goes beyond discussion, group and individual work at ESBAC, what is the work required and is there an organisation that ESBAC can call on to do this?

## ESBAC Horizon Scanning Pro-forma: worked example

New advance	Social network health research		
Issue raised	Potential benefits of this approach to research, concerns about ethical oversight of studies and peer pressure, ability to avoid UK ethics frameworks via the internet		
Likelihood of impact	80%	Timing of impact	2-5 years
Impact if nothing is done	Scale of impact low. Benefit (or missed benefits) of patient-led research via social networks, misleading patient information or research results		
Suggested policy actions now	Set up framework for ethical oversight for social network health research involving UK patients		
Source	Mr Example Example, example@example.com		
Further details	Research data collection from patients directly via self-recorded internet upload on social networks is already happening and results are being published. It is unclear what the requirements for ethical oversight and review are for this sort of research. <a href="http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001402">http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001402</a>		
Uniqueness	No on-going work known.		
Resources	Review and recommendation from ESBAC on who is responsible for this area and if any action is required.		

# In conclusion

Comments & questions on the pro-forma?

Suggestions for organisations to target with pro-forma

What do you consider to be the issues likely to arise/emerge over the next 12-24 months that ESBAC might want to keep an eye on?

What are the biggest challenges the Committee should be focusing on?

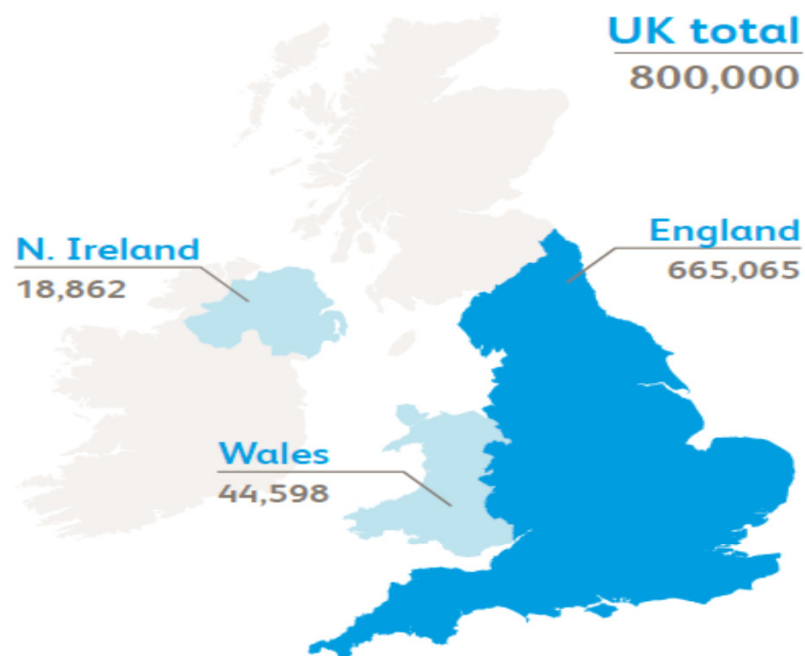
# Dementia Focus Group

Diana Sternfeld, ESBAC Member

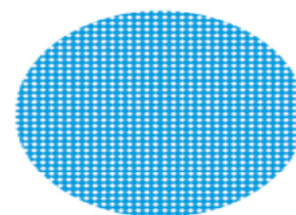
(on behalf of the ESBAC Dementia Focus Group)

## The size of the challenge

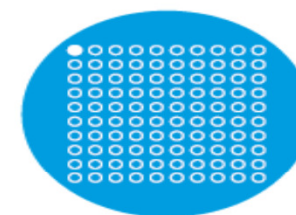
The breakdown of the population with dementia across the UK.



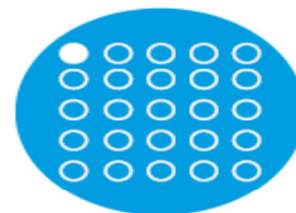
Dementia is most common in older people but younger people (under 65) can get it too.



40–64 years  
1 in 1,400



65–69 years  
1 in 100



70–79 years  
1 in 25



80+ years  
1 in 6



Two thirds of people  
with dementia  
are women



One in three people  
over 65 will develop  
dementia

Source and copyright: Alzheimer's Society

# ESBAC topic selection criteria:

Relevant

- YES

Applicable to policy

- YES

Timely

- YES

Realistic

- YES

Unique

- YES

# Dementia Proposal

- The proposed work aims to develop a broad landscape of the scientific advances being made in diagnostics for dementia and the direction in which therapeutic responses are developing.
- It will then explore the ethical, legal, social and economic issues raised by the future scenario of being able to diagnose the presence of dementia earlier on in the disease progression and in younger age groups than is currently possible.
- The ethical imperative underpinning this work is the need to prepare individuals and society as a whole for making qualitatively different decisions in relation to the diagnosis and treatment of dementia.

# Focus Group Members

- Professor Bobbie Farsides (Champion)
- Dr Stuart Hogarth
- Ms Diana Sternfeld
- Professor Neil Scolding
- Professor Nicholas Lemoine
- Dr Paula Boddington
- Dr Jonathan Mill
- Ms Katharine Wright (Nuffield Council on Bioethics)
- Dr Bella Starling (from January 2013)
- Ms Katherine Littler (from February 2013)



# How will we work? What will we deliver?

- the key word is 'collaboration'

## Suggested stakeholders include:

- Age UK
- Alzheimer's Society
- Alzheimer's Research UK
- BIVDA
- Dementia Action Alliance
- DeNDRoN
- DH policy colleagues
- European Federation of Neurological Associations
- Industry representatives
- NICE Diagnostics Advisory Committee
- Patient groups
- Research
- SAGA
- Sciencewise
- Technology Strategy Board (TSB)
- Other experts
- Contributors to the NCoB dementia report
- Others

# A call to arms

- We cannot and should not work in isolation, we have much to learn and hopefully a unique contribution to make.
- We want to hear from and speak to experts in the field and we want to benefit from the very special skills of those who work alongside and on behalf of people living with dementia and their families.
- We also want to reach those already affected by a dementia diagnosis and those who live with the possibility of dementia affecting themselves or their loved ones in the future.

# Let's get started

Comments

Questions

Suggestions

# Innovative Governance Focus Group

Julian Hitchcock, ESBAC Member

(on behalf of the ESBAC Innovative Governance Focus Group)

Innovative Governance Focus Group

# **INTRODUCTION**

# Relevant Issues

- Tensions and interactions arising in development of appropriate and adaptive regulatory responses to emerging biomedical sciences.
- Competing governance drivers:
  - improving public health by facilitating useful innovation and its translation
  - protecting public from unsafe technologies
  - efficacy
  - precaution
  - morality
  - wealth creation / health subsidy
  - avoiding healthcare expenditure on unproven healthcare technologies.
- How to improve and expedite responsible translation, without compromising safety, in the United Kingdom.

Innovative Governance Focus Group

# **OVERVIEW: OBJECTIVES**

# Objectives

- To identify governance opportunities for simplifying, rationalising and expediting the responsible translation of biomedical innovation.
- To develop an integrative framework to guide and optimise regulatory and policy decision-making, taking account of interactions between:
  - scientists and innovators;
  - policy makers and government; and
  - members of the public;
  - stakeholder groups.
- To assess how regulation can better reflect changes in risk
- To validate the framework using test cases.



# Overview

## **Policy-Innovation Interactions**

## **Stakeholder & Citizen Engagement/Dialogue**

### **Case studies**

- Synthetic biology (e.g. phytopharmaceuticals)
- Cell therapies
- Stratified medicine (e.g. regulatory developments for diagnostics)

# Examples of current developments

- *Clinical Trials Regulation*
- *Medical Devices Regulation*
- *In Vitro Medical Devices Regulation*
- *Data Protection Regulation*
- Pharmacovigilance consultations.
- 'Red tape' initiatives
- Provision of early access to medicines (adaptive licensing);
- *ATMP Regulation* consultation
- Human embryonic stem cell patent policy in EU and EPO
- House of Lords Inquiry into Regenerative Medicine
- Interactions between Health Technology Assessment and regulation.

Innovative Governance Focus Group

# **ESBAC RATIONALE**

# Governance Framework

ESBAC's remit:

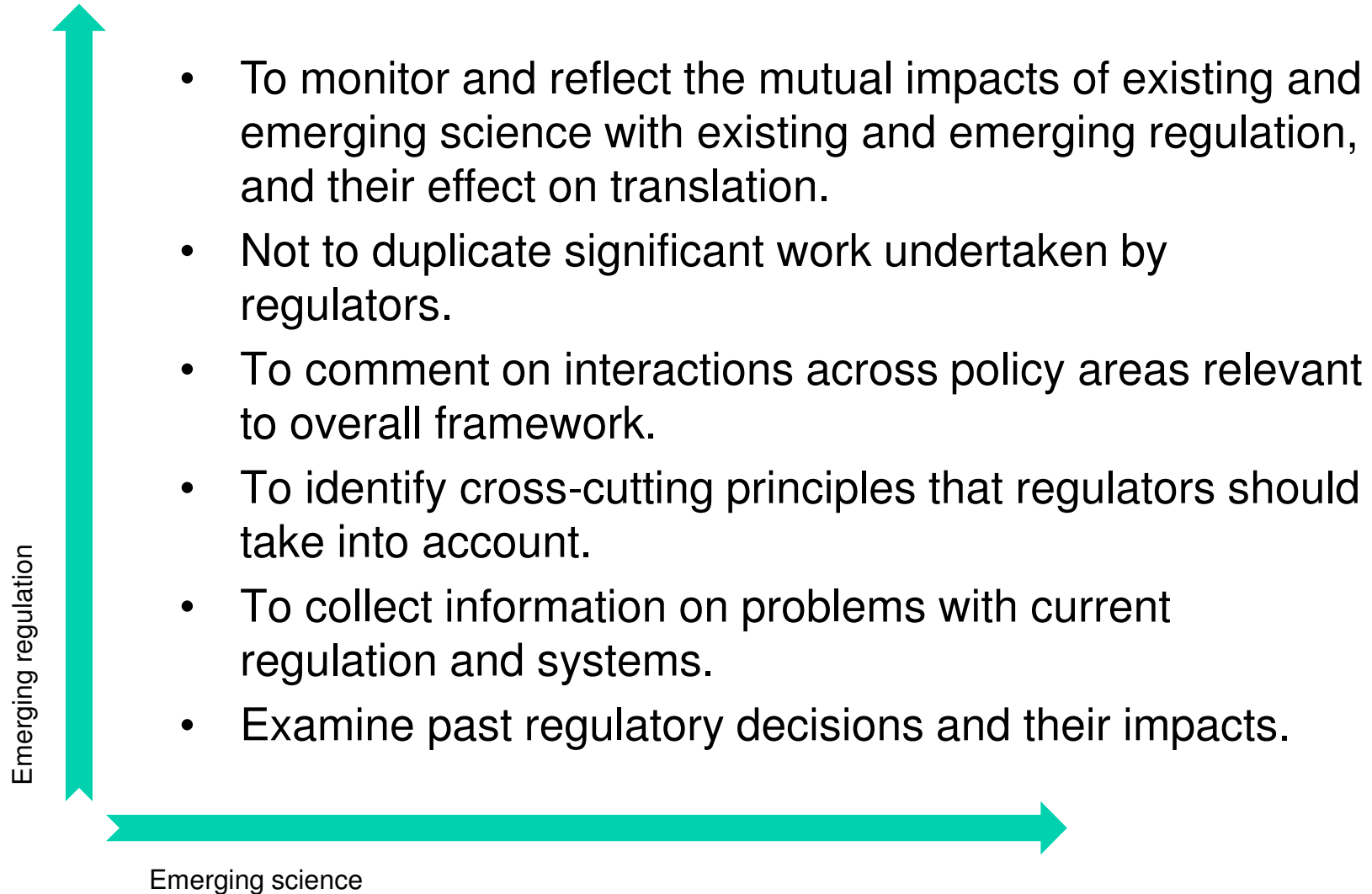
*“... to add value, interfacing science with ethical, social and economic implications to inform policy making”...*

implies a role in contributing to development of health-related governance systems that, among other considerations, continue to meet societal healthcare needs while also enabling faster, more cost-effective development of new healthcare technologies.

Innovative Governance Focus Group

# SCOPING

# Scope



# Delivery Mechanism

- Expertise, knowledge and collective insights of ESBAC Members.
- Inclusion of stakeholders as temporary, or possibly ‘virtual’, working group or hold one-off workshop.

# Deliverables

- A policy framework tool for:
  - expediting the responsible translation and approval of innovative healthcare products and services in the UK
  - removing unreasonable impediments to translation.
- Placing of framework tool and case studies in the public domain.



Innovative Governance Focus Group

# **STAKEHOLDERS**

# Stakeholders

- ESBAC's Innovative Governance work will involve a range of key stakeholders, including:
  - MHRA
  - Health Technology Assessment
  - NICE
  - Health Research Authority
  - Patient groups

Innovative Governance Focus Group

# **ESBAC MEMBERS**

# Members

- Professor Joyce Tait (Champion)
- Professor Sir Alasdair Breckenridge
- Professor Bobbie Farsides
- Dr David Townend
- Ms Diana Sternfeld
- Dr Dipti Amin
- Professor Duncan McHale
- Mr Julian Hitchcock
- Dr Rachel Quinn
- Dr Stuart Hogarth
- Dr Bernadette Hannigan
- Professor Andrew Baker
- Dr Bella Starling (from February 2013)
- Ms Katherine Littler (from February 2013)

# Discussion & Questions

- First impressions of the proposal (does it make sense?)
- What do you think of the three areas proposed - would you like to suggest other case studies, examples
- What needs clarification
- Follow-up questions on the proposal
- Who could help progress the work
- Would you like to be involved in the development of this work

# Technologies to Optimise Treatment Focus Group

Professor Sir Alasdair Breckenridge, ESBAC Chair

(on behalf of the ESBAC Technologies to Optimise Treatment Focus Group)

# Objectives

- Instead of merely adding to technology, we should aim to optimise the use of innovation
- Delivery of innovation / innovation of delivery
- Improve outlook for public health and the individual patient
- More effective use of resources with potential for cost savings
- Contribute to better research and clinical development

# Technology types

- Technologies to improve patient adherence
- Technologies to optimise treatment in other ways
- Technologies that monitor overall patient health status (out of scope)



“Keep a watch also on the faults of the patients, which often make them lie about the taking of things prescribed. For through not taking disagreeable drinks, purgatives or other, they often die. What they have done never results in a confession, but blame is thrown on the physician.”

Hippocrates

14<sup>th</sup> Saying in the Decorum

THE TIMES | Tuesday March 26 2013

**Schizophrenic  
accused of plan to  
decapitate singer  
'was on day out'**



## Half of women with breast cancer fail to take the full course of drugs

[illegible]

# Importance of patient adherence

- Potential to improve patient health
- Savings on healthcare budget
- Antibiotic resistance
- Adaptive licensing

# Technologies to improve adherence

- Directly observed treatment
- Reminder via email or phone
- Slow release formulations of medicines
- Innovative packaging
- Electronic boxes
- Smart chips in medicines

# Ethical aspects

- Personal freedom v social responsibility
- Consent to treatment
- Health professional / patient relationship

# Technologies to optimise treatment in other ways

- Blood sugar monitors
- Disposable delivery systems for devices
- Smart syringes for auto injection

# ESBAC topic selection criteria

- Relevant
- Applicable to policy
- Timely
- Realistic
- Unique



# Deliverables

- Workshop with experts to develop ideas
- Peer reviewed report or framework in public domain
  - Map of technology examples
  - Framing of the issues raised

# Suggested Stakeholders

- NHS England
- DH Medicine, Pharmacy and Industry colleagues (MPI)
- MHRA
- NICE
- Faculty of Pharmaceutical Medicine
- DH Commercial Medicines Unit (CMU)
- Industry
- Experts in the area
- Patient groups and their carers
- Clinicians/prescribers
- Others?

# Focus Group Members

- Professor Sir Alasdair Breckenridge (Champion)
- Dr Rachel Quinn
- Professor Angus Clarke
- Professor Duncan McHale
- Mr Hugh Whittall
- Dr Julie Maxton
- Ms Katherine Littler
- Ms Madeleine Colvin
- Dr Paula Boddington
- Professor Peter Littlejohns

# Discussion & Questions

- First impressions of the proposal (does it make sense?)
- What needs clarification
- Follow-up questions on the proposal
- Who could help progress the work
- Would you like to be involved in the development of this work

# Closing comments

- Please complete the comments form and let us know if you would like to be involved as work progresses
- All comments/feedback will be reviewed as part of taking the work forward
- Output from the Forum will be added to the ESBAC webpage (currently being developed on GOV.UK)
- Networking opportunity over lunch

Thank you