August 2019

Legal and Ethical Update

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Legal & Ethical Issues

Agenda	
1	**Cannabis-based products for medicinal use**
2	**Assisted Dying**
3	**Genetic testing**
4	**Withdrawal of assisted ventilation**

Dear Dr….

I am a new Consultant in a small Palliative Care unit. A patient with refractory cancer pain has moved to our area. Having tried a wide variety of medications, she is now asking for medicinal cannabis.

‘I’m so relieved that it’s finally legal Dr…now you can prescribe it’

Is she right?

Legal Changes – Cannabis-based products for medicinal use

July 18

Medicinal value recognised by UK Government

Nov 2018

Change of law

CBPM rescheduled -> Schedule 2

Exert panel approval no longer needed

Limit on conditions removed

Unlicensed -> Restricted to Dr on Specialist Register

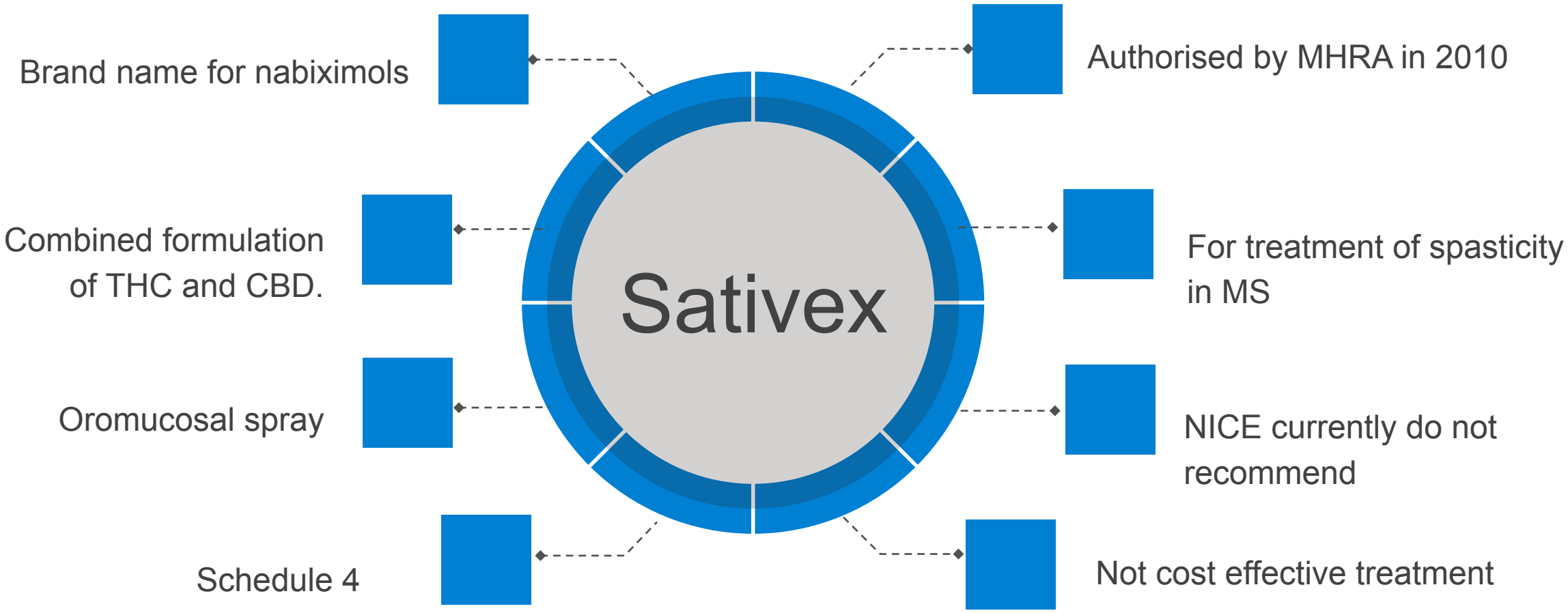
Once licensed-> available on prescription as per other Sched 2 drugs

Prescriptions must be for a specific patient

Despite this, numbers of prescriptions remain low

The cannabis plant synthesises many cannabinoids	The major psychoactive constituent	Pure CBD is not a controlled drug, but most includes THC
Includes THC and CBD	**THC**	**CBD**

Products in Schedule 2	Varying quantities and ratios of THC and CBD Range of forms: herbal materials, extracts for oils/capsules
Exemptions	Sativex (Nabiximols), Specific synthetic cannabinoids (Nabilone, Dronabinol)


Sativex
Brand name for nabiximols
Authorised by MHRA in 2010
Combined formulation of THC and CBD.
For treatment of spasticity in MS
Oromucosal spray
NICE currently do not recommend
Schedule 4
Not cost effective treatment

‘Cannabis oil’

- Non-medicinal CBD products
- Can be found in health food shops
- Marketed as food supplements, not regulated as medicinal products
- Contain low concentrations of CBD

- Difficult to purify CBD from plants so that no trace of THC remains

- MHRA says that if a CBD product contains any controlled cannabinoids, then it is highly liked that the product would be controlled under the Misuse of Drugs regulations.

Recommendations

Royal College of Physicians (London)

- CINV
  Good evidence of effect
  High side effect profile
  Not first line
- Pain
  Limited research in palliative patients
  Mixed results or uncertain significance
  Not recommended in routine clinical practice.
- Non-CBPM not supported
  Variety of preparations; lack of any trial evidence
  Potential of harm and diversion

MHRA

- Outline a general process for prescribing, supplying and importing unlicensed cannabis-based medicinal products
- Suggests licensed medicines indicated for condition first
- Then licensed off-label medicines
- Follow local governance procedures for unlicensed medicines

Recommendations

NHS England

- Only if clear published benefit or UK guidelines
- If clinical need which cannot be met by a licensed medicine/established treatment
- Prescribe within own area of practice
- MDT agree decision
- Content of cannabinoid constituents must be known

MPS

- Similar guidance to NHS England

Advice for the Public

Very few people in England are likely to get a prescription for medicinal cannabis

Only likely to be prescribed for:

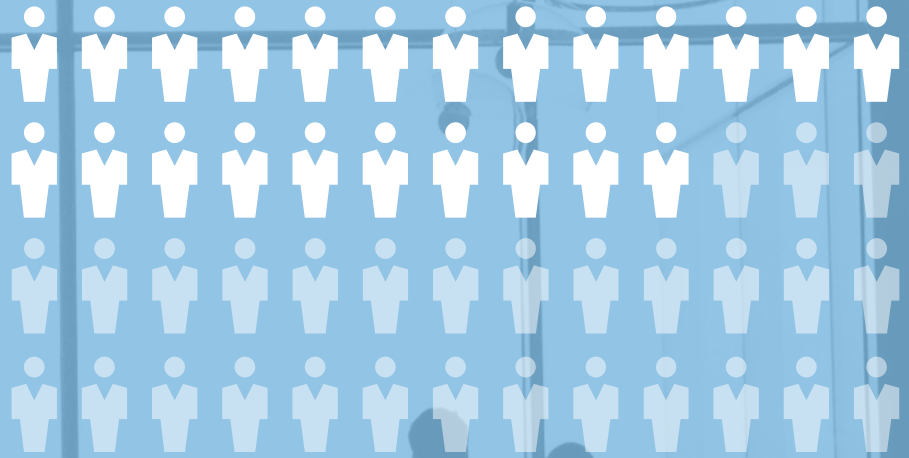
- Rare/severe epilepsy
- CINV
- MS Spasticity

The cannabis-based products available on prescription are likely to benefit a very small number of patients.

Products can be bought in health food stores such as ‘CBD oil’ and ‘hemp oil’ – claim to be medicinal cannabis but being sold as food supplements

No guarantee about quality or health benefit for OTC oils

NICE releasing Guidance in October 2019



Dear Dr….

I am a Registrar looking after an 80 year old man with cancer. He has been consistently expressing the wish to pursue assisted dying. He is isolated with no next of kin. He does not have internet access and is asking for assistance to get contact information for Dignitas. Can we help him without breaking the law?

Under the Suicide Act 1961, suicide itself is not a Criminal offence, but the act of encouraging or assisting someone else's suicide is.

Anyone assisting a patient could face prosecution and up to 14 years in prison.

Definitions

Witholding or withdrawing of treatment

Intentional, at the request of a patient with capacity (or in best interest of patient without capacity)

Physician-assisted dying

A physician intentionally supplies a patient who has capacity with the means to self-administer a lethal dose of medicine

Voluntary euthanasia

A physician intentionally administers a lethal dose of a medicine to a patient who has capacity and who has expressed a wish to die

Assisted Dying

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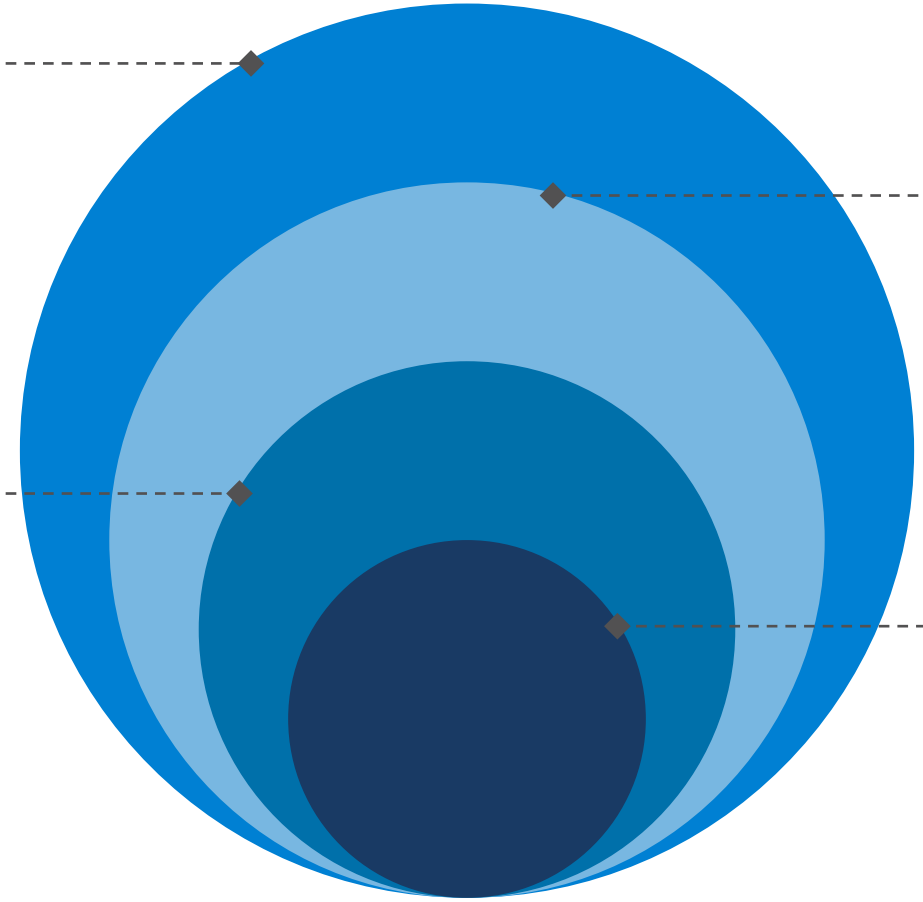
2019 debate
Debate House of Commons 4th July 2019 about current law

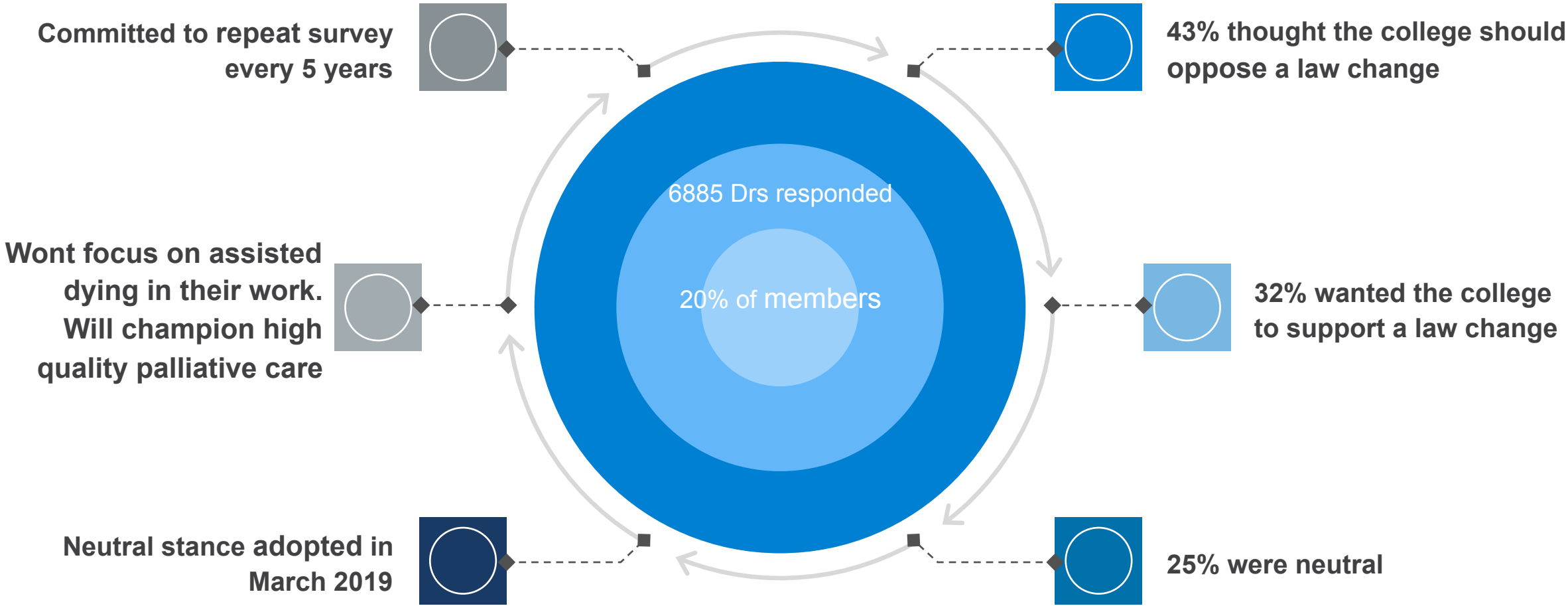
RCP London
Adopted a neutral stance on assisted dying



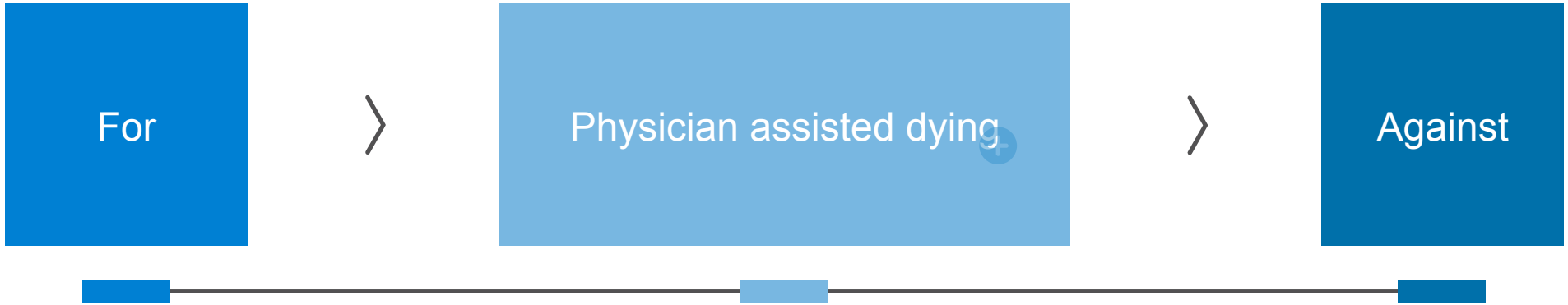
2015 vote
Parliament rejected by 330 to 118

Geoffrey Whaley
80 year old with MND. Died at Dignitas 7 Feb 2019. Reported to police and social services.

RCP London


Committed to repeat survey every 5 years
43% thought the college should oppose a law change
Wont focus on assisted dying in their work. Will champion high quality palliative care
32% wanted the college to support a law change
Neutral stance adopted in March 2019
25% were neutral
6885 Drs responded
20% of members

Ethical arguments



- Autonomy
- No morally significant distinction between witholding/ withdrawing treatment (foreseeing death) and assisting a patient to die
- Professional duty to relieve suffering
- Procedural safeguards

- Current law deters exploitation and abuse
- Adequate safeguards impossible
- Assisting suicide is an active promotion of death
- Deliberate killing is wrong
- Incompatible with the practice of medicine to aid death

Ethical arguments

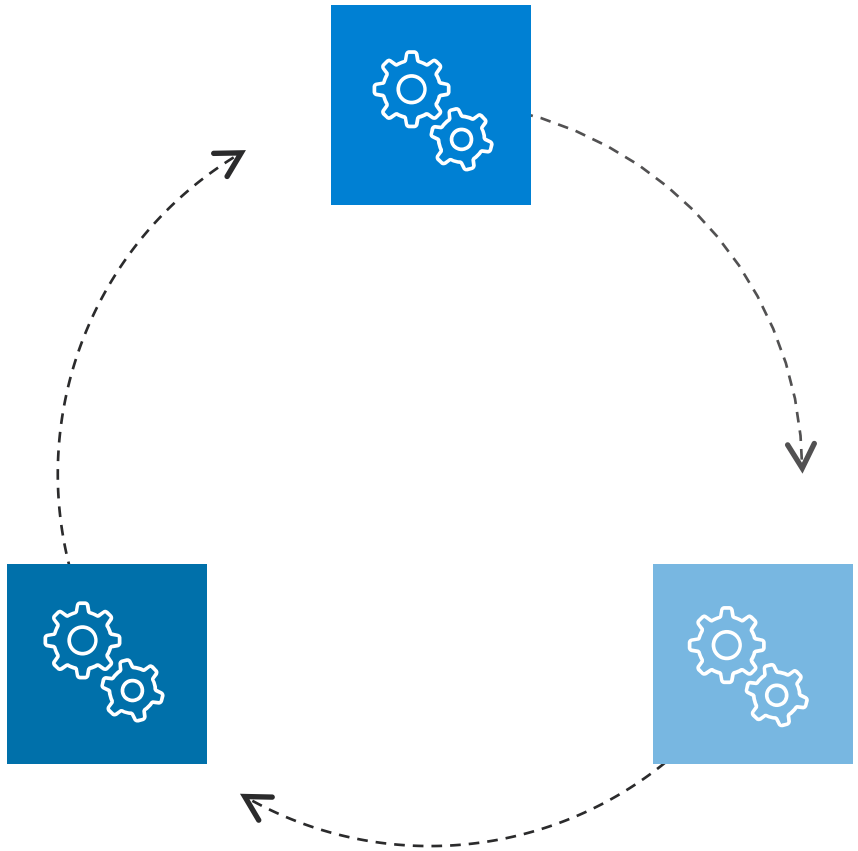
Subtitle goes here

- Arguments on both sides involve judgements of **Principle** and **Consequences**
- Judgements of **Principle** are beliefs or values
- Judgements of **Consequence** relate to matters of fact
- Decision = combination of assessing the facts and acknowledging own moral position
- Many of the arguments are mirror images of the other.

Dear Dr….

I am a Registrar who looked after a 36 year old lady with metastatic cancer. She had a 5 year old son. In the last hours of her life, her husband asked whether we could take a blood sample for genetic testing. He had been told that her cancer 'might be genetic'. The patient remained unconscious. What should I have done?

Decision making – lacks capacity



What request involves/risks

- Taking a blood sample
- Potential pain, distress (or not)
- Invasive treatment near death

Consequences of refusing test

- Potential harm to child
- Psychological distress for husband

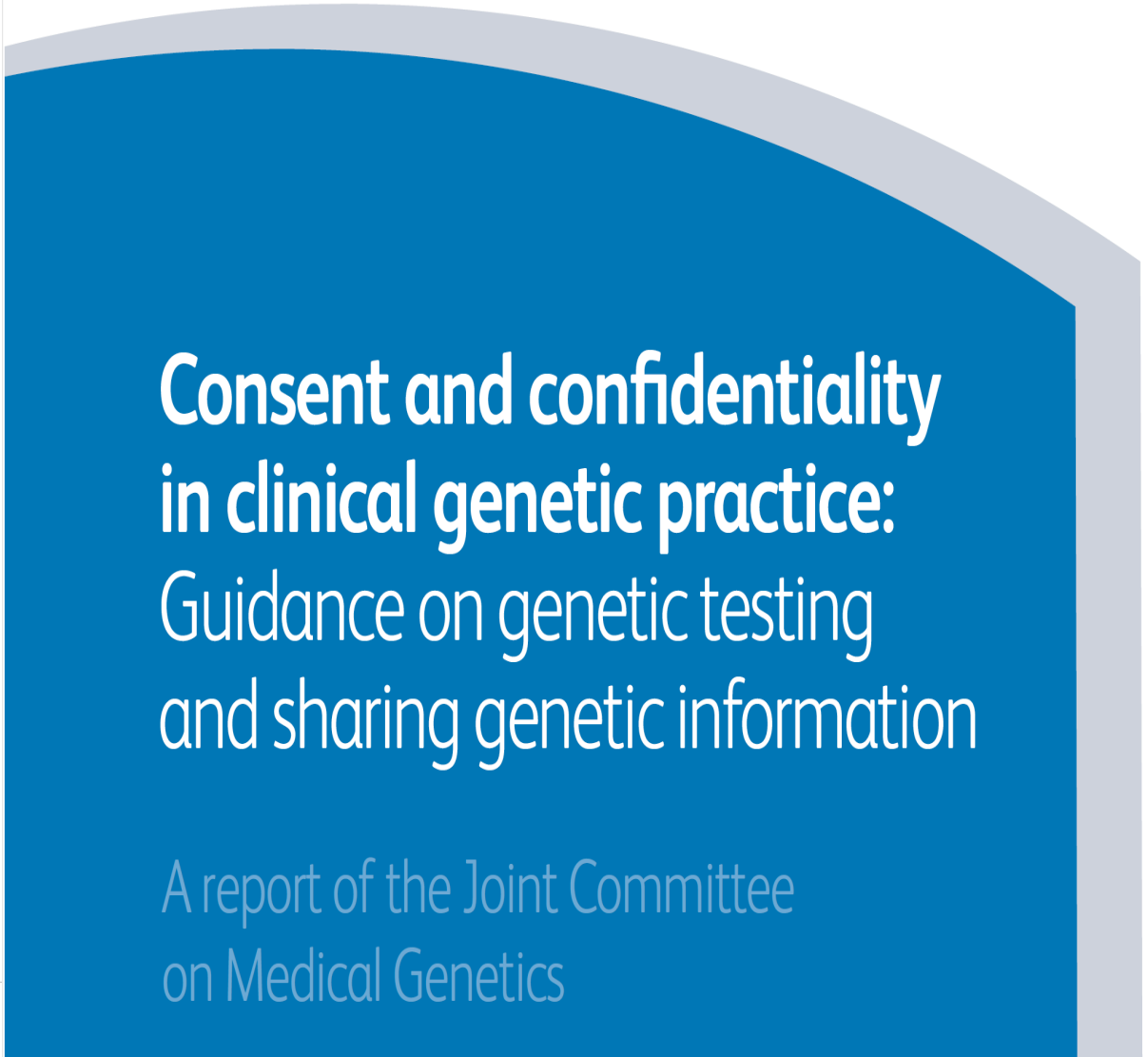
Best interest?

- Any prior wishes?

Genetic testing

- Distinctive nature of consent
- Information also affects family members
- Unable to consent?
  - Mental capacity act 2005
  - Best interest decision
- Best interest?
  - Can include indirect benefit
  - eg the well being of their child
- Needs careful consideration

Royal College of Physicians | The Royal College of Pathologists Pathology: the science behind the cure | BSHG The British Society for Human Genetics



Dear Dr…

I am a Palliative Medicine Consultant on a hospice inpatient unit. We are looking after a 60 year old woman with advanced MND. She has consistently expressed her wish to avoid life prolonging measures and to remove her NIV. There is much disagreement amongst our MDT as several staff feel very uncomfortable that we will be 'hastening' her death. What would you advise?

Withdrawal of Assisted Ventilation at the Request of a Patient with MND – APM Guidance 2015

- Legal and ethical right to refuse assisted ventilation.
- Patients should be made aware of their right (Standard)
- No doubts that withdrawal of assisted ventilation at the request of a patient is both ethical and legal
- A senior clinician should lead the planning of withdrawal (Standard). Includes capacity assessment.
- The professional team may require debriefing
- APM have compiled a list of senior HCPs who have experience in withdrawing assisted ventilation

Withdrawal of Assisted Ventilation
APM Legal and Ethical Position Statement

- In UK law, a refusal of a medical treatment must be respected
- …even if this could lead to death
- Treating without consent legally constitutes a criminal offence of battery
- Assisted ventilation is a medical treatment. Withdrawing it is not assisted dying, even if the treatment is life sustaining.
- A patient with capacity may also make an ADRT
- Timing of death may be medically manipulated but cause of death is the advanced neurological disease.
- The classification of death should be natural causes.

Withdrawal of Assisted Ventilation
APM Legal and Ethical Position Statement

- Some professionals may not feel able to support the withdrawal of assisted ventilation.
- The GMC acknowledges this
- Patient must be referred on

Access to Palliative Care Bill - Why is it needed?

2 Certainties about life

We are all born and we all die

470,000

Deaths in England per year, 3 quarters not sudden

Early palliative care

Patients live better and longer, at no additional cost

92,000

Estimated number who would benefit from PC but don't receive any at all

29 CCGs

Stated the number of their patients with pall care needs

163 CCGs

Commissioned 7 day admission to specialist pall care beds

47% hospitals

Have 7 day face to face pall care

Disparity

In resources allocated to palliative care

Access to Palliative Care Bill – CCGs must ensure:

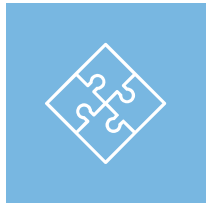
Subtitle goes here

Access to pain and symptom management

Psychological support for the person and their relatives

Information regarding the person's condition and palliative care

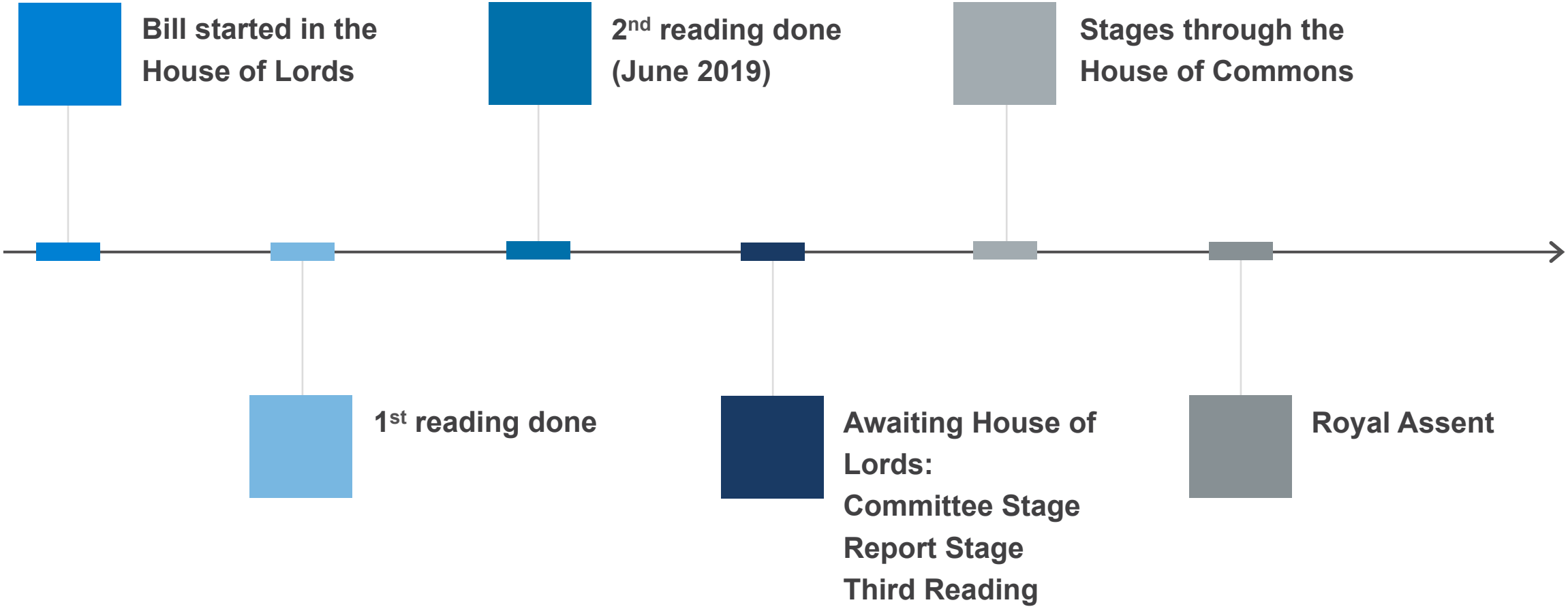
A published strategy including expected palliative care needs for their area



A strategy detailing how the needs will be met and how specialist palliative care will be provided

A strategy published within 9 months of the Act and be reviewed at least 3 yearly

Access to Palliative Care Bill



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