

# Royal College of Surgeons

## Parliamentary Briefing



## Medical Innovation Bill

### Briefing for House of Lords (Third Reading)

The Royal College of Surgeons (RCS) recognises the good intentions behind the Medical Innovation Bill. While we believe the Bill has been strengthened by a number of amendments since Committee stage, the College continues to have significant reservations with the present draft. In particular, we believe the Bill lacks the detail to provide sufficient safeguards for patient safety, particularly in the surgical context.

The RCS position therefore remains unchanged and we cannot currently support the Bill as it applies to surgery. Our reasoning is outlined in further detail below.

#### **Reliance on consultation with “one or more appropriately qualified doctors”**

Under the Bill a doctor in deciding to responsibly innovate need only obtain the views of one colleague at a minimum. The Bill specifies that the responsible doctor must take “full account of those views”. This compares with the existing common law arrangements in which the doctor’s decision must be supported by a “responsible body of medical opinion”. Under the provisions of the Bill a medical professional could consult with colleagues, take account of their views, and yet continue with an innovative treatment without demonstrating support for that course of action. We see

this lack of peer validation for an untested treatment as an unacceptable patient safety risk.

We recognise that the definition of what is meant by “appropriately qualified” is deliberately open so as to not be overly prescriptive, and therefore maintain the Bill’s flexibility and scope. However, we would contend that further definition is required to ensure that such an individual is of the required experience.

These two concerns are important because in surgery the effects of treatment cannot be “undone”. The decision to operate is never taken lightly as surgery always confers an inherent element of risk. The degree of risk is considerably enhanced when undertaking a procedure that is untested, unproven, and where the full effects are yet to be completely evaluated. The College therefore continues to believe that any decision to adopt an innovative approach must be taken in full consultation with a multi-disciplinary team. In our opinion the requirements detailed in the first clause of the Bill do not supersede the safeguards that are intrinsic as part of a full discussion with medical colleagues.

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## **Recording actions in the patient's notes**

We welcome the introduction of clause 1(5) requiring the steps taken to depart from the existing range of medical treatments for a condition (clause 1(3)) to be recorded in the patient's notes. This includes requiring the doctor to record details relating to the views they have obtained from colleagues. Such a record greatly improves the transparency and accountability of the entire process and is welcome not only from a legal viewpoint but also because it acts as a further barrier in dissuading irresponsible practice.

## **Excluding cosmetic surgery**

The College supports the exclusion of cosmetic surgery from the scope of the Bill. The Bill is intended to facilitate innovative practice when all conventional avenues have failed to benefit the patient, such as at the end of life. Surgery carried out purely for cosmetic surgery falls outside this definition.