Belfast Health and Social Care Trust
caring supporting improving together

FOI/25757

5 November 2021

Medical Devices

1) Who ultimately authorises the use of medical devices like Essure within a Specific Trust?

The use of a medical device will be authorised based on a combination of clinical need, best practice (professional body guidance, national standards, clinical evidence) and the clinical experience of the practitioner.

2) Who is ultimately responsible for procurement of the medical devices used within the Trust?

The procurement of medical devices and equipment will be on the basis of clinical need and may be authorised by an individual ward or department manager, or if more costly and/or in widespread use may be authorised by a Service Manager or Co-Director. Staff will also be nominated to represent the Trust on Contract Adjudication Groups (CAGs) with regard to the tendering and procurement of medical devices used within the Trust.

3) Is it the Department of Health or each individual Trust who should be satisfied with the adequacy of a medical device before use on patients?

It would be the individual Trust who would decide on the suitability of equipment for clinical use including efficacy.

4) Is it the Department of Health or each individual Trust who should be satisfied with the safety of a medical device before use on patients?

It would be the responsibility of each individual Trust to be satisfied with the safety of a medical device before use on patients. The Trust service management, staff and clinicians will report any issues and concerns with medical devices via the Trust Datix Incident Reporting System. There is also the requirement to report to NIAIC (Northern Ireland Adverse incident Centre at the Department of Health) any incidents that meet their reporting criteria "An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users including staff, patients or other persons".