Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Biological Mesh

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for the use of Biological Mesh		
EA Author	David King	**Team**	Equality and Diversity
Date Started	13/08/2019	**Date Completed**	
EA Version	2	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Surgical Mesh

Surgical mesh is a screen-like material that is used as a reinforcement for tissue or bone. It can be made of synthetic polymers or biopolymers.

Materials used for surgical mesh include:

- **Non-absorbable synthetic polymers** (polypropylene)
- **Absorbable synthetic polymers** (polyglycolic acid or polycaprolactone)
- **Biologic** (acellular collagen sourced from cows or pigs)
- **Composite** (a combination of any of the three previous materials)

Mesh implants may be used in a number of surgical procedures to provide additional support when repairing weakened or damaged tissue.

Over recent years attention has increased on complications that can occur with the use of this mesh in urogynaecological procedures to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). These complications can include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel. There has been an acknowledgement from the NHS England mesh working group that there is a lack of comprehensive data on these complications. Work is ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

Currently, the use of mesh in urogynaecological procedures to treat pelvic organ prolapse and stress urinary incontinence is not supported, wider NHS review of the use of mesh means that at the current time the CCG does not support the use of mesh implants in these clinical circumstances.

However, surgical mesh implants (non-biological mesh) are routinely used across the NHS to address the clinical problem of hernia. These implants typically restore structural domain to the abdominal/pelvic wall and prevent extrusion of visceral contents. Surgery takes place either as an open or laprascopic procedure.

Open Surgery

The surgeon makes a single cut (incision) over the hernia. This incision is usually about 6 to 8cm long. The surgeon then places the lump of fatty tissue or loop of bowel back into your abdomen (tummy). A mesh is placed in the abdominal wall, at the weak spot where the hernia came through, to strengthen it. When the repair is complete, your skin will be sealed with stitches. These usually dissolve on their own over the course of a few days after the operation.
If the hernia has become strangulated and part of the bowel is damaged, the affected segment may need to be removed and the 2 ends of healthy bowel rejoined. This is a bigger operation and you may need to stay in hospital for 4 to 5 days.

Laparoscopic (keyhole) Surgery

During keyhole surgery, the surgeon usually makes 3 small incisions in your abdomen instead of a single larger incision. A thin tube containing a light source and a camera (laparoscope) is inserted through one of these incisions so the surgeon can see inside your abdomen. Special surgical instruments are inserted through the other incisions so the surgeon can pull the hernia back into place.

There are 2 types of keyhole surgery:

- Transabdominal preperitoneal (TAPP)

Instruments are inserted through the muscle wall of your abdomen and through the lining covering your organs (the peritoneum).
A flap of the peritoneum is then peeled back over the hernia and a piece of mesh is stapled or glued to the weakened area in your abdomen wall to strengthen it.

- Totally extraperitoneal (TEP)

This is the newest keyhole technique and involves repairing the hernia without entering the peritoneal cavity.
Once the repair is complete, the incisions in your skin are sealed with stitches or surgical glue.

Evidence Review

A review of the clinical evidence found mixed clinical review, with no strong basis for the use of biological mesh over standard mesh. Standard of the evidence reviewed comprised mainly of retrospective studies of low to moderate quality, but with hernia reoccurrence being higher following the use of biological mesh, but no significant difference was determined in the occurrence of wound and mesh infection. Therefore, in light of the currently available low-quality evidence, to support the use of biological mesh over standard mesh, the use of biological mesh is not routinely commissioned.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Not Routinely Commissioned

Due to the currently available low-quality evidence, to support the use of biological mesh over standard mesh, the use of biological mesh is not routinely commissioned.

This means the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data 2018/19

Number of Procedures	BSOL	Sandwell

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance 1. Barber,S. 2018 BRIEFING PAPER: Surgical mesh implants Number CBP 8108, 15 January 2018. House of Commons Library. https://www.baus.org.uk/_userfiles/pages/files/Patients/CBP-8108.pdf 2. RCOG. (2019) https://www.rcog.org.uk/globalassets/documents/guidelines/safety-alerts/nhs-mesh-letter-extension-of-pause-on-the-use-of-vaginal-mesh-29-march-2019.pdf		

3. F. Köckerling, N. N. Alam, S. A. Antoniou, I. R. Daniels, F. Famiglietti, R. H. Fortelny, M. M. Heiss, F. Kallinowski, I. Kyle-Leinhase, F. Mayer, M. Miserez, A. Montgomery, S. Morales-Conde, F. Muysoms, S. K. Narang, A. Petter-Puchner, W. Reinpold, H. Scheuerlein, M. Smietanski, B. Stechemesser, C. Strey, G. Woeste, N. J. Smart. What is the evidence for the use of biologic or biosynthetic meshes in abdominal wall reconstruction? Hernia. 2018; 22(2): 249–269. Published online 2018 Jan 31. doi: 10.1007/s10029-018-1735-y https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5978919/

4. Biologic versus Synthetic Mesh Reinforcement: What are the Pros and Cons?
James F. FitzGerald, Anjali S. Kumar. Clin Colon Rectal Surg. 2014 Dec; 27(4): 140–148. doi: 10.1055/s-0034-1394155
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4477030/

5. Majumder A[1], Winder JS[2], Wen Y[1], Pauli EM[2], Belyansky I[3], Novitsky YW[4] Comparative analysis of biologic versus synthetic mesh outcomes in contaminated hernia repairs. Surgery. 2016 Oct;160(4):828-838. doi: 10.1016/j.surg.2016.04.041. Epub 2016 Jul 21. https://www.ncbi.nlm.nih.gov/pubmed/27452954

6. Carver DA, Kirkpatrick AW, Eberle TL, *et al.* Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial
BMJ Open 2019;9:e024091. doi: 10.1136/bmjopen-2018-024091 .
https://bmjopen.bmj.com/content/9/2/e024091

7. C. S. Seefeldt; J. S. Meyer; J. Knievel; A. Rieger; R. Geißen,R. Lefering; M. M. Heiss (2019) BIOLAP: biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: study protocol for a randomized, multicenter, self-controlled clinical trial. *Trials*2019**20**:55. https://doi.org/10.1186/s13063-018-3122-5https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-3122-5

8. Loes Knaapen, Otmar Buyne, Harry van Goor, Nicholas J (2016) Synthetic vs biologic mesh for the repair and prevention of parastomal hernia. *World J Meta-Anal* 2017 December 26; 5(6): 150-166. DOI: 10.13105/wjma.v5.i6.150.

https://f6publishing.blob.core.windows.net/66e60003-20b2-4ada-9595-26b5152dc122/WJMA-5-150.pdf

9. David A Carver, Andrew W Kirkpatrick, Tammy L Eberle, Chad G Ball (2019)Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial BMJ Open. 2019; 9(2): e024091. Published online 2019 Feb 15. doi: 10.1136/bmjopen-2018-024091

10. Hubert Scheuerlein, Andreas Thiessen, Christine Schug-Pass, Ferdinand Köckerling. (2018)

11. What Do We Know About Component Separation Techniques for Abdominal Wall Hernia Repair?

12. Front Surg. 2018; 5: 24. Published online 2018 Mar 27. doi: 10.3389/fsurg.2018.00024

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Although developing a hernia can affect those from birth up to old age, the most common type diagnosed is often associated with ageing, the diaphragm becoming weaker with age and repeated strain/pressure on the stomach.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

3. Impact and Evidence:

No impact identified based on available data, however a link can be made with degenerative conditions where the person experiencing is likely to have a disability. Limiting this procedure may have an impact on this group as a result. This should be balanced against the lack of clinical evidence.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

Those who are pregnant may have an increased risk of hernias because of the increased pressure pregnancy puts on the abdomen.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

No impact identified

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

Biological mesh although not routinely commissioned can be made from porcine / bovine or human tissues due regard to a patient's faith should be taken into consideration if biological mesh is commissioned.

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

Depending on the type of hernia diagnosed there is a correlation that males and females are more prone to a developing particular type due to the nature of the condition. However, the most common type diagnosed mainly affects men.

3. Impact and Evidence:
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation.

Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	If biological mesh is commissioned due regard to a patient's faith must be taken into consideration. (Regard to use of pork / bovine derived products and their unacceptability to those of certain faith groups)
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made.
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments as there is no clear evidence to support the use of biological mesh over standard mesh.

This must be balanced against the need to adhere to the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available. Consideration must be made to a patient's faith if the procedure is used since Bovine / Porcine derived products maybe unacceptable to certain faith groups.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.
None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):
This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee		
	Name	**Date**
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net