

# Supporting shared decision making for treating complications from pelvic mesh surgery

Andy Hutchinson  
Senior Medicines Adviser, NICE

Jacqueline Emkes  
Urogynaecology Expert Patient

**NICE** National Institute for  
Health and Care Excellence



# Declarations of interest

## Andy Hutchinson

- No interests to declare
- All income is from employment by NICE, all expenses are reimbursed by NICE or other NHS organisations
  - NICE is an executive non-departmental public body, sponsored by the UK Department of Health and Social Care

## Jacqueline Emkes

- No interests to declare
- Expenses and honoraria solely from NHS England or other NHS bodies

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# What we're going to cover

- Background
  - Mesh use and complications
  - The Cumberlege report
- What we did
  - The context
  - How we did it
- Learning points to share

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# Background



# What health problems are we talking about?

## Stress urinary incontinence (SUI)

- Leaking urine when the bladder is under pressure

## Pelvic organ prolapse (POP)

- When 1 or more pelvic organs drops out of normal position, often pushing into the vagina

# Mesh for urogynaecology surgery

- Polypropylene surgical mesh has been used for many years for surgical repair
- In the late 1990s, mesh began to be used to treat SUI
  - A strip is used to support the neck of the bladder
- For many women, mesh surgery is trouble-free and beneficial
- Some women experience severe complications with devastating effects on their quality of life
- For many years, many mesh-affected women felt they were not listened to and that their concerns were minimised and ignored

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# The Cumberlege report

[www.immndsreview.org.uk/Report.html](http://www.immndsreview.org.uk/Report.html)

- In 2018 the UK Independent Medicines and Medical Devices Safety Review was announced
  - Chaired by Baroness Julia Cumberlege
  - Reported July 2020
- Looked at harms from medicines and medical devices and how the UK healthcare system had responded
  - Hormone pregnancy tests (from the 1970s and earlier)
  - Sodium valproate
  - Pelvic mesh implants

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## First Do

**The report of the  
Medicines and  
Safety Review**



What NICE did





# Cumberlege recommendations

[www.immndsreview.org.uk/Report.html](http://www.immndsreview.org.uk/Report.html)

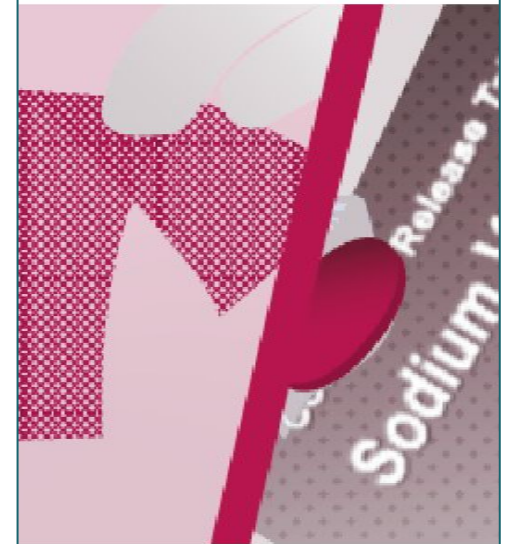
- ‘Networks of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh’

*Recommendation 5*

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## First Do

**The report of the  
Medicines and  
Safety Review**



# Cumberlege on informed consent

[www.immdsreview.org.uk/Report.html](http://www.immdsreview.org.uk/Report.html)

- “[Patients’] care and treatment should not be a series of events that happened to them. Rather, every patient should be able to stand back, look at their patient journey and say ‘I recognise my handwriting all over those choices.’ ”

*Paragraph 2.17*

- "Patients must have sufficient understanding of their treatment, including the potential risks it presents, and the alternative treatment options, in order to decide whether they are willing to have that treatment."

*Paragraph 5.60*

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## First Do

### The report of the Medicines and Safety Review



# Cumberlege on PDAs

[www.immndsreview.org.uk/Report.html](http://www.immndsreview.org.uk/Report.html)

- ‘Patient decision aids [PDAs] must reflect the most up-to-date and valid clinical consensus of the risks and benefits associated with the intervention in question, including what is not known ...
- ‘They must have been jointly developed with patients so that they accurately and fully reflect the patient experience and outcomes ...
- ‘NICE should lead in facilitating that clinical consensus.’

*Paragraph 2.22*

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## First Do

**The report of the  
Medicines and  
Safety Review**



# Challenges

- The evidence base about treating complications related to mesh surgery is very limited
- We needed to ensure that the mistakes around information for mesh insertion were not repeated
  - Ensure women were not on a 'conveyor belt' for surgery
- Many women affected by mesh are very sceptical about the health system
- Specialist surgical societies had already started some work in this area
  - Needed to ensure alignment of purpose
- We had limited time to develop PDAs
  - Commissioned 1 December 2020, Centres opened 1 April 2021

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# The plan

- Worked to IPDAS recommendations
- Separated 'shared decision making' from 'consent for surgery'
  - Ensured non-surgical options were explored
  - Tiered information
- Formed an expert oversight group
  - Mesh-affected women, surgeons, public involvement experts, editors
  - Engaged with stakeholders critical of previous health system actions
- Stuck strictly to NICE guidance and the evidence review (NG123, 2019)
- Extensive stakeholder review
- User feedback and validation planned

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# Decision aid format

[www.nice.org.uk/guidance/ng123/resources](http://www.nice.org.uk/guidance/ng123/resources)

- pdf booklet: users indicated a hard copy option was valuable
- Content:
  - Is this decision aid for me?
  - How this decision aid can help
  - What type of mesh did you have?
  - How might mesh have caused your complications?
  - What are the options for treating mesh complications?
    - Non-surgical and surgical
  - How do you feel about the options?

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decision aid



(sticker)

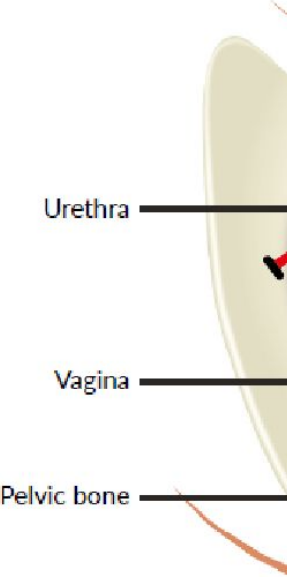
Treating urinary incontinence with mesh  
Options for specialist consultation  
Patient decision aid

What type of Non-surgical or surgical treatment?

To help with your stress urinary incontinence, a mesh tube coming out of your bladder can be used.

There are different types of options are suitable for you. They are:

- (A) retropubic mid-urethral sling
- (B) single-incision mini-sling
- (C) transobturator mesh



- Specialist pelvic health specialist fields may not to have surgery including bladder surgery, your physiotherapist can enhance your recovery and your general wellbeing.
- Specialist pain management nurses, physiotherapists can help with pain and its impact on your life. Your treatment options are tailored to you.
- Psychological and emotional problems caused by your treatment for urinary incontinence.

If you have only a small amount of oestrogen treatment removed. If the mesh is removed, you can have surgery later. If you have a mesh, however, vaginal areas of vaginal mesh conditions.

Surgical options to treat urinary incontinence

For more details of what the procedure involves, see the section on choosing.

| What type of complication does this surgery treat? | Division of mesh to tension   |
|--|---|
| What does this involve?                            | A mesh sling is placed under the vagina. It is usually placed under local general anaesthesia, with a short stay in hospital. |
| How much mesh is removed?                          | No mesh is removed.   |
| How extensive is the surgery?                      | The least extensive option.   |
| How does average time to recover compare?          | This option has the shortest recovery time.   |

How do you feel about the options?

You can use this section to write down what is most important to you and what you think about the options. You might also want to discuss this with family or friends. This will help you and your healthcare team decide together what is likely to be the best option for you.

My goals and fears

Which problems are most troubling to you? Which do you hope will be helped by treatment?

What possible problems from treatment are you most concerned about?

My preference at the moment (I can change my mind later)

What do you think is likely to be the best option for you right now? Why is that? Or are you not sure at the moment?

What other things would you like to talk to your healthcare team about?



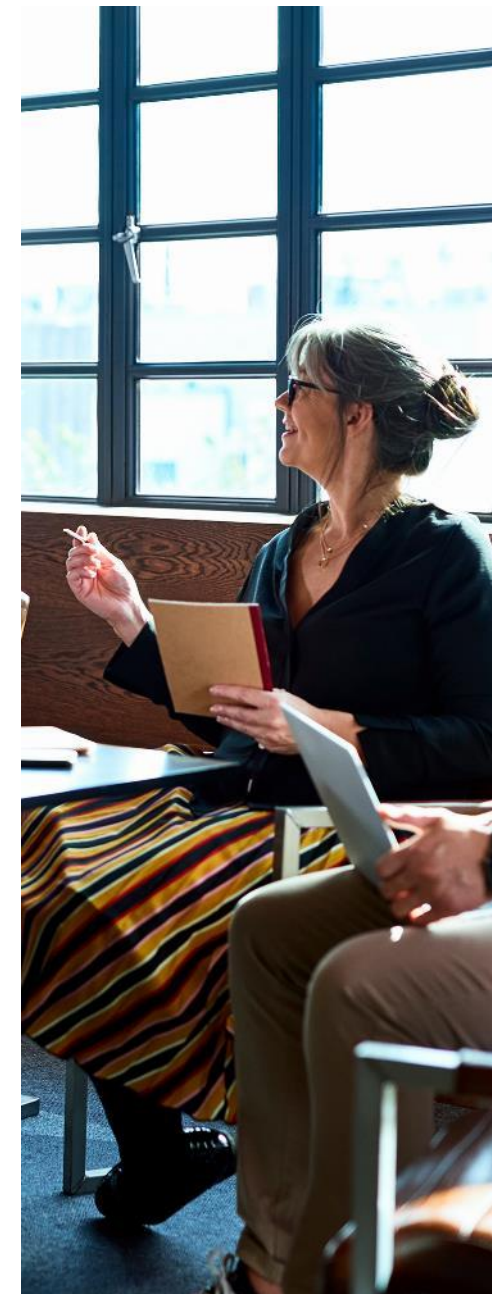
Diagram based on original developed by NHS Lothian. Used with permission.



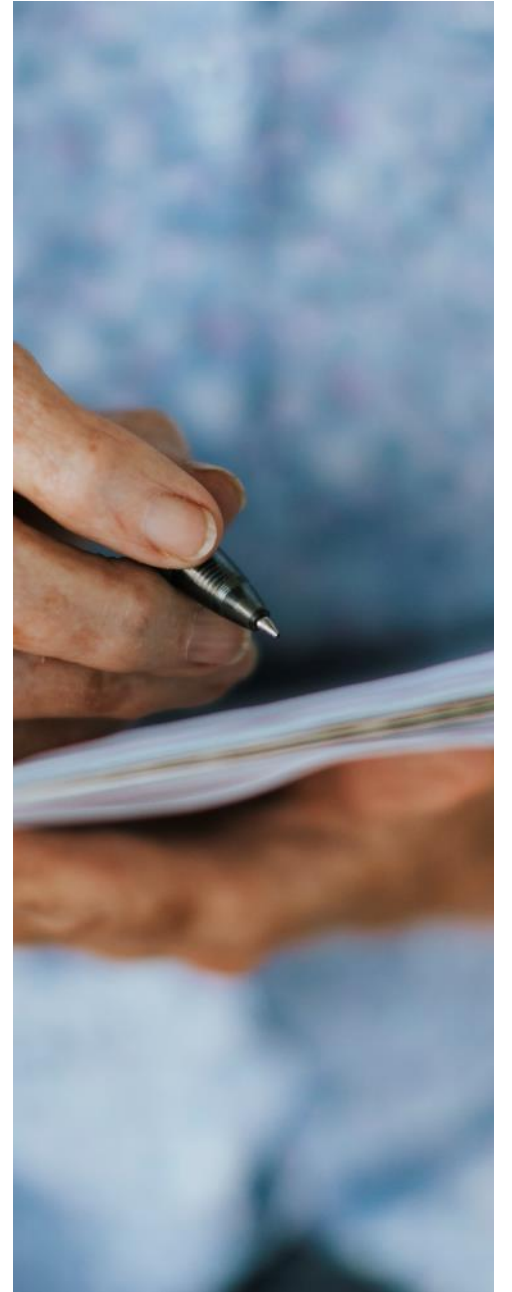
# User feedback and evaluation

- The COVID-19 pandemic has complicated things
- Anecdotal comments from clinicians and patients in specialist treatment centres are generally positive
- Specialist treatment centres will carry out a series of focus groups with women who have had experience of using the PDAs during 2022
  - Follow up those with interviews and questionnaires
  - Report in March 2023
- National funding grant application for academic evaluation

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# Lessons learned



# Lessons learned

- Co-production is essential
- Be clear on the scope, terms of reference and what can and cannot be included
- Take time to listen to patients' stories
- Do not be afraid to explain the limits of the evidence
- Ensure everyone with an interest is aware of what is happening
- Seek comments from a wide range of stakeholders

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Thank you for your attention

Any final questions?

[www.nice.org.uk/guidance/ng123/resources](https://www.nice.org.uk/guidance/ng123/resources)

[www.nice.org.uk/sdm](https://www.nice.org.uk/sdm)

