Public/patient involvement in NICE guidelines: positives and problems

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Overview of current stages of input

Stages of guidance development - opportunities for direct involvement or participation				
	Lay members	Expert witnesses	Stakeholder organisations	General public
Topic selection and referral	N	N	Med tech only	N
Committee chair selection	Social care only	N	N	N
Writing the scope	Diagnostics & SC only	N	Y	Y
Scope consultation	N	Y	Y	Y
Setting clincial/key questions and defining outcomes	Diagnostics & SC only	N	Y	N
Development - refining review questions and protocols	Variable	N	Variable	N
Development - committee membership	Y	N	Y	N
Development - providing evidence	Variable	Y	Variable	N
Development - social value judgements	N	N	N	Y
Consultation on draft	N	Y	Y	Y
Revision	Y	N	N	N
Plain language versions	Variable	N	N	N
Publication, promotion and implementation	Variable	N	Variable	N
Updating	Y	Y	Y	N

Public/Patient participation in TA committee decisions?

- Discussions at TA Committee meetings are divided into clinical and cost effectiveness
- Patient groups or individuals submit evidence which is summarised in the slides presented at the beginning of the clinical discussions – summaries are part of our job as lay reps.
- Patient representatives and/or individual patients are also invited to attend the meeting

Evidence we ask patient/carer organisations to submit.

- What is it like to live with the condition and/or what do carers experience when caring for someone with the condition?
- Which treatment outcomes are important to patients or carers?
- What is your organisation's experience of currently available NHS care and of specific treatments for the condition? How acceptable are these treatments and which are preferred and why?

Patient/carer evidence continued

- What do patients or carers consider to be the advantages of the treatment being appraised?
- What do patients and/or carers consider to be the disadvantages of the treatment being appraised?
- Are there any groups of patients who might benefit more from the treatment than others?
- Any “equality” issues i.e. any patients in the so-called “protected” groups who might be disadvantaged

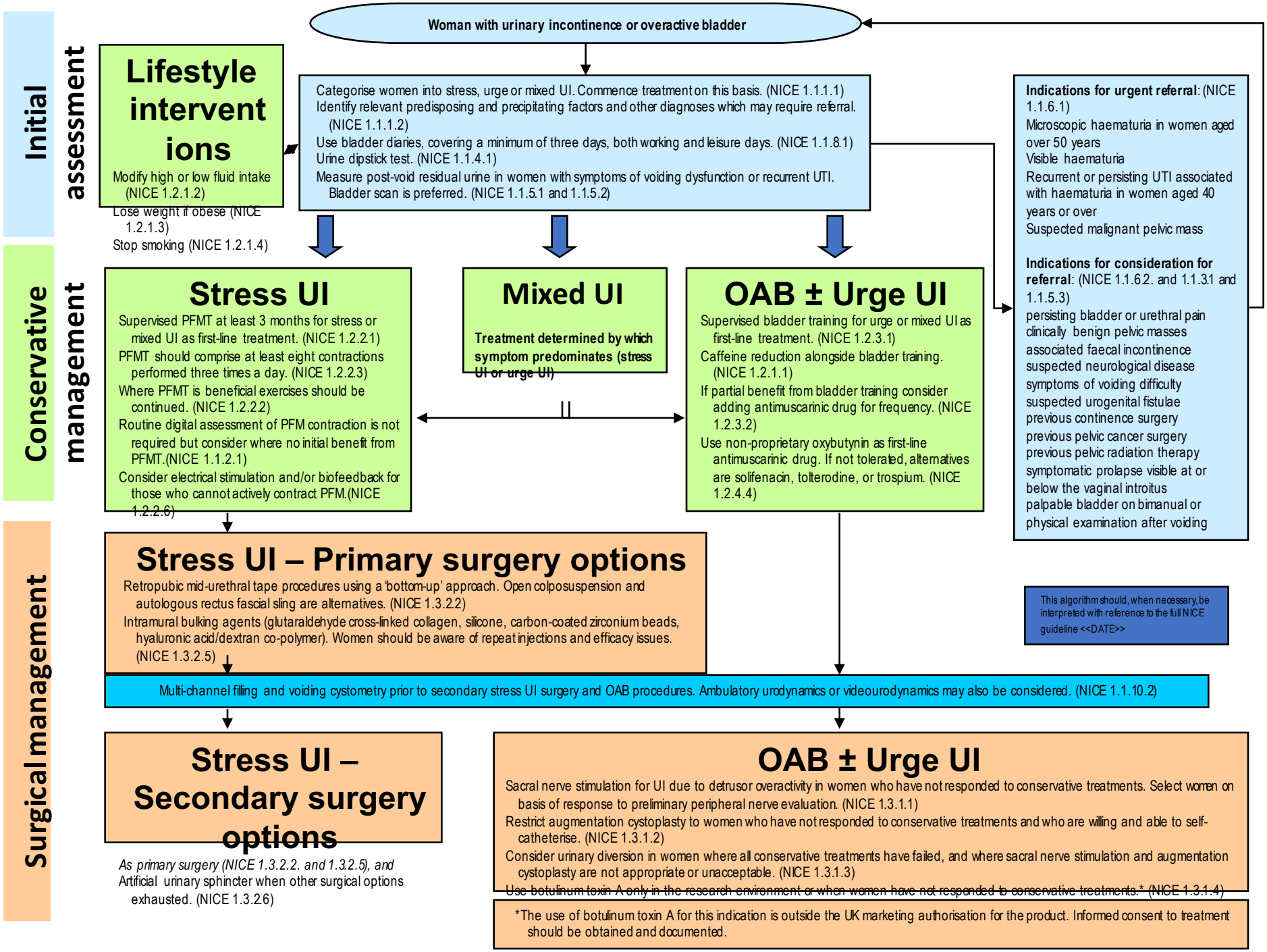
Patients' expectations are generally realistic

- Key patient/family goal is survival but Quality of Life (QoL) also very important

- Patient goals for treatment include:
  - Improved Progression Free Survival (PFS) & Overall Survival (OS)
  - Lasting response to treatment
  - Improved quality of life – including tolerable side effects
  - Active treatment as opposed to Best Supportive Care

Shared decision making?

- This is one of those mantras frequently recommended by the Dept of Health – but how often does patient involvement in NICE guidance result in guidelines where the clinicians are reminded to ask the patient what their goals are for treatment, and when they will decide not to have any more treatment?


Initial assessment
Conservative management
Surgical management
Woman with urinary incontinence or overactive bladder
Lifestyle interventions
Modify high or low fluid intake (NICE 1.2.1.2)
Lose weight if obese (NICE 1.2.1.3)
Stop smoking (NICE 1.2.1.4)
Categorise women into stress, urge or mixed UI. Commence treatment on this basis. (NICE 1.1.1.1)
Identify relevant predisposing and precipitating factors and other diagnoses which may require referral. (NICE 1.1.1.2)
Use bladder diaries, covering a minimum of three days, both working and leisure days. (NICE 1.1.8.1)
Urine dipstick test. (NICE 1.1.4.1)
Measure post-void residual urine in women with symptoms of voiding dysfunction or recurrent UTI. Bladder scan is preferred. (NICE 1.1.5.1 and 1.1.5.2)
Indications for urgent referral: (NICE 1.1.6.1)
Microscopic haematuria in women aged over 50 years
Visible haematuria
Recurrent or persisting UTI associated with haematuria in women aged 40 years or over
Suspected malignant pelvic mass
Indications for consideration for referral: (NICE 1.1.6.2. and 1.1.3.1 and 1.1.5.3)
persisting bladder or urethral pain
clinically benign pelvic masses associated faecal incontinence
suspected neurological disease
symptoms of voiding difficulty
suspected urogenital fistulae
previous continence surgery
previous pelvic cancer surgery
previous pelvic radiation therapy
symptomatic prolapse visible at or below the vaginal introitus
palpable bladder on bimanual or physical examination after voiding
Stress UI
Supervised PFMT at least 3 months for stress or mixed UI as first-line treatment. (NICE 1.2.2.1)
PFMT should comprise at least eight contractions performed three times a day. (NICE 1.2.2.3)
Where PFMT is beneficial exercises should be continued. (NICE 1.2.2.2)
Routine digital assessment of PFM contraction is not required but consider where no initial benefit from PFMT.(NICE 1.1.2.1)
Consider electrical stimulation and/or biofeedback for those who cannot actively contract PFM.(NICE 1.2.2.6)
Mixed UI
Treatment determined by which symptom predominates (stress UI or urge UI)
OAB ± Urge UI
Supervised bladder training for urge or mixed UI as first-line treatment. (NICE 1.2.3.1)
Caffeine reduction alongside bladder training. (NICE 1.2.1.1)
If partial benefit from bladder training consider adding antimuscarinic drug for frequency. (NICE 1.2.3.2)
Use non-proprietary oxybutynin as first-line antimuscarinic drug. If not tolerated, alternatives are solifenacin, tolterodine, or trospium. (NICE 1.2.4.4)
Stress UI – Primary surgery options
Retropubic mid-urethral tape procedures using a 'bottom-up' approach. Open colposuspension and autologous rectus fascial sling are alternatives. (NICE 1.3.2.2)
Intramural bulking agents (glutaraldehyde cross-linked collagen, silicone, carbon-coated zirconium beads, hyaluronic acid/dextran co-polymer). Women should be aware of repeat injections and efficacy issues. (NICE 1.3.2.5)
This algorithm should, when necessary, be interpreted with reference to the full NICE guideline <<DATE>>
Multi-channel filling and voiding cystometry prior to secondary stress UI surgery and OAB procedures. Ambulatory urodynamics or videourodynamics may also be considered. (NICE 1.1.10.2)
Stress UI – Secondary surgery options
As primary surgery (NICE 1.3.2.2. and 1.3.2.5), and
Artificial urinary sphincter when other surgical options exhausted. (NICE 1.3.2.6)
OAB ± Urge UI
Sacral nerve stimulation for UI due to detrusor overactivity in women who have not responded to conservative treatments. Select women on basis of response to preliminary peripheral nerve evaluation. (NICE 1.3.1.1)
Restrict augmentation cystoplasty to women who have not responded to conservative treatments and who are willing and able to self-catheterise. (NICE 1.3.1.2)
Consider urinary diversion in women where all conservative treatments have failed, and where sacral nerve stimulation and augmentation cystoplasty are not appropriate or unacceptable. (NICE 1.3.1.3)
Use botulinum toxin A only in the research environment or when women have not responded to conservative treatments.* (NICE 1.3.1.4)
*The use of botulinum toxin A for this indication is outside the UK marketing authorisation for the product. Informed consent to treatment should be obtained and documented.

Baseline assessment and initial management of patients with faecal incontinence

START

Patient reports or is reported with faecal incontinence

To identify contributory factors to faecal incontinence carry out and record:

- Comprehensive medical history covering the patient's bowel symptoms, contributory factors and impact of symptoms on quality of life (see list of questions)
- General examination
- Anorectal examination[1]
- Cognitive assessment[2] (if appropriate)

As appropriate assess and treat any suspected clinical problems[3] contributing to faecal incontinence and as appropriate:

- patient education and understanding
- address bowel habit[4]
- modify dietary and fluid intake
- review and adjust medications contributing to faecal incontinence and modifying stool consistency[5]
- address any toilet access issues[6]
- prescribe anti-diarrhoeal drugs for people with loose stool
- identify any psychological problems related to faecal incontinence

Ask patient if symptoms have improved. **If appropriate** adjust intervention/ or combination of interventions. **If symptoms persist discuss further treatment options with patient and/ or carer**.

If patient does not wish to continue provide patient with coping strategies, including psychological support, as appropriate.

If patient has cognitive or behavioural problems that may be contributing to faecal incontinence refer to recommendations for this group of patients.

FI persists in the absence of major cognitive impairment: see specialised assessment and management algorithm

NICE review of PPI

NICE review of its PPI Strategy started out with some grand ideas about principles such as:

- NICE has clarity of purpose about its PPI activities, and about patients and the public as a key audience for NICE
- NICE's work programmes are shaped where possible by patients and the public
- Key questions and outcomes (scopes) are informed by the perspectives of those directly affected by the topics
- Recommendations take account of the perspectives of those directly affected by the recommendations
- NICE outputs are written clearly and comprehensibly

NICE PPI Review

- These principles have not been abandoned but they are no longer central to the consultation document. Instead it focuses on how people will be recruited and retained, with a passing suggestion that Chairs and staff **might** get training about working better with lay people.
- Nevertheless, I would urge those of you who care about the involvement of lay people in NICE processes to read and comment on the consultation: https://www.nice.org.uk/about/nice-communities/public-involvement/consultation