

Purpose

- To undertake initial evaluation and treatment of female urinary incontinence.
- To distinguish between: 1. urge urinary incontinence (UUI)/ Overactive bladder syndrome (OAB); 2. Stress urinary incontinence (SUI); 3. Mixed urinary incontinence.
- To prevent the need for secondary care assessment of female urinary incontinence.
- To enhance control of female incontinence by self care and improved compliance with pelvic floor exercises, bladder training, general lifestyle advice and caffeine reduction.
- To initiate pre-prescribed anti-cholinergic medication for UUI patients who fail conservative measures.
- To discover whether the patient feels depressed, and offer GP care or simple approaches to self-management.

Setting

Primary care setting including incontinence clinic.

Selection of patients

All patients presenting to their GP with female urinary incontinence

Patients attending the community continence service

The following patients are excluded from enrolment in Flo and should be referred urgently to a urologist/gynaecologist as appropriate:

- microscopic haematuria aged > 50 years
- visible haematuria
- recurrent or persistent UTI associated with haematuria in patients aged 40 years or greater
- suspected pelvic mass arising from the urinary tract or reproductive system

The following patients are excluded from enrolment in Flo and should be referred routinely to a urologist/gynaecologist as appropriate:

- symptomatic prolapse visible at or below the vaginal introitus
- palpable bladder on bimanual or physical examination after voiding

The following patients can be enrolled in Flo but referral to a consultant should be considered:

- persistent bladder or urethral pain
- clinically benign pelvic masses
- associated faecal incontinence
- suspected neurological disease
- voiding difficulty
- suspected urogenital fistula

- previous incontinence surgery
- previous pelvic cancer surgery
- previous pelvic irradiation

Expected outcomes

1 Changes in healthcare usage:

- Fewer GP appointments for female urinary incontinence.
- Fewer referrals to secondary care for female urinary incontinence.
- Decreased use of incontinence aids.
- Fewer community continence nurse home visits/consultations

2 Patient empowerment:

- Ability to self manage their female urinary incontinence

3 Improved clinical outcomes:

- Improvement in individuals' continence – demonstrated via validated incontinence questionnaires (ICIQ-UI Short Form)

4 Popularity of Flo:

- Patients find Flo messages helpful and reassuring
- Clinicians find Flo reinforces clinical management without excessive clinical time

5 Cost effectiveness:

- Reduction in costs of avoided GP / practice nurse consultations
- Reduction in costs of secondary care usage (outpatient referral)
- Reduction in costs of community continence care usage
- Reduction in incontinence aid usage / supply

6 Other:

- Information gathered by 'Flo' will aid management decisions including modified input / output chart, predominant stress / urge symptoms.

Success criteria

- 20% reduction in outpatient referral of patients to secondary care in patients with female urinary incontinence.
- 20% of patients have improved continence scores (both general practice and community settings)
- 10% decreased use of incontinence aids

Protocol

In summary in general practice setting:

- Patient is enrolled on the 'Flo' tele-health system by their GP or practice nurse to provide initial assessment and treatment of female urinary incontinence.
- Patients stratified into 1. Urge urinary incontinence (UUI)/ Overactive bladder syndrome (OAB); 2. Stress urinary incontinence (SUI); 3. Mixed urinary incontinence (MUI). (see starter pack)

- Patient given patient education leaflet describing the different types of urinary incontinence, talked through with clinician (see starter pack)
- The patient and GP agree anti-cholinergic medication if deemed appropriate by Flo as part of agreed dual management plan in urge urinary incontinence or mixed urinary incontinence only. Flo will ask about medication at 6 weeks but it can be given earlier if patient is not improving (particularly if they have bothersome urinary urgency and frequency).
- Patient completes a validated incontinence questionnaire (ICIQ-UI Short Form) and frequency volume chart as part of the initial assessment at 1 month, 2 months and at the end of the period of evaluation (3 months). Patient will be supplied with input/ output diary forms to collate data before sending scores to Flo and have copies of ICIQ-UI Short Form (See starter pack).
- Patients will be asked about pad usage each week as part of the protocol.
- Daily, the patient receives automated text messages about conservative management and recommended lifestyle changes
- Evaluation (optional) – capture of healthcare usage, patient experience, questionnaire data.

Patient:

- signs contract, agreeing to respond to messages from Flo for 3 month trial period.
- signs a consent form accepting that they remain responsible for their health, and understanding that messages are sent to an inanimate machine.
- responds to monthly questions about improvements in symptoms.
- receives daily information messages, and tries to adopt the advice contained in them.

Clinician:

- verifies by urine dipstick that no UTI is present at enrolment.
- organises the initial assessment; issues the input / output chart with instructions on how to do simple analysis. Issues a validated incontinence questionnaire (ICIQ-UI Short Form). Issues patient information leaflet. These tasks are simplified by a simple enrolment document with important exclusions listed as part of the starter pack.
- agrees a dual management plan with the patient, which includes the use of Flo.
- explains to the patient that readings are sent to an inanimate machine which is not monitored continuously, and obtains their signed consent form which states that the patient remains responsible for their own health.
- obtains patient's signed agreement to respond to Flo.
- enrolls patient on Flo by using the patient's current mobile phone number and NHS number, then selecting the appropriate service for them.
- prescribes an appropriate anticholinergic drug at the lowest dose of the medication (e.g. solifenacin 5mg od). Flo will ask about starting medication at 6 weeks but it can be given earlier if patient is not improving to allow patient to continue with the evaluation (particularly if they have bothersome urinary frequency).
- monitors the patient's readings once per month, and if unable to do so, ensures another member of the practice team does so.

- after three months, concludes Flo treatment, unless patient wants to continue using it. Evaluation at 1 month, 2 months and face to face at 3 months. Option to continue if the patient wishes.
- if practice is undertaking substantial evaluation, writes patient's details on evaluation form, and files this for assessment by project administrator.

Practice administrator:

- keeps a note of patients enrolled on telehealth project and who completes three months of interactive messaging.
- Organises completes evaluation form if practice undertaking substantive evaluation.

Outcome measures

Outcome questions at enrolment and then at month 1, month 2 and month 3 (end of evaluation)

(Patient Training)

In the starter pack there's a questionnaire, the ICIQ-UI short form. Please complete it and text the score in the double lined box Text Q then the number, eg Q18

Thank you. Can you please keep the questionnaire in your starter pack so your doctor can look at it later? Remember to fill in the date on the form please.

Input Output Chart Assessment (Start, month 1, 2 and 3)

Hi, in your starter pack there's an input output chart. Please fill it in at your convenience and choose any 24 hour period. I will ask you for the results.

One day later

(Diary)

Have you filled in an input output chart yet? Please text INOUT 1 if you have, or INOUT 2 if you haven't filled it in. Thanks, Flo

NO – response:

If you fill in your input / output chart then I can assess how well you are doing. When you have completed your chart, text INOUT 1 Thank you Flo.

YES – response:

(Incont Count)

How many times did you pass urine in the 24 hours? Please reply UR, followed by the number of times, eg UR 8 if you passed urine 8 times. Thanks, Flo.

Response:

(Incont Urine-Loss)

Thank you. How many times did you leak urine in the 24 hours? Please reply LK followed by the number of times, eg LK 7

Response:

(Incont Intake)

Thank you. How much fluid did you drink in the 24 hours? Please reply FL, followed by the amount in mls. Thanks, Flo.

Response:

(Incont Volume)

Thank you. How much urine did you pass in the 24 hours? Please reply WE followed by the amount in mls, eg WE 2000 if you passed 2 litres. Thanks, Flo

Response:

Thank you. Take care, Flo

Weekly question

(Incont Pad-Count)

In the last 24 hours how many incontinence pads did you use? Please reply PAD followed by the number of pads, eg PAD 6. Thanks, Flo

Response 0-3 pads:

You are doing quite well. Keep up with the advice I am sending you and you should notice further improvements. Take care, Flo.

Response 4-20 pads:

You are clearly still struggling. Keep trying to use the advice that I suggest to improve your symptoms. Take care, Flo.

Fortnightly question

(Incont Between)

In the last 24 hours what was the longest time you managed between needing a wee? Please reply NE, followed by the number of minutes. Thanks, Flo.

60-600 minutes:

You are doing quite well. Concentrate on your bladder training and you may start to be able to control the need to wee.

<60 minutes:

You are clearly still struggling. Avoid tea, coffee and coke based drinks. Keep doing your bladder training and pelvic floor exercises.

(Wellbeing)

How many cups of tea or coffee do you drink a day? Please reply DRINK, followed by the number of cups. Thanks, Flo

1-3 cups:

You don't drink that much tea and coffee but reducing this may still help your symptoms. Take care, Flo.

4-6 cups:

You drink more tea and coffee than is good for your bladder. Try and decrease this to 2 cups per day. Drinking weak squash is a good alternative.

7-20 cups:

You are drinking too much tea and coffee for your bladder and general health. Try and decrease this to 2 cups a day. Drinking weak squash is a good alternative.

Anti-cholinergic Rx question

Week 6

(Medication)

Are you satisfied with your progress? Please reply MED 1 if you are or MED 2 if you are not satisfied. Thanks, Flo.

A Yes

I will continue to text you questions as long as you wish to receive them.

A No

Start taking the medication prescribed at your consultation with your GP. as agreed in your progress plan. Will you take the medication? Text Z1 = yes; Z2 = no

(My Medication)

Answer (Z1 or Z2) is in My Medication

Daily messages

Tea, coffee and coke drinks can irritate your bladder. Try to avoid these types of drinks.

Try to limit your fluid intake to approximately 6-8 glasses per day.

If you drink too little concentrated urine can irritate your bladder. Try and drink 6-8 glasses per day.

Try and drink a normal quantity of fluid. 6-8 glasses is recommended.

Make sure it is easy to get to the toilet to avoid accidents

Limit your alcohol intake, excess alcohol can make your symptoms worse

Weight loss can improve incontinence if you're overweight, even if you lose only 5% of your body weight.

Make sure you don't drink too many cups of tea or coffee. Try and drink 6-8 glasses of fluid per day.

Highly concentrated fruit drinks, such as fresh orange juice, can irritate the bladder. Try and reduce these types of drinks.

Some people notice that certain foods can affect their bladder function. Try and eliminate one food each week to see if you have any improvement.

Why not try and have a day when you drink no coffee, tea or coke based drinks to see if it improves your symptoms?

If you do have a cup of coffee, tea or a glass of cola make sure you are near a toilet first?

Why not wear clothing that is easier to remove. This will give you more confidence that you can get to the toilet in time.

Make sure you only go to the toilet when you really need to. Going too often can reduce the size of your bladder.

Try and avoid drinking anything for 2-3 hours before you go to bed.

If you're a smoker, quitting smoking can help with your bladder symptoms.

You can drink water, diluted fruit juice, milk, fruit tea or herbal teas.

Eat more fruit and vegetables to maintain your health. Take care, Flo

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You are not alone. 1 in 6 patients in the United Kingdom have bladder problems. 20. Retraining your bladder, avoiding tea, coffee and cola can really help your symptoms.

Try and spread your fluid intake evenly over the entire day. Try to avoid drinking anything for 2 hours before you go to bed.

Bladder training is hard work. Be strong and focussed. Concentrate on your successes not your failures. Concentrated citrus drinks (e.g. fresh orange juice) can irritate your bladder. Try and avoid these types of drinks.

There maybe something in your diet that affects your bladder. Try and exclude a component of your diet each week to see if there is any improvement.

Changing to Decaff tea and/ or coffee can help improve your urinary symptoms.

Try and link your pelvic floor exercises to something you do often during the day such as having a drink. Have you tried avoiding lifting heavy objects to decrease your leaking and improve your confidence?

Try to limit your fluid intake to approximately 6-8 glasses per day.

Your pelvic floor exercises need to be done 8 times a day every day for 3 months.

Make sure it is easy to get to the toilet to avoid accidents.

Make sure you do your slow and fast pelvic floor muscle exercises at least 8 times per day.

If you're a smoker, quitting smoking could stop you coughing. This will reduce the number of times you leak.

Exercise such as swimming or yoga should make you leak less - rather than running or jumping. Exercise will help you strengthen your pelvic floor muscles.

Weight loss can improve incontinence if you're overweight - even losing 5% of your body weight.

Highly concentrated fruit drinks, such as fresh orange juice, can irritate your bladder. Try and reduce these types of drinks.

To perform pelvic floor exercises identify the muscles that need training. Be aware of the muscle that you use to stop passing urine, stop a motion or control diarrhoea.

Why not try and have a day when you drink no coffee, tea or coke based drinks to see if that improves your symptoms?

If you drink too little, concentrated urine can irritate your bladder. Try and drink 6-8 glasses per day.

Pelvic floor exercises should also include fast one second muscle holds. Do this 5 times. Remember to do them at least 8 times per day every day.

Only go to the toilet when you really need to. Going too often can reduce the size of your bladder.

Each time you do a pelvic floor muscle exercise, try and hold the muscle for a count to 5. Do this 5 times. These are slow muscle holds.

Try and avoid drinking anything for 2 hours before you go to bed.

Try and drink a normal quantity of fluid. 6-8 glasses are recommended.

Try and cross your legs before you sneeze, laugh or cough. Tighten your pelvic floor muscles first.

Drink water, diluted fruit juice, milk, fruit tea or herbal teas.

Eat more fruit and vegetables to maintain your health. Take care Flo

Wear clothing with a loose fitting waistband to avoid pressure on your abdomen.

If you have to lift a heavy object lift it with a straight back, tighten your pelvic floor muscles before you lift and keep the object close to your body.

Have you filled in an input output diary to see how you are doing?

You are not alone. 1 in 6 patients in the UK have bladder problems. Pelvic floor exercises can really help to reduce your incontinence.

Try and spread your fluid intake evenly over the entire day. Try to avoid drinking anything for 2 hours before you go to bed.

Pelvic floor exercises are hard work. Be strong and focussed. Concentrate on your successes not your failures.

Patient experience questions

Baseline

xEval-01

Please text CC1 if you agree with the statement "I know what to do to fill in my ICIQ-UI questionnaire", or CC2 if you disagree.

xEval-02

Do you think that you have good continence control? Reply CC1 for yes; CC2 for no; CC3 for unsure. Thanks, Flo.

Thank you

End of month 1

xEval-03

Please text CC1 if you agree with the statement "I have no difficulty with filling in my input output chart", or CC2 if you disagree. Thanks, Flo.

xEval-04

Please text CC1 if you agree with the statement "I have no difficulty with filling in my ICIQ-UI questionnaire", or CC2 if you disagree. Thanks, Flo.

xEval-05

Hi. Do you agree with the statement 'I find the messages helpful and interesting'? Please text CC1 if you do, or CC2 if you do not. Thanks, Flo.

Thank you

End of Month 2

xEval-06

Please text CC1 if you have no difficulty filling in your input-output chart; CC2 if you have some difficulty, or CC3 if it's very difficult. Thanks, Flo

xEval-07

Please text CC1 if you find the messages helpful and interesting, or CC2 if you don't. Thanks, Flo

xEval-08

Please text CC1 if you prefer to send information to Flo rather than face to face in consultations, CC 2 if you aren't sure, or CC3 if you don't like using Flo.

Thank you

End of month 3

xEval-09

Please text CC1 if you prefer to send information to Flo rather than face to face in consultations, CC 2 if you aren't sure, or CC3 if you don't like using Flo.

xEval-10

Do you agree with the statement 'I find the messages helpful and interesting'? Please text CC1 if you do, or CC 2 if you do not. Thanks, Flo.

Diary 10

Please text CC1 if you feel Flo has helped you improve your continence, CC2 if you aren't sure, or CC3 if you think Flo didn't help at all. Thanks

Thank you