



A Knowledge Broker Organisation for NHSScotland

Prepared by: Karen Ritchie, Head of Knowledge and Information

Organisational Purpose

to support healthcare providers in Scotland to deliver high quality, evidence-based, safe, effective and person-centred care

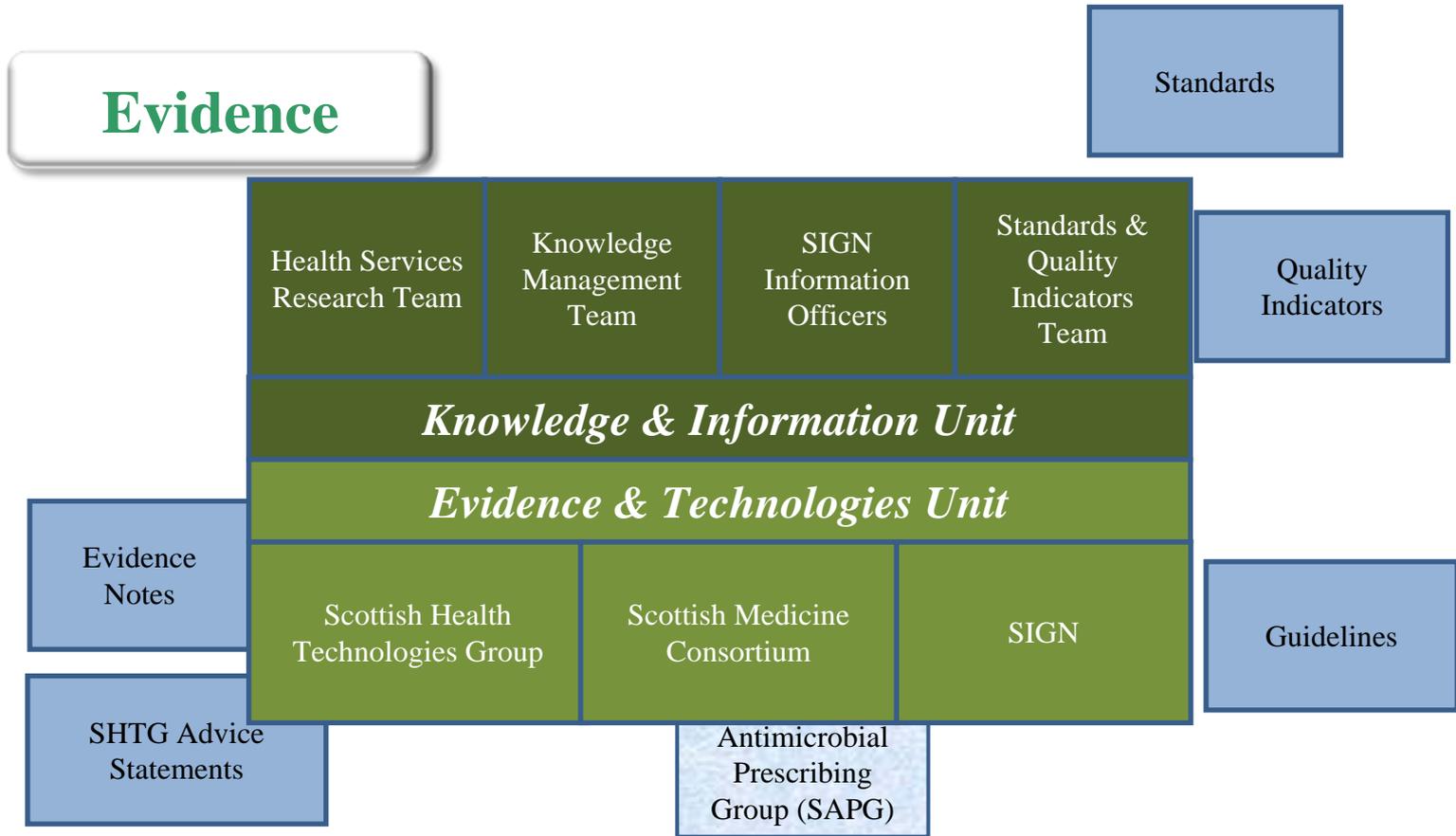
to scrutinise those services to provide public assurance about the quality and safety of that care



Four strategic objectives



Evidence & Improvement Directorate





Non-medicines technologies



Scottish Intercollegiate Guidelines Network

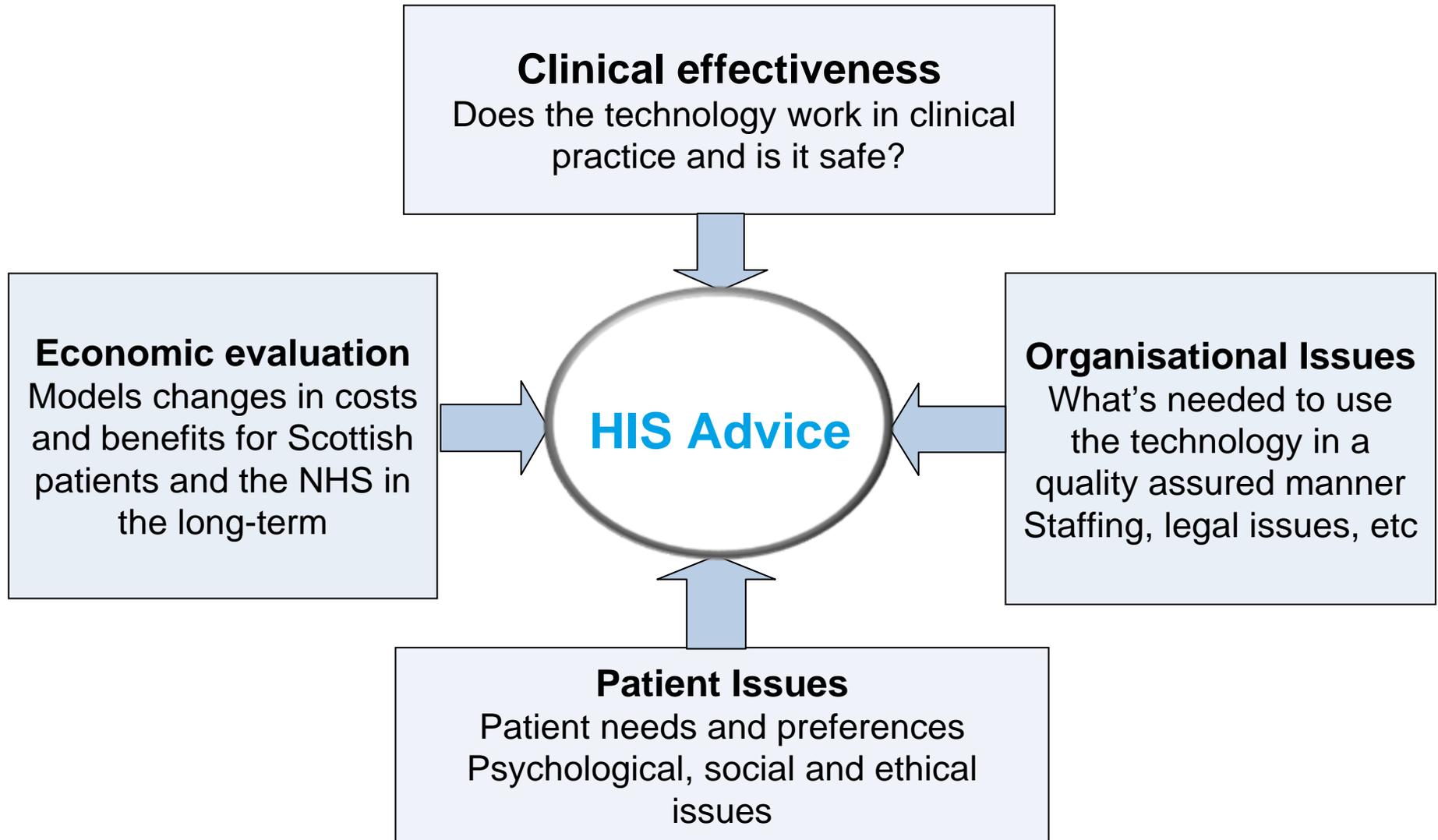
SIGN guidelines

Evidence into Practice



Quality Performance Indicators

Non-medicines technologies



Transcatheter aortic valve implantation (TAVI) for severe symptomatic aortic stenosis in adults

Introduction

This Evidence Note was undertaken to inform the work of the National Planning Forum subgroup on TAVI. This Evidence Note includes the recently published results from the PARTNER randomised controlled trial (cohort A) which reported on transcatheter versus surgical aortic valve replacement in high-risk surgical patients. This Evidence Note will be reviewed again following publication of the National Institute for Health Research HTA on the cost effectiveness of TAVI for aortic stenosis in patients who cannot undergo surgery.

Health technology description

Surgical aortic valve replacement (AVR) is the current standard treatment for patients with severe symptomatic aortic stenosis (AS)^{1,2}. Transcatheter aortic valve implantation (TAVI) is a minimally invasive procedure in which a bioprosthetic replacement valve is delivered percutaneously through the vascular system inside a catheter. Transcatheter access to the aortic valve is achieved mainly by the retrograde transfemoral (TF), transapical (TA) or transaxillary/subclavian routes^{1,3}. The TA and transaxillary/subclavian routes have developed as alternative approaches for patients with peripheral vascular disease that precludes femoral access. The TA procedure involves a mini-thoracotomy to gain access to the aortic valve through the apex of the left ventricle and hence is not strictly percutaneous.

TAVI devices and delivery systems have developed rapidly since the first in-man procedure was reported in 2002. The devices with current European CE mark approval are the balloon-expandable Edwards SAPIENTM and SAPIEN XTTM bovine pericardium tissue valves (Edwards Lifesciences Inc, Irving, CA) and the self-expanding Medtronic porcine pericardium tissue CoreValve[®] ReValving system (Medtronic, Minneapolis, MN). The Edwards SAPIENTM valves can be implanted using the retrograde TF or the TA approach, and CoreValve[®] devices by the retrograde TF or transaxillary/subclavian arterial route. At least 20 other devices

Key points

- In the only randomised controlled trial (RCT) (PARTNER cohort B), TAVI significantly reduced the risk of death from any cause after 1 year compared with medical management in patients who were unsuitable candidates for surgery.
- In the only RCT (PARTNER cohort A), TAVI was not inferior to surgical aortic valve replacement with respect to death from any cause after 1 year in candidates for surgery who were at high risk of increased operative complications and death.
- In the RCT, TAVI was associated with a significantly higher incidence of major vascular complications and neurological adverse events, in both cohorts A and B.
- There are limited published data on TAVI outcomes beyond 1 year of follow up.
- There is limited information on the impact of TAVI on quality of life compared with alternative interventions.
- There are currently no published evaluations of the cost effectiveness of TAVI.
- Patient selection for TAVI should be undertaken by a multidisciplinary team.

have been identified as being in various stages of development^{1,4}.

TAVI has been advocated for the treatment of patients who are unsuitable for conventional AVR as the risks of surgery are unacceptably high because of advanced age, frailty and/or the presence of cardiac or non-cardiac co-morbidities. The current alternative for these patients is palliative medical management with or without balloon aortic valvuloplasty (BAV), although BAV is not commonly performed in Scotland^{1,5}. TAVI may also represent a replacement technology as a possible alternative to conventional AVR surgery for a wider patient group⁶. The long-term durability of bioprosthetic percutaneous prosthetic valves, which are susceptible to

Transcatheter aortic valve implantation (TAVI) for severe symptomatic aortic stenosis in adults

September 2011

Advice Statement 005/11

In response to an enquiry from the National Planning Forum

Advice: SHTG notes that the case for the routine use of TAVI is not supported for the treatment of patients with aortic stenosis.

Based on a recently commissioned Evidence Note on TAVI, updated to include the results from cohort A of the PARTNER trial, this Advice Statement reiterates SHTG Advice Statement 001/2011 published in March 2011.

- In the only randomised controlled trial (RCT) (PARTNER cohort B), TAVI significantly reduced the risk of death from any cause after one year compared with medical management in patients who were unsuitable candidates for surgery.
- In the only RCT (PARTNER cohort A), TAVI was not inferior to surgical aortic valve replacement with respect to death from any cause after one year in candidates for surgery who were at high risk of increased operative complications and death.
- In the RCT, TAVI was associated with a significantly higher incidence of major vascular complications and neurological adverse events in both cohorts A and B.
- There is currently limited evidence of long-term clinical efficacy, and no published evaluations of the cost effectiveness of TAVI.

The National Planning Forum has requested ongoing SHTG review of any material evidence on TAVI. This Advice Statement will be reviewed following publication of the National Institute for Health Research HTA.

Advice context

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the SHTG at the date noted. It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was accurate and based upon the most up-to-date evidence available at the time of publication. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current.

This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Chairman
Scottish Health Technologies Group

In response to an enquiry from the National Planning Forum

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Chairman
Scottish Health Technologies Group

Technologies advice implementation



**Scottish
Health
Technologies
Group**





Non-medicines technologies



Scottish Intercollegiate Guidelines Network

SIGN guidelines

Evidence into Practice



Quality Performance Indicators

SIGN 88: Management of suspected bacterial urinary tract infection (UTI) in adults

Management of bacterial UTI in adult women

Diagnosis

- D** Consider empiric treatment with an antibiotic for otherwise healthy women aged less than 65 years presenting with severe or > 3 symptoms of UTI.
- E** Explore alternative diagnosis and consider pelvic examination for women with symptoms of vaginal itch or discharge.
- D** Consider the possibility of UTI in patients presenting with symptoms or signs of UTI who have a history of lower or back pain.
- B** Use dipstick tests to guide treatment decisions in otherwise healthy women under 65 years of age presenting with mild or < 2 symptoms of UTI.
- C** Discuss the risks and benefits of empirical treatment with the patient and manage treatment accordingly.
- C** In older patients (over 65 years of age), diagnosis should be based on a full clinical assessment, including vital signs.

Antibiotic treatment of UTI

- A** Do not treat non-pregnant women of any age with asymptomatic bacteriuria with an antibiotic.
- B** Treat non-pregnant women of any age with symptoms or signs of acute UTI with a three day course of trimethoprim or nitrofurantoin.
- C** Particular care should be taken when prescribing nitrofurantoin in the elderly, who may be at increased risk of toxicity.
- C** Investigate other potential causes in women who remain symptomatic after a single course of treatment.
- D** Take urine for culture to guide change of antibiotic for patients who do not respond to trimethoprim or nitrofurantoin.

Treatment of UTI

- C** Upper urinary tract infection can be accompanied by bacteraemia, making it a life threatening infection.
- C** Consider hospitalization for patients unable to take fluids and medication or showing signs of sepsis.
- D** Where hospital admission is not required, take a midstream urine sample for culture and begin a course of antibiotics. Advise the patient to complete if there is no response to the antibiotic within 24 hours.
- D** Treat non-pregnant women with symptoms or signs of acute UTI with oral trimethoprim (1.5 daily) or (20-40mg daily) 14 days.
- C** A 14 day course of trimethoprim can be considered where the organism is known to be sensitive to the antibiotic.

Treatment of recurrent UTI

- A** Advise women with recurrent UTI to consider using cranberry products to reduce the frequency of recurrences.
- C** Women should be advised that cranberry capsules may be more convenient than juice and that high strength capsules may be most effective.

Management of bacterial UTI in pregnant women

Diagnosis

- C** Symptomatic bacteriuria occurs in 5-10% of pregnancies and is associated with pre-labour, premature rupture of membranes (PROM), and pre-term labour. Unobscured upper urinary tract infection in pregnancy also carries risks of morbidity, and rarely mortality to the pregnant woman.
- A** Standard quantitative urine culture should be performed routinely at first antenatal visit.
- A** Confirm the presence of bacteriuria in urine with a second urine culture.
- A** Do not use dipstick testing to screen for bacterial UTI at the first or subsequent antenatal visits.

Antibiotic treatment

- B** Treat symptomatic UTI in pregnant women with an antibiotic.
- C** Take a single urine sample for culture before empirical antibiotic treatment is started.
- C** Refer to local guidance for advice on the choice of antibiotic for pregnant women.
- C** A seven day course of treatment is normally sufficient.
- C** Given the risks of symptomatic bacteriuria in pregnancy, a urine culture should be performed whenever an after completion of antibiotic treatment at a first visit.

Antibiotic treatment of asymptomatic bacteriuria in pregnancy reduces the risk of upper urinary tract infection, pre-term delivery and low birth weight babies.

- A** Treat asymptomatic bacteriuria detected during pregnancy with an antibiotic.
- C** Refer to local guidance for advice on the choice of antibiotic for pregnant women.
- C** A seven day course of treatment is normally sufficient.
- D** Do not prescribe trimethoprim for pregnant women with established folate deficiency, low dietary folate intake, or women taking other folate antagonists.
- C** Women with bacteriuria confirmed by a second urine culture should be treated and have repeat urine culture at each antenatal visit until delivery.

- C** Women who do not have bacteriuria in the first trimester should not have repeat urine cultures.

Management of bacterial UTI in adult men

Diagnosis

- C** Urinary tract infections in men are generally viewed as complicated because they result from an anatomical or functional anomaly or instrumentation of the genitourinary tract.
- C** Conditions like prostatitis, chlamydia infection and epididymitis should be considered the differential diagnosis of men with acute dysuria or frequency and appropriate diagnostic tests should be considered.
- C** In all men with symptoms of UTI a urine sample should be taken for culture.
- C** In patients with a history of lower or back pain the possibility of UTI should be considered.

Antibiotic treatment

- C** Due to their ability to penetrate prostatic fluid, quinolones rather than tetracyclines or cephalosporins are indicated.
- B** Treat bacterial UTI empirically with a quinolone in men with symptoms suggestive of prostatitis.
- A** Four week course is appropriate for men with symptoms suggestive of prostatitis.
- D** Refer men for urological investigation if they have symptoms of upper urinary tract infection, fail to respond to appropriate antibiotics or have recurrent UTI.

General principles

Broad spectrum antibiotics (eg co-amoxiclav, quinolones and cephalosporins) should be avoided as they increase the risk of *Clostridium difficile* infection, MRSA and resistant UTIs. Guidance from the Health Protection Agency (HPA) suggests considering narrow spectrum antibiotics such as trimethoprim or nitrofurantoin as first line treatment.

Resistance is increasing to all of the antibiotics used to treat UTI and there is no clear first choice alternative to trimethoprim or nitrofurantoin.

Infections due to multiresistant organisms including extended-spectrum beta lactamase (ESBL) are on the increase. Susceptibility results are essential to guide treatment. Oral antibiotics such as nitrofurantoin, pivmecillinam and occasionally trimethoprim are often effective.

Nitrofurantoin is contraindicated in the presence of significant renal impairment. The British National Formulary advises against its use in patients with CrCl < 10.



SIGN 88: Management of suspected bacterial urinary tract infection (UTI) in adults

Management of bacterial UTI in adult women

Diagnosis

- D** Consider empirical treatment with an antibiotic for otherwise healthy women aged less than 65 years presenting with severe or > 3 symptoms of UTI.
- E** Explore alternative diagnosis and consider pelvic examination for women with symptoms of vaginal itch or discharge.
- D** Consider the possibility of LUTTI in patients presenting with symptoms or signs of UTI who have a history of fever or back pain.
- B** Use dipstick tests to guide treatment decisions in otherwise healthy women under 65 years of age presenting with mild or < 2 symptoms of UTI.
- D** Discuss the risks and benefits of empirical treatment with the patient and manage treatment accordingly.
- D** In elderly patients (over 65 years of age), diagnosis should be based on a full clinical assessment, including vital signs.

Antibiotic treatment of LUTTI

- A** Do not treat non-pregnant women of any age with asymptomatic bacteriuria with an antibiotic.
- B** Treat non-pregnant women of any age with symptoms or signs of acute LUTTI with a three day course of trimethoprim or nitrofurantoin.
- D** Particular care should be taken when prescribing nitrofurantoin in the elderly, who may be at increased risk of toxicity.
- D** Investigate other potential causes in women who remain symptomatic after a single course of treatment.
- D** Take urine for culture to guide change of antibiotic for patients who do not respond to trimethoprim or nitrofurantoin.

Treatment of UTI

- Upper urinary tract infection can be accompanied by bacteraemia, making it a life threatening infection.
- D** Consider hospitalization for patients unable to take fluids and medication or showing signs of sepsis.
- D** Where hospital admission is not required, take a midstream urine sample for culture and begin a course of antibiotics. Admit the patient to hospital if there is no response to the antibiotic within 24 hours.
- D** Treat non-pregnant women with symptoms or signs of acute UTI with cephalexin (1 day) or co-amoxiclav (14 days).
- D** A 14 day course of trimethoprim can be considered where the organism is known to be sensitive to the antibiotic.

Treatment of recurrent UTI

Diagnosis

- A** Advise women with recurrent UTI to consider using cranberry products to reduce the frequency of recurrences.
- D** Women should be advised that cranberry capsules may be more effective than juice and that high strength capsules may be most effective.

Management of bacterial UTI in pregnant women

Diagnosis

- Symptomatic bacteriuria occurs in 5-10% of pregnancies and is associated with pre-eclampsia, premature rupture of membranes (PROM) and pre-term labour. Untreated upper urinary tract infection in pregnancy also carries risks of morbidity and early mortality to the pregnant woman.
- A** Standard quantitative urine culture should be performed routinely at first antenatal visit.
- A** Confirm the presence of bacteriuria in urine with a second urine culture.
- D** Do not use dipstick testing to screen for bacterial UTI at the first or subsequent antenatal visits.

Antibiotic treatment

- A** Treat symptomatic UTI in pregnant women with an antibiotic.
- D** Take a single urine sample for culture before empirical antibiotic treatment is started.
- D** Refer to local guidance for advice on the choice of antibiotic for pregnant women.
- D** A seven day course of treatment is normally sufficient.

Management of bacterial UTI in adult men

Diagnosis

- D** Urinary tract infections in men are generally viewed as complicated because they result from an anatomical or functional anomaly or instrumentation of the genitourinary tract.
- D** Conditions like prostatitis, chlamydia infection and epididymitis should be considered as the differential diagnosis of men with acute dysuria or frequency and appropriate diagnostic tests should be considered.

Antibiotic treatment

- D** Due to their ability to penetrate prostatic fluid, quinolones rather than nitrofurantoin or cotrimoxazole are indicated.
- D** Treat bacterial UTI empirically with a quinolone in men with symptoms suggestive of prostatitis.
- A** Four week course is appropriate for men with symptoms suggestive of prostatitis.
- D** Refer men for urological investigation if they have symptoms of upper urinary tract infection, fail to respond to appropriate antibiotics or have recurrent UTI.

General principles

- D** Women who do not have bacteriuria in the first trimester should not have repeat urine cultures.

SIGN 88 • Management of suspected bacterial urinary tract infection in adults

A national clinical guideline *Updated July 2012*

Managing bacterial urinary-tract infections in adults

A booklet for patients and carers **October 2012**

 Evidence

SIGN 88: Management of suspected bacterial urinary tract infection (UTI) in adults

<http://www.scottishmedicines.org.uk/SAPG>



... may suggest the presence of infection, (low temperature of <36°C) may also indicate infection,

Contact medical/clinical staff to request review of patient/resident

Take appropriate specimens and manage following local antibiotic policy

Take action based on advice from nursing and care staff. But action based on advice from nursing staff and prescribers (medical and non-medical).

Are there any symptoms suggestive of non-urinary infection?

Respiratory – shortness of breath, cough or sputum (phlegm) production, new pleuritic chest pain (sharp pain across ribs)

Gastrointestinal – nausea/vomiting, new abdominal pain, new onset diarrhoea

Skin/soft tissue – new redness, warmth, swelling, purulent drainage (pus)

NO

Does the patient/resident have a urinary catheter?

YES NO

Does patient/resident have one or more of the following signs or symptoms?

NO YES

- shaking chills (rigors)
- new costovertebral (central low back) tenderness
- new onset or worsening delirium (confusion)

NO YES

- dysuria (pain on urination)
- urgent need to urinate
- frequent need to urinate
- new or worsening urinary incontinence
- shaking chills (rigors)
- pain in flank (side of body) or suprapubic (above pubic bone) flank haematuria (visible blood in urine)
- new onset or worsening of pre-existing confusion or agitation

NO YES

UTI unlikely but continue to monitor symptoms for 72 hours

NO YES

UTI unlikely but continue to monitor symptoms for 72 hours

NO YES

UTI unlikely

NO YES

UTI unlikely but continue to monitor symptoms for 72 hours

NO YES

UTI unlikely

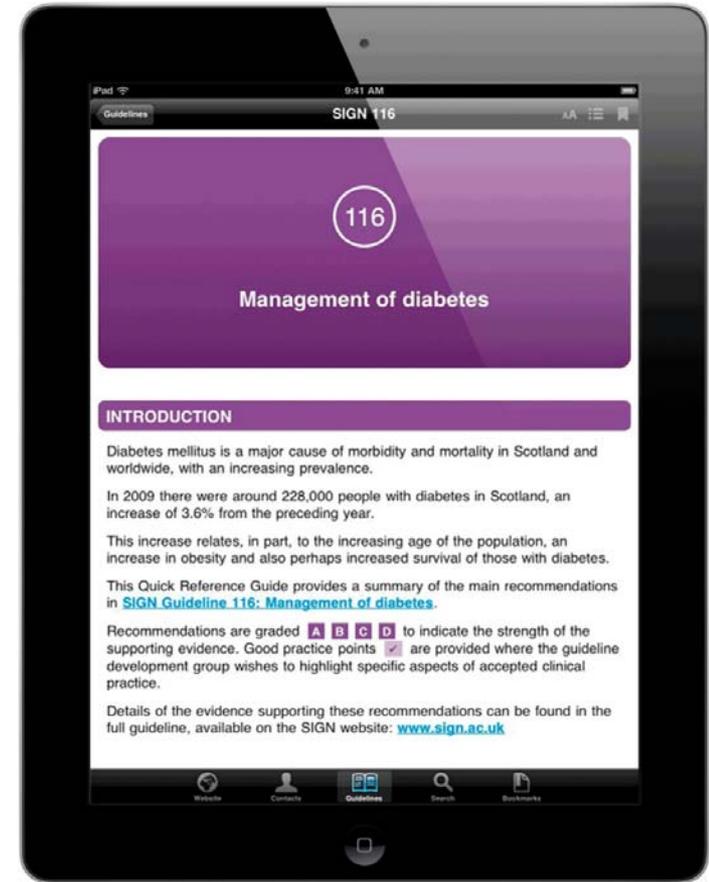
NO YES

UTI unlikely but continue to monitor symptoms for 72 hours

Contact medical/clinical staff to request review of patient/resident

- Assess if retention or sub-acute retention of urine is likely – blocked catheter or distended bladder
- DO NOT use dipstick test in diagnosis of UTI in older people
- Obtain a sample for urine culture and send to Microbiology
- Start antibiotic therapy following local policy or as advised by Microbiology
- If patient has a urinary catheter, remove and replace it. Consider the ongoing need for a long term catheter in consultation with specialists.
- Consider use of analgesia (paracetamol or ibuprofen) to relieve pain
- Consider admission to hospital if patient has fever with chills or new onset hypotension (low blood pressure)
- Review response to treatment early and if no improvement of symptoms or deterioration, consider admission to hospital or an increased level of care
- Ensure urine culture results are reviewed when available in order to streamline antibiotic therapy

August 2012 Review date August 2013



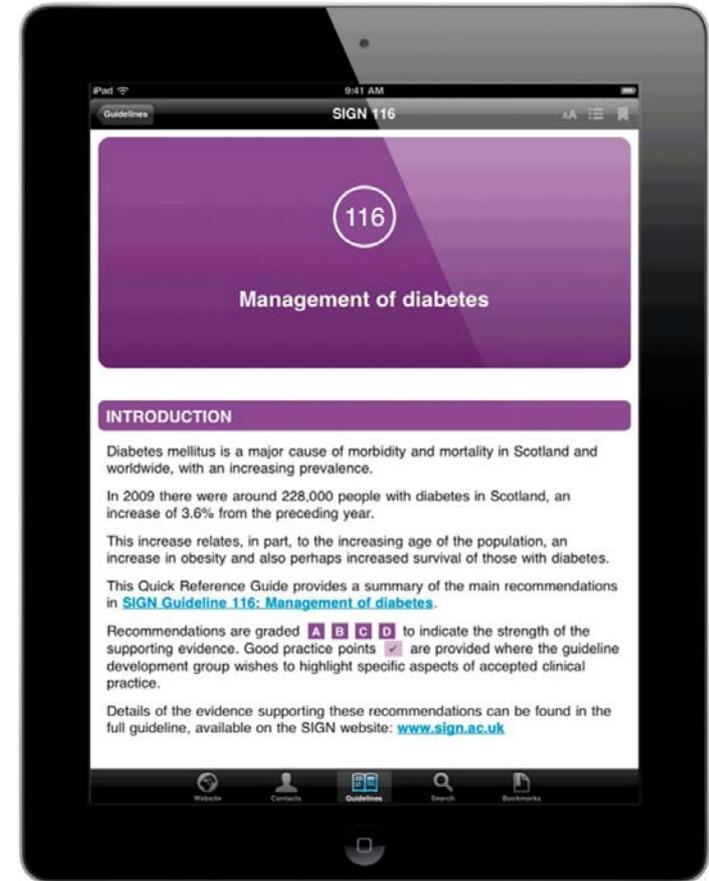
SIGN 88: Management of suspected bacterial urinary tract infection (UTI) in adults

<http://www.scottishmedicines.org.uk/SAPG>



... may suggest they have an infection, especially if the temperature is below 36°C (low temperature of <36°C) may also indicate infection,

This decision aid is titled 'Decision aid for diagnosis and management of suspected urinary tract infection (UTI) in older people'. It is presented as a flowchart with a central box labeled 'UTI likely'. The flowchart starts with a question: 'Does patient have symptoms?' with options for 'shaking chills', 'new onset', and 'new onset'. If 'Yes', it leads to 'UTI likely'. If 'No', it leads to 'UTI unlikely but continue to monitor symptoms for 72 hours'. Below the 'UTI likely' box, there is a question: 'Ongoing fever and development of one or more of above symptoms?'. If 'Yes', it leads to 'UTI likely'. If 'No', it leads to 'UTI unlikely but continue to monitor symptoms for 72 hours'. The flowchart also includes a section for 'Contact medical/clinical staff to request review of patient/resident' with a list of actions: 'Assess if retention or sub-acute retention of urine is likely - blocked catheter or distended bladder', 'DO NOT use dipstick test in diagnosis of UTI in older people', 'Obtain a sample for urine culture and send to Microbiology', 'Start antibiotic therapy following local policy or as advised by Microbiology', 'If patient has a urinary catheter, remove and replace it. Consider the ongoing need for a long term catheter in consultation with specialists.', 'Consider use of analgesia (paracetamol or ibuprofen) to relieve pain', 'Consider admission to hospital if patient has fever with chills or new onset hypotension (low blood pressure)', 'Review response to treatment early and if no improvement of symptoms or deterioration, consider admission to hospital or an increased level of care', and 'Ensure urine culture results are reviewed when available in order to streamline antibiotic therapy'. The document is dated August 2012 and has a review date of August 2013.





Non-medicines technologies



Scottish Intercollegiate Guidelines Network

SIGN guidelines

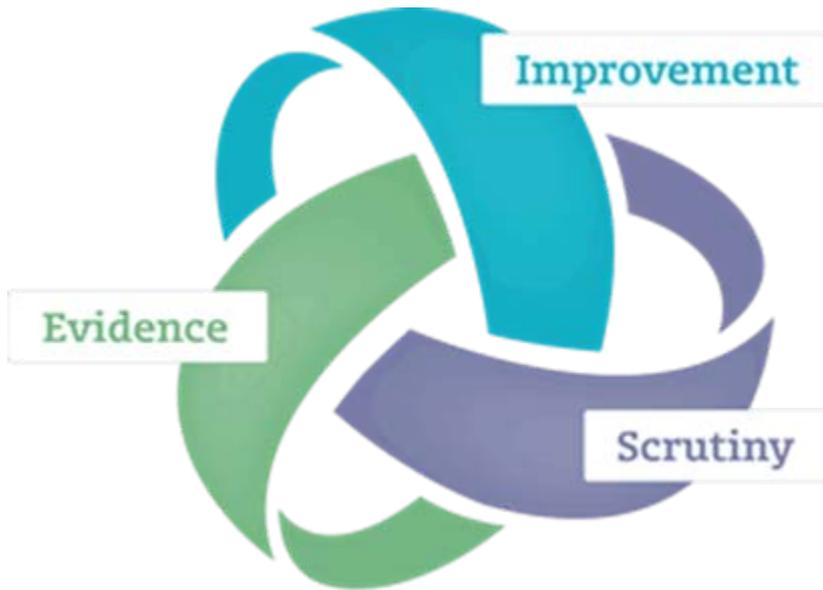
Evidence into Practice



Quality Performance Indicators

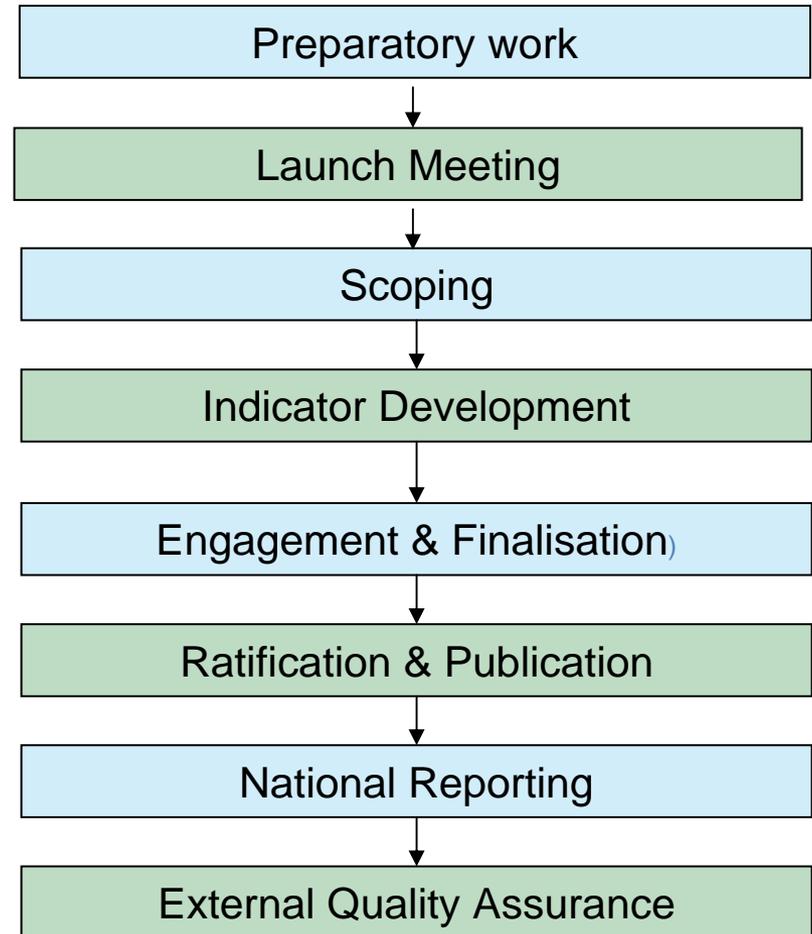
Cancer Quality Performance Indicators (QPIs)

Cancer standards

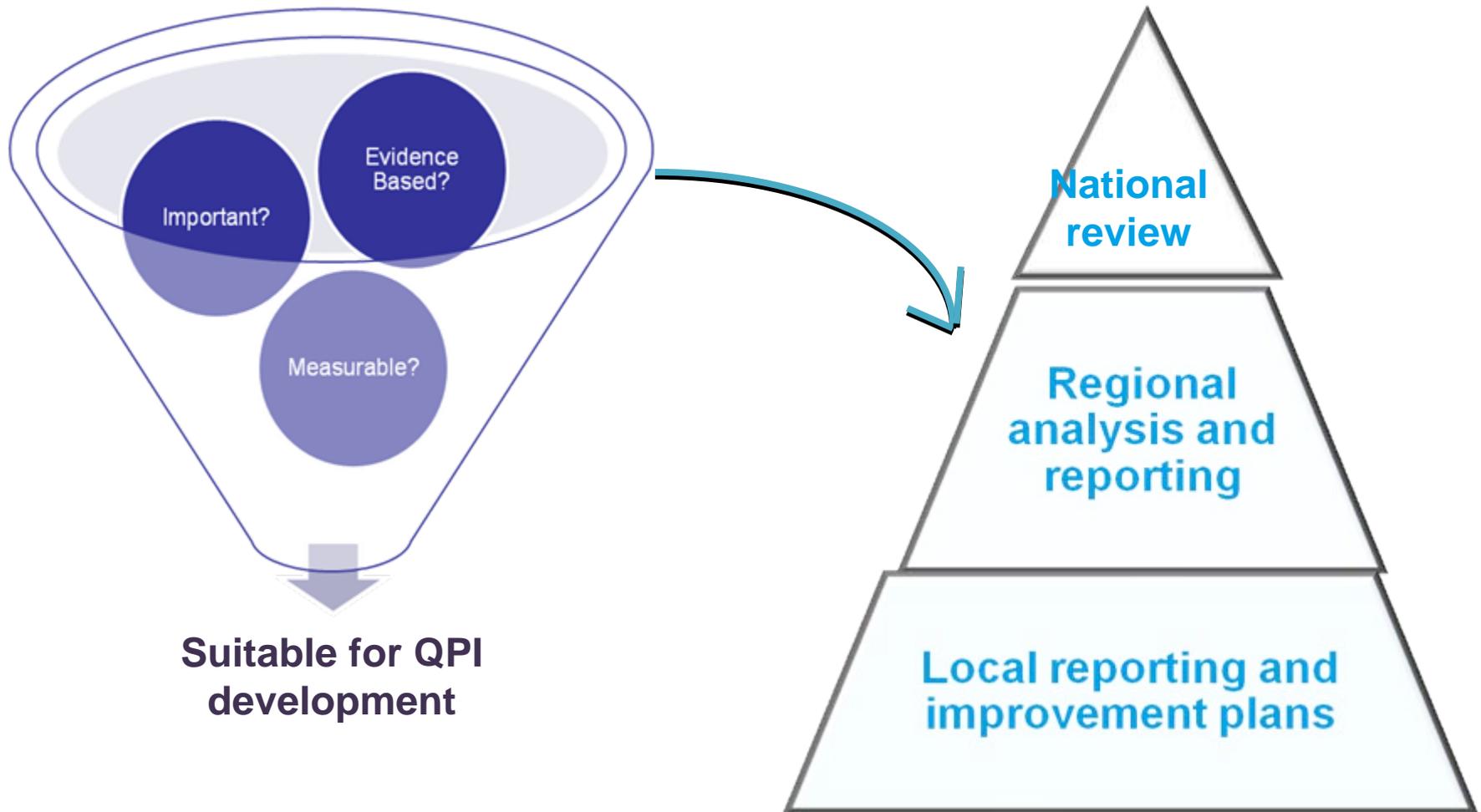


Integrated Cycle of Improvement

8-10 Months



Evidence Based & Reported On



Summary

1

Strategic leadership for change and embedding into policy

2

Provision of a range of tools to make access and use of evidence base products easy for practitioners

3

Establishing evidence based outcome targets and supporting cross organisational reporting and improvement activity

**Three
approaches**