

2017

Commissioning Guide:

Painful Deformed Great Toe In Adults

Sponsoring Organisation: British Orthopaedic Foot & Ankle Society, British Orthopaedic Association (BOA), Royal College of Surgeons of England (RCSEng)

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NICE has accredited the process used by Surgical Speciality Associations and Royal College of Surgeons to produce its Commissioning guidance. Accreditation is valid for 5 years from September 2017. More information on accreditation can be viewed at www.nice.org.uk/accreditation



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Introduction

This guidance covers the management of the painful deformed great toe.

Hallux valgus (often referred to as a bunion) (1) is the deviation of the big toe (the hallux) away from the mid-line towards the lesser toes. The metatarsal head drifts towards the midline and this together with its overlying bursa and inflamed soft tissue is known as the bunion, which causes pain and rubbing on shoes.

Hallux rigidus (2) is the development of arthritic changes within the joint causing stiffness, pain and deformity.

Hallux valgus and rigidus are frequently accompanied by lesser toe changes such as hammer or claw toes and abnormal weight distribution under the lesser toes which can be painful (metatarsalgia) (3).

Hallux valgus is often accompanied with, or mistaken for, hallux interphalangeus, where the tip of the big toe is deviated laterally, although symptoms may be similar.

Deformity may contribute to impaired balance, which can increase the incidence of falls (4).

Untreated hallux valgus deformity in patients with diabetes (and other causes of peripheral neuropathy) may lead to ulceration, deep infection and even below knee amputation (5).

Hallux valgus is common with a prevalence of 28.4% in adults older than 40 years (6)(7) 28% of General Practitioner consultations for musculoskeletal problems relate to pain in the foot and ankle (8).

Prevalence of the painful great toe increases with age and is higher in women.⁷ Footwear often contributes to this problem.

Patients with hallux valgus and rigidus have worse pain than the general population. Surgery can improve the quality of life in this group (9).

Overall satisfaction rates following surgery are good (more than 80% in most studies), but studies are small and follow up short.

Evidence of effectiveness of conservative treatment, surgical treatment, or the potential benefit of one over the other is limited (10)(11).

Please refer to Appendix 1 for additional information.

This pathway is a guide which can be modified according to the needs of the local health economy.

1 High Value Care Pathway for Painful Deformed Great Toe

1.1 Primary Care

It is expected that the vast majority of patients with great toe deformity and mild pain will be managed in primary care (7). Providers must adopt a shared decision making model, define treatment goals and take into account personal circumstances.

Assessment:

- History - pain, functional impairment, difficulty fitting footwear.
- Examination - foot deformity, check pulses and sensation.
- **X-rays are not indicated.**

Urgent referral (<2/52):

- Impending or non-healing skin ulcer.
- Peripheral limb ischaemia.

Mild symptoms:

- Patient information.¹
- Simple analgesia and anti-inflammatory measures.
- Bunion pads and footwear modification (lower heels, wider fitting shoes, high toe box).

Refer to specialist provider:

- Deteriorating symptoms.²
- Functional impairment.
- Inability to wear suitable shoes.
- Any pain under the ball of the foot.
- **DO NOT refer for prophylactic or cosmetic reasons.**

1.2 Intermediate Care³

Commissioned services must be integrated into a multidisciplinary network and include the skills for example:

- Musculoskeletal (MSK) physiotherapy
- Podiatry (non-surgical and surgical)
- Orthotics
- Rheumatology

¹ Patients do not understand 43% to 61% of patient information leaflets (Rowlands et al 2015). Information should be delivered in such a way that the patient can understand and act upon it. Consider use of AHRQ Health Literacy Universal Precautions Toolkit and information produced by Information Standard members. This statement applies to all uses of patient information.

² For further details see flow chart in Appendix 2.

³ Those services that do not require the resources of a general hospital, but are beyond the scope of the traditional primary care team. (Rene JFM, Marcel GMOR, Stuart GP, et al. What is intermediate care? BMJ 2004; 329 (7462): 360-61)

- Orthopaedic surgery

Assessment:

- History - as above
- Examination:
 - As above
 - Examine for metatarsalgia
 - Lesser toe deformity
 - Overall lower leg alignment
 - Presence of tibialis posterior dysfunction
- Investigation - weight bearing X-rays (only if indicated, such as to guide injection) (12)

Management:

- Providers must adopt a shared decision making model, define treatment goals and take into account personal circumstances.
- Patient information should be provided.
- Footwear assessment and provision of offloading orthotics as appropriate.
- Physiotherapy:
 - Balance, proprioception, and core stability, calf muscle stretches, and to treat features of tibialis posterior tendon dysfunction (13).
 - Injections:
 - Only indicated if inflammation or arthritis is suspected or if patient unfit for surgery.
 - Contraindicated if infection is suspected.

Radiographs (X-rays) should be performed prior to procedure.

Refer for surgery:

- Deteriorating symptoms.⁴
- Failure of appropriate conservative measures after three months.
- Persistent pain and disability not responding to up to 12 weeks of non-surgical treatments; this time to include any treatment received in primary care.
- Patient must be prepared to undergo surgery understanding that they will be out of sedentary work for 2-6 weeks and physical work for 2-3 months and they will be unable to drive for 6-8 weeks (2 weeks if left foot and driving automatic car).
- Age, gender, smoking, obesity and co-morbidity should not be barriers to referral.
- Patients with significant co-morbidities [systemic or local] should have treatment which optimises these before referral.
- For clarification, co-morbidities must be managed through a shared decision making process with the patient, enabling patients to make joint decisions on referral and treatment.
- Patients who are not suitable for surgery should be referred for a complex care package.

1.3 Secondary Care

Assessment:

- History - as above, diagnosis confirmed.
- Examination - as above, other pathologies excluded.

⁴ For further details see flow chart in Appendix 2.

- Investigation:
 - Weight bearing X-rays (12) and;
 - Further imaging (e.g.: Ultrasound, MRI) as indicated.

Management:

- Providers must adopt a shared decision making model, define treatment goals and take into account personal circumstances, all alternatives **MUST** be discussed.
- Patient information should be provided.

Surgery:

- Criteria for intervention are the same as the criteria for referral.
- **MUST NOT** be undertaken for prophylactic or cosmetic reasons.
- Should be undertaken by orthopaedic surgeons trained in foot and ankle surgery or HCPC registered podiatric surgeons (CCPST), integrated into a multi-disciplinary network (Appendix 2).
- Is usually day case or 23-hour admission, unless clinical or social circumstances dictate otherwise.
- A minimum of 3 outpatient follow up appointments by appropriately experienced foot and ankle clinicians.
- Review of standing radiographs within 8 weeks by surgeon.
- It is recommended that PROM scores be recorded 12 months following surgical episode.
- There are a number of surgical options for Hallux valgus (14) (16) and Hallux rigidus (17) (19) (Appendix 2). The procedure selected will depend on: patient symptoms/signs and patient choice having considered with the surgeon the risk and benefits of each. These require appropriate facilities. (20) There is no conclusive evidence for the superiority of one operation over another.
- Surgery is simpler and more successful in the earlier stages of deformity.
- Recurrence of deformity after hallux valgus surgery occurs in 8 - 15% of patients.(21)
- Non-union of fusion for hallux rigidus occurs in up to 10% of cases. (22) (23)
- Complex surgery (e.g. complex revision infection with bone loss avascular necrosis and neurological deformity) must be undertaken by surgeons with a recorded interest in complex foot and ankle surgery working in high volume centre with appropriate facilities.
- Minimal access techniques must only be undertaken as part of a research project or where special arrangements for audit are in place (NICE IPG 332). (8)
- In cases of post-operative complications, primary care should ideally be able to refer the patient back to the same surgical team, should the patient want this.

Patients should be informed that the decision to have surgery can be a dynamic process and a decision to not undergo surgery does not exclude them from having surgery at a future time point.

2 Procedures Explorer for Painful Deformed Great Toe

Users can access further procedure information based on the data available in the quality dashboard to see how individual providers are performing against the indicators. This will enable CCGs to start a conversation with providers who appear to be 'outliers' from the indicators of quality that have been selected.

The Procedures Explorer Tool is available via the [Royal College of Surgeons](#) website.

| Procedure | OPCS4 codes* |
|-----------------------|--|
| Soft Tissue Procedure | T702, W791-2 |
| Osteotomy | W121-129, W131-2, W138-9, W141-6, W148-9, W151-7 |
| Arthrodesis | W03, W591-5, W598-9 |
| Replacement surgery | W532-2, W542-4, W573-4, W596 |

3 Quality Dashboard for Painful Deformed Great Toe

The quality dashboard provides an overview of activity commissioned by CCGs from the relevant pathways, and indicators of the quality of care provided by surgical units.

The quality dashboard is available via the [Royal College of Surgeons](#) website.

For current dashboard indicators (see Appendix 1).

| Measure | Definition | Data Source* |
|-------------------------------|--|----------------------------------|
| 1. Standardised activity rate | Activity rate standardised for age and sex | HES/Quality Dashboard appendix 1 |
| 2. Average length of stay | Total spell duration/total number of patients discharged | HES/Quality Dashboard appendix 1 |
| 3. Day case rate | Number of patients admitted and discharged on the same day/total number of patients discharged | HES/Quality Dashboard appendix 1 |
| 4. Short stay rate | Number of patients admitted and discharged within 48 hours /total number of patients discharged | HES/Quality Dashboard appendix 1 |
| 5. 7/30 day readmission rate | Number of patients readmitted as an emergency within 7/30 days of discharge /total number of patients discharged | HES/Quality Dashboard appendix 1 |
| | Excludes Cancer, dementia, mental | |

| | | |
|---|--|----------------------------------|
| | health | |
| 6. Reoperations within 30 days/ 1 year | Number of patients re-operated during an emergency readmission within 30 days/1 year/total number of patients discharged | HES/Quality Dashboard appendix 1 |
| 7. In hospital mortality rate | Number of patients who die while in hospital/total number of patients discharged | HES/Quality Dashboard appendix 1 |

Areas for development of dashboard in future:

| Measure | Evidence Base | Data Source* |
|--|--|--|
| PROMS (MOXFQ)^{23,24}, QoL (EQ-5D) change at 12 months post-surgery | Change in MOXFQ*** at 12 months | BOFAS recommends that these scores are done before and at 12 months post-surgery |
| Infection rate | | Provider HES PASCOM** |
| Radiographs | % of patients with pre & post-operative (weight-bearing) radiographs | Provider Trust or AQP |

* includes data from HES- Hospital Episode Statistics, National Clinical Audits, Registries.

**PASCOM Podiatric Surgery and Clinical Outcome Measure.

***MOXFQ Manchester and Oxford Foot Questionnaire.

4 Levers for Implementation

4.1 Audit and Peer Review Measures

Levers for implementation are tools for commissioners and providers to aid implementation of high value care pathways.

| Measure | Standard | Data source |
|---|---|-------------------------|
| Shared decision making | Progressive improvement on Outcome measurement tools such as SURE (AQuA) or collaboRATE | |
| Complication rate | % cases done who have had a complication | Provider HES, PASCOM |
| Time off work | Days off work | HES, PASCOM |
| Collection and publication of (Patient Reported Outcome Measures) PROMs and QoL measures | Publication of PROMs and QOL measures | Provider |

4.2 Quality Specification/CQUIN (Commissioning for Quality and Innovation)

| Measure | Description | Data source |
|---|---------------------------|-----------------------------------|
| Preoperative assessment clinic. Telephone contact with patient within 7 days of admission | Reduces late cancellation | Provider |
| Wound infection rate | <1% | HES, Provider PASCOM |
| Satisfaction rate | >80% | Provider or AQP |
| Day case rates | >80% | HES, Quality Dashboard, PASCOM |

5 Directory

5.1 Patient Information for Painful Deformed Great Toe

| Name | Publisher | Link |
|------------------------|-------------|--|
| Bunions | EMIS | www.patient.co.uk |
| Bunion | NHS Choices | www.nhs.uk |
| Hallux valgus (Bunion) | BOFAS | www.bofas.org.uk |
| Hallux rigidus | BOFAS | www.bofas.org.uk |
| Patient leaflets | CoP | http://www.scpod.org |

5.2 Clinician Information for Painful Deformed Great Toe

| Name | Publisher | Link |
|----------------|---------------------------------|---|
| Bunion | BOFAS | www.bofas.org.uk |
| Bunion | Clinical Knowledge Summaries | http://cks.nice.org.uk/bunions#azTab |
| Hallux rigidus | Multiple | Medical literature |

6 Benefits and Risks

Benefits and risks of commissioning the pathway are described below:

| Consideration | Benefit | Risk |
|---------------------------|---|---|
| Patient outcome | Ensure access to effective conservative, medical and surgical therapy | Prolonged treatment with patients who are disabled and dependant, and may not be able to work if of working age |
| Patient safety | Reduce chance of complications | Patient develops ulceration |
| Patient experience | Improve access to patient information | Patients not taking charge of their care, dependence on primary and secondary care |
| Equity of access | Improve access to effective procedures | Withholding access for financial reasons alone |
| Resource impact | Reduce unnecessary investigation, referral and intervention | Resource required to establish community specialist provider |

7 Further Information

7.1 Research Recommendations

- Outcomes in forefoot surgery: the role of validated patient reported outcome measures and quality of life scores in hallux valgus and hallux rigidus for non-surgical and surgical treatments.
- The clinical and cost-effectiveness of hallux valgus and hallux rigidus non-surgical and surgical treatments. (NIHR Health Technology Assessment Call).
- Prospective randomised clinical trials comparing routine hallux valgus/rigidus surgery against minimally invasive hallux valgus/rigidus surgery.

7.2 Other Recommendations

- Improve patient information.
- Mandatory data collection.
- Consider a national non-arthroplasty registry (BOFAS SOFA).

7.3 Evidence Base

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Additional Reading:

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7.4 Guide Development Group for Painful Deformed Great Toe

A commissioning guide development group was established to review and advise on the content of the commissioning guide, as part of the review process. This group met on a number of occasions, via teleconference, with additional interaction taking place via email. Details of the Guideline Development Group involved in the original production of the guide is available on request.

| Name | Job Title/Role | Affiliation |
|---------------------------------|--|-------------------------------------|
| Kartik Hariharan (Chair) | Immediate Past President British Orthopaedic Foot & Ankle Society (BOFAS) Orthopaedic Foot and Ankle Surgery | BOFAS Aneurin Bevan Health Board |
| Donald McBride | Consultant Orthopaedic Surgeon | BOA Executive |
| Zoe Schaedel | General Practitioner | Sussex MSK Partnership |
| Stephen Finney | Consultant Podiatric Surgeon | Faculty of Podiatric Surgery |
| Carl Davies | Programme/Commissioning Manager MSK CPG & Dermatology Pathways | NHS Gloucestershire CCG |
| Sue Bennett | PatientT | |
| Elsbeth Insch | Patient | |
| Aimee Robson | Physiotherapist | Chartered Society of Physiotherapy |
| Matthew Solan | Consultant Foot and Ankle Surgeon | Royal Surrey County Hospital |



7.5 Funding Statement

The development of this commissioning guidance has been funded by the following sources:

- The Royal College of Surgeons of England and the British Orthopaedic Association (BOA) provided staff, literature search and funding to support the guideline development.
- The British Orthopaedic Association also commissioned a literature search from Bazian.

7.6 Methods Statement

The development of this guidance has followed a defined, NICE Accredited process. This included a systematic literature review, public consultation and the development of a Guidance Development Group which included those involved in commissioning, delivering, supporting and receiving surgical care as well as those who had undergone treatment. An essential component of the process was to ensure that the guidance was subject to peer review by senior clinicians, commissioners and patient representatives. Details are available at this site:

<http://www.rcseng.ac.uk/healthcare-bodies/nscg/commissioning-guides>

7.7 Conflict of Interest Statement

Individuals involved in the development and formal peer review of commissioning guides are asked to complete a conflict of interest declaration. It is noted that declaring a conflict of interest does not imply that the individual has been influenced by his or her secondary interest, but this is intended to make interests (financial or otherwise) more transparent and to allow others to have knowledge of the interest. All records are kept on file, and are available on request.

Appendix 1: Dashboard

To support the commissioning guides the Quality Dashboards show information derived from Hospital Episode Statistics (HES) data. These dashboards show indicators for activity commissioned by CCGs across the relevant surgical pathways and provide an indication of the quality of care provided to patients.

The dashboards are supported by a metadata document to show how each indicator was derived.





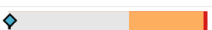


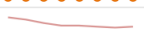
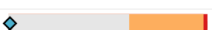
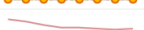

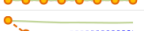
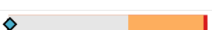

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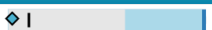

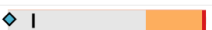

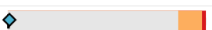

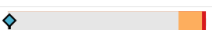

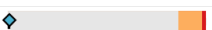

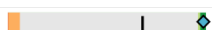

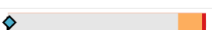

Example CCG:

Orthopaedics-Painful Great Toe





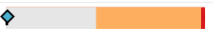



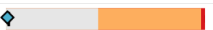

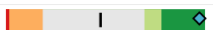



Arthrodesis

| Metric | Period | Value | Mean | Chart | Trend |
|--|------------|-------|-------|---|---|
| Age/Sex Standardised Activity (per 100,000 population) | RY Q4 1213 | 2.88 | 10.63 |  |  |
| Average Length of Stay (Days) | RY Q4 1213 | 1.00 | 0.61 |  |  |
| 7 Day Readmission Rate (%) | RY Q4 1213 | 0.00 | 0.30 |  |  |
| 30 Day Readmission Rate (%) | RY Q4 1213 | 0.00 | 0.70 |  |  |
| 30 Day Reoperation Rate (%) | RY Q4 1213 | 0.00 | 0.38 |  |  |
| Daycase Rate (%) | RY Q4 1213 | 14.29 | 58.66 |  |  |
| In Hospital Mortality Rate (per 1,000 discharges) | RY Q4 1213 | 0.00 | 0.21 |  |  |

Arthroplasty

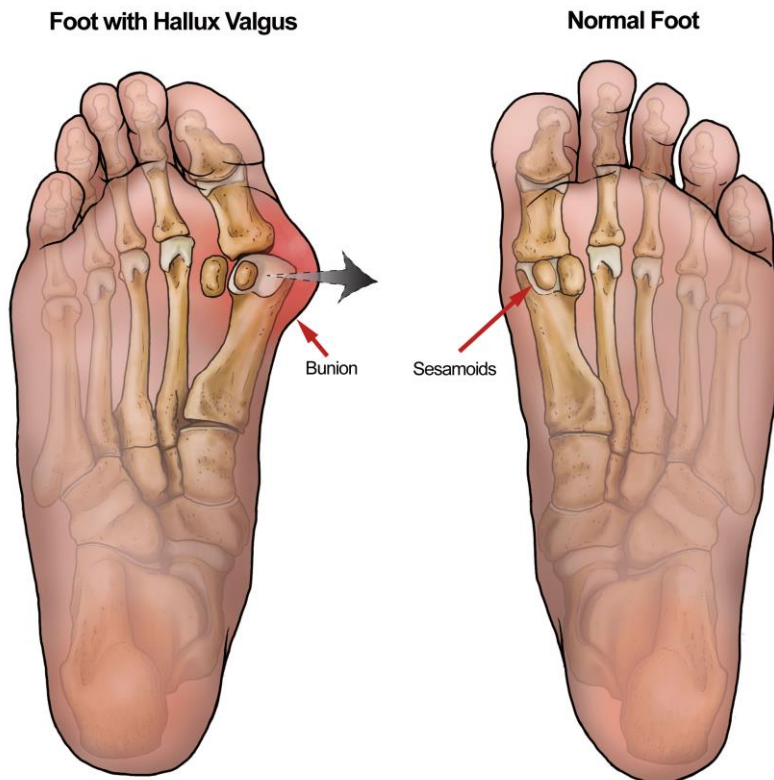
| Metric | Period | Value | Mean | Chart | Trend |
|--|------------|--------|-------|---|---|
| Age/Sex Standardised Activity (per 100,000 population) | RY Q4 1213 | 0.46 | 3.44 |  |  |
| Average Length of Stay (Days) | RY Q4 1213 | 0.00 | 0.63 |  |  |
| 7 Day Readmission Rate (%) | RY Q4 1213 | 0.00 | 0.25 |  |  |
| 30 Day Readmission Rate (%) | RY Q4 1213 | 0.00 | 0.75 |  |  |
| 30 Day Reoperation Rate (%) | RY Q4 1213 | 0.00 | 0.50 |  |  |
| Daycase Rate (%) | RY Q4 1213 | 100.00 | 70.85 |  |  |
| In Hospital Mortality Rate (per 1,000 discharges) | RY Q4 1213 | 0.00 | 0.00 |  |  |

Osteotomy

| Metric | Period | Value | Mean | Chart | Trend |
|--|------------|-------|-------|---|---|
| Age/Sex Standardised Activity (per 100,000 population) | RY Q4 1213 | 13.79 | 21.42 |  |  |
| Average Length of Stay (Days) | RY Q4 1213 | 0.03 | 0.50 |  |  |
| 7 Day Readmission Rate (%) | RY Q4 1213 | 0.00 | 0.10 |  |  |
| 30 Day Readmission Rate (%) | RY Q4 1213 | 0.00 | 0.52 |  |  |
| 30 Day Reoperation Rate (%) | RY Q4 1213 | 0.00 | 0.30 |  |  |
| Daycase Rate (%) | RY Q4 1213 | 97.37 | 70.74 |  |  |
| In Hospital Mortality Rate (per 1,000 discharges) | RY Q4 1213 | 0.00 | 0.00 |  |  |

Appendix 2: Background Information

Hallux Valgus



Note in this illustration of two feet from underneath – that the metatarsal of the foot on the left is drifting inwards (as indicated by the black arrow), subluxing off from the sesamoid bones, which should glide underneath it. The sesamoids remain in the correct place within the flexor tendons. The prominent metatarsal head and its overlying bursa is known as a bunion. The tip of the big toe (the hallux) deviates outwards (laterally).

Background data

- Hallux valgus (HV) is common with a standardised prevalence of 28.4% in adults older than 40 years (2, 3).
- 8% of General Practitioner consultations for musculoskeletal problems relate to the foot and ankle and of these 28% are for foot pain (4).
- Hallux valgus is frequently accompanied by lesser toe deformity such as hammer or claw toes and/or hallux interphalangeus (where the tip of the big toe is deviated laterally).
- In some cases arthritic changes may be present within the joint causing pain and stiffness (hallux rigidus or osteoarthritis).
- Deformity of the big toe results in pain, difficulty with shoe fitting and secondary effects due to overload of the rest of the foot. Non-operative treatments are of limited value (6). Modern surgical techniques provide effective and reproducible outcomes. Risk of complication is small. Surgery for cosmetic reasons is not advisable.

Essential requirements to be able to offer surgery for Hallux Valgus and Hallux Rigidus

- Appropriately qualified Foot and Ankle Specialists for the treatment of Hallux Valgus and Hallux Rigidus are Orthopaedic Surgeons specialising in foot and ankle surgery and HCPC registered podiatric surgeons (CCPST), who are fully integrated into a Multi-disciplinary Network that includes service level agreements to ensure appropriate and timely Critical care, Microbiological, Vascular and Orthopaedic back-up as required.
- Surgery should only take place within units that are integrated within a broader framework with a governance structure that underpins the recommendations below.
- It is recognised that hallux valgus/rigidus surgery is done in a variety of settings including secondary care, standalone day surgery units, community centres, Independent Sector Providers and private hospitals.
- It is expected that surgical units performing surgery on the big toe must have the resources and support to manage patients under their care.
- It is expected that surgical units operate within a multidisciplinary network that ensures patients receive surgery in the most appropriate location.
- Patients should undergo adequate pre-operative assessment, to ensure fitness for surgery and to confirm social plans are in place for day case surgery or next day discharge.
- Units should have an infection control policy administered by a consultant microbiologist. Antibiotic usage should be governed by such a policy which should include guidance on MRSA screening.
- There should be a thromboprophylaxis policy governed by relevant foot and ankle guidelines and suitable precautions taken when indicated.
- Preoperative investigations should be available including standing radiographs and where necessary bloods, ECG's etc.
- Anaesthesia should be undertaken by suitably qualified practitioners with requisite training in this area and the ability to deal with any complications that may arise from administration of anaesthetic drugs.
- Surgery likewise should be undertaken by qualified practitioners with requisite training in this area and the ability to deal with any complications that may arise during surgery or thereafter.
- Surgery should take place in appropriately resourced, equipped and staffed units.
- There should be facilities for X-ray imaging in theatre.
- The use of ultra clean air theatres with laminar flow 18 is recommended but plenum theatre airflow is the minimum standard expected (CQC HTM 03-01).
- Standard post-operative care usually involves a post-operative shoe, analgesia, patient instructions and information on wound care and exercises.
- Minimal invasive surgery for hallux valgus is relatively new in the treatment for this condition. Procedures for hallux valgus using minimally invasive surgery are still being investigated (NICE IPG 332 and PCT NICE sub-committee recommendation 4). Such surgery should be carried out only as part of a properly constructed audit or research programme.
- Complex surgery (e.g. complex revision infection with bone loss avascular necrosis and neurological deformity) must be undertaken by surgeons with a recorded interest in complex foot and ankle surgery working in high volume centre with appropriate facilities.

