Patient held instrumentation
Clinical Guideline

Infection Control Group
Date Approved

Clinical Guideline Consistency Group
Date Approved

Quality and Safety Committee
Date Ratified

Signature

Reference Number Clinical
Version Version 1
Review Date October 2013
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Introduction</td>
<td>3</td>
</tr>
<tr>
<td>2.0</td>
<td>Current National position and patient held instruments</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>• Health Professions Council</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>• Society of Chiropodists and Podiatrists</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>• South Staffordshire PCT decontamination Policy</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>• Care Quality Commission (CQC)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>• Infection Control leads decision making</td>
<td>5</td>
</tr>
<tr>
<td>3.0</td>
<td>Scope of the clinical guideline</td>
<td>5</td>
</tr>
<tr>
<td>4.0</td>
<td>Abbreviations</td>
<td>6</td>
</tr>
<tr>
<td>5.0</td>
<td>Exclusion criteria from the process</td>
<td>6</td>
</tr>
<tr>
<td>6.0</td>
<td>Inclusion criteria</td>
<td>6</td>
</tr>
<tr>
<td>7.0</td>
<td>Clinical process</td>
<td>7</td>
</tr>
<tr>
<td>7.1</td>
<td>Risk assessment</td>
<td>7</td>
</tr>
<tr>
<td>7.2</td>
<td>Consent</td>
<td>7</td>
</tr>
<tr>
<td>7.3</td>
<td>Patient information</td>
<td>7</td>
</tr>
<tr>
<td>7.4</td>
<td>Subsequent appointments</td>
<td>7</td>
</tr>
<tr>
<td>7.5</td>
<td>Patients who fail to bring instruments with them at their appointments</td>
<td>7</td>
</tr>
<tr>
<td>7.6</td>
<td>Before and after use</td>
<td>7</td>
</tr>
<tr>
<td>7.7</td>
<td>Damaged or suspected contamination with body fluids</td>
<td>8</td>
</tr>
<tr>
<td>7.8</td>
<td>Faulty instruments</td>
<td>8</td>
</tr>
<tr>
<td>8.0</td>
<td>Management arrangements</td>
<td>8</td>
</tr>
<tr>
<td>8.1</td>
<td>Chief Executive</td>
<td>8</td>
</tr>
<tr>
<td>8.2</td>
<td>Directors and Managers</td>
<td>8</td>
</tr>
<tr>
<td>8.3</td>
<td>Employees</td>
<td>8</td>
</tr>
<tr>
<td>8.4</td>
<td>Infection Prevention and Control Team</td>
<td>9</td>
</tr>
<tr>
<td>8.5</td>
<td>Occupational Health Department</td>
<td>9</td>
</tr>
<tr>
<td>9.0</td>
<td>Audit and Monitoring</td>
<td>9</td>
</tr>
<tr>
<td>10.0</td>
<td>Training</td>
<td>9</td>
</tr>
<tr>
<td>11.0</td>
<td>Links to policies</td>
<td>9</td>
</tr>
<tr>
<td>12.0</td>
<td>References</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Appendix 1</td>
<td>Patient held instruments risk assessment checklist</td>
</tr>
<tr>
<td></td>
<td>Appendix 2</td>
<td>Patient agreement</td>
</tr>
<tr>
<td></td>
<td>Appendix 3</td>
<td>Issue of Nail Clippers and File to NHS Podiatry Patients leaflet</td>
</tr>
<tr>
<td></td>
<td>Appendix 4</td>
<td>Instrument issue flow chart</td>
</tr>
</tbody>
</table>
1.0 Introduction

Improving and sustaining re-usable medical device decontamination services forms an important component of the Chief Medical Officer’s strategy to combat Healthcare Associated Infection (HCAI) and is included in the reports ‘Winning Ways(1)’ and ‘Getting Ahead Of The Curve(2)’.

Healthcare organisations are required by the Health Act “The Health and Social Care act 2008, Code of Practice on the prevention and control of infections and related guidance”(3) to provide a safe decontamination service that generates a clean and sterile product and is embedded as part of the Service culture in support of successful clinical outcomes and the associated wellbeing of patients and staff.

Major medical device decontamination improvement policies have, over the last eight years, focussed upon secondary or ‘Acute Services’ as this is where the perceived major risks of infection transmission particularly by surgical instruments exist. Much of this thinking was stimulated by continuing concerns over residual protein contamination, following decontamination, and the possibility that human prions could be spread in this way. Recent guidance from NICE draws renewed attention to the prion issues and has a particular focus on ‘high risk tissues’ including the brain and the structure of the back of the eye (posterior ophthalmics)4. Within the Podiatry profession there is a risk that high risk tissue can be contacted in terms of neurological tissue particularly in the areas of Podiatric surgery, nail surgery and diabetes wound care.

The approach to the implementation of the NICE guidance together with other issues related to the Engineering and Science Advisory Committee into the decontamination of surgical instruments including Prion removal (ESAC-Pr) 2006 reports are described in a Professional Letter from CMO February 07.(6).

However, the duty of care to all patients and staff crosses boundaries into all sectors of healthcare services and the risk of encountering pathogens, which may lead to Healthcare Associated Infection (HCAI), exists in Primary care as well as the Secondary and Tertiary care sectors. General Medical and Dental Services and other healthcare service providers will need to have in place modern services, and where relevant facilities that ensure decontamination is achieved in compliance with current DH Clinical Guideline such that the quality and safety of the reprocessed or single use products is equal across all sectors.

All Podiatry reusable instrumentation classification is A1, in the same manner as all dental and other surgical instruments. This means that the same standards of decontamination have to apply to Podiatry instruments as other.

Following an internal audit of facilities and equipment carried out in 2007 in the ten PCT it was decided that it was far cheaper to provide all Podiatry services by the way of using single use disposable instrumentation.
Since the introduction of this system there has been a rapid increase in instrument disposal costs and further production of guidance from the Department of Health and other regulatory bodies.

A group of Podiatry Managers and the Head of the School of Podiatry at Salford University applied to Sir Liam Donaldson to ask for a clearer definition of a medical device as nail clippers were not invasive and the general population had one pair per household which everyone shared and were never sterilised. It was felt by the podiatry profession that nippers should not fall into the same category as invasive instruments. The argument was put that bench top sterilisation was more than adequate and that single use was excessive, would add to landfill and cost money that Trusts didn’t have.

Sir Liam initially concurred with this but subsequently a second letter came out from his office re-enforcing the medical devices Clinical Guideline and from that Trusts have now spent over £50 million each year on podiatry instruments. (8)

2.0 Current National position and patient held instruments

There have been three important publications from the Microbiology Advisory Committee (MAC) who advise the Health Protection Agency (HPA) and the Department of Health, through the MHRA, on disinfection and sterilization practices for medical devices applicable in and appropriate to the health service to Medical Devices Agency MDA.

Part 1 of the manual (8) discusses the principles of decontamination; Part 2(8) provides suggested protocols for various decontamination regimes. Part 3(8) is published in two sections (revised 2006). Unfortunately Podiatry as a profession is not included in any of the guidance specifically.

Based on the “principles” of the MAC guidance, two NHS Trusts have adopted and implemented a programme of “patient held instrumentation” this being defined as using reusable instrumentation but only on the same patient whereby low risk patient procedures are carried out and the patient carries their own instrumentation to each clinic visit. The Podiatrist has the responsibility for cleaning the instrumentation before and after treatment. (See appendix 1).

This process has made significant savings for all organisations affected.

Following discussion with the South Management Team the Professional Lead for Podiatry sought advice from regulatory bodies on this approach.

• Health Professions Council (HPC)

As multi-professional regulator, the HPC do not set standards to the level of specificity for this area, they believe these issues relating to specific techniques for each profession are best decided by employers and relevant professional organisations.
Society of Chiropodists and Podiatrists (SOC&P)

SOC&P advocate decontamination with ultrasonic cleaners and autoclaves. Problem is that these standards do not comply with the Healthcare Products Regulatory Agency MHRA guidance and other national guidance about instrument traceability.

From Staffordshire and Stoke on Trent partnership PCT decontamination Clinical Guideline.

“Where a medical device is reusable, information on the appropriate processes to allow reuse must be provided by the manufacturer (Medicines and Healthcare Products Regulatory Agency MHRA 2006). All medical devices bought must now be CE marked; this, amongst other things, means that the manufacturer has to supply decontamination instructions for the device. Health Service Circular 1999/179 stated that ‘Any device / equipment that cannot be cleaned effectively prior to disinfection or sterilisation should be considered for replacement’.

“You are required to consider the risk of a particular piece of equipment poses as a route for the potential transmission of micro-organisms using table 1 as a guide. It is then possible to choose an appropriate method of decontamination.”

Care Quality Commission (CQC)

In August 2011 a spot visit was made to Solent NHS Trust St James Hospital where the patient held instrument process is in place. The report advocated that with all of the appropriate documentation and process the CQC supported by them as safe practice. (9)

This supports and gives validity and credibility to the process applied and gives a mandate for any NHS Podiatry services to use this option as part of the clinical process.

Infection Control

Following a meeting held with Infection Control leads on 13th May 2011 to discuss the use of patient held instruments, (appendix 2) it was agreed that patient held instrumentation was classed as “low risk” as defined by the MAC guidance part 1 (Pg5), this is concurrent with the current Staffordshire and Stoke on Trent partnership Decontamination Clinical Guideline.

Potential suppliers of CE marked instruments have (Medicines and Healthcare Products Regulatory Agency MHRA 2006) indicated that only soap and water are needed to clean them. (Appendix 3). It must be noted that this does not include files and blacks files used for filing nails.

3.0 Scope of the clinical guideline

This document applies to all Podiatry service employees of Staffordshire and Stoke on Trent Partnership NHS Trust and applicable to all Podiatry staff agency/bank/locum staff, students and volunteers providing Podiatry care to patients.
4.0 Abbreviations

- HCAI Healthcare Associated Infection
- ESAC-Pr Engineering and Science Advisory Committee into the decontamination of surgical instruments including Prion removal
- MAC Microbiology Advisory Committee
- HPA Health Protection Agency
- MHRA Medicines and healthcare Products regulatory Authority
- MDA Medical Devices Agency
- HPC Health Professions Council
- SOC&P Society of Chiropodists and Podiatrists
- CQC Care Quality Commission
- PPE Personal protective equipment

5.0 Exclusion criteria from the process

The exclusion criteria below is based on those patient who have disease processes that may require immune-suppression or who are treated in an environment whereby there is difficulty in controlling the risk of cross contamination or may be of a client group who may be more at risk of possessing transmissible disease through body fluids or body tissue.

- Rheumatoid arthritis.
- Immune suppressed medications.
- Patient who have a previous history foot ulceration.
- Active ulceration or infection.
- Any open wound or skin breakage on clinical presentation.
- Active dermatological disease (e.g. Psoriasis).
- Crohn's disease (chronic inflammation of the digestive tract).
- Alopecia.
- Long term steroid therapy. (This does not include infrequent use of inhalers)
- Transplant patients.
- Hospital ward patients.
- Hospice ward rounds.
- Terminal illness.
- Active cancer.
- Prison environment
- Known Hepatitis B or C
- Known AIDS

All of the above patients must be treated with single use Podiatry instrumentation

6.0 Inclusion criteria

Only patients who are receiving direct care from the Podiatry department are to be included in the process. Nursing or residential home patients who have been assessed and discharged to the care of residential or nursing home carers will not be included.
7.0 Clinical process (see appendix 4)

At each visit:

7.1 Risk assessment

All staff will risk assess a patient’s need for a non-sterile nail care set where decontamination will be through cleaning. This will be in conjunction with updating the patient’s medical history (10). If thought to be suitable for the process complete the risk assessment checklist completed (appendix 1). A copy of the risk assessment checklist is to be kept within the clinical record.

7.2 Consent

If the patient is identified as suitable for patient held instrumentation patient consent (both verbal and written) in line with the patient consent policy (11) is sought. The documentation in appendix 2 is completed and a copy given to the patient and a copy retained within the patient record.

7.3 Patient information

Once having been identified as suitable for the process staff will issue the leaflet about patient held instruments to patients (Appendix 3) and issue the patient held instruments. (It must be stressed that the patient must bring the equipment to each appointment). Demonstrate the use of the nail care equipment to patients or advocates expressing the benefits of this where a risk assessment consideration has been undertaken.

7.4 Subsequent appointments

Staff will seek verbal consent for the process at each subsequent visit and the entry made within the clinical record.

7.5 Patients who fail to bring instruments with them at their appointments;

If the patient fails to bring the nail care set to an appointment;

If lost The clinician should review the patients’ suitability for the process and issue another set of instrumentation only if reassured. Only 2 sets of instrumentation may be issued in these cases and a return to single use disposable instrumentation should be considered.

If forgotten The clinician should review the patient’s suitability for the process and request the patient bring the set with them for the next visit. At this appointment a disposable set of instrumentation is to be used. If the patient fails to bring them a second time, a return to single use disposable instrumentation should be considered.

7.6 Before and after use.

Prior to use at any time, all clinicians must clean instruments thoroughly with a disinfectant detergent wipe (Sporicidal Disinfectant Detergent Wipe recommended - Tuffie 5 by Vernacare) ensuring no physical debris or staining is present. If for any reason it is considered that the instruments cannot be cleaned satisfactorily they should be discarded and a new set issued and the reason entered in the clinical record. Following treatment, clean thoroughly with detergent wipe and placed back in storage container for patient to take away.
7.7 Damaged or suspected contamination with body fluids
If the nail care set is damaged or contaminated with, or suspected to be contaminated with either blood or body fluids the kit must be discarded and a new set issued.

7.8 Faulty instruments
If a set of instruments is faulty and suspicion is due to the instrument manufacture, these are to be appropriately cleaned and retained by the clinicians to be returned to the supplier using the appropriate returns process. A further set of instrumentation is to be provided to the patient.

HOWEVER if at any time the clinician has any reason to be concerned that the nail care set has been used on anyone or anything other than the person they were issued to they are freely able to dispose of these and issue another set recording the reason in the clinical record

AND should the clinician have any concern that the toe is infected or has a break in skin integrity or the clinician cuts the patient with the instrumentation, the instrument MUST be discarded. Any wound should receive an assessment and an appropriate plan.

Single patient use nail instruments are available to anyone who is undergoing a management or prevention plan. People who do not require any follow up intervention at initial assessment should be encouraged to purchase appropriate instrumentation. Clinician's judgement can override this principle, particularly when the patients’ cognitive understanding is in question.

8.0 Management arrangements

8.1 Chief Executive will:
Be responsible for ensuring that there are effective arrangements are in place for the implementation

8.2 Directors and Managers will:
• Ensure that this Clinical Guideline and its associated procedures are fully adhered to within their area of responsibility.
• Establish local policies and practices with advice and guidance from the Infection Control Team, to ensure local work instructions reflect best practices in the prevention and control of infection.
• Ensure the appropriate risk assessments are carried out.
• Provide any required PPE.
• Ensure that their staff receives appropriate training.

8.3 Employees will:
• Co-operate and assist with the implementation of this Clinical Guideline, and its associated Procedures.
• Bring to the notice of management, any problems or failings associated with the Clinical Guideline.
• Attend training as required.
• Make themselves aware of, and follow safe systems of work and control methods (including personal protective equipment) provided for their safety and the safety of others.
• Promptly report all incidents concerning the risks associated with the use of patient held instrumentation in accordance with the Trusts’ Clinical Guideline and Procedure on reporting incidents.

8.4 **Infection Prevention and Control Team will:**
• Promote good infection control practice in line with the Clinical Guideline.
• Provide information, advice and training to enable managers and users to undertake risk assessments as required.
• Conduct investigations into areas of special risk advising on safe practice.
• Review Clinical Guideline every three years or sooner should updated guidance be published.
• Monitoring standards in line with current legislation and guidance.
• Identify areas for improvement and report to Managers, Infection Control Group/Committee/Board, Clinical Risk Committee, Health & Safety Committee and others as appropriate.
• Report on incidents to:
  o Staffordshire and Stoke on Trent partnership Primary Care Trust Health Economy Group
  o Health Protection Agency.
• Train and educate staff within Trusts and by special arrangement with Care Homes
• Communicate and liaise with the appropriate personnel on the care and management of known or at risk patients.

8.5 **Occupational Health Department will:**
• Be responsible for monitoring of staff when required.
• Liaise with the Infection Control Team as and when required.

9.0 **Audit and Monitoring section**
Following the introduction of the process there will be an audit of infection rates relating to use of patient held instrumentation.

This audit will be carried out once every 12 months.

10.0 **Training**
Training will be carried out by the Infection Prevention and control as part of the South Staffs PCT Mandatory Training programme, attendance figures are collected and reported to the Infection Control Group and the PCT board by the Training department, non attendance will be followed up by the training department.

11.0 **Links to policies**
- Clinical 18 Hand Decontamination Clinical Guideline
- Clinical 09 glove Clinical Guideline
- Clinical 24 Management of Clinical sharps injuries and exposure to blood and high risk body fluids
- Clinical 73 Standard Infection Control Precautions
12.0 References


8. Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health: www.mhra.gov.uk/Publications/Safetyguidance/Otherdevicesafetyguidance/CON007438


Patient held instruments Risk Assessment checklist
Does your patient suffer with or fit into the following categories/criteria of treatment environment;

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatoid arthritis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immune suppressed medications.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient who have a previous history foot ulceration.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active ulceration or infection.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active dermatological disease.(e.g.Psoriasis).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crohn's disease (chronic inflammation of the digestive tract).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alopecia.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long term steroid therapy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transplant patients.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital ward patients.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospice ward rounds.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terminal illness.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active cancer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prison environment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Known Hepatitis B or C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Known AIDs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

You must not issue patient held instrumentation if they fit into the above categories.

Podiatrist___________________ Signed ___________________ Date__________________

(Print name)____________________
Appendix 2

Staffordshire and Stoke on Trent Partnership NHS Trust

Patient agreement

Issue of Nail Instruments and File to NHS Podiatry Patients

The nail instruments and file in this container have been issued to you by Staffordshire and Stoke on Trent partnership NHS Trust because you are undergoing a period of foot health care.

The instruments remain the property of the Trust but we would like you to keep them safe and to look after them in the container provided.

These instruments are for your use only.

We are putting this change in place to keep the risk of cross infection low, reduce costs and help the environment. If you use the instruments are used on anyone or anything else we cannot be certain that they will protect you. Therefore they are not to be used for any other purposes than your own personal foot care.

You will need to bring the instruments with you to each podiatry service appointment and keep them safe, dry and warm between visits.

If you are able, we would strongly encourage you to use the nail file as regularly as possible but please check with your practitioner before using the nail instruments.

If at any time you need to speak to a Podiatrist please contact your local booking centre for advice. (The number is on your appointment letter).

Clinician declaration
I have issued the signed patient with a set of instrumentation in line with the current protocol and explained their usage clearly.

Signed _______________ Date __________
Print __________________________

Patient declaration
I accept the instrumentation provided to me by the Podiatrist and clearly understand the limitations of their use.

Signed _______________ Date __________
Print __________________________

One copy to be kept on patient record.
Appendix 3

Issue of Nail Clippers and File to NHS Podiatry Patients

Introduction
The nail clippers and file in this pouch have been issued to you by Staffordshire and Stoke on Trent Partnership NHS Trust Podiatry service, because you are undergoing a period of foot health care. The instruments remain the property of the Trust but we would like you to keep them safe and to look after them. Please note these instruments are for your use only.

Why have you been issued a personal nail cutters?
The Podiatry department is responding to concerns from the general public about cost effectiveness and unnecessary clinical waste. Historically the Podiatry department has been treating you with disposable or reprocessed clinical instrumentation. This has resulted in ever increasing costs of providing the service and increasing the amount of clinical waste that has serious effects on the environment. To reduce both of these and to maintain the high standards of clinical cleanliness we are putting this process in to operation.

After talking to experts about infection risks and helping the environment, we have decided that the most practical way of maintaining our high standards of cleanliness, keeping Podiatry cost effective and helping the environment, is for you to hold and look after your own nail clippers.

This will reduce the numbers of instruments that need to be thrown away without compromising your care.

If we provide you with your own instruments and they are used only for you and by you, there is very little risk of transferring an infection.

However, there are some important safeguards which are explained in this leaflet that you must consider to keep that risk low.

How much is this going to cost the NHS and who is paying for it?
We have looked at all the alternative options but we believe by issuing you with a nail care set is not only just as safe but the most cost effective method.

The savings made with this process will help maintain the quality of service we provide without affecting patient care.

How does the process work?
1. You will be issued with your instrument set by the Podiatrist or Podiatry assistant and you will be asked to sign a “patient agreement” that you understand the process.

2. You will need to bring the instruments with you to each podiatry service appointment and keep them safe between visits.

3. The Podiatrist or Podiatry assistant will clean the instruments with disinfectant wipes before & after use, we will then give them back to you to keep at home until your next visit in the package provided.

What happens if I can’t find them or forget to bring them with me?
We may not be able to carry out a full treatment if this happens. We will provide treatment using either single use instruments or reprocessed instruments but please remember this is much more expensive and less environment friendly.

Can I use the instruments at home?
Only if you are able to do so and the Podiatrist / Podiatry Assistant advise/ recommends you to do so,

Please remember do not use them unless you are advised to do so by the Podiatrists or Podiatry assistant.

Safe Nail Cutting:
Your nails will be softer and easier to cut if you do so after a bath or a soak. Always cut nails straight across. Finish off by filing any rough edges and the corners, this will smooth your nail and help prevent any snagging in your socks, sheets or digging in to other toes.
Never cut down the sides of the nail this can cause painful in growing toenails.

Safe use of the Nail File:
Regular use of the nail file at home can make such a difference in controlling nail growth and discomfort. Please find a way of using this at least once or twice each week.

The foot file can also be used to prevent the build up of dry or hard skin. If the clinician has advised that this is part of your treatment plan then gently apply the file in one direction over the skin. This is most effective when carried out at least twice a week and followed up with the application of a suitable emollient cream.

Please remember these are only for use on your feet – not for anyone or on anything else! There is a risk of spreading infection if used on anything or anyone other than you.

If you use them between your podiatry service visits, please remember to wash them in warm soapy water, then dry them & store them in the wallet provided.

Podiatry Booking Centre Tel no: .................................................................

Nail Care Pack Information for Patients
Appendix 4  Patient held instruments issue flow Chart

Patient assessment
1. Update medical history
2. Complete Risk assessment checklist

Suitable for patient held instruments
1. Complete Risk assessment checklist
2. File in clinical record.

Not suitable for patient held instruments
1. Complete Risk assessment checklist
2. File in record card.
3. Write in record reason for non issue.

Discuss with patient
1. Gain patient consent and give patient copy and place copy in record.
2. Issue Patient leaflet.
3. Provide patient with instruments.
4. Explain to the patient the instructions for use.