Management of early voice prosthesis failure associated with Candida infection (Revised October 2016).

Recommendation

This guideline has been approved for use in East Kent to support requests to GPs from specialists trained and experienced in the management of laryngectomy voice prostheses for maintenance therapy

It provides the background for requests to GPs to consider a prescription for provision of maintenance therapy of either nystatin or miconazole.
Where immediate treatment is required this will be provided by EKHUFT to avoid an urgent request to a GP

To avoid pressure on appointment systems, patients are informed that they do not usually have to see their GP to obtain prescriptions for maintenance items and it should be available through the practice's normal prescription collection process. Process obviously does vary across practices but this wording is included in patient letters and copies are provided.

Note about the revised version 1.2: The clinical guidelines for the management of early voice prosthesis failure associated with Candida infections using out of license products were approved for use in the East Kent health economy in December 2015. It has since been discovered that while there are no problems with the first line nystatin preparations on the market that some component of at least one of the miconazole products on the market is causing voice prosthesis to perish after about 8 months use. As a safety measure, in those patients where miconazole is being used to prevent early voice prosthesis failure the prosthesis will be replaced routinely at 6 months. **The previously approved policy has been changed to reflect this change in practice**.

The document includes

1) Voice Prosthesis Candida Management Pathway
2) Patient guidance document: Fluconazole
3) Patient guidance document: Itraconazole
4) Nystatin prescription request templates:
   a) For ENT Doctor (treatment regime)
   b) For GP (maintenance regime)
5) Patient guidance document: Nystatin
6) Miconazole prescription request templates:
   a) For ENT Doctor
   b) For GP
7) Patient guidance document: Miconazole

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*
Date: October 2016 (Revised version 1.2)
Address: c/o *Canterbury and Coastal CCG, Ground Floor, Council Offices, Military Road, Canterbury, Kent,CT1 1YW* **Contact:** T: 03000 425 019 | E: accg.eastkentprescribing@nhs.net

East Kent Hospitals University NHS Foundation Trust

Clinical guidelines

Management of early voice prosthesis failure associated with Candida infection

Version:	1.2
Ratified by:	EKHUFT Drugs and Therapeutics Committee East Kent Prescribing Group
Date ratified:	December 2015
Name of originator/author:	Specialist Speech and Language Therapists (EKHUFT and KCHFT)
Director responsible for implementation:	Medical Director, Surgical Division
Date issued:	October 2016
Review date:	November 2018 (issue date plus 2 years)
Target audience:	Clinical staff specialising in the management of patients who have had a laryngectomy and surgical voice restoration: ENT Specialist Nurses, Head and Neck Specialist ENT Surgeons, Specialist Speech and Language Therapists

Version Control Schedule

Version	Date	Author	Status	Comment
1	2.12.2015	Sarah Stevens and Leila Williams	Final	Approved December 2015 for local health economy wide implementation
1.1	Feb 2016 20.05.16 Sept 2016	Sarah Stevens and Leila Williams	Amended and submitted to MDM	Updated to include clarity on unlicensed use. New recommendation to change voice prosthesis at 6 months when Miconazole is being used. Incorporation of July 2016 Trust agreed nystatin dosing
1.2	12.10.16	Dr Jenkinson, Lead clinician D&TC	Final	Amended version noting need to change voice box at 6 months with miconazole approved by Chairs action on safety grounds submitted for noting to November D&TC and October EKPG .

Contributors:
Professor Fritz Mühlschlegel, Consultant Microbiologist, EKHUFT
Mr Alistair Balfour, Consultant ENT Surgeon, EKHUFT
Dr Campbell Gourlay, Senior Lecturer in Cell Biology, University of Kent
Julie Hawkes-Reekie, Lead Antimicrobial Pharmacist, EKHUFT
Moira Talpaert, former Lead Antimicrobial Pharmacist, EKHUFT
Dr Mark Baker, Senior Biomedical Scientist, EKHUFT

1 Policy Summary

This document is designed to support staff in the management of early voice prosthesis failure in patients who have had a total laryngectomy and surgical voice restoration.

2 Purpose and Scope

This document describes a robust clinical care pathway for the management of early voice prosthesis failure in patients who have had a total laryngectomy and surgical voice restoration.

This pathway is intended for use by those specialists trained and experienced in the management of laryngectomy voice prostheses (Specialist Speech and Language Therapists, Specialist ENT Nurses and Head & Neck Specialist ENT Surgeons) within East Kent.

3 Introduction

A total laryngectomy is the surgical removal of the larynx, usually to treat cancer. During the operation, the trachea is separated from the oesophagus and diverted to form a permanent stoma at the front of the neck through which the patient breathes. There is no longer a connection between the airway and the mouth, nose or upper digestive tract.

Surgical voice restoration (SVR) is the “gold standard” in speech restoration and should be available to all patients who are to undergo laryngectomy (NICE, 2004). SVR involves the creation of a surgical puncture (tracheoesophageal puncture) in the tracheoesophageal wall, into which a small, silicone voice prosthesis is fitted. This voice prosthesis acts as a one way valve, allowing pulmonary air to be directed into the oesophagus and up into the mouth for speech but prevents backflow of drinks/food/saliva/oesophageal contents into the airway.

When the valve mechanism of the voice prosthesis fails to prevent leakage of oesophageal contents into the airway this is described as device failure. Once the voice prosthesis begins to fail it needs replacing as soon as possible (within hours to days) to prevent the patient from developing an associated chest infection. Voice prostheses are expected to function for at least six months for ‘indwelling’ (clinician-placed) voice prostheses and at least nine weeks for exdwelling (patient-changeable) voice prostheses.

When a pattern of repeated early device failure emerges, action needs to be taken to establish the cause and manage the problem, as the potential implications of frequent changes of voice prosthesis are:

- Damage to the tissue of the tracheoesophageal wall (which could potentially require further surgery and hospital admission to manage)
- Increased risk of aspiration and chest infections
- Increased burden on the patient
- Increased cost to the NHS (equipment and clinical time)

The most common cause of early voice prosthesis failure is due to Candida colonisation of the device.

Candida yeasts are part of the human body’s normal flora but can lead to fungal infections, especially in individuals with weakened immune systems. When a voice prosthesis is placed in the

tracheoesophageal puncture (TEP) it becomes covered with a biofilm (a thin layer of microorganisms which adhere to its surface), which Candida attaches to and from there can infiltrate the silicone of the voice prosthesis. Plaques of Candida may develop on the voice prosthesis and can affect the valve mechanism, e.g. when the presence of a Candida plaque prevents the valve from fully closing.

Candida may also develop on the parts of the voice prosthesis that are in contact with TEP walls. The Candida hyphae (branching tubes) can then burrow into the tissue of the TEP walls which may cause the formation of granulation tissue.

Locally (in East Kent) all patients who are to undergo a total laryngectomy operation will be offered surgical voice restoration unless there is a clinical indication not to do so. All East Kent laryngectomy patients who have a voice prosthesis remain under the care of specialist ENT nurses at the William Harvey Hospital and/or laryngectomy specialist Speech and Language Therapists for ongoing support/management of their prostheses.

There are no nationally agreed guidelines or pathways for managing early voice prosthesis failure associated with Candida infection and the evidence-base is limited. Consequently some recommendations in this document are based on expert opinion. The need for a multi-disciplinary approach was identified and so a team of specialists in the following fields: Microbiology, ENT, Cell Biology (University of Kent), Pharmacy and Speech and Language Therapy, have formed the East Kent Voice Prosthesis Infection Management MDT. This team has considered the evidence-base (and reached consensus where the evidence-base is lacking) to devise a robust clinical care pathway for managing early voice prosthesis failure associated with Candida infection.

The majority of patients with early voice prosthesis failure due to Candida colonisation can be effectively managed through implementation of the pathway and the use of topical antifungal medication. However, there may be some more complex cases which, despite implementation of the pathway, will not respond to antifungal medication alone. These patients will require a multi-disciplinary approach to management.

This document does not duplicate or supersede any other documents.

4 Recommendations for Practice

Please see appendix 1 for the Laryngectomy Candida Management Pathway.

What follows supports the implementation of the pathway by giving guidance notes and rationale for each section.

Box 1

International expectation amongst clinicians who work in surgical voice restoration is that ‘indwelling’ voice prostheses (clinician-placed) should function for a minimum of six months and ‘exdwelling’ (patient-changeable) voice prostheses should last a minimum of nine weeks. Failure of valve function sooner than this is considered to represent early device failure. The clinician may decide not to implement the pathway if the voice prosthesis lasts almost as long as the expected lifespan.

Candida colonisation is the most common cause of early voice prosthesis failure. Candida plaques attached to the voice prosthesis are often, although not always, visible to the naked eye. Early voice prosthesis failure can be caused by other factors and these should also be considered, especially where there is no visible sign of Candida on the failed device.

Voice prostheses which have failed early because of suspected Candida colonisation should be sent to Microbiology for Candida typing and sensitivity testing. This enables the clinician to be confident that the correct treatment is being prescribed and allows change to be monitored over time.

Voice prostheses sent to Microbiology should specify in the ‘tests required’ box “for Candida typing and sensitivity testing: please test against Nystatin, Miconazole, Fluconazole and Itraconazole”. Candida ‘typing’ refers to the identification of Candida species, of which there may be more than one type present. ‘Sensitivity testing’ refers to the process of determining the susceptibility of the Candida to

antifungal therapy. The sample should be placed straight into the specimen pot without rinsing, as there may be the possibility of adding contaminants and washing away microbes in the saliva and the biofilm .

Box 2

Clinical experience has shown a common link between patients with granulation tissue and frequent early device failure associated with Candida colonisation of the voice prosthesis. Where granulation tissue is evident in the region of the TEP, infection by Candida is a possible cause. Group consensus is that a systemic antifungal (e.g. Fluconazole, Itraconazole) is recommended to treat such granulation tissue.

Box 3a

If granulation tissue is present around the TEP, topical antifungals are insufficient to treat any potential candida infection within the tissue and therefore systemic treatment is indicated.

If granulation tissue develops at any stage during implementation of the pathway, refer to the guidelines in this section (box 3a). The patient should be referred to ENT and if there is excessive granulation tissue then consider surgical removal and send samples to microbiology and histology.

Fluconazole has a proven safety and efficacy profile and should be the first treatment option to be considered (Lass-Florl, 2011). The recommended treatment regime for Fluconazole is a 21 day course (100mg once daily) (BNF, 2015). Fluconazole is not recommended for long-term use as prolonged exposure to Fluconazole may carry the risk of anti-fungal resistance (Rex et al, 1995).

Patients will need to have a liver function test to ensure adequate liver function before starting Fluconazole. This should be repeated on day 7 of the regime and results obtained on the same day to ensure it is safe to continue and complete the course.

It is theoretically possible that the TEP tissue could be reinfected from Candida within the material of the voice prosthesis. Therefore to prevent cross-infection from the voice prosthesis back into the surrounding tissue, group consensus is that, unless contraindicated, the voice prosthesis should be changed towards the end of the course. By this time the antifungal should have reached a therapeutic level in the tissue.

See appendix 2 for the Fluconazole patient guidance document.

Itraconazole is more toxic than Fluconazole, with increased risk of severe side-effects (Lass-Florl, 2011). Therefore Itraconazole should only be used following careful MDT consideration and when the use of Fluconazole is an unsuitable option.

The recommended treatment regime for Itraconazole is a 10mls (100mg of a 10mg/1ml solution) twice daily for 14 days (BNF, 2015). Liver function tests are advised before commencing the course and on days five and ten of the course. A change of voice prosthesis is recommended on or soon after day 10 of the course.

See appendix 3 for the Itraconazole patient guidance document.

Whilst taking systemic antifungals, patients who are already on the pathway and using Nystatin/Miconazole can continue daily brushing through the voice prosthesis with the topical antifungal.

<u>Following completion of systemic antifungal regime</u>

If new to the pathway, continue to box 3b and commence Nystatin maintenance regime (once daily brushing only).

Patients already on the pathway should resume the pathway from the point at which they were prior to the development of granulation tissue.

Box 3b

Upon initial identification of early device failure associated with Candida colonisation, use of Nystatin should be initiated for the following reasons:

- The Candida is highly likely to be sensitive to Nystatin (Jennison et al, 1957)
- Nystatin has few side effects, no drug interactions and a proven efficacy record (Melkoumov et al, 2013)

Treatment should ideally be commenced within 24 hours of a new voice prosthesis placement so as to prevent Candida colonisation. It is therefore recommended that the patient is provided with a prescription for one month's supply of Nystatin via an EKHUFT ENT Doctor. See appendix 4a for treatment regime ENT Nystatin prescription request template letter.

Treatment regime:
For optimum treatment results, Nystatin should be administered both orally and applied directly to the voice prosthesis. Oral administration treats any infection in the oral/pharyngeal/oesophageal mucosa. A 14 day course (1ml (100,000 units), 4 times daily) taken orally was the optimum treatment regime for oral and peri-oral fungal infections (BNF, 2015). While in 2016, the treatment dose in the BNF changed to 4-6ml (400,000-600,000 units) 4 times daily our Trust recommendation for this indication remains at 1ml 4 times daily, as we do not appear to have treatment failure at this dose given local sensitivity patterns for candida.

Direct application of Nystatin to the voice prosthesis is achieved by brushing through the device with a small amount of Nystatin coating the bristles of a voice prosthesis cleaning brush. Care should be taken that there is not excessive Nystatin on the brush that could enter the airway. Multi-disciplinary consensus is that it is clinically appropriate and safe to directly apply Nystatin to the voice prosthesis. Since the use of Nystatin in this manner is outside the product license, prescribers should refer to the Trust's Unlicensed Medication Policy (available on Sharepoint). Patient consent for unlicensed use of medication should be gained and the consent form filed in the patient's notes (see 'unlicensed products patient consent form' in the Trust's Unlicensed Medication Policy).

Maintenance regime:
After the 14 day course, oral administration of Nystatin should be discontinued and a maintenance regime of daily brushing only should be continued. This ensures that a maintenance dose continues to be delivered to the material of the voice prosthesis but greatly limits the amount of Nystatin that is being taken into the body.

Written patient guidance about the use of Nystatin (see appendix 5) should be provided to optimise compliance with the regime.

Microbiology results are accessed via the DART pathology system and are usually available within 96 hours. If the Candida is confirmed to be sensitive to Nystatin, send a letter to the GP to request ongoing prescription request for Nystatin or CCG recommended brand. Due to an unusual structure mechanism, Nystatin may be substantially more cost effective when prescribed in primary care by brand and CCG systems will be advising GPs of this. See appendix 4b for maintenance regime GP prescription request template letter.

If the Candida proves to be resistant to Nystatin, but is sensitive or has intermediate sensitivity to Miconazole, progress to box 5b (Miconazole regime). Miconazole showing intermediate sensitivity under test conditions should be considered sensitive to topical application.

If there are multiple Candida species there may be variation in their sensitivity to Nystatin – in this event, continue with the Nystatin treatment regime as the Candida species sensitive to Nystatin may be the organism responsible for early device failure.

If microbiology results indicate that the Candida is resistant to all topical antifungals, consider taking the case to the MDT for discussion regarding management.

There is an insufficient evidence-base for consideration of routine treatment of other microorganisms (e.g. Staphylococcus aureus, Streptococci) that are isolated from the voice prosthesis.

Box 4

Monitoring the lifespan of the next two voice prostheses is required (even in the presence of suitable treatment) as the first prosthesis may fail early if hyphae attach to the voice prosthesis because either:

- There is a delay in initiating the new antifungal regime or
- The infection is not immediately brought under control

If there is on-going early device failure, it is important to ensure that the patient is compliant with the recommended treatment regime before considering a change in management.

Further voice prostheses should be sent for microbial testing so that any changes in Candida species or sensitivity can be identified and management tailored accordingly.

Box 5a

Group consensus is that Nystatin should continue to be applied directly to the voice prosthesis as a maintenance regime (once daily brushing). It is expected that this will help to protect against future Candida colonisation of the voice prosthesis but with minimal use of medication.

If the voice prosthesis lifespan significantly reduces again this could represent a new Candida infection, in which case return to box 1.

Box 5b

Microbiology testing should be repeated in case there is a change in the Candida species/sensitivity. Miconazole showing intermediate sensitivity under test conditions should be considered sensitive to topical application.

Multi-disciplinary consensus is that it is clinically appropriate and safe to directly apply Miconazole to the voice prosthesis <u>for a maximum of six months per voice prosthesis</u>. Since the use of Miconazole in this manner is outside the product license, prescribers should refer to the Trust's Unlicensed Medication Policy (available on Sharepoint). Patient consent for unlicensed use of medication should be gained and the consent form filed in the patient's notes (see 'unlicensed products patient consent form' in the Trust's Unlicensed Medication Policy). There is no data for the use of Miconazole for more than two weeks. Local expert opinion is that it is safe to continue using the minimal amounts of Miconazole oral gel directly applied to the voice prosthesis in the long-term (as long as the voice prosthesis is changed routinely at 6 months) and there is no need for liver function tests to be carried out.

The prescription for the first month's supply of Miconazole should be arranged via an EKHUFT ENT Doctor. See appendix 6a for the ENT Miconazole prescription request template letter. Further supply should be requested via the patient's GP. See appendix 6b for GP Miconazole prescription request template.

Written patient guidance about the use of Miconazole (see appendix 7) should be provided to optimise compliance with the regime.

Use of Nystatin should be discontinued because either microbiology results have shown that the Candida is not sensitive to Nystatin or the lifespan has not sufficiently increased in response to the previous treatment regime.

Multi-disciplinary consensus is that it is clinically appropriate and safe to directly apply Miconazole to the tissue surrounding the TEP, which may help to protect against development of a Candida infection.

If there is on-going early device failure, it is important to ensure that the patient is compliant with the recommended treatment regime before considering a change in management.

Box 6

Monitoring the lifespan of the next two voice prostheses is required (even in the presence of suitable treatment) as the first prosthesis may fail early if hyphae attach to the voice prosthesis.

If there is on-going early device failure, it is important to ensure that the patient is compliant with the recommended treatment regime before considering a change in management.

Further voice prostheses should be sent for microbial testing so that any changes in Candida species or sensitivity can be identified and management tailored accordingly.

Box 7a

Group consensus is that Miconazole should continue to be applied directly to the voice prosthesis as a maintenance regime (once daily brushing). It is expected that this will help to protect against future Candida colonisation of the voice prosthesis but with minimal use of medication.

The voice prosthesis should be changed routinely at 6 months, as our experience is that the material of the voice prosthesis may deteriorate beyond 8 months.

If the device life becomes significantly reduced, following previous improvement with use of Miconazole, retest microbiology and refer to the MDT.

Box 7b

Microbiology testing should be repeated in case there is a change in the Candida species/sensitivity.

More complex cases that do not respond to use of Nystatin or Miconazole as described in this pathway should be referred for discussion at the Voice Prosthesis Infection Management MDT.

The following information should be presented to the MDT:

- Patient case history (e.g. date of laryngectomy, history of radiotherapy, relevant medical history)
- All current and previous microbiology results
- Lifespans of voice prostheses prior to commencement and during implementation of the pathway

Options for consideration by the MDT include:

- Treatment of co-existing microorganisms
- Other factors that may be reducing voice prosthesis lifespan (consider need for videofluoroscopy to investigate)
- Modified/alternative voice prosthesis, e.g. Blom-Singer Advantage, Blom-Singer Dual Valve, Provox Activalve
- Use of systemic antifungals (e.g. Fluconazole, Itraconazole)

Although there is insufficient evidence to recommend routine treatment of other microorganisms that are isolated from the voice prosthesis, the MDT may, at this stage, consider treatment of such microorganisms on a case-by-case basis. Ideally the MDT would seek to investigate the interaction between the Candida and the other existing microorganism(s) (e.g. via co-culturing in the laboratory).

Even when microbial analysis provides evidence of the presence of Candida there is still the potential for other factors to contribute to early device failure and these should be considered and potentially investigated.

Clinicians should be familiar with alternative voice prostheses which have been designed to resist Candida colonisation or delay device failure associated with Candida growth. These include:

- Blom-Singer Advantage (valve embedded with silver-oxide)
- Blom-Singer Dual Valve (valve embedded with silver-oxide and a secondary valve helps prevent leakage of oesophageal contents when the primary valve fails)
- Provox Activalve (valve lid constructed using Candida-resistant fluoroplastic) (NB: this is considered to be a last-resort option because of consistent local experience of a detrimental impact on voicing)

When considering the use of systemic antifungals (e.g. Fluconazole, Itraconazole), it is essential to weigh up the benefits and associated risks. Itraconazole should be the last resort as it is more toxic than Fluconazole, with increased risk of severe side-effects. Long term use of Fluconazole and Itraconazole is contraindicated.

5 Approval and ratification process

This document has been viewed and approved by:

- East Kent Voice Prosthesis Infection Management MDT – September 2016
- EKHUFT Antimicrobial Stewardship Group – 4 November 2015
- EKHUFT Drugs and Therapeutics Committee – 18 November 2015
- EKHUFT ENT Audit Group – 18 November 2015
- EKHUFT Adult Speech and Language Therapy Service – November 2015
- East Kent Prescribing Group – 16 December 2015
- This version which has been approved for safety reasons for immediate implementation is to be noted by EKHUFT and East Kent CCG Governance by November 2016

6 Review and Revision Arrangements

These guidelines will be reviewed and updated two years from the date of ratification via the East Kent Voice Prosthesis Infection Management MDT in the first instance and groups involved in the original ratification process if indicated.

7 Dissemination and Implementation

This document will be available via Sharepoint and circulated to clinical staff specialising in the management of patients who have had a laryngectomy and surgical voice restoration: ENT Specialist Nurses, Head and Neck Specialist ENT Surgeons, Specialist Speech and Language Therapists. Training will be provided by the EKHUFT Laryngectomy Specialist Speech and Language Therapist to all relevant clinical staff to support the implementation of these guidelines.

8 Monitoring Compliance

Monitoring will be carried out via annual audit of five case notes, led by the Specialist Speech and Language Therapist in conjunction with the Voice Prosthesis Infection Management MDT. An annual

report will be prepared and an action plan agreed. This report will be shared with the groups consulted in the ratification process. The audit will review whether the pathway was implemented correctly and clinical decision making was appropriate and documented.

9 Professional, Trust and Legal Requirements – Nurses and Allied Health Professionals (AHPs)

Professional

a) The nurse must have knowledge of personal accountability for his/her practice, acknowledging limitations of professional competence and only undertake and accept responsibility for those activities for which he/she is competent (NMC 2008).
b) All AHPs are State Registered with The Health and Care Professions Council, which states that all AHPs 'Will keep their knowledge and skills up to date and act within the limits of their knowledge skills and experience' (Health Professions Council 2003).
c) Nurses and AHPs must work within this role development policy and protocols for specific patient groups.
d) The nurse/AHP must have attended the appropriate training and have achieved competency.

Trust

e) The Trust accepts liability for the action of those practitioners who have completed the identified training for this skill, are competent to carry it out, and who have updated their skills according to the competency framework.

10 References

British National Formulary, www.medicinescomplete.com/mc/bnf/current, accessed 15 October 2015.

Evans E, Hurren A, Govender R, Radford K, Robinson H F, Batch A, Samuel P, Prosthetic Surgical Voice Restoration (SVR): The role of the speech and language therapist. RCSLT Policy Statement 2010

Jennison, RF and Stenton, P (1957) Sensitivity of Candida strains to Nystatin; J Clin Path. 1957**;** 10 (3) 219-221

Lass-Florl C (2011) Triazole Antifungal Agents in Invasive Fungal Infections; A Comparative Review, Drugs; 71 (18); 2405-2419

Melkoumov A, Goupil M, Louhichi F, Raymond M, de Repentigny L, Leclair G (2013) Nystatin nanosizing enhances in vitro and in vivo antifungal activity against Candida albicans; J. Antimicrobial Chemother.; 68 (9); 2099-2105

National Institute for Clinical Excellence (NICE) (2004) Improving outcomes in head and neck cancers: the manual

Rex J, Rinaldi M and Pfaller M (1995) Resistance of Candida Species to Fluconazole; Antimicrobial agents and chemotherapy; 31 (1); 1-8

11 Appendices

1. Voice Prosthesis Candida Management Pathway

2. Patient guidance document: Fluconazole

3. Patient guidance document: Itraconazole

4. Nystatin prescription request templates:

    a. For ENT Doctor (treatment regime)
    b. For GP (maintenance regime)

5. Patient guidance document: Nystatin

6. Miconazole prescription request templates:

    a. For ENT Doctor
    b. For GP

7. Patient guidance document: Miconazole

8. Author's Checklist of compliance with the Policy for the Development and Management of Organisation Wide Policies and Other Procedural Documents

9. Plan for Dissemination of Policies

East Kent Hospitals University NHS
NHS Foundation Trust

Kent Community Health NHS
NHS Foundation Trust

Voice Prosthesis Infection Management MDT
Laryngectomy Candida Management Pathway

1) Send voice prosthesis to microbiology for Candida typing and sensitivity testing

↓

2) Is granulation tissue present around the voice prosthesis/tracheoesophageal puncture
YES NO

YES ↓ NO ↓

3a) If granulation tissue is present:
- Refer to ENT and request prescription for 21 day course (100mg once daily) NB Fluconazole is not recommended for long-term use
- Provide patient guidance document and support patient in use of Fluconazole
- Change the VP towards the end of the course where clinically appropriate (between days 14 and 20)
- If Candida is resistant to Fluconazole or there are persistent problems with granulation tissue then liaise with ENT Consultant about use of Itraconazole 10mls (100mg of a 10mg/1ml solution) twice daily for 14 days
- Commence topical antifungals

3b) If granulation tissue is not present:
- Request prescription for 1 month's supply of Nystatin via ENT (1ml orally 4 times daily for 14 days plus once daily brushing through VP) plus ongoing daily brushing after the 14 day course
- Provide patient guidance document and support patient in use of Nystatin (oral administration and brushing through VP).
- Obtain results from microbiology re. Candida +/- other microorganisms* and seek to change antifungal if not sensitive to Nystatin. If any clarification is required seek guidance from VP MDT
- If the Candida is sensitive to Nystatin send letter to GP requesting repeat prescription for maintenance regime

* Other microorganisms will not routinely be treated as part of the pathway at this stage but may need later MDT consideration

↓

4) Monitor lifespan of next 2 VPs, continue to send early failing VPs to microbiology and check results

↓

5a) If VP lifespan increases to expected level:
- Continue once daily brushing with Nystatin in the long-term
- Continue to monitor device lifespan – if it becomes significantly reduced again, recommence the pathway at box 1

5b) If lifespan remains significantly less than expected:
- Review microbiology results
- If Candida is sensitive to Miconazole, request 1 month's supply of Miconazole oral gel via ENT (for brushing through VP once daily) and send letter to GP requesting repeat prescription for maintenance regime
- Provide patient guidance document and support patient in use of Miconazole
- Advise patient to discontinue Nystatin
- SLT/specialist nurse to use Miconazole oral gel on new VP and apply into TEP at time of VP changes
- Change the VP routinely if it lasts for 6 months

↓

6) Monitor lifespan of next 2 VPs, change routinely at 6 months or else send early failing VPs to microbiology

↓

7a) If VP lifespan increases to expected level:
- Continue once daily brushing with Miconazole in the long-term
- Continue changing the VPs at 6 months
- Continue to monitor device lifespan – if it becomes significantly reduced again, retest Microbiology and refer to the Voice Prosthesis Infection Management MDT

7b) If insufficient increase in VP lifespan then retest microbiology and seek specialist MDT advice via presentation of case at Voice Prosthesis Infection Management MDM

East Kent Hospitals University NHS
NHS Foundation Trust

Kent Community Health NHS
NHS Foundation Trust

Guidelines for use of Diflucan (Fluconazole) for people who have had a laryngectomy

You have been prescribed Diflucan oral suspension to treat a candida (yeast) responsible for the early failure of your voice prosthesis.

Before taking Diflucan

You will need to have a blood test (liver function test) BEFORE you start the Diflucan to check that your liver is working well. You will also need to have a further blood test on day 7 of commencing the Diflucan to check that your liver continues to work well.

We also need to check you are not on any medications which could interact with Diflucan – we will ask for a list of all your current medications and ask the pharmacist to check this against the contraindicated medications.

Please read the full manufacturer's leaflet before commencing Diflucan.

Guidance for taking the Diflucan

We recommend you start taking Diflucan on a **weekday** because you will need to arrange to have a blood test on day 7 of the course, so this day should not fall on a weekend. **We also need to change your voice prosthesis between day 14 and day 20 of the course – please make sure you have an appointment with your speech therapist/specialist nurse for this.**

Your pharmacist should have made the Diflucan up into a liquid for you. Shake the closed bottle every time before taking Diflucan. Take 10mls (100mg of a 10mg/1ml solution) of Diflucan once daily for 21 days. Diflucan can be taken with or without food and is best taken at the same time each day. Swish the oral solution around your mouth for approximately 20 seconds before swallowing it. Do not rinse your mouth after swallowing the oral solution.

You may continue brushing through the voice prosthesis with Miconazole gel during your course of Diflucan if you already do so (but do not take it orally if this has previously been recommended). If you are taking Nystatin you may continue to take this during your Diflucan course.

You will need to have a blood test on day 7 of your Diflucan course. This can usually be arranged at your GP surgery. Arrange to have the blood test in the morning so you can get the results later that same day. Do not proceed with the course until you have the results and are advised that your liver is not being adversely affected by the treatment.

Please be sure to read the manufacturer's leaflet, in particular the sections about possible side effects and symptoms of liver problems.

Voice Prosthesis Infection Management Multidisciplinary Team
February 2016

Patient's name:
D.O.B.:
NHS number:

East Kent Hospitals University NHS
NHS Foundation Trust

Kent Community Health NHS
NHS Foundation Trust

Guidelines for use of Sporanox for people who have had a laryngectomy

You have been prescribed Sporanox (Itraconazole) oral solution to treat a candida (yeast) responsible for the early failure of your voice prosthesis.

Before taking Sporonox

You will need to have a blood test (liver function test) BEFORE you start the Sporanox to check that your liver is working well. You will also need to have a further two blood tests on day 5 and day 10 of commencing the Sporanox to check that your liver continues to work well.

We also need to check you are not on any medications which could interact with Sporanox – we will ask for a list of all your current medications and ask the pharmacist to check this against the contraindicated medications.

Please read the full manufacturer's leaflet before commencing Sporanox.

Guidance for taking the Sporanox

We recommend you start taking Sporanox on a **Monday** because you will need to arrange for blood tests on day 5 and day 10 of the course, so these days should not fall on weekends. **We also need to change your voice prosthesis on or soon after day 10 of the course – please make sure you have an appointment with your speech therapist/specialist nurse for this.**

Take 10mls (100mg of a 10mg/1ml solution) of Sporanox twice daily for 14 days (a measuring cup is provided with the bottle). Always take Sporonox one hour before food or drink. Swish the oral solution around your mouth for approximately 20 seconds before swallowing it. Do not rinse your mouth after swallowing the oral solution.

You may continue brushing through the voice prosthesis with Miconazole gel during your course of Sporanox if you already do so (but do not take it orally if this has previously been recommended). If you are taking Nystatin you may continue to take this during your Sporanox course.

You will need to have blood tests at day 5 and day 10 of your Sporanox course. This can usually be arranged at your GP surgery. Arrange to have the blood test in the morning so you can get the results later that same day. Do not proceed with the course until you have the results and are advised that your liver is not being adversely affected by the treatment.

Please be sure to read the manufacturer's leaflet, in particular the sections about possible side effects and symptoms of liver problems.

Voice Prosthesis Infection Management Multidisciplinary Team
February 2016

Patient's name:
D.O.B.:
NHS number:

Appendix 4a

East Kent Hospitals University NHS
NHS Foundation Trust

Insert address

To:
Date:

Dear

Re: Patient Name:
DOB:
Address:
NHS No:
Local pharmacy:

Request for Nystatin prescription

This patient is experiencing early voice prosthesis failure. As per the **EKHUFT Clinical Guidelines for the Management of Early Voice Prosthesis Failure Associated with Candida Infection**, please could you write a prescription for one month's supply of Nystatin as follows:

- 3x 30ml bottles of Nystatin oral suspension (100,000 units/ml)
- 1ml QDS for 14 days
- Further supply to be used as directed

The patient has received instructions about how to take this medication, in accordance with the above Clinical Guidelines.

This prescription will need to be sent to the pharmacy at the patient's nearest acute hospital site or faxed and then sent to their local pharmacy. The ENT Nurse Specialist/Nursing Sister on Rotary Ward can facilitate this.

Please do not hesitate to contact me if you require any further information.

Yours sincerely

Name
Job Title

Appendix 4b

East Kent Hospitals University NHS
NHS Foundation Trust

Insert address

To:
Date:

Dear

Re: Patient Name:
DOB:
Address:
NHS No:

Request for Nystatin prescription

Following early device failure, I recently sent this patient's voice prosthesis to microbiology for Candida typing and sensitivity testing. The results indicate presence of Candida which is sensitive to Nystatin.

To manage this (as per the **EKHUFT Clinical Guidelines for the Management of Early Voice Prosthesis Failure Associated with Candida Infection**) we recommend:

- Treatment regime: Take 1ml Nystatin oral suspension (100,000 units) by mouth four times daily for 14 days plus, once daily, after cleaning the voice prosthesis brush through it with a small amount of Nystatin on the voice prosthesis cleaning brush
- Maintenance regime: continue once daily brushing with Nystatin oral suspension through the voice prosthesis on an ongoing basis - this may need to be life-long (but please note that Nystatin use will be minimal, so each bottle is expected to last many weeks)

We have arranged a prescription for the treatment regime to cover the patient for the first month, as per EKHUFT contractual obligations. **After this time the patient will need a repeat prescription to cover the maintenance regime. Please could you arrange a repeat prescription for Nystatin or other CCG approved brand* oral suspension (maintenance regime), as required?**

It is important that we endeavour to increase the lifespan of this patient's voice prostheses, as the implications of frequent changes of voice prosthesis are:

1) Damage to the tissue of the tracheoesophageal wall which could require further surgery and prolonged hospital stays to manage
2) Increased risk of aspiration and chest infections
3) Increased cost to the NHS in terms of equipment and clinical time

To avoid pressure on your appointment system, the patient has been informed that they do not usually have to see their GP to obtain this prescription and it should be available through the practice's normal prescription collection process. I hope this is acceptable.

If you require further information please refer to the full clinical guidelines or contact me directly.

Yours sincerely

Name
Job Title

Copy to: Patient
Medical notes

*Due to an unusual structure mechanism, Nystatin may be substantially more cost effective when prescribed in primary care by brand and CCG systems will be advising GPs of this.

East Kent Hospitals University NHS
NHS Foundation Trust

Kent Community Health NHS
NHS Foundation Trust

Guidelines for use of Nystatin for people who have had a laryngectomy

You are recommended to take this medication to treat the Candida (yeast) responsible for the early failure of your voice prosthesis.

For the first 14 days:

- Take 1ml (100,000 units) Nystatin oral suspension **four times** daily (equally spaced throughout the day)
- Hold orally for a minimum of 30 seconds before swallowing
- Swallow this same 1ml to coat the throat and back of the voice prosthesis (valve)
- Try to take **nothing** orally for 30-60 minutes afterwards (no food or drink). This is to allow the medicine to stay in contact with the back of your voice prosthesis for longer.

Once daily (until advised otherwise):

- After cleaning the voice prosthesis, put a small amount of Nystatin on the brush and brush through the voice prosthesis

Nystatin liquid is photosensitive and must be stored in the dark and in a cool place.

Voice Prosthesis Infection Management Multidisciplinary Team
February 2016

Patient's name:
D.O.B.:
NHS number:

Appendix 6a

East Kent Hospitals University NHS
NHS Foundation Trust

Insert address

To:
Date:

Dear

Re: Patient Name:
DOB:
Address:
NHS No:
Local pharmacy:

Request for Miconazole prescription

This patient is experiencing early voice prosthesis failure. As per the **EKHUFT Clinical Guidelines for the Management of Early Voice Prosthesis Failure Associated with Candida Infection**, please could you write a prescription for one month's supply of Miconazole oral gel as follows:

- 1x 15g tube Miconazole oral gel 2%
- To be used as directed

The patient has received instructions about how to take this medication, in accordance with the above Clinical Guidelines.

This prescription will need to be sent to the pharmacy at the patient's nearest acute hospital site or faxed and then sent to their local pharmacy. The ENT Nurse Specialist/Nursing Sister on Rotary Ward can facilitate this.

Please do not hesitate to contact me if you require any further information.

Yours sincerely

Name
Job Title

Appendix 6b

East Kent Hospitals University NHS
NHS Foundation Trust

Insert address

To:
Date:

Dear

Re: Patient's name:
DOB:
Address:
NHS No:

Request for Miconazole prescription

Following early device failure, I recently sent this patient's voice prosthesis to microbiology for Candida typing and sensitivity testing. The results indicate presence of Candida which is sensitive to Miconazole.

To manage this (as per the **EKHUFT Clinical Guidelines for the Management of Early Voice Prosthesis Failure Associated with Candida Infection**) we recommend:

- Once daily, after cleaning the voice prosthesis, put a small amount of Miconazole oral gel on the brush and brush through the voice prosthesis

We have arranged a prescription to cover the patient for the first month, as per EKHUFT contractual obligations. After this time the patient will need a repeat prescription for ongoing use. This may need to be life-long (but please note that use of Miconazole oral gel will be minimal, so each tube is expected to last many weeks). **Please could you arrange a repeat prescription for Miconazole oral gel, as required?**

If you have received previous correspondence regarding prescribing Nystatin for management of early failing voice prostheses, please note that this can now be discontinued.

It is important that we endeavour to increase the lifespan of this patient's voice prostheses, as the implications of frequent changes of voice prosthesis are:

1) Damage to the tissue of the tracheoesophageal wall which could require further surgery and prolonged hospital stays to manage
2) Increased risk of aspiration and chest infections
3) Increased cost to the NHS in terms of equipment and clinical time

To avoid pressure on your appointment system, the patient has been informed that they do not usually have to see their GP to obtain this prescription and it should be available through the practice's normal prescription collection process. I hope this is acceptable

If you require further information please refer to the full clinical guidelines or contact me directly.

Yours sincerely

Name
Job Title

Copy to: Patient
Medical notes

East Kent Hospitals University NHS
NHS Foundation Trust

Kent Community Health NHS
NHS Foundation Trust

Guidelines for use of Miconazole Oral Gel for people who have had a laryngectomy

You are recommended to take this medication to treat the Candida (yeast) responsible for the early failure of your voice prosthesis.

Once daily:

- After cleaning the voice prosthesis (valve), put a small amount of Miconazole Oral gel on the brush and brush through the voice prosthesis

Every time you attend for a change of voice prosthesis:

- Please bring your tube of Miconazole gel so that your speech therapist/specialist nurse can apply some gel directly to the puncture site and your new voice prosthesis

(The same tube of Miconazole gel can be used for up to three years/up to use by date)

Please note that a potential side effect of this medicine with prolonged use is deterioration of the material of the voice prosthesis. To reduce the risk of this happening, we will plan to change the voice prosthesis at least every six months. **Please be vigilant for signs of deterioration, such as discolouration, distortion or fragmentation of the voice prosthesis and contact your speech therapist or specialist ENT nurse immediately should this occur.**

Voice Prosthesis Infection Management Multidisciplinary Team
September 2016

Patient's name:
D.O.B.:
NHS number:

Appendix 8 – Author's Checklist of compliance with the Policy for the Development and Management of Organisation Wide Policies and Other Procedural Documents

POLICY:

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

	Requirement:	Compliant Yes/No/ Unsure	Comments
1.	**Style and format**	Yes	
2.	**An explanation of any terms used in documents developed**	Yes	
3.	**Consultation process**		Ongoing
4.	**Ratification process**		Pending
5.	**Review arrangements**	Yes	
6.	**Control of documents, including archiving arrangements**	Unsure	For Sharepoint. No documents for archiving
7.	**Associated documents**	N/A	
8.	**Supporting references**	Yes	
9.	**Relevant NHSLA criterion specific requirements**	N/A	
10.	**Any other requirements of external bodies**	N/A	
11.	**The process for monitoring compliance with NHSLA and any other external and/or internal requirements**	N/A	

Appendix 9 – Plan for Dissemination of Policies

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

Acknowledgement: University Hospitals of Leicester NHS Trust (Amended)

Title of document:	Clinical guidelines: Management of early voice prosthesis failure associated with Candida infection		
Version Number:	1		
Approval Date:		**Dissemination lead:**	Sarah Stevens
Previous document already being used?	No		
If yes, in what format (paper / electronic) and where (e.g. Directorate / Trust wide)?	N/A		
Proposed instructions regarding previous document:	N/A		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Format**	**Comments:**
Head and Neck Specialist ENT Surgeons	Via ENT Audit group (18 November 2015) by Sarah Stevens and Alistair Balfour (Consultant ENT Surgeon)	Paper	
Specialist ENT Nurses	Via 1:1 training delivered by Sarah Stevens, October 2016	Paper	

Author's Dissemination Record - to be used once document is approved

Date document forwarded to be put on the Trust's central register / in Sharepoint:		**Date document put on Directorate register (if appropriate) / on Directorate webpage (if applicable)**	

Disseminated to: (either directly or via meetings, etc.)	**By Whom?**	**Format (i.e. paper or electronic)**	**Date Disseminated:**