



# Family Nursing & Home Care

## **Standard Operating Procedures**

### **Probiotics (VSL#3) for prevention of Clostridiodes difficile)**

November 2022

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**Contents**

Introduction.....4

SOP 1 Assessing Patients for VSL#3.....5

SOP 2 Ordering, Storing and Supplying VSL#3 .....8

SOP 3 Supporting VSL#3 Treatment ..... 11

SOP 4 Transferring Care to the District Nursing Service..... 13

## Introduction

VSL#3 is a probiotic used for the prevention of Clostridium Difficile in high risk patients on intravenous (IV) antibiotics. This treatment and process has been requested by the Health & Community Services Consultant Microbiologist and at this time is only being made available to patients receiving care initially through Rapid Response and Reablement (RRRT).

The use of this nutritional supplement can be started in Jersey General Hospital and continued at home when discharged into the care of the RRRT for ongoing IV antibiotic therapy OR it can be initiated by RRRT for their patients who meet the inclusion/exclusion criteria.

## Adverse effects

Occasional bloating and flatulence may be experienced while taking VSL#3, however these are usually mild and subside with continuous use. The dose frequency may be reduced if the patient suffers significant discomfort after intake.

One theoretical concern associated with probiotics includes the potential for these viable organisms to move from the gastrointestinal tract and cause systemic infections. Although rare, probiotic related bacteraemia has been reported, but these are isolated reports and none of the clinical trials have reported any serious adverse effect or systemic infection with probiotics.

It is estimated that the risk of developing bacteraemia from ingested *Lactobacilli* probiotics is less than 1 per 1 million users. However it is recommended by Health and Community Services to follow all exclusion criteria before prescribing VSL#3 for patient safety (see [SOP1](#)).

## Procedures

These standard operating procedures include the process to be used when the patient has been discharged home without a supply of probiotics. Their purpose is to ensure that relevant staff understand and follow the correct process for:

- assessing patient suitability for VSL#3
- obtaining, storing and supplying VSL#3
- supporting VSL#3 treatment
- transferring care to the District Nursing Service

## SOP 1 Assessing Patients for VSL#3

### **Purpose**

To ensure the correct patient group receives VSL#3, specific inclusion and exclusion criteria must be observed. Clients assessed as suitable for probiotic therapy should be discharged from Jersey General Hospital with a supply sufficient for the duration of their treatment. If no supply has been given, this SOP should be followed.

### **Scope**

This SOP will only be relevant to the Rapid Response & Reablement Team (RRRT) as currently, they are the only Family Nursing & Home Care service that can initiate and supply VSL#3 in the community. This SOP includes inclusion and exclusion criteria and a table of [equivalent anti-inflammatory doses of oral corticosteroids](#).

### **Core Requirements**

Discuss use of this nutritional supplement with the patient including benefits and risks of its use.

Give patient the [Probiotic \(VSL#3\) Patient Information Leaflet](#)

If patient consents to this treatment, assess their suitability for receiving VSL#3.

Take account of **both** inclusion and exclusion criteria when assessing if probiotics should be used.

### **Inclusion criteria**

#### **Group 1**

**All** of the following criteria should be met before considering probiotic therapy:

- ☐ patients over **60 years of age**
- ☐ patient is under the care of the **Rapid Response Team**
- ☐ patient has been prescribed intravenous antibiotics for the **treatment** of a bacterial infection

Probiotic supplement is **not** required when antibiotics are used as a single dose for procedure prophylaxis.

In some circumstances, where clinical assessment indicates high risk of Clostridium Difficile, probiotics can be considered in a younger adult (< 60 years old) when high risk antibiotics are prescribed (see [hospital antimicrobial guidelines](#)).

## Group 2

Patients of **any age** who have been diagnosed Glutamate dehydrogenase (GDH), and Polymerase Chain Reaction (PCR) positive in any stool sample (current or previously within the last 2 years), and require an IV antibiotic during their current care episode.

A positive PCR test identifies Clostridium difficile bacteria is present in the patients gut. A positive GDH test shows the bacteria are producing toxins.

## Exclusion criteria

The use of probiotics should be **avoided** in:

- ☐ immunosuppressed patients (e.g. haematology, HIV)
- ☐ patients receiving chemotherapy, or taking any immunosuppressants including:
  - Azathioprine
  - Ciclosporin
  - Mercaptopurine
  - Methotrexate
  - Mycophenolate
  - Sirolimus
  - Tacrolimus
  - Tumor necrosis factor alpha [TNF- $\alpha$ ] inhibitors (e.g. Adalimumab, Etanercept, Rituximab)
- ☐ acute pancreatitis
- ☐ patient with organ transplantation
- ☐ patient with prosthetic heart valve
- ☐ patient with risk of aspiration
- ☐ patient with no spleen/hyposplenism
- ☐ patient with long term (>1 month) high dose systemic steroid (equivalent to 20mg Prednisolone daily)\* See conversion table [Equivalent anti-inflammatory doses of oral corticosteroids](#) (also below)

| <p>*Equivalent anti-inflammatory doses of oral corticosteroids</p> <p>This table does not take into account mineralocorticoid effects or variations in duration of action of the corticosteroids</p> |  |
|--|--|
| <b>Corticosteroid</b>  | <b>Dose equivalent to 20mg Prednisolone</b>                                  |
| Betamethasone  | 3mg  |
| Budesonide   | Not applicable<br>(local anti-inflammatory action in gastrointestinal tract) |
| Cortisone acetate  | 100mg  |
| Deflazacort  | 24mg   |
| Dexamethasone  | 3mg  |
| Fludrocortisone  | Not applicable (mineralocorticoid action only)                               |
| Hydrocortisone   | 80mg   |
| Methylprednisolone   | 16mg   |
| Prednisolone   | 20mg   |
| Triamcinolone  | 16mg   |

Patients meeting the VSL#3 criteria must have this documented on the treatment plan in their EMIS care record.

## SOP 2 Ordering, Storing and Supplying VSL#3

### **Purpose**

To ensure the correct procedure is used by clinical staff involved in the ordering, storing and supply of VSL#3 to patients in the community. This includes the collection and delivery to the patient's home.

### **Scope**

This SOP covers how to order VSL#3, where it should be stored and how it is supplied to the patient. It is relevant to staff involved in these processes

### **Core Requirements**

#### **Ordering Process**

VSL#3 must be ordered via FNHC stores and charged to Business unit KMT600.

Order code is ABX66149 (30 sachet pack).

#### **Storage**

The order is collected by FNHC stores staff from HCS Central Stores and brought directly to FNHC for storage into the Rapid Response Team Fridge. As the product is a nutritional supplement and not patient specific, it is not logged into the fridge and not named specifically for individual patients.

VSL#3 sachets should be stored in the Rapid Response Team medicine fridge (2-8°C). If necessary it can be stored at room temperature (up to 25 °C) for up to 7days.

The Rapid Response Team medicine fridge must be used for the probiotics storage within Family Nursing & Home Care. The fridge temperature gauge should be clearly visible to read without needing to open the fridge door.

As a minimum for providing adequate refrigerator conditions, the fridge should have:

- have a unique identifier, such as a serial number
- the refrigerator is safe, for example by undertaking regular visual inspections and Portable Appliance Testing (PAT).
- the refrigerator is lockable
- the refrigerator is placed in a suitable position (ventilated and away from heat sources)
- the refrigerator is maintained in a clean condition



2 November 2022

- ice is not building up in the fridge. If defrosting is necessary, the probiotics should be stored temporarily in a suitable alternative refrigerator or in a validated medical-grade cool box, but for the minimum possible time
- there is a maintenance contract that allows for at least yearly servicing and calibration of the temperature gauge
- steps have been taken to reduce the probability of accidental interruption of electricity supply, by labelling the vaccine refrigerator plug.

Records should be kept of regular servicing, defrosting and cleaning, calibration and electrical testing. All maintenance actions should be recorded on a log sheet.

Temperatures in the fridge are to be monitored and recorded once each working day, and documented as maximum reading, minimum reading and actual reading. The maximum and minimum functions must be reset after each temperature reading.

The monitoring of fridges is often referred to as observing the four Rs:

- Read - at the same time every day during the working week and signs the sheet
- Record - in a standard fashion and on a standard form
- Reset - resets the thermometer after each reading.
- React - if the temperature falls outside +2°C to +8°C

If there is evidence or a suspicion that the probiotic has been exposed to temperatures outside the recommended 2-8°C range:

- Establish the time period of temperature deviation using the paper records or min/max temperatures.
- If the VSL#3 has been stored at a temperature more than 8°C but below 25°C then it is safe to use but must be used within 7 days. Clearly document on the VSL boxes the new expiry date – 7 days from the established temperature deviation.
- If the VSL#3 temperature is less than 2°C it should be thawed, then maintained at refrigeration temperature, the box marked to indicate it has been stored at this sub-temperature and can be used. It should be discarded if it reaches this sub-temperature again as the temperature fluctuations can stress the bacterial cell membranes.
- Report details of the incident on the Assure reporting system.
- Inform the person designated to be in charge of all the refrigerators or a manager, in their absence, so that a repair engineer can be called.

## Supplying the Patient

Rapid Response Team staff will supply the patient with the number of probiotics that correlates with the total number of days the patients is on intravenous and oral antibiotics for.

The patient will be advised to;

- Store their probiotics in their fridge
- Take one VSL#3 sachet per day for the duration of the antibiotic course
- Mix the sachet contents in either a cold, non-fizzy drink or sprinkle on/mix with cold food, to be eaten straight away and not saved for later
- If necessary probiotics can be stored at room temperature (up to 25°C) for up to 7 days.

The patient will be provided with a [Probiotic \(VSL#3\) Patient Information leaflet](#) if they do not already have one.

## SOP 3 Supporting VSL#3 Treatment

### **Purpose**

VSL#3 is a nutritional supplement and should be either self-administered or administered by the patient's carer. This SOP provides nursing staff with information about this treatment so they can support the client to take it correctly.

### **Scope**

This SOP includes guidance on the recording of VSL#3 in the patient care records and information about VSL#3 to help support safe self-administration/carer-administration.

### **Core Requirements**

VSL#3 is a nutritional supplement and is not a medication and therefore does not need to be prescribed, however it should ideally be recorded on the medication administration record to monitor compliance.

VSL#3 should be documented onto the medication administration record (drug chart) by a doctor or a non-medical prescriber to ensure the inclusion and exclusion criteria has been considered.

VSL#3 can be transcribed by a RRRT nurse from a hospital patient's medication discharge summary sheet onto their drug chart, if the doctor has omitted to add it to the drug chart. The nurse would write 'in line with RRRT probiotics policy' in the prescribers signature box on the drug chart.

VSL#3 should be discussed with a referring GP looking at the inclusion and exclusion criteria, to see if the GP consents for the patient to take the probiotic. If the patient meets the criteria the GP is to be asked to document VSL#3 onto the patients drug chart.

VSL#3 should be given to patients who meet group 1 or 2 of the inclusion criteria, but should be avoided in patients who meet any of the exclusion criteria (see SOP 1).

Check that the patient is taking/receiving the VSL#3 and appropriate usage.

### **Dose**

VSL#3: 1 sachet daily.

VSL#3 can be taken orally or via an enteral feeding tube. It should be mixed with a cold (non-fizzy) drink or sprinkled on/mixed with cold food. The mixture should be eaten/drunk right away and not saved for later.

### **Duration**

VSL#3 should be continued for the duration of the antibiotic treatment only. This should include the oral antibiotic if this follows on from a course of IV antibiotics.

Patients who are discharged from hospital during treatment should continue the VSL#3 until the antibiotic course is complete.

The Microbiologist should be contacted for advice on the duration of VSL#3 for patients on long term antibiotics (e.g. TB therapy, bone & joint infections), this should be determined on an individual patient basis with supplies for long term antibiotics supplied by Jersey General Hospital.

### **Adverse effects**

Monitor for adverse side effects (see introduction).

Occasional bloating and flatulence may be experienced while taking VSL#3, however these are usually mild and subside with continuous use. The dose frequency may be reduced if the patient suffers significant discomfort after intake.

## SOP 4 Transferring Care to the District Nursing Service

### **Purpose**

When the care of a patient on VSL#3 is to be transferred to the District Nursing (DN) Service, they need to be made aware that the patient is on this treatment so appropriate management can be continued.

### **Scope**

This SOP is relevant to both the Rapid Response and Reablement Team and the District Nursing Service. It includes transfer of care and ongoing management.

### **Core Requirements**

#### **Rapid Response and Reablement Team**

Before transferring the patient's care to the DN Service, check that the patient has sufficient supply of VSL#3 for the expected duration of the treatment.

Inform the receiving team that the patient is taking VSL#3 and details of this treatment.

#### **District Nursing Service**

The patient will be self-administering this nutritional supplement or it will be given by their recognised carer. A Medication Administration Record Sheet can be provided by the Rapid Response and Reablement Team if required. On admission to the caseload, check to confirm that the probiotic therapy is being taken as guided.

Monitor compliance with probiotic therapy and for side effects (see [Introduction](#)).

VSL#3 should be continued for the duration of the antibiotic treatment only. This should include the oral antibiotic if this follows on from a course of IV antibiotics.