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Royal Cornwall Hospitals NHS Trust

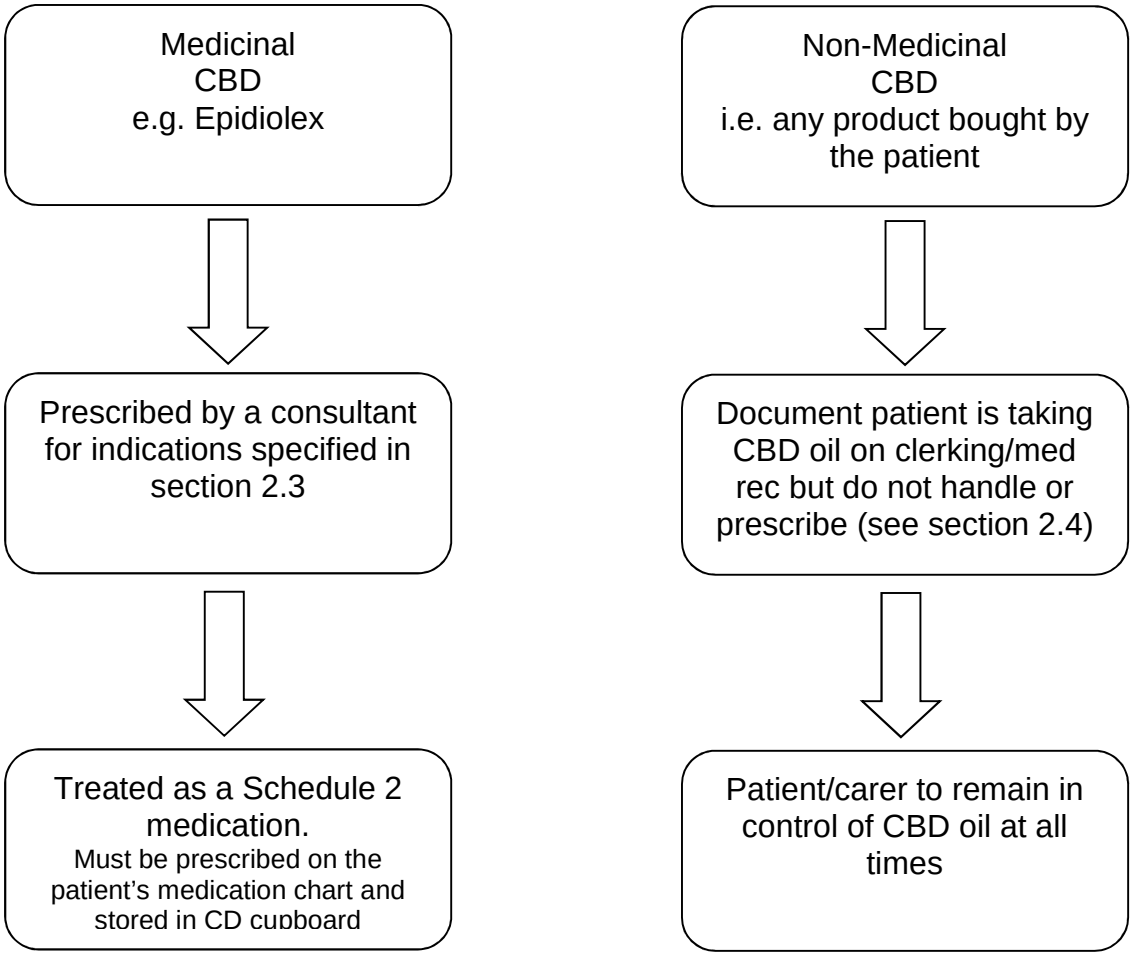
Cannabidiol (CBD) Products

Clinical Guideline

V1.0

March 2019

Summary


Medicinal
CBD
e.g. Epidiolex
Prescribed by a consultant for indications specified in section 2.3
Treated as a Schedule 2 medication.
Must be prescribed on the patient's medication chart and stored in CD cupboard
Non-Medicinal
CBD
i.e. any product bought by the patient
Document patient is taking CBD oil on clerking/med rec but do not handle or prescribe (see section 2.4)
Patient/carer to remain in control of CBD oil at all times

1. Aim/Purpose of this Guideline

1.1. This guideline covers the use of CBD oil in all inpatient areas within RCHT

1.2. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We can't rely on Opt out, it must be Opt in.

The DPA18 covers how the Trust obtains, hold, record, use and store all personal and special category (e.g. Health) information in a secure and confidential manner. This Act covers all data and information whether held electronically or on paper and extends to databases, videos and other automated media about living individuals including but not limited to Human Resources and payroll records, medical records, other manual files, microfilm/fiche, pathology results, images and other sensitive data.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the 'information use framework policy', or contact the Information Governance Team rch-tr.infogov@nhs.net

2. The Guidance

2.1 Introduction

CBD, a constituent of cannabis, is widely available to purchase online and from health food shops. These are marketed and sold as dietary supplements, but are commonly bought by patients/carers for use as a medicine for a variety of ailments including anxiety, muscle spasticity and epilepsy.

2.2 Background

Cannabis is controlled under the misuse of drugs legislation. CBD as an isolated substance would not be controlled under the Misuse of Drugs Act. However, if a CBD 'product' contained any controlled cannabinoids, unintentially or otherwise (e.g. THC or CBD-V), then it is highly likely that the product would be controlled. In practice it is very difficult to isolate pure CBD, and due to the nature of the products available the contents are often not fully disclosed. As a result of this it has to be assumed that CBD containing products would be controlled under the MDA 1971/MDR 2001 as a result of other cannabinoid content.

An amendment to the Misuse of Drugs Regulations 2001 came into force 1st November 2018, which allows the use of cannabis-based products, such as CBD oil, for medicinal use. This amendment states that products will only fall under the definition of "cannabis based products for medicinal use" if it fulfils the three limbs of the definition of 'cannabis-based product for medicinal use in humans', whereby it will

be treated as a Schedule 2 drug under the 2001 regulations. The three limbs are that the preparation or product (other than Sativex or those with a home office exemption):

1. Is or contains cannabis, cannabis resin, cannabinol or cannabinol derivative (e.g. THC)
2. Is produced for *medicinal use* in humans
3. Is a medicinal product, or a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product

Cannabis based products for medicinal use may be legally accessed in 3 ways, as stated in the November 2018 amendment:

"A person shall not order (whether by issuing a prescription or otherwise) a cannabis based product for medicinal use in humans for administration to himself or herself or to another unless that product is:

1. A special medicinal product (e.g. unlicensed medicines) that is for use in accordance with a prescription or direction of a specialist medical practitioner
2. An investigational medicinal product without marketing authorisation that is for use in a clinical trial or
3. A medicinal product with a marketing authorisation."

Prescribing is currently restricted to doctors on the Specialist General Medical Council Register.

2.3 What does this mean in practice?

In practice this means that only consultants within the Trust are able to prescribe products which have been produced for medicinal use and have been approved for importation by the MHRA (Medicines and Healthcare products Regulatory Agency) or are licensed as medicines for use in the UK. It is recommended that prior to use approval will be obtained from the medical director or the chair of the Medicines Practice Committee (MPC) on a named patient basis. NHS England have also stipulated that the only approved indications are:

- Children and adults with rare forms of epilepsy
- Adults with nausea and vomiting caused by chemotherapy

All other CBD products e.g. herbal remedies and other products that are not prescribed for that patient must continue to be treated as controlled substances under the misuse of drugs legislation.

Epidiolex is a product that, although not licensed in the UK, has been used in clinical trials in the UK. It is likely that this will be the preferred product to be used. RCHT will be treating this product as a Schedule 2 controlled drug, and as such it will need to be stored in a controlled drug cupboard.

2.4 Use of non-medicinal Cannabidiol within RCHT

2.4.1. Non-medicinal Cannabidiol for the purposes of this guidance is defined as any cannabidiol product that is being used outside of the November 2018 amendment to the Misuse of Drugs Regulations 2001 i.e. any cannabidiol which has not been prescribed by a consultant and dispensed by a registered pharmacy.

2.4.2. Actions for prescribers

- Document the fact that the patient is taking CBD oil on the admission paperwork
- Be aware that CBD oil has potential drug interactions
- Do NOT prescribe CBD oil
- The patient (or carer) should be informed that if the patient wishes to continue to take CBD oil, they must do so themselves as staff will not legally be able to administer it. In order for this to occur, the patient must be assessed under the self-administration of medicines policy , and only those patients (or parents/carers for paediatric patients) assessed as suitable to self-administer will be able to take their own CBD
- Do not handle or accept the CBD oil, and then return it to the patient, as doing so could be construed as 'supply of an illegal substance'
- Include the fact the patient takes CBD oil in the discharge summary, but do not prescribe it in the medicines section

2.4.3. Actions for pharmacists

- Include CBD oil in the medicines reconciliation
- Assess the patient (or parent/carer for paediatric patients) for suitability to self-administer under the self-administration of medicines policy
- Ensure that CBD oil is not prescribed or included in the medicines section of the discharge summary. Where it is prescribed the prescribing doctor should be notified and the CBD oil removed from the chart by the prescriber.
- Add a pharmaceutical care plan note to alert all staff involved in the patient's pharmaceutical care that the patient is taking CBD oil to allow for interactions to be checked

2.4.4. Actions for nurses

- Assess the patient (or parent/carer for paediatric patients) for suitability to self-administer under the self-administration of medicines policy
- Do not administer CBD oil to the patient
- Do not handle a patient's CBD oil unless they authorise you to destroy it on their behalf. If this occurs record this in the patient's own CD register and notify the ward pharmacist to arrange collection (see section 13)

2.4.5. Actions for patients

Patients (carers) will need to keep the CBD oil in their possession in a locked medicines cabinet, and remain responsible for it throughout their stay

3. Monitoring compliance and effectiveness

Element to be monitored	Storage errors
Lead	Accountable officer or deputy
Tool	Review of DATIX and CD variance reports
Frequency	Annually
Reporting arrangements	Reports will be reviewed by Medication Practice Committee (MPC) Reviews will be minuted at this meeting and any actions logged.
Acting on recommendations and Lead(s)	Accountable office or deputy
Change in practice and lessons to be shared	Required changes in practice will be identified and actioned within 3 months. A lead member from MPC will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion & Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Cannabidiol (CBD) Products Clinical Guideline V1.0					
Date Issued/Approved:	07.03.2019					
Date Valid From:	March 2019					
Date Valid To:	March 2022					
Directorate / Department responsible (author/owner):	Pharmacy (Sabrina Tierney, Helen McClay)					
Contact details:	01872 252590					
Brief summary of contents	This guidance covers the use of CBD oil in all inpatient areas within RCHT					
Suggested Keywords:	CBD; cannabidiol					
Target Audience	RCHT	CFT	KCCG			
	✓					
Executive Director responsible for Policy:	Medical Director					
Date revised:	14.11.2018					
This document replaces (exact title of previous version):	New Document					
Approval route (names of committees)/consultation:	Medication Practice Committee					
Divisional Manager confirming approval processes	Iain Davidson					
Name and Post Title of additional signatories	Not Required					
Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings	{Original Copy Signed}					
	Name: Kevin Wright					
Signature of Executive Director giving approval	{Original Copy Signed}					
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only			

Document Library Folder/Sub Folder	Clinical
Links to key external standards	None
Related Documents:	Ward and Department Standard Operating Procedure for Controlled Drugs – Royal Cornwall Hospital Trust
Training Need Identified?	No

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
14/11/18	V1.0	Initial Issue	Sabrina Tierney, Clinical Pharmacist

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Initial Equality Impact Assessment Form

<table>
<tr><td colspan="6">Cannabidiol (CBD) Products Clinical Guideline V1.0</td></tr>
<tr><td colspan="3">Directorate and service area:
Clinical Support, Pharmacy</td><td colspan="3">Is this a new or existing Policy?
New</td></tr>
<tr><td colspan="3">Name of individual completing assessment:
Sabrina Tierney</td><td colspan="3">Telephone:
01872 252590</td></tr>
<tr><td>1. Policy Aim*

Who is the strategy / policy / proposal / service function aimed at?</td><td colspan="5">This guideline covers the use of CBD oil in all inpatient areas within RCHT, providing information on safe storage and who can prescribe</td></tr>
<tr><td>2. Policy Objectives*</td><td colspan="5">To provide information on safe storage and use of CBD oil within RCHT</td></tr>
<tr><td>3. Policy – intended Outcomes*</td><td colspan="5">Safe and legal use of CBD oil</td></tr>
<tr><td>4. *How will you measure the outcome?</td><td colspan="5">DATIX, CD variance reports</td></tr>
<tr><td>5. Who is intended to benefit from the policy?</td><td colspan="5">All staff involved with medicine prescribing and storage</td></tr>
<tr><td rowspan="3">6a Who did you consult with

b). Please identify the groups who have been consulted about this procedure.</td><td>Workforce</td><td>Patients</td><td>Local groups</td><td>External organisations</td><td>Other</td></tr>
<tr><td>x</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">Please record specific names of groups
Child Health Guidelines Committee
Medication Practice Committee</td></tr>
<tr><td>What was the outcome of the consultation?</td><td colspan="5">Agreed.</td></tr>
</table>

7. The Impact
Please complete the following table. **If you are unsure/don't know if there is a negative impact you need to repeat the consultation step**.

Are there concerns that the policy **could** have differential impact on:

Equality Strands:	Yes	No	Unsure	Rationale for Assessment / Existing Evidence
Age		**X**		
Sex (male, female, trans-gender / gender reassignment)		**X**		
Race / Ethnic communities /groups		**X**		
Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.		**X**		
Religion / other beliefs		**X**		
Marriage and Civil partnership		**X**		
Pregnancy and maternity		**X**		
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		**X**		

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**

Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended.	**Yes**		**No**	**x**

9. If you are **not** recommending a Full Impact assessment please explain why.

No areas indicated

Signature of policy developer / lead manager / director S Tierney	Date of completion and submission 14/11/18

Names and signatures of members carrying out the Screening Assessment	1. S Tierney 2. Human Rights, Equality & Inclusion Lead	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.

A summary of the results will be published on the Trust's web site.

Signed: Helen McClay

Date: 07 03 19