Prescribing of cannabis based products - a summary

Almost all Professionals are currently being asked in their clinical practice about the use of Cannabidiol products for various medical conditions.

The National Institute for Health and Care Excellence (NICE) has been asked by the Department of Health and Social Care to produce a clinical guideline on the prescribing of cannabis-based products for medicinal use in humans. This guidance is expected by October 2019. In the interim, NHS England asked the British Paediatric Neurology Association (BPNA) and the Royal College of Physicians (RCP) to develop additional advice. Meanwhile the Royal College of Paediatrics and Child health (RCPCH) along with the British Paediatric Neurology Association (BPNA) have issued Q&As in relation to cannabis-based products for medicinal use. These Q&As mention that the child may not be currently prescribed Epidiolex to treat Epilepsy. We hope that the following gives our readers the current status on this situation in the UK: Interim advice by the British Paediatric Neurology Association (BPNA):



'We advise that pure CBD (Epidiolex®) should be the default choice when considering prescription of a cannabis-based product for medicinal use (CBPM) in intractable epilepsy (The International League Against Epilepsy proposed a definition of drug-resistant epilepsy as a failure of adequate trials of 2 tolerated and appropriately chosen and used AED schedules in children). It does not yet have an EMA licence and is currently going through the application process. It has already acquired a licence from the US Food and Drug Administration. The trial evidence suggests that dose of 20mg/kg/day of CBD (Epidiolex®) is effective at reducing seizures in Dravet and Lennox-Gastaut syndromes. Dosing typically starts between 2-5mg/kg/day.' In order to prescribe a cannabis-based product for medicinal use, the practitioner must be on the Specialist Register. BPNA strongly recommends that only specialists with paediatric neurology expertise and training prescribe for children in this context.

Interim advice by the Royal College of Physicians (RCP):

'There is good evidence that cannabinoids are effective in preventing chemotherapy induced nausea and vomiting (CINV) but they have a high side effect profile. Cannabinoids should remain an option for those who have failed standard therapies but not used as a first-line treatment'.

'There is no robust evidence for the use of CBPM in chronic pain and their use is not recommended'.

Other: There is no published evidence recommending the use of CBMP for pain symptoms in Chronic fatigue Syndrome.

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References:

- Davies PDS. Cannabis Scheduling Review Part 1: The therapeutic and medicinal benefits of Cannabis based products - a review of recent evidence. London: Department of Health and Social Care. 2018.https://www.gov.uk/ government/publications/cannabisscheduling-review-part-1
- 2. British Paediatric Neurology Association. BPNA statement on use of marijuana (cannabis) related products in the treatment of complex epilepsies. 2018
- Devinsky O, Cross JH, Laux L, et al. Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. *The New England Journal of Medicine* 2017;376(21):2011-20 doi: 10.1056/NEJMoa1611618[published Online First: Epub Date]].
- Devinsky O, Patel AD, Cross JH, et al. Effect of Cannabidiol on Drop Seizures in the Lennox-Gastaut Syndrome. *The New England Journal of Medicine* 2018;378(20):1888-97 doi: 10.1056/NEJMoa1714631[published Online First: Epub Date]

Guideline update: The radiological investigation of suspected physical abuse in children revised guidelines

Paediatricians engaging in child protection work regularly (and those of you who are regular readers of BACCH News) will be aware that the Royal College of Radiologists published new guidance on the radiological investigation of suspected physical abuse in children in 2017¹. You can read a review of the document in the December 2017 edition of BACCH News². A number of these recommendations had significant implications for paediatric practice and structural processes, with others being more relevant to radiology colleagues. The recommendation that generated a lot of interest amongst paediatricians was Recommendation Number 4:

Skeletal survey should be done on all children under 2 years old who are siblings or in the same house as the index case

This raised questions both in terms of the implications on services, but also in the acceptability to families of the need for this lengthy and sometimes distressing procedure in additional children who may not have any obvious injuries.

Shortly after publication, the document was rescinded for further review. It has recently been re-published, the authors stating that the revision was brought about "following a consultation of some of the recommendations based on new evidence brought to the attention of the working party". This article therefore aims to inform readers of the changes to the guidance document and discuss the implications of it to community paediatric practice.

The recommendations that have been reworded are as listed in the table below. In addition to these, Appendix D, relating to recommendation 15, has been removed.

I will not comment further on Recommendation 35 as this applies more to radiologists, but the others merit discussion.

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Updated 2018 Guidan

for health care staff.

- 4. 4When serious injury is identified in a child 4. Skeletal survey should be done on all children due to suspected physical abuse: - Any multiple birth sibling(s) of an index
- case less than two years should have the same recommended imaging as the index case
- Age-appropriate imaging should be considered in all siblings and children less than two years old living in the same household or in the household of the alleged or suspected perpetrator(s) on a case-by-case basis.

 15. Two radiographers with documented
- physical abuse and forensic radiography techniques should perform the examinations. They should also have level 3 knowledge, skills and competence as set out in Safeguarding children and young people: roles and competences
- children's nurse or an appropriately educated paediatric nurse or registered health or care should be present during the examination. This survey. This person should be someone who should be a healthcare professional who: a) is able to act autonomously and b) has a scope of practice which includes an understanding of the legislation applying to children with suspected physical abuse. Examples of appropriate staff roles include registered children's nurse or registered social 35. Unenhanced cranial CT scanning should
- be performed from immediately below the skull base to above the vertex as soon as the patient is stable on the day of admission. All cranial CT scanning should be undertaken using a multi-slice technique, with a thickness of 0.8 mm and routine 3D surface reconstructed images generated and stored at the time of the scan, see Appendix I. 44. Further follow-up MRI of the head may be indicated. See Appendix I for timetable for neurological imaging and Appendix J for

recommended protocols.

Original 2017 Guidar

- under 2 years old who are siblings or in the same house as the index case
- 15. Two radiographers with documented education education and training in imaging of suspected and training in paediatric and forensic radiography techniques should perform the skeletal survey.
- 18. In addition to the radiographers, a registered 18. In addition to the radiographers, a registered health or care practitioner on a statutory register practitioner should be present during the skeletal understands the legal framework of child protection and can act autonomously.

44. Follow-up MRI head should be done within 3 months (Appendix J).

Firstly, considering recommendation number 4, this is a shift back towards what most of us were probably doing previously and considering most sibling investigations on a case-by-case basis. "Serious injury" is specified as: "fracture(s), burns >5% total body surface area, traumatic brain injury, intra-abdominal trauma, intrathoracic trauma, injuries requiring paediatric intensive care unit (PICU) admission or death". However the specific recommendation on multiple birth siblings is important and relates to some compelling evidence from the United States³. This prospective, observational, cross-sectional and multi-centre study by Lindberg et al looked at the sibling or household contacts of all children under 10 years old that were examined for possible physical abuse. The contacts of those that were concluded to have been subject to physical abuse were then given the same imaging that the protocol determined for the index case. Of 134 sibling or household contacts, 16 were twin siblings of the index case. 56.3% of these had fractures on skeletal survey, none of which had clinical signs to direct the examiner towards imaging. Overall the authors found fractures in 11.9% of contacts, with rates decreasing with increasing age of the contacts. These findings are supported by a study by Lang et al4, who did a retrospective case-controlled study looking at multiple-birth children in whom at least one had experienced child maltreatment. Controls were singleton maltreated children matched for age, gestational age at birth and injury type. Out of 19 sets of multiple birth children, each child in the set had been abused in 10 sets. Particularly pertinent to our discussion is the finding that multiple birth children were significantly more likely than singleton children to have suffered fractures. Interestingly in sets where both children were maltreated, they usually shared the same injury. Both of these studies help us to understand the particular mention

of multiple birth siblings in this recommendation. It is not surprising that multiple-birth children are more likely to be abused than singletons when one considers the additional emotional and physical demands and fatigue placed on parents with multiple birth children, not to mention the increased likelihood that the children may have been born prematurely or have a disability when compared to singleton children.

In a different paper, the same authors looked at the yield of skeletal survey by age⁵, extending this up to 60 months of age, looking at index cases only. Usual practice in the US is as per the UK, that skeletal survey is advised in children below the age of 24 months. However the study found that children aged 24-36 months were receiving skeletal surveys as often as children less than 24 months, and with similar yields of around 10%. The authors made an interesting comparison of yields of abdominal and head CT scans done as routine in childhood trauma cases, where yields are cited as 6.3% and 2.5% respectively. The suggestion is made that the decision of whether to do a skeletal survey on children between the ages of 24-36 months, suspected to have been abused, is considered with regard to their development and language ability, and whether they would be able to articulate painful or traumatic experience or not. This is the principle behind not doing skeletal surveys in older children unless there is significant history or clinical findings, and given the yield in this study it certainly deserves careful thought.

The revised wording for Recommendations 15 and 18 provides welcome clarifications on specific expectations for staff in performing the skeletal survey and accompanying the patient. The addition of social worker into those considered appropriate accompanying persons is useful in terms of hospital staffing, however, practically speaking when considering the responsibilities of person accompanying children for such procedures (which are listed below the recommendation), some social workers may feel these go beyond their scope of practice.

Rewording of Recommendation 44 makes it a little less prescriptive, and Appendix I provides a clear and detailed algorithm for when to consider follow-up MRI head scans.

Overall, the revised guidance continues to be a useful, clear and easy to follow document. Rewording of the recommendation regarding sibling skeletal surveys provides for greater clinical discretion, and other reworded recommendations give clarity. The potential impact on services from increased numbers of skeletal surveys is likely to be less than under the original publication. As previously, a meeting with your local radiology department to discuss any necessary revisions to current procedures would seem advisable.

It will be interesting to observe for any change in practice in terms of the numbers of skeletal surveys requested in both index cases and contacts and the yield from these over the next few years.

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References

- The radiological investigation of suspected physical abuse in children. The Royal College of Radiologists. The Royal College of Radiologists & The Society & College of Radiographers. October 2017
- 2. BACCH News. The quarterly newsletter of the British Association for Community Child Health. Rowena Yates. December 2017, page 18-19.
- 3. Lindberg DM, Shapiro RA, Laskey AL et al. Prevalence of abusive injuries in siblings and household contacts of physically abused children. Paediatrics 2012: 130(2): 193-201.
- Lang CA, Cox MJ, Flores G. Maltreatment in multiple birth children. Child Abuse Negl 2013; 37(12): 1109-1113.
- Lindberg DM, Berger RP, Reynolds MS et al. Yield of skeletal survey by age in children referred to abuse specialists. J Pediatr 2014; 164(6): 1268-1273