

MCST 604 Assignment 6.1 – Appraise & Apply



Case:

JR is a 7-year-old male with a history of seizures that began at age 2 years. He was as then prescribed valproic acid (an anti-seizure medication) which he continues to take at steadily increasing doses due to recurrent seizures. Since that time seizures have decreased in severity and duration but continue to occur several times per month. JR experiences daytime somnolence which is negatively impacting his school performance.

He is brought in for an evaluation by his mother because she is concerned about possible adverse effects of increasingly high doses of valproic acid and was not comfortable with her sister-in-law 's advice that she should purchase some CBD oil online to see if it will help. She wants to know what you think about CBD oil for seizures.


Other than his seizures, JR's past medical history is significant only for recurrent ear infections during first 2 years.

Medications:

- Valproic acid
- Multivitamin

Allergies: Amoxicillin

Appraise (20 points)

|  | 2. Appraise |
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| <p>Directions:</p> <ol style="list-style-type: none">1. You will appraise the following systematic review, using the CASP Systematic Review Standard Checklist: Elliot J, et al. Cannabis-based products for pediatric epilepsy: An updated systematic review. Eur J Epilepsy. 2020; (75):18-22.2. Select the 'Yes', 'No' or 'Can't tell' box in response to the questions. | |

3. Record the reasons for your answers in the Response section next to each question.

Section A: Is the basic study design **valid** for a randomized controlled trial?

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| <p>7. Did the study address a clearly focused research question?</p> <p>CONSIDER: Is the research question 'focused' in terms of:</p> <ul style="list-style-type: none"> • Population studied • Intervention given • Outcomes measured? | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't Tell</p> <p>Response: The authors wanted an up to date study on the benefits and harms of cannabis based products for children with epilepsy. The outcomes that were measured included seizure freedom, quality of life, seizure frequency and death.</p> |
| <p>8. Did the authors look at the right type of papers?</p> <p>CONSIDER: The 'best sort of studies' would:</p> <ul style="list-style-type: none"> • Address the review's question • Have an appropriate study design (Usually RCTs for papers evaluating therapy questions) | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't Tell</p> <p>Response: The authors studied 4 randomized control trials (RCT's). The study did address the review question about benefits and harm of cannabis.</p> |

Section B: Is the study worth continuing?

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| <p>9. Do you think all the important, relevant studies were included?</p> <p>HINT:</p> <ul style="list-style-type: none"> • Which bibliographic databases were used? • Follow up from reference lists • Personal contact with experts • Unpublished as well as published studies • Non-English language papers | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't Tell</p> <p>Response: The authors used RCT's and non- randomized studies from multiple databases including ones that were mentioned in this course. There is more information used that is included in the Appendix Pubmed was the only one that I didn't see used.</p> |
| <p>10. Did the review's authors do enough to assess the quality of the studies?</p> <p>HINT:</p> <ul style="list-style-type: none"> • The authors need to consider the rigor of the studies they have identified. Lack of rigor may affect the studies' results | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't Tell</p> <p>Response: The authors reviewed multiple publications, deleted those that were duplicates, excluded records and assessed the remaining for eligibility. They started with 904 sources and narrowed it down to 123 that were included in their study.</p> |
| <p>11. If the results of the review were combined, was it reasonable to do so?</p> | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't Tell</p> <p>Response: The authors reviewed each outcome, combined the data</p> |

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| <p>CONSIDER:</p> <ul style="list-style-type: none"> • If results were similar from study to study • If results of all included studies are clearly displayed • If results of different studies are similar • If reasons for any variations in results are discussed | <p>from each study and published the median results of each outcome. They separated the results from the randomized and non-randomized studies.</p> |
| <p>Section C: What are the results?</p> | |
| <p>12. What are the overall results of the study?</p> <p>CONSIDER:</p> <ul style="list-style-type: none"> • If you are clear about the review’s ‘bottom line’ results? • What are the results (if numerically appropriate)? | <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can’t Tell</p> <p>Response: (Question didn’t call for a checked answer)</p> <p>Thirty-five studies, including four RCTs, have assessed the benefits and harms of cannabis-based products in pediatric epilepsy (12 since April 2018). All involved cannabis-based products as adjunctive treatment, and most involved cannabidiol. In the RCTs, there was no statistically significant difference between cannabidiol and placebo for seizure freedom (relative risk 6.77, 95 % confidence interval [CI] 0.36–128.38), quality of life (mean difference [MD] 0.6, 95 %CI –2.6 to 3.9), or sleep disruption (MD –0.3, 95 %CI –0.8 to 0.2). Data from both RCTs and NRS suggest that cannabidiol reduces seizure frequency and increases treatment response; however, there is an increased risk of gastrointestinal adverse events</p> |
| <p>13. How precise are the results?</p> <p>HINT:</p> <ul style="list-style-type: none"> • Look at the confidence intervals, if given | <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can’t Tell</p> <p>Response: :(Question didn’t call for a checked answer)</p> <p>The results varied by study type. I noticed that the confidence intervals reflected N/a on the non-randomized side of the study resources. The intervals also varied by outcome.</p> |
| <p>D. Will the results help my patients?</p> | |
| <p>14. Can the results be applied to your patient?</p> <p>CONSIDER:</p> <ul style="list-style-type: none"> • Are the study participants similar to the patient in your care? • Are the outcomes important to your patient? • Are there any outcomes you would have wanted information on that have not been studied or reported? • Are there any limitations of the study that would affect your decision? | <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Can’t Tell</p> <p>Response: I selected can’t tell because the ages of the patients are not present in the study. The patient in the case is 7 and the pediatric range is 0-18 years of age. The outcomes would be important to the patient, and I would still recommend since the study was for pediatric patients. I would recommend starting off very low and slow. One concern for the patient would be somnolence. Out of the 171 patients studied only one had sleep apnea.</p> |
| <p>15. Were all important outcomes considered?</p> | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can’t Tell</p> |

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| <p>HINT:</p> <ul style="list-style-type: none"> Consider whether there is other information you would have like to have seen | <p>Response: The study reviewed reverse reactions that the patients could encounter such as impaired sleep, diarrhea, and death. What I would have liked to see was the ages of the patients in the study.</p> |
| <p>16. Do the benefits of the experimental intervention (cannabis) outweigh the potential harm it might cause to the patient?</p> <p>CONSIDER:</p> <ul style="list-style-type: none"> Has your patient tried all traditional treatment options before trying this therapy? What benefit does this experimental intervention have over traditional therapy options? What was the size of the intervention or treatment effect? Were harms or unintended effects reported for each study group? | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't Tell</p> <p>Response: The benefits outweighed the potential harm. According to the findings the death rate was very low and the only side effects that may have cause for alarm would be gastrointestinal. The study showed that patients had a reduction in seizures compared to the placebo or traditional methods of treatment.</p> |
| <p>Appraisal</p> | |
| <p>17. APPRAISAL SUMMARY: Record 3 key points from your critical appraisal in this box. What is your conclusion about the systematic review?</p> <ol style="list-style-type: none"> The authors reviewed various studies from multiple databases and eliminated those that were duplicates or not valuable to the current study. They used randomized and non-randomized research resources to evaluate and compared both. The research stayed in line with the purpose of the study to derive at the conclusion of whether cannabis was a viable option for children with epilepsy. | |

Apply (10 points)

Directions: Answer the following questions. Please cite any additional sources used.



Apply (EBM Step 5)

Directions:

Based on the research you reviewed about cannabinoids and epilepsy in children, explain the results of the systematic review you appraised in part one of this assignment to the patient's mother in layman's terms and educate the patient's mother about the potential role for cannabinoids in managing epilepsy in 5 – 10 sentences. When educating this caregiver, consider what the evidence shows and what the evidence does not show. Consider both the quality and quantity of the available evidence (i.e., overall, how robust is the evidence for cannabinoids in the management of seizures in children?). Cite any additional resources used.

The research that was conducted shows that cannabis is effective in reducing seizures. The study was conducted comparing pediatric patients who have epilepsy and use cannabis against the same type of patient that doesn't use it. The results were favorable. I would like to alert you of the potential side effects of vomiting and diarrhea but according to the study the risks were low. The study didn't include the age range of the participants but did state that the patients fell into the pediatric category. I know that one of your concerns is JR experiencing sleepiness during the day. Out of 171 patients that were studied only one had an issue with sleep. Based upon the results of the study I would recommend usage of CBD but to start off low and document the results before increasing the dosage.

