

Bleeding Disorder Collaborative
April 13, 2016
Meeting Minutes

7:01 a.m. **Bleeding Disorder Collaborative for Care (BDC) Convenes**

Members Present: Rebecca Kruse-Jarres, Dana Matthews, Donna Sullivan, Stephanie Simpson, Lisa Humphrey, Dan Lessler, Heidi Forrester

Members Absent: Judy Felgenhauer, Mike Recht, Michael Birmingham, Amanda Blair

Guests: Ryan Pistoresi, Sarah Roberge

7:02 a.m. Rebecca introduces Sarah Roberge who has been identified as the Research Coordinator for the Bleeding Disorder Collaborative. Sarah will be assisting Rebecca on finalizing the protocol for next week's meeting.

7:03 a.m. **Review Public Comments for Bleeding Disorder Collaborative Research Proposal and Medicaid Evidence-based Decisions Project (MED) Research Proposal**

Ryan reviews all public comments received, beginning with public comments that have been reviewed during previous webinars. Ryan begins with the first comment from Joan Zerzan of WA Department of Health (DOH) on Body Mass Index (BMI) criteria for children and adolescents. Comment was reviewed at 3/23 webinar and Mike Recht agreed to consult with a pediatric nutritionist. The second comment from Joan Zerzan provided two names of registered dietitians from WA DOH. However, Mike had already contacted and discussed BMI criteria with Dr. Natasha Polensek from Oregon Health & Science University (OHSU). John Sandstrom of Baxalta provided 5 comments on Table 1 of the MED research proposal. This comment was reviewed during the 3/31 webinar and members agreed with the need to differentiate between regular and extended half-life products. Members suggested removing the table and to simply list "plasma derived, recombinant, recombinant extended half-life, and recombinant porcine".

7:09 a.m. Dana raises concern about how public views MED research proposal due to comments received on the draft proposal. Dana suggests clarity is needed for the public to understand the purpose of the draft proposal and the difference between the MED report and the BDC research. Dana expresses concern over the response to the BMI criteria. Mike is absent and will respond to Dana's comment during the next meeting.

7:14 a.m. Members review comments from Briana Buckley of Biogen. First comment is on interventions listed in Table 1 and that the search may not include newer therapies, especially prolonged half-life products. Table 1 is being removed which addresses this comment. Members express concern over the purpose of the MED proposal. Ryan provides clarity on the purpose of the MED research

proposal in relation to the mandated legislative report. Stephanie explains the language from the directive of the legislature. Rebecca says that the BDC should respond stating they understand there is a limited amount of research on extended half-life products and will consider this with the report.

- 7:30 a.m. Members review second comment from Briana Buckley on relevance of treatment regimens. Ryan explains that the rationale for this type of search is due to limitations in the budget and timeline. Rebecca agrees that this is an adequate response. Members review third comment from Briana Buckley on outcomes included in the search. Ryan explains that the reasons for the broad nature of the key questions is that this is typical for MED reports and that remaining broad means capturing more information rather than narrowing the scope. Dana feels that the same response to the last comment is adequate here, that there are limitations with the budget and timeline.
- 7:43 a.m. Members review fourth comment from Briana Buckley on search strategy. Ryan explains that the rationale for this type of search is due to limitations in the budget and timeline. Dana says that providers are able to assess and evaluate primary literature in the context of treating patients. Members agree.
- 7:45 a.m. Members review fifth comment on Pharmacokinetics (PK) protocol. Rebecca agrees with comment that more time points should be added for hemophilia B extended half-life. Rebecca will incorporate this change into the updated draft proposal. Members review sixth comment on criteria for local lab selection. Rebecca agrees with comment that labs selection criteria will need to include specific details on appropriate use of reagents.
- 7:49 a.m. **Update Bleeding Disorder Collaborative Research Proposal**
- Rebecca says that she and Sarah will work on updating the research proposal and case report form. Ryan updates document to include accepted recommendations from public comments by the BDC. Ryan will send updated draft to Rebecca. Stephanie requests time for someone to explain the final reports and deliverables of the BDC.
- 7:57 a.m. **Bleeding Disorder Collaborative for Care Adjourns**