

# Newborn Screening Advisory Committee

Wednesday, October 25, 2023  
9:00 am - 1:00 pm



# Role Call / Introductions

1. Name
2. Organization
3. Role
4. Physical Description (e.g. age, skin color, gender, hairstyle and hair color, clothes description, any distinctive accessories)\*

\*Please include a physical description of yourself for meeting participants who may be visually impaired. Share only those attributes you feel comfortable sharing. Thank you!

# Icebreaker



# Agenda

Time	Agenda Item
9:00a - 9:30a	<b>Welcome &amp; Roll Call</b> <ul style="list-style-type: none"><li>● Icebreaker</li><li>● Voting &amp; Non-Voting Members</li></ul>
9:30a - 10:00a	<b>Unfinished Business</b> <ul style="list-style-type: none"><li>● Updated Condition Nomination Form</li><li>● Updated Bylaws &amp; Vote</li><li>● Additional members determination</li></ul>
10:00a - 10:10a	<b>Vote on x-ALD</b> <ul style="list-style-type: none"><li>● Explanation of voting options</li><li>● Vote to recommend the addition of x-ALD to the Montana Newborn Screening panel</li><li>● Vote count</li></ul>
10:10a - 10:20a	<b>Break</b>

10:20a - 10:30a **Condition Nomination Process Review**

Agenda Continued

10:30a - 11:30a **Krabbe Presentation**

- Krabbe updates from Hunter's Hope Foundation, Duke University, and Mayo Clinic team

11:30a - 12:00p **Krabbe Discussion**

- Question & Answer with presenters
- Discussion on reconsideration of Krabbe

12:00p -  
12:10p **Break**

12:10p -  
12:30p **Newborn Screening Advisory Committee Next Steps**

- Prepare document outlining Advisory Committee's decision and rationale
- Send document to DPHHS Director for review
- Schedule next meeting

12:30p -  
12:50p **Public Comment Period**

# Public Comment Period (10 minutes)

- Moderator will announce comment period
- Use “raise hand” feature”
- Moderator will call your name
- Unmute yourself
- 2 minute max per comment
- Please email additional comments up to 1 hour after meeting ends to:  
[HHSNewbornAdvisoryCommittee@mt.gov](mailto:HHSNewbornAdvisoryCommittee@mt.gov)

# Ground Rules

- Mute
- Video
- Clarifying questions
- Avoid interrupting
- Avoid acronyms
- Use specific examples
- Focus on the collective interests and goals
- Additional meetings or communications may be scheduled
- Next steps assigned to ensure accountability
- Facilitators may call on attendees for input
- Safe space

# Voting

- Only voting members who have submitted their COI statement can vote on x-ALD
- Quorum = simple majority



# Voting Members with COI

- Dr. Abe Elias
- Dr. Allison Young
- Amanda Osborne
- Jennifer Banna
- Marion Rudek
- Miranda Prevel
- Sarah Sullivan
- Shelly Eagen

# Non-Voting Members

- Amber Bell
- Crystal Fortune
- Jeanne Lee
- Jacqueline Isaly
- Deborah Gibson
- Margaret Cook-Shimanek

# Unfinished Business

# Updated Condition Nomination Form

- Review changes to [form](#)
- Once changes are approved, the updated form will be posted to the public website
  - Will be a fillable PDF now

# Updated Bylaws

- Review changes to [Bylaws](#)
- Vote
  - Verbal for in-person voting members
  - Survey link in chat for online voting members

# Additional Committee Members Determination

- Recommendation was brought forward in last meeting
- State determined it is not possible to add members with the current bill wording

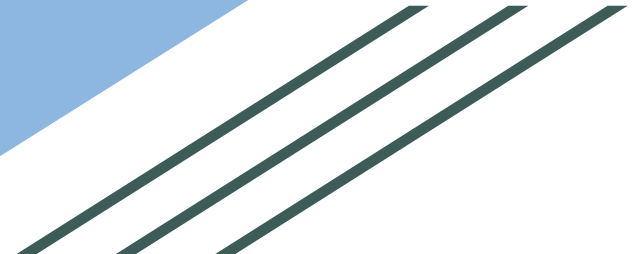
# External Communications

- Going forward - will hide guest list on calendar invites
- Establish process for advocates / public to contact Advisory Committee
  - Direct all to NBS AC email
    - Will add communications to unfinished business in future meetings
  - If sharing information for committee to review, needs to be presented at public comment

Vote on x-ALD



# Quorum Confirmation



# Voting Considerations

- Voting members only
- Voting Options:
  - Recommend
  - Do not recommend
  - Do not have enough information to make a decision at this time

**“Do not have enough information to make a decision at this time”**

**What does this mean?**

Your final decision depends on specific information that you know is coming. The conversation is expected to continue at the next / upcoming meeting.

# Montana NBS Advisory Committee: Voting Members

- Dr. Abe Elias
- Dr. Allison Young
- Amanda Osborne
- Jennifer Banna
- Marion Rudek
- Miranda McCabe
- Sarah Sullivan
- Shelly Eagen
- Kotie Dunmire

## Selection Criteria

Selection Criteria	True	Unsure	No
1. It can be identified at a period of time (24 to 48 hours after birth) at which it would not ordinarily be clinically detected.	X		
2. A test with appropriate sensitivity and specificity is available.	X		
3. There is a significant risk of illness, disability, or death if babies are not treated promptly (within the recommended time frame for the condition).	X		
4. Effective treatment is available and access to follow-up care and counseling is generally available.	X	Some concerns w/ availability (transplant not avail. In MT)	
5. There are demonstrated benefits of early detection, timely intervention, and efficacious treatment.	X		
6. The benefits to babies and to society outweigh the risks and burdens of screening and treatment	X		

## Selection Criteria (Continued)

	True	Unsure	No
7. There are minimal financial impacts on the family.	X		
8. There is a public health benefit to conducting the test.	X		
9. There exist responsible parties who will follow up with families and implement necessary interventions.	X		
10. The condition's case definition and spectrum are well described.	X - but remember it is a spectrum		
11. FOR LAB USE ONLY - The public health laboratory can support the testing resources and expertise necessary to provide accurate and timely results.	X		

# X-ALD Cost Analysis

- Adding x-ALD will increase NBS fee
  - Referral to WSLH: \$5/sample
- Either in house or sent out will need to be determined

# Vote on x-ALD

- Verbal for in-person voting members
- Survey link in chat for online voting members



# x-ALD Vote Count

**10 Minute Break**

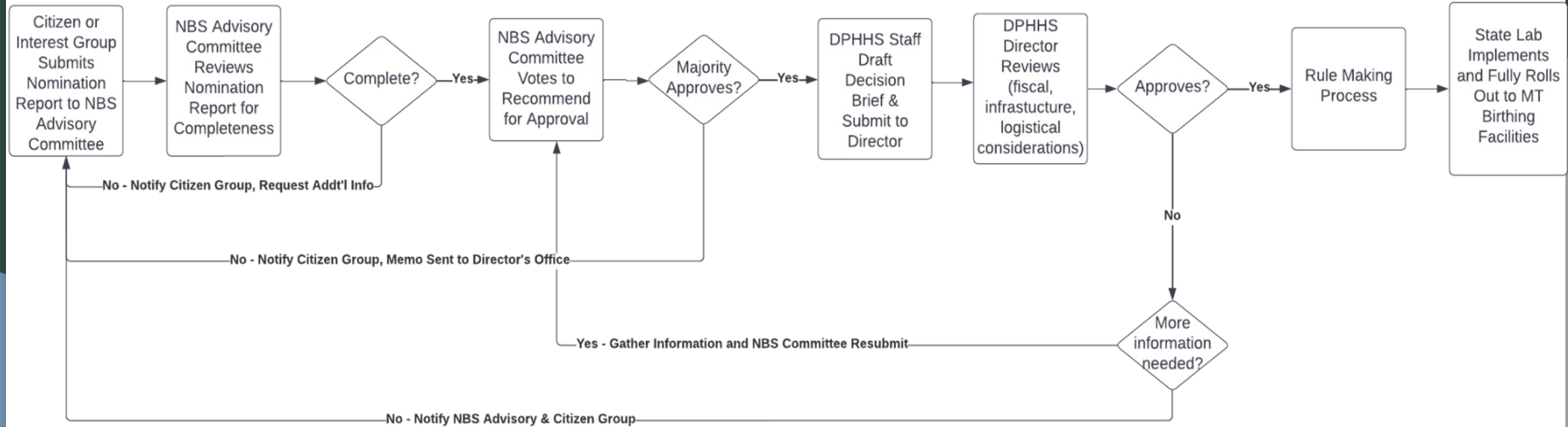


## Nomination Process Procedures

Activity	Timeline	Next Steps
1. Nomination packet is sent to NBS Program joint email: <a href="mailto:HHSNewbornAdvisoryCommittee@mt.gov">HHSNewbornAdvisoryCommittee@mt.gov</a>	48 hours	Notify the sender that the packet was received.
2. CSHS & Lab (and potentially Chair and Vice Chair) decide if the nomination packet is complete. Additional information may be requested.	2 weeks	Notify the sender that the packet was complete / incomplete.
3. Send completed nomination packet to full Advisory Committee for review.	1 month prior to meeting where it will be reviewed*	Put the nominated condition on the next available meeting agenda.
4. Designated person (or Chair) leads the Advisory Committee through the nomination packet during the meeting. Additional information will be presented from SME, Lab, and Family Story as appropriate.	X number of meetings*	Vote on the nominated condition in a Committee meeting once the process is complete.
5. Hold vote for nominated condition at Committee Meeting	1 week	Send report to DPHHS Director for review

\*Depends on the number of conditions that are already in the queue to be reviewed.

# Nomination Flow Chart



# Krabbe Presentation

# Krabbe Discussion

# Next Steps

- Follow Up from this Meeting
  - Meeting materials will be shared
  - Public website will be updated
  - Decision memo packet will be drafted & sent to DPHHS Director
  - Director will make a decision & decision will be posted to website
- Next Meeting
  - Doodle Poll will be sent out to determine dates for Spring meeting
    - Will be virtual
    - April?
  - Will include Pompe nomination review

# Public Comment Period (10 minutes)

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# Follow Up & Thank You

Please email if you have any questions, comments, or need anything  
[HHSNewbornAdvisoryCommittee@mt.gov](mailto:HHSNewbornAdvisoryCommittee@mt.gov)