Readiness Tool Data



Limitations

- Just a reminder that these data are based on what 32 states submitted.
 - Most have not started to get ready to bring on these 3 conditions.
 - When we look at timing we typically only 1-5 states who have a start and stop date.



Pompe Overview

Where States Are at in Based on Readiness Tool Data – Phase 2

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■Completed ■Started ■Not Started ■NA

Pompe (n=33)

Describe and ensure adequate space for testing (n=30)

Develop adjusted workflow to accommodate new test (n=31)

Identify need for additional equipment and procure (n=31)

Identify/modify laboratory space; install equipment (n=31)

Calibrate equipment (n=31)

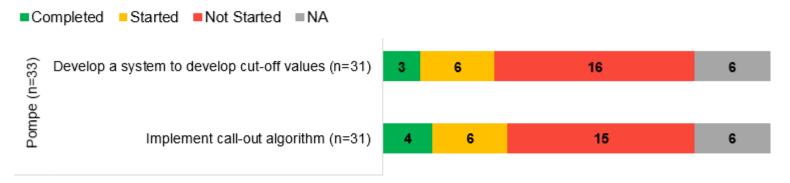




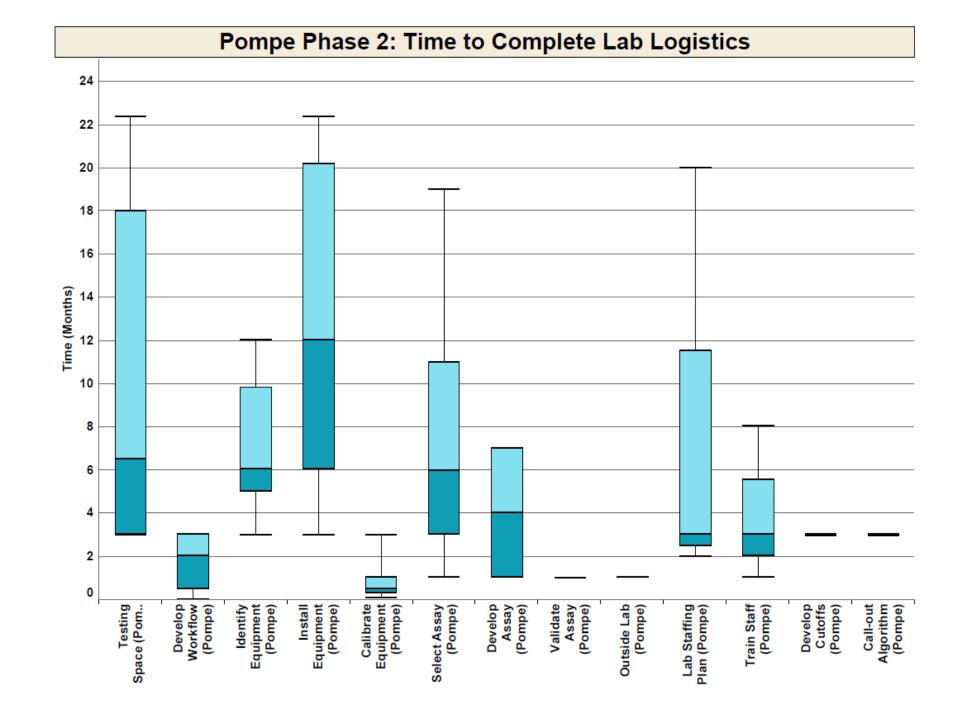
Phase 2: Lab Staffing Readiness



Phase 2: Lab Reporting Readiness







Phase 2: Follow-up Readiness

■Completed ■Started ■Not Started ■NA

Develop staffing plan and ensure adequate staffing (n=31)

Develop and gain buy-in on STFU protocols (n=31)

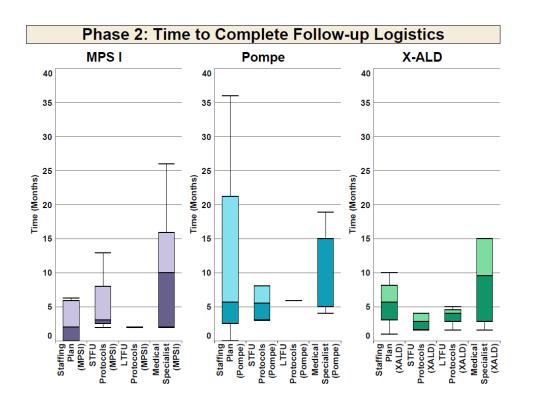
Develop and gain buy-in on LTFU protocols (n=31)

Identify medical specialists/treatment center; establish contract (n=30)



Pompe 40 35 30 25 Time (Months) 15 10 5 0 (Pompe) Staffing Plan STFU Protocols LTFU Protocols Medical Specialist (Pompe) (Pompe) (Pompe)

Time to Complete Follow-Up Logistics – Pompe





MPS I Overview

Where States Are at Based on Readiness Tool Data – Phase 2

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Phase 2: Lab Facility/Infrastructure Readiness

■Completed ■Started ■Not Started ■NA

Describe and ensure adequate space for testing (n=32)

Develop adjusted workflow to accommodate new test (n=31)

Identify need for additional equipment and procure (n=32)

Identify/modify laboratory space; install equipment (n=31)

Calibrate equipment (n=31)





Phase 2: Lab Staffing Readiness

■Completed ■Started ■Not Started ■NA

Develop staffing plan and ensure adequate staffing (n=32)

5 9 13 5

5

4

6

16

Train staff to begin testing for the new condition (n=31)

Phase 2: Lab Reporting Readiness

■Completed ■Started ■Not Started ■NA

Develop a system to develop cut-off values (n=30)

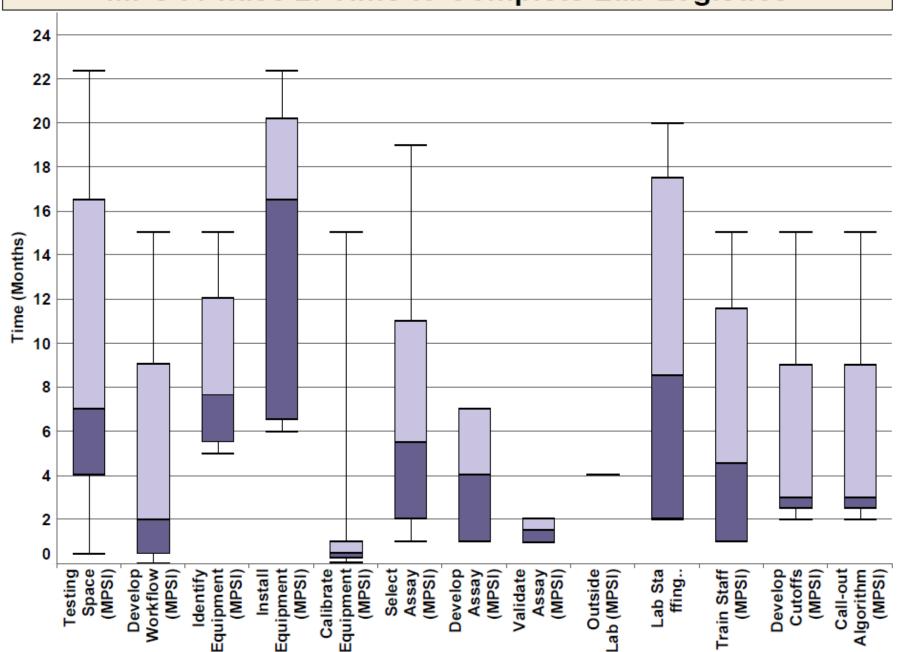
4 6 16 4

20

Implement call-out algorithm (n=32)



MPS I Phase 2: Time to Complete Lab Logistics



Phase 2: Follow-up Readiness

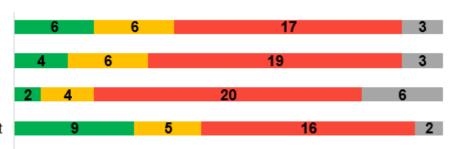
■Completed ■Started ■Not Started ■NA

Develop staffing plan and ensure adequate staffing

Develop and gain buy-in on STFU protocols

Develop and gain buy-in on LTFU protocols

Identify medical specialists/treatment center; establish contract

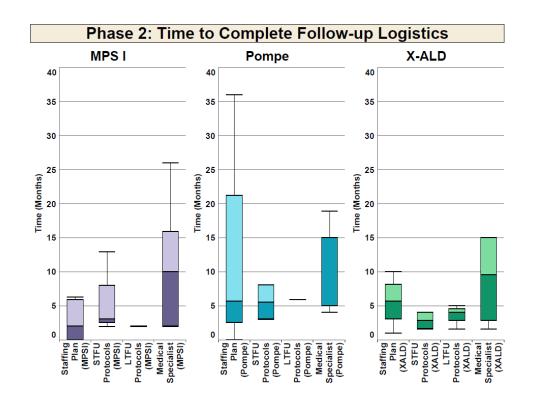






MPS I 40 35 30 25 Time (Months) 15 10 5 Staffing (MPSI) STFU Plan (MPSI) (MPSI) LTFU Protocols (MPSI) Specialist Protocols Medical

Time to Complete Follow-Up Logistics – MPS I





X-ALD Overview

Where States Are at Based on Readiness Tool Data – Phase 2

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Phase 2: Lab Facility/Infrastructure Readiness

■Completed Started Not Started NA

Describe and ensure adequate space for testing (n=29)

Develop adjusted workflow to accommodate new test (n=30)

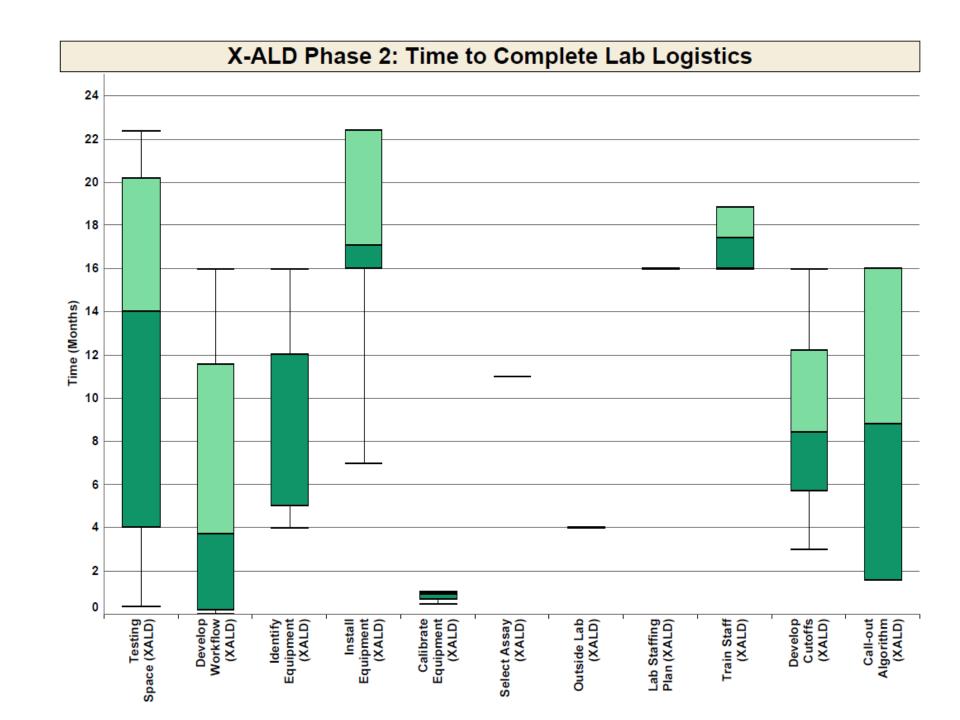
Identify need for additional equipment and procure (n=30)

Identify/modify laboratory space; install equipment (n=30)

Calibrate equipment (n=29)







Phase 2: Lab Staffing Readiness

■Completed ■Started ■Not Started ■NA

Develop staffing plan and ensure adequate staffing (n=30) 1 12 11 6

Train staff to begin testing for the new condition (n=30) 2 5 18 5

Phase 2: Lab Reporting Readiness

■Completed ■Started ■Not Started ■NA

Develop a system to develop cut-off values (n=30) 3 3 19 5 $\widehat{\mathbb{Q}}_{\times}^{\mathbb{Q}}$ Implement call-out algorithm (n=30) 2 3 21 4



Phase 2: Follow-up Readiness

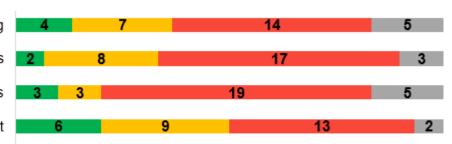
■Completed ■Started ■Not Started ■NA

Develop staffing plan and ensure adequate staffing

Develop and gain buy-in on STFU protocols

Develop and gain buy-in on LTFU protocols

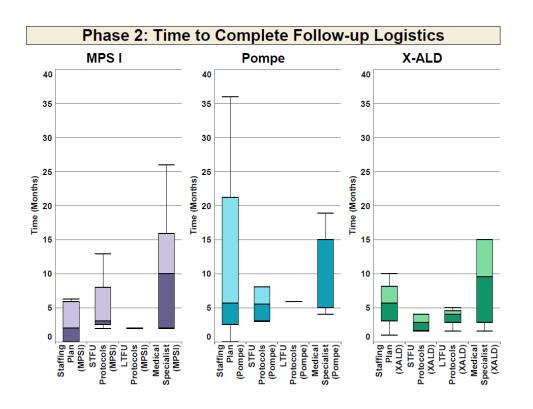
Identify medical specialists/treatment center; establish contract





X-ALD 40 35 30 25 Time (Months) 15 10 5 0 Staffing Plan (XALD) STFU Protocols Medical Specialist (XALD) (XALD) (XALD) LTFU Protocols

Time to Complete Follow-Up Logistics – X-ALD





Overview of Phase 1 - Legislation/Mandate Stage

Where States Are at Based on Readiness Tool Data

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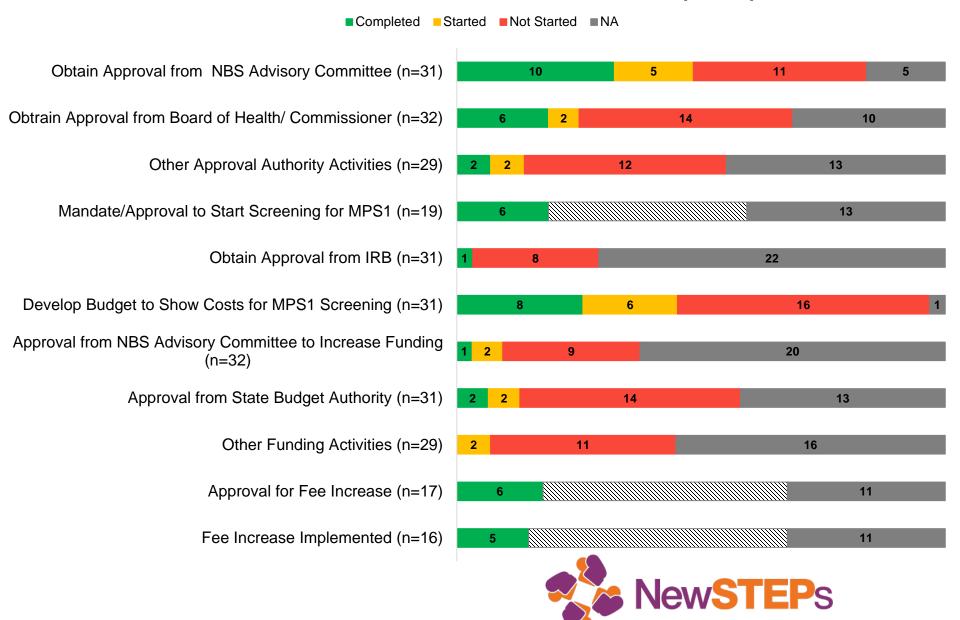
Status of Phase 1 Activities for Pompe (n=33)

■ Completed ■ Started ■ Not Started ■ NA

Obtain Approval from NBS Advisory Committee (n=32) 12 5 Obtrain Approval from Board of Health/ Commissioner (n=33) 11 Other Approval Authority Activities (n=29) 10 15 Mandate/Approval to Start Screening for Pompe (n=19) 13 Obtain Approval from IRB (n=31) Develop Budget to Show Costs for Pompe Screening (n=31) 10 14 Approval from NBS Advisory Committee to Increase Funding 2 10 20 (n=33)Approval from State Budget Authority (n=32) 2 1 17 12 Other Funding Activities (n=28) 10 Approval for Fee Increase (n=17) 12 Fee Increase Implemented (n=16) 12

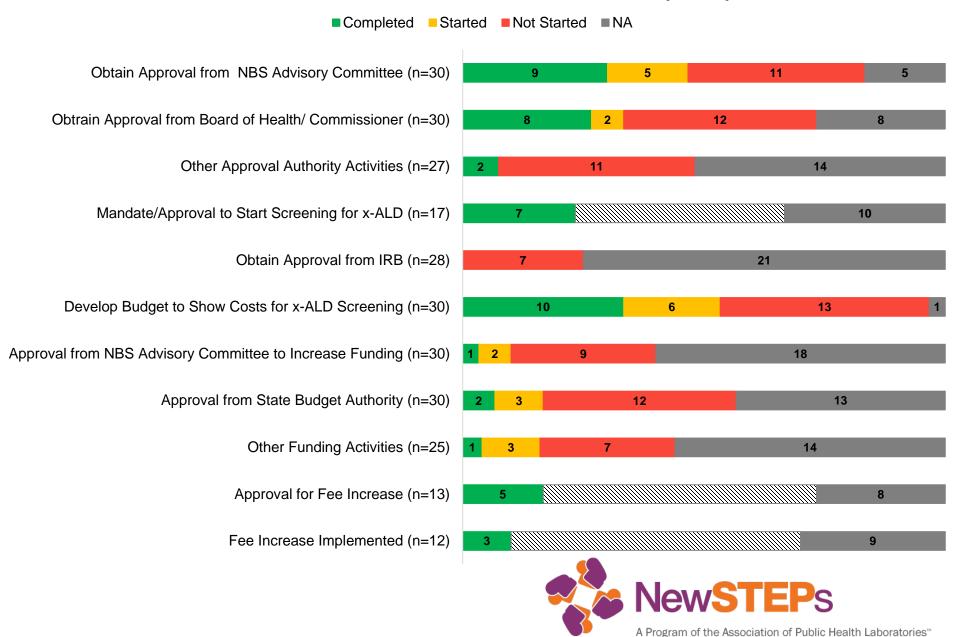


Status of Phase 1 Activities for MPS I (n=32)



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Status of Phase 1 Activities for x-ALD (n=30)



Phase One Approval/Authority To Screen MPS1 (12-36 months) 4 states Fee MPS1 (5 to 49 months) 4 states Total Phase 1 MPS1 (5 to 54 months) 4 states 2 states Approval/Authority To Screen Pompe (12 to 18 months) 4 states Fee Pompe (5 to 21 months) Total Phase 1 Pompe (5 to 21 months) 4 states 4 states Approval/Authority to Screen X-ALD (6 to 13 months) Fee X-ALD (5 to 21 months) 3 states

Total Phase 1 X-ALD (5 to 21 months)

2 states



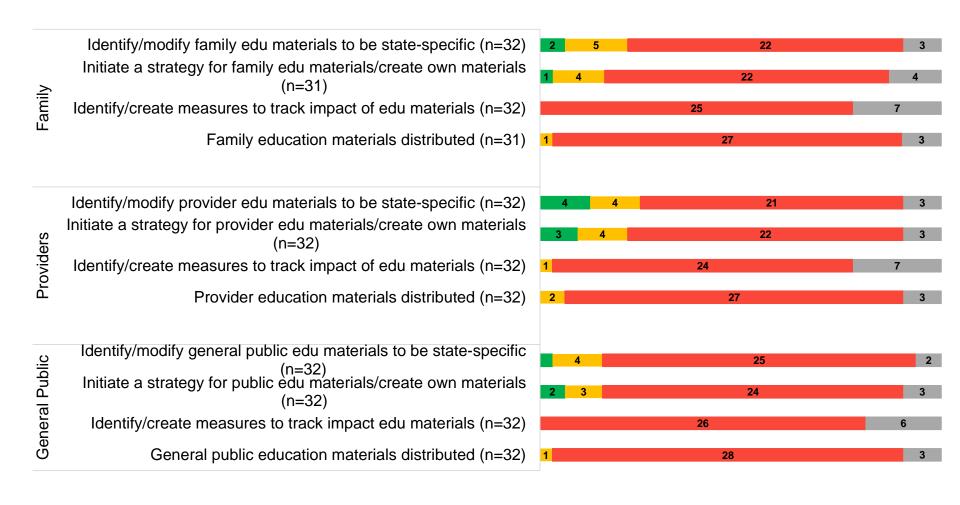
Overview of Phase 3 - Education Activities For the New Disorders

Where States Are at Based on Readiness Tool Data

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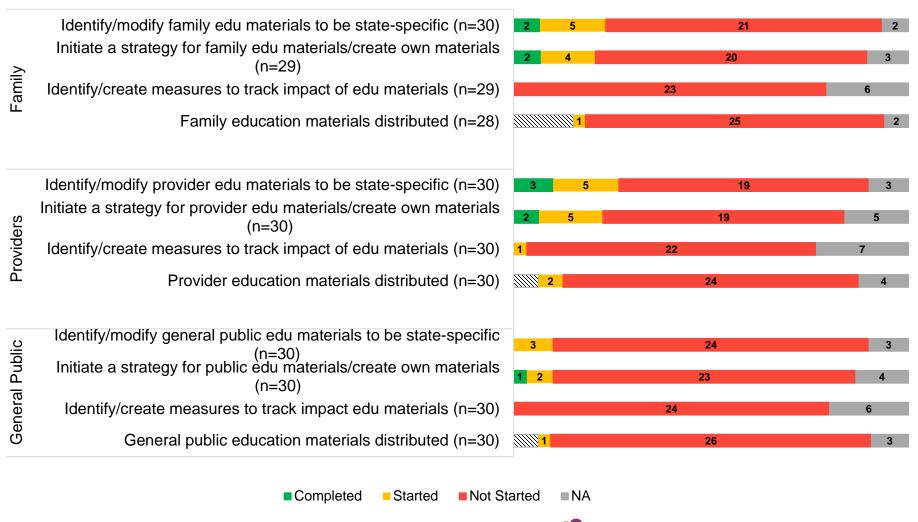
MPS I-Phase 3: Status of Education Activities (n=32)



Completed

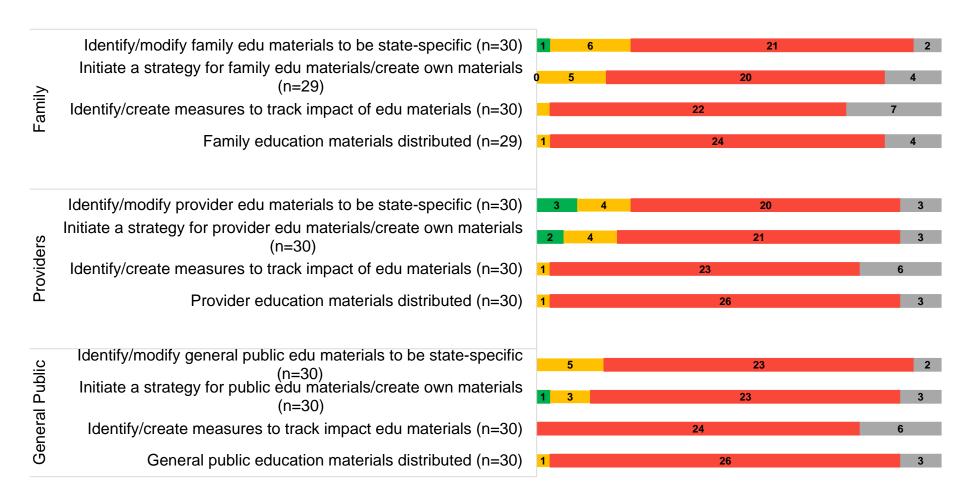


xALD-Phase 3: Status of Education Activities (n=30)





Pompe-Phase 3: Status of Education Activities (n=33)



■ Completed ■ Started ■ Not Started



Thank you to Our Village

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- Tony Steyermark
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