Hepatic Encephalopathy App for Liver Disease (HEALD)

A Novel Activity Monitoring Tool to Prevent Decompensation and Readmissions for Patients with End Stage Liver Disease

October 18th, 2019, Idea² Global Review Workshop



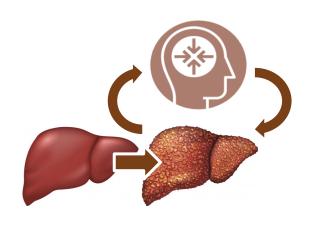
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Hepatic encephalopathy (HE) is a highly prevalent, disabling and costly problem in the US



- 600K people with cirrhosis in the US; 70% will develop HE
- >115K admissions per year due to HE, accounting for >\$7 billion healthcare charges



 HE is neurocognitive decline due to toxin accumulation in the brain as a result of liver dysfunction



- Cause of mortality and loss of functional independence
- Second most
 preventable cause for cirrhosis-related
 hospital admissions

The average HE patient journey – meet Joe, 48, who has cirrhosis from fatty liver disease



Seen in liver clinic with improved cognition

Lactulose decreased to twice a day



Self-stopped lactulose due to side effects (i.e. diarrhea)



Started to become more confused



Seen in clinic but due to severity (caught too late) sent to ED





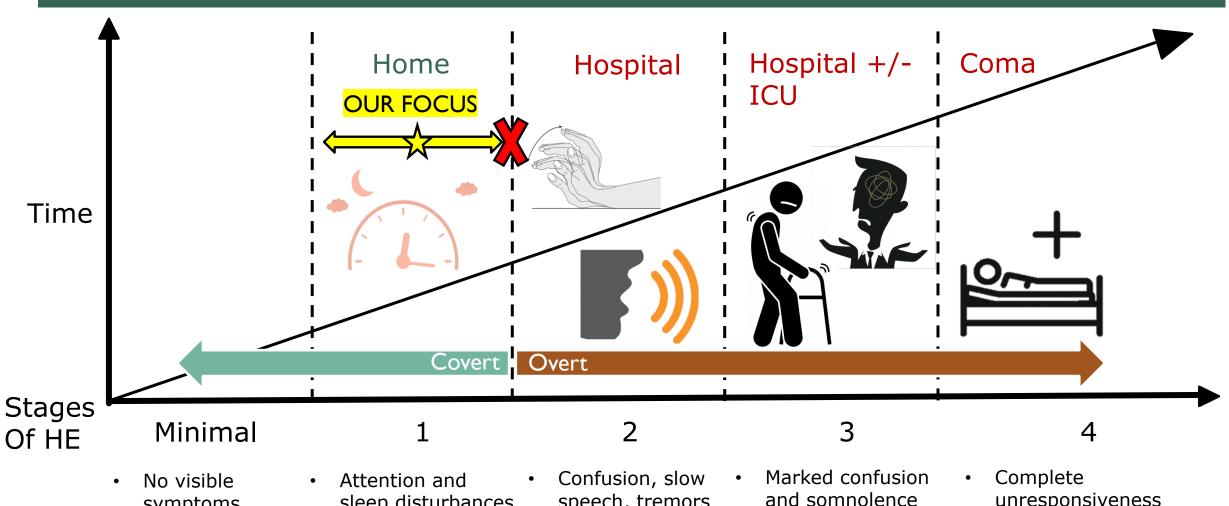
Hospitalized for 1 week for HE

Discharged with lactulose three times a day



- Hospitalized for 5 days for HE
- Discharged with lactulose 2-3 times a day and rifaximin

HE is often a slow and progressive condition, and can be reversible if caught and treated early



speech, tremors

sleep disturbances

symptoms

unresponsiveness

Prompt and appropriate outpatient medication titration can lead to decreased and/or shortened hospitalizations



- Lactulose promotes toxin elimination from the GI tract, but patient dislikes it due to diarrhea
- Can be titrated from once a day to up to once every hour to improve mental status
- Medication adherence is a big problem
- Finding the optimal lactulose dose is a dynamic process, but difficult for providers who see patients on average every few months
- Outpatient optimization and earlier detection can lead to fewer unnecessary hospitalizations and improve patient outcomes

Detecting/monitoring early HE progression is an untapped space

Current clinical practice for HE

- Relies on patient or family recognition of confusion (which can be highly variable)
- Once a patient presents to clinic, often the diagnosis is already delayed, leading to hospitalization

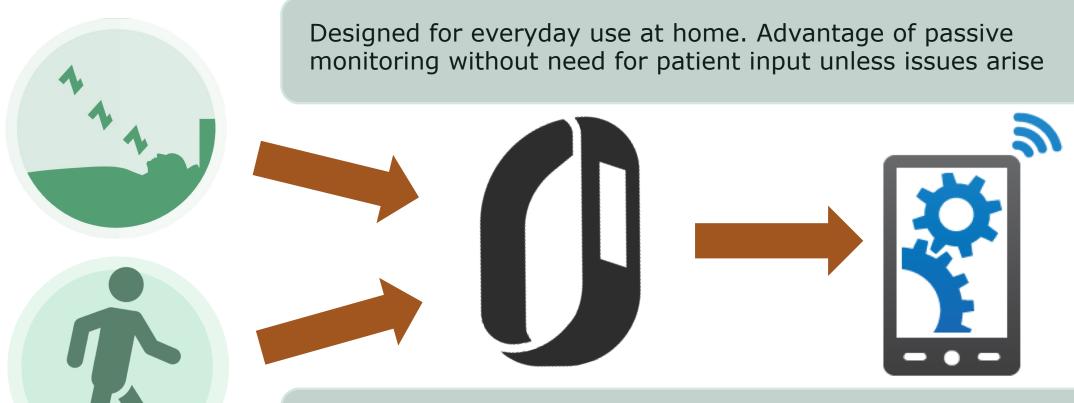
Diagnostics for early HE limited

- Not detected based on clinical symptoms
- Gold standard currently is psychometric testing (PHES)
- Time-intensive, needs supervision, mostly for research settings

Other budding tools

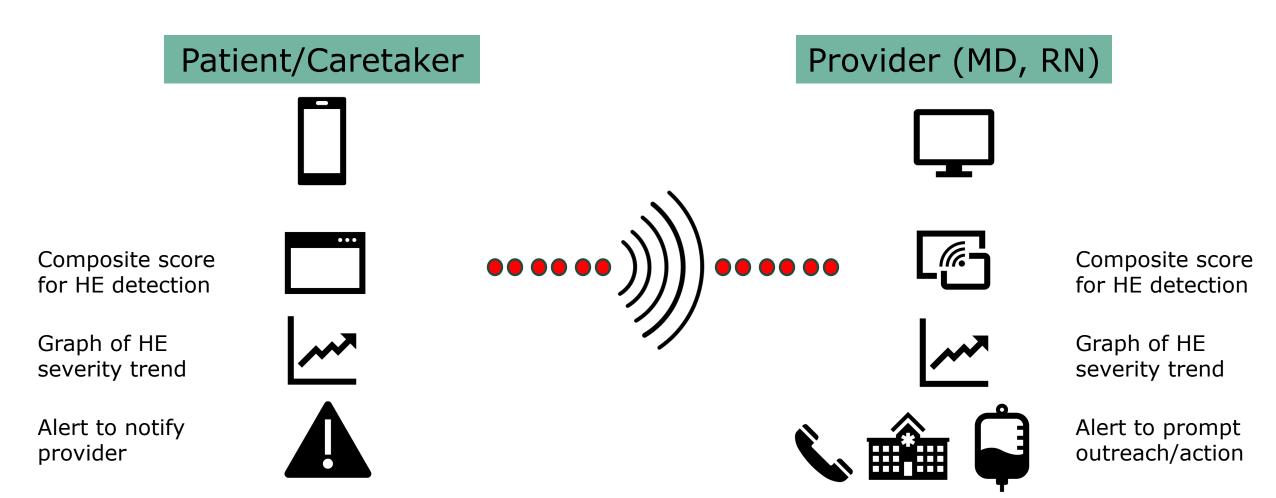
- EncephalApp, based on the Stroop test, validated to diagnose covert HE, but not for monitoring purposes
- Takes 15 20 min to complete, boring, difficult for patients to adhere routinely

We propose an app-linked wristwatch tool to detect and track progression of early HE at home for patients and/or caregivers



Tracks both quantity (sleep-wake and activity pattern, which is the earliest sign of HE onset) and quality of movements over time feeding into a machine-learning algorithm to predict progression

The app will allow patients to visualize trend of HE, and be able to trigger alerts to providers to enact change



Our solution addresses the unique challenges of managing HE in the outpatient setting

Promote patient adherence through passive monitoring

Emphasis on tracking of encephalopathy progression

Maintain patients' cognitive function and independence at home

Dynamic and timely outpatient medication adjustment

Individualized tailored therapy based on longitudinal data

Traction

Market research: Interviewed a dozen clinicians, who uniformly recognized unmet need, and thought idea was likely clinically impactful in improving outcomes and reducing readmissions

Intellectual Property: Discussed with MGH patent office Research/funding: Began IRB and grant seeking process

Team

Cofounders:

Thomas Wang, MD – clinician, expertise in research design/implementation and innovative technology Xing Li, MD, MBA – clinician, business and financial strategy

Current advisors:

Jason Tucker–Schwartz – strategy, idea² advisor Claire Zhao – machine learning, idea² advisors Raymond Chung – clinical, MGH liver department chair

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Thank you for listening!

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Update for IDEA²

Key Accomplishments:

- Pivoted approach from active to passive monitoring based on clinician interviews and stakeholder analysis, with focus on tracking sleep and activity data which is easily obtainable in currently available commercial wristwatch
- Validated unmet need and idea with clinicians

Next Steps:

- Reach out to computing media lab at MIT re: machine learning and data extraction
- Explore utility of Apple watch/Geneactiv wristband further
- Apply for further grants/research funding
- Submit preliminary IRB on seeking patient data for patients with Apple watches