LEADING MEDICINE: A TOWN HALL CONVERSATION WITH DR. MARC BOOM

Town Hall Conversation XXIX

Taking Stroke Care to the Next Level:

Patient-Centered Neurological Care

Today's Agenda

Discuss current challenges in stroke care

How should we meet this challenge?

How has virtual care changed our field?

The Baseline State:

A 58-year-old woman comes to the ER with dizziness and blurry vision.

Stroke Triage in 2022

Triage

RN intake

CT scan

ER provider: go or no-go stroke call

Stroke team evaluation

The Problem

Very human dependent

- How experienced and effective is the triage nurse?
- How busy are the providers?
- How experienced and effective is the radiologist?

Very environment dependent

- How crowded is the ER?
- How good are the resources at the facility?

Very patient dependent

- Risk factors?
- Able to tell their story?
- Did they come too late?

The Solution

Provide the highest-level expertise first

Triage

- ER provider: ***go or no-go stroke call***
  - ***Tendency to over-call ~30% of cases "just in case"***
  - ***Unfortunately misses ~20% of subtle cases***
  - ***Meaning Roughly half of all calls are wrong***

Stroke team evaluation

But resources are limited so we need...

An infinitely intelligent,

Inexpensive,

Never tired,

Always ready assistant who is a

Good listener

And even better observer.

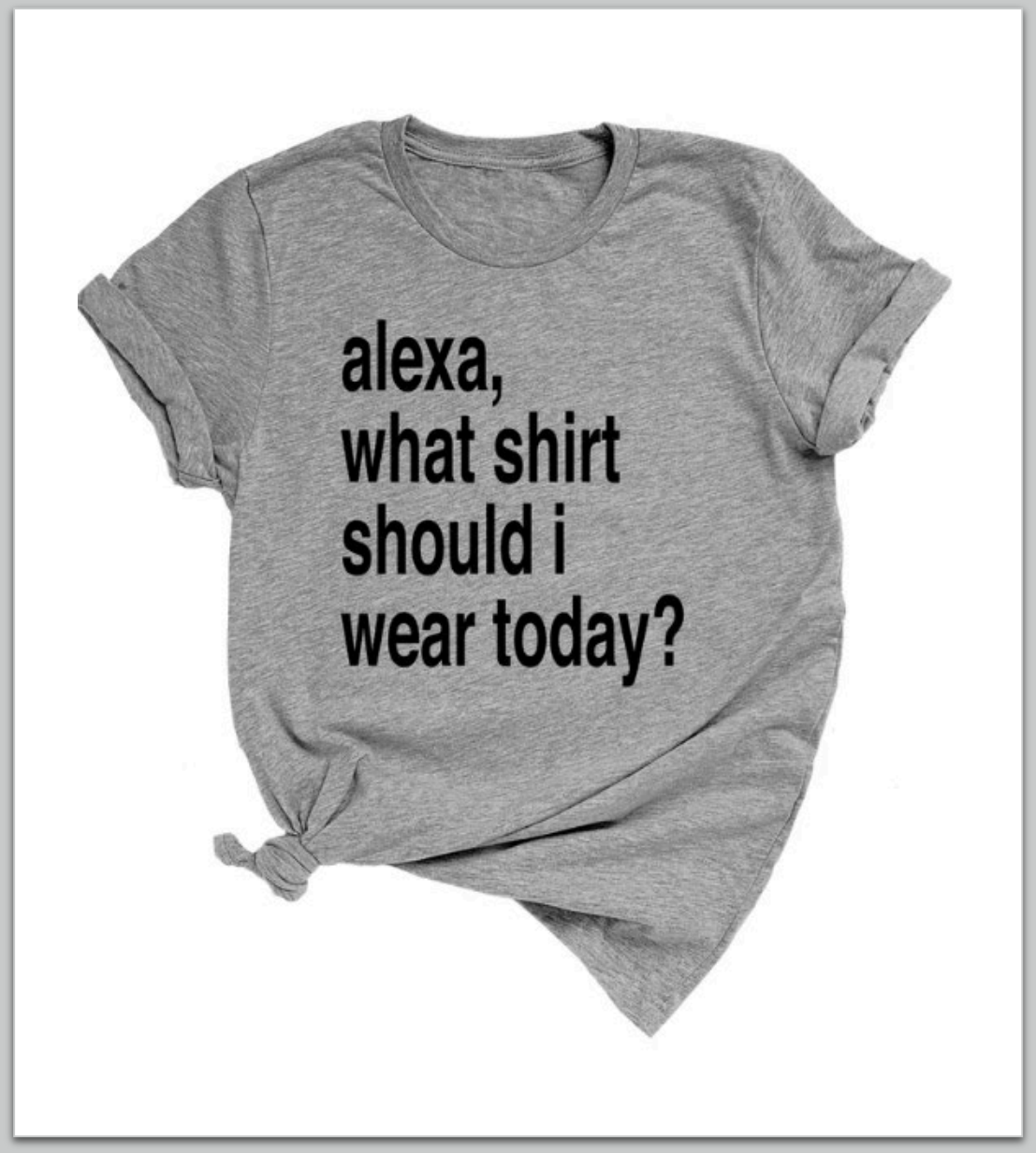
We need a...

Stroke “Alexa”

Stroke App

Development of a Stroke App

- Always available, personal digital assistant who can answer one question:



Development of a Stroke App

- Always available, personal digital assistant who can answer one question:

Is this patient having a stroke?

Development of a Stroke App

Data Rich Inputs:

Face

Speech

Imaging

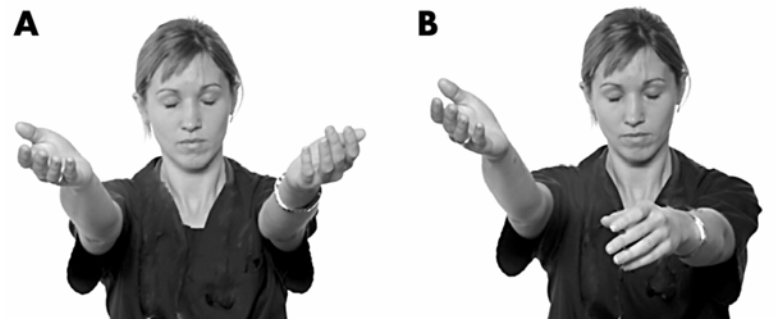
Output:

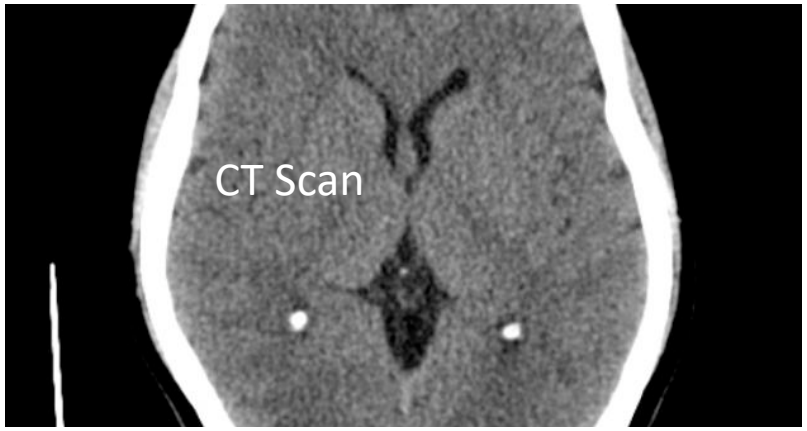
Is this patient having a stroke?

SORT Study

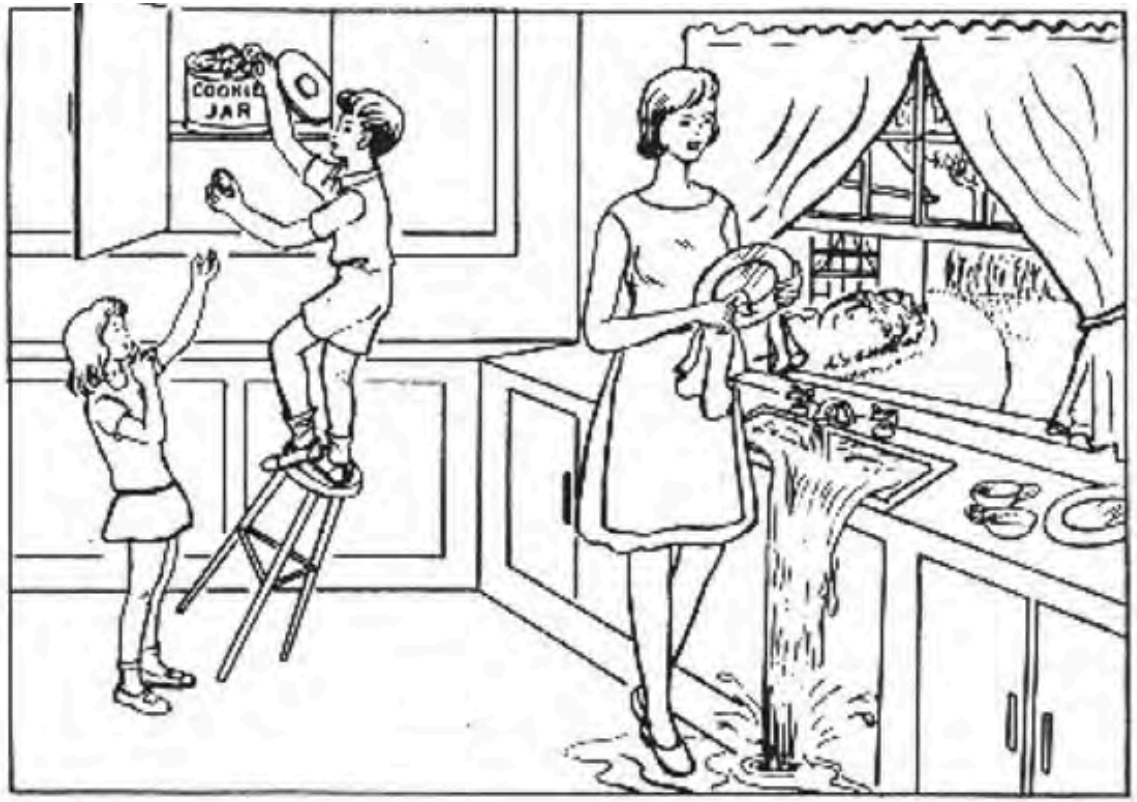
- Used an iPhone X
  - Records patient facial movements describing a picture
  - Voice during spontaneous speech and after a prompt
- Only additional inputs are the ABCs:
  - Age, blood pressure, “chief complaint”
- Total time for interaction less than 5 mins and designed to seamlessly integrate into EMS or RN initial triage

Arm test

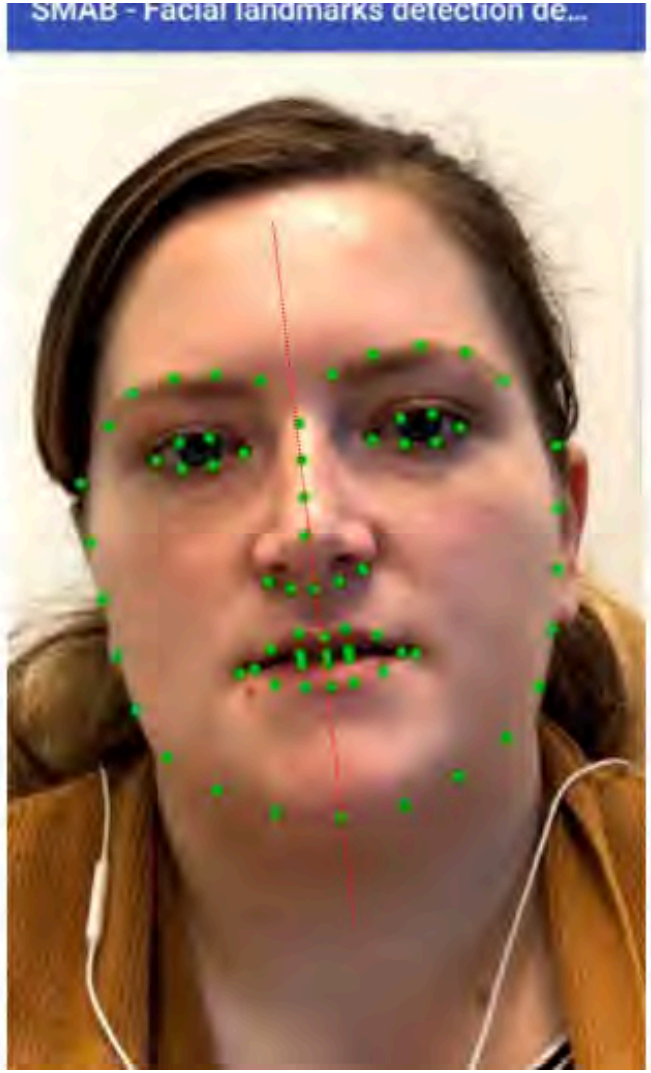




Development of a Stroke App



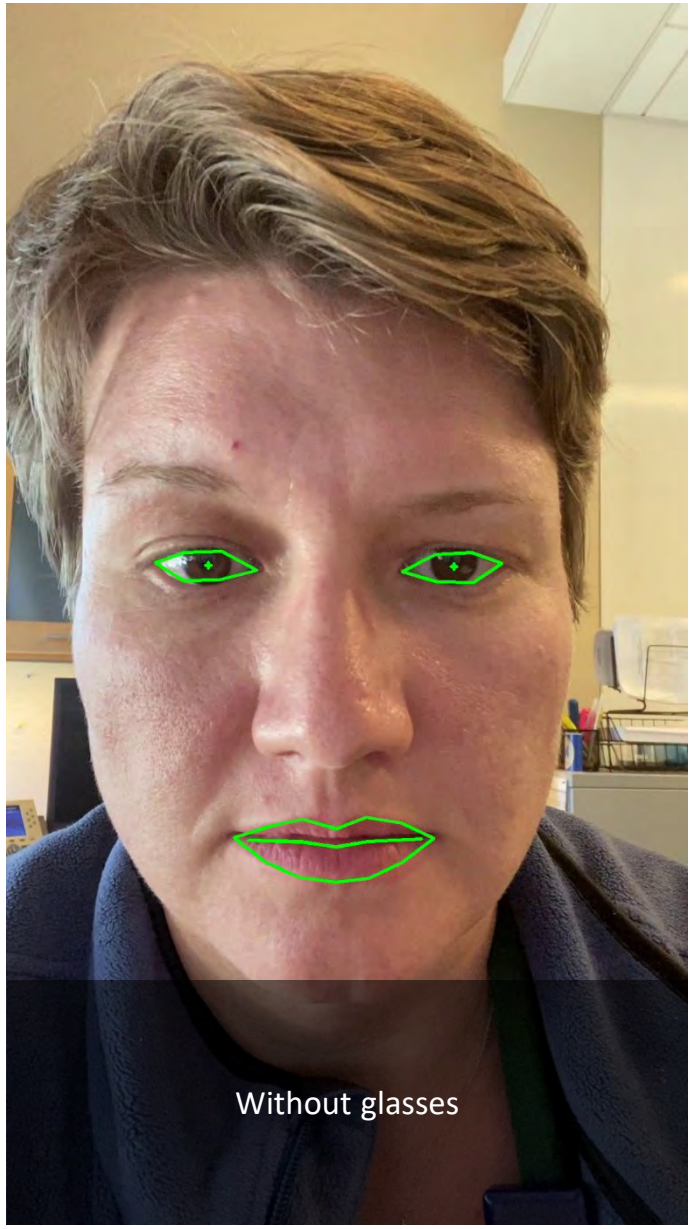
Tell me what is going on?

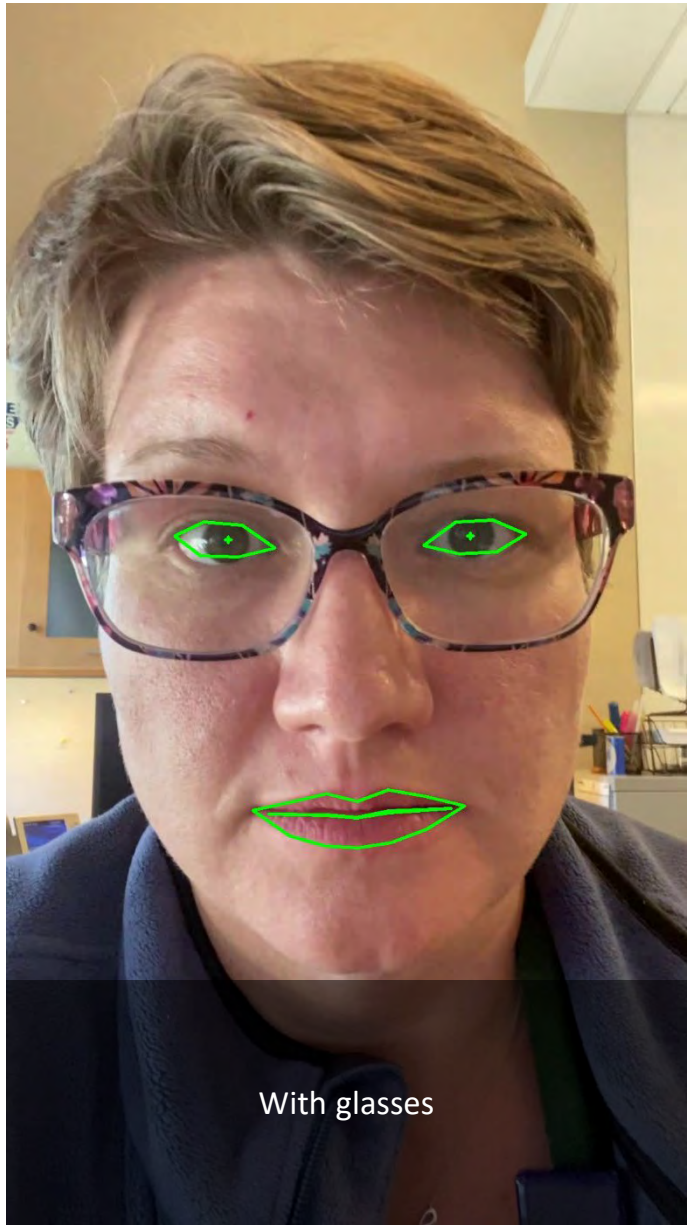


Eye tracking

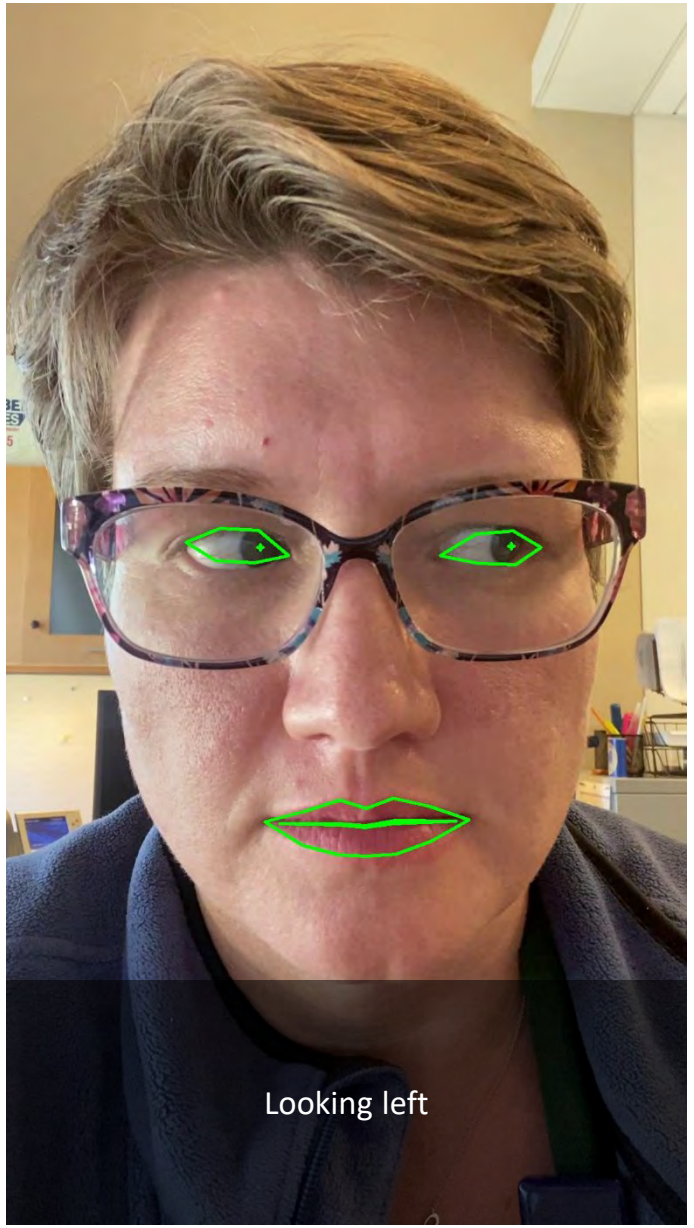
“Look to the left then to the right”

58-year-old woman with dizziness and blurry vision





58-year-old woman with dizziness and blurry vision

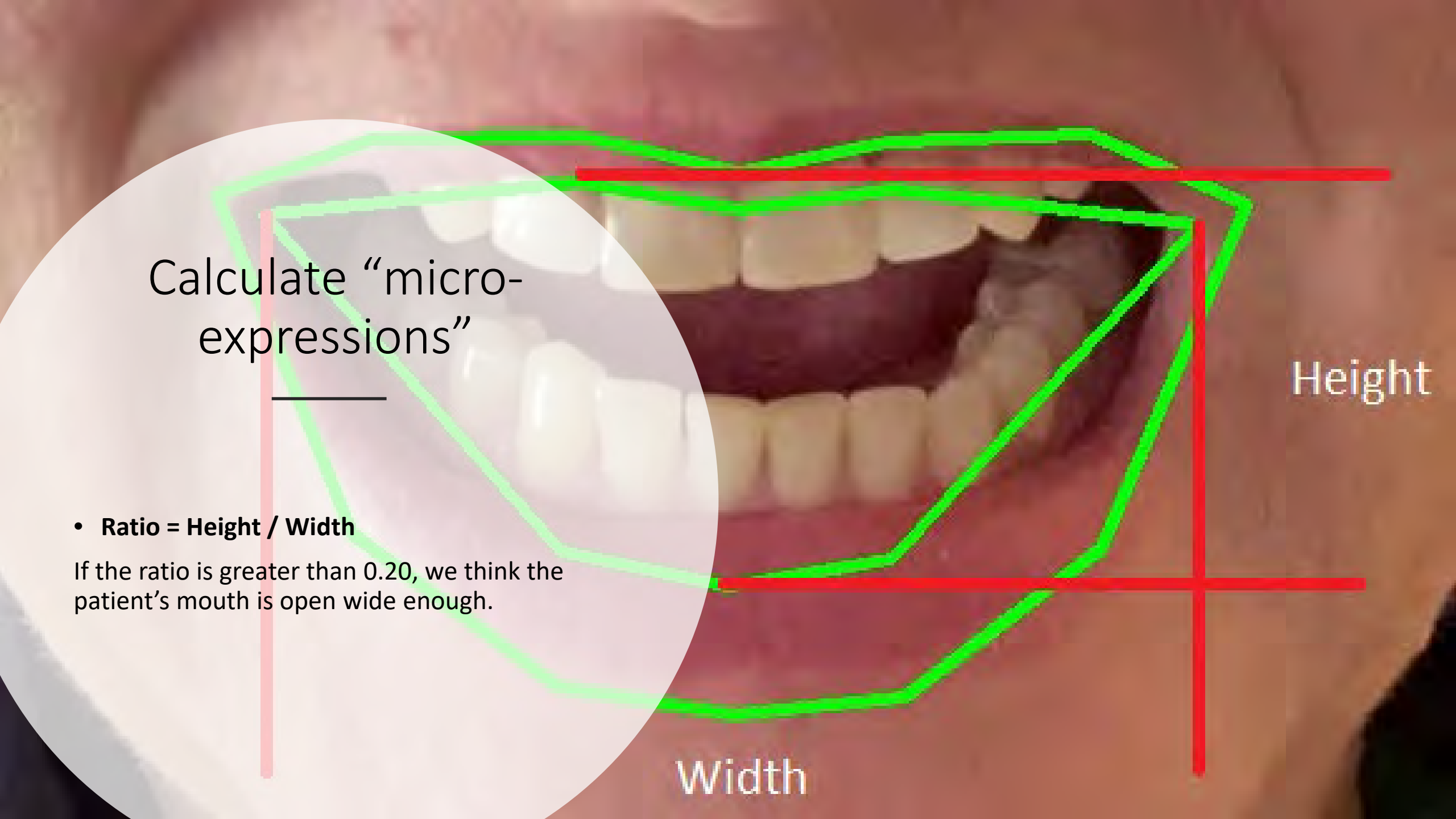


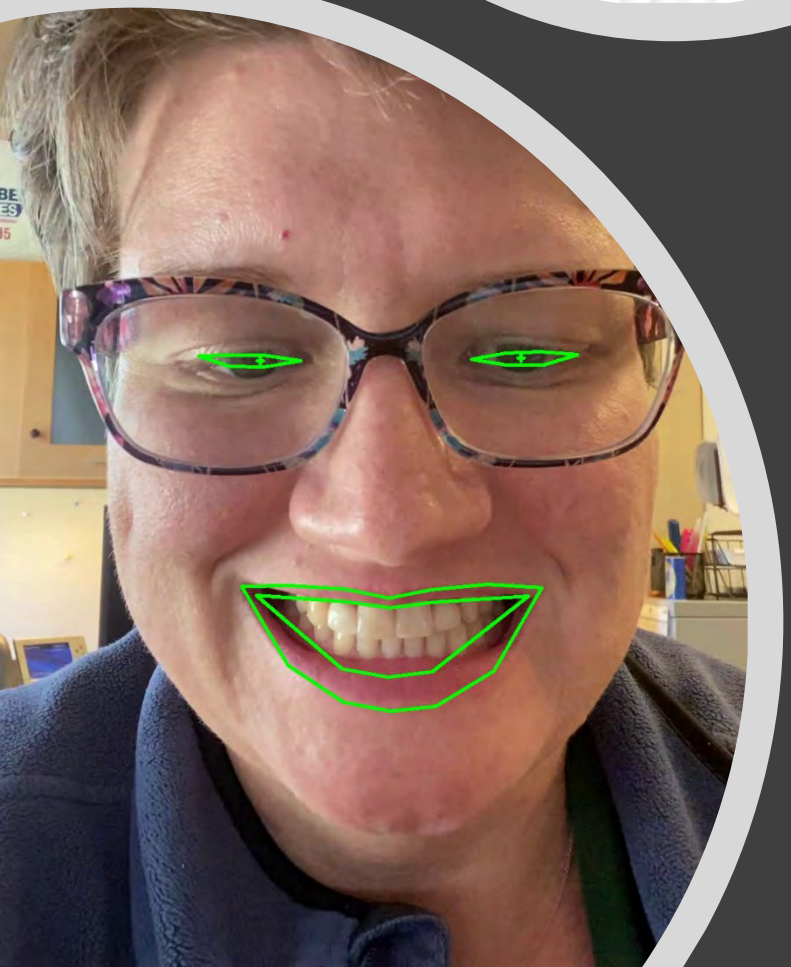
“Show me your teeth”

Calculate “micro-expressions”

- **Ratio = Height / Width**

If the ratio is greater than 0.20, we think the patient’s mouth is open wide enough.





Measure the contour of mouth, which is more accurate.

Opening Ratio = 0.27

Teeth Area Percentage(White/black) = 56%

Why us?

The key ingredient in the process is the connection we have to patients.

This allows us to create a high-quality data library.

Our current library has over 6 years of high-quality stroke patient data, over 300 videos of acute stroke patients, over 700 normal subjects, and more than 7000 acute stroke brain scans.

Google or Amazon cannot easily access patient data or front-line triage video/audio of actual patients to learn from, but we can use their tools with our library of normal/abnormal to create this tool.

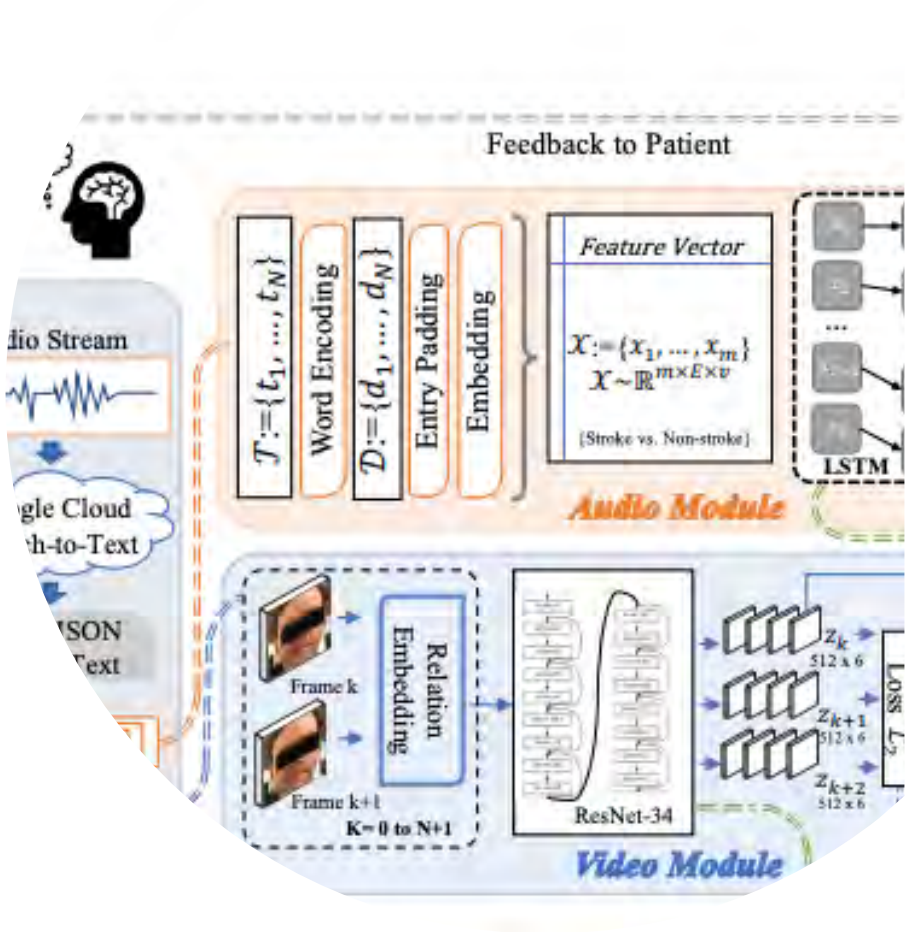
Why now?

COVID has fundamentally changed the doctor-patient relationship.

Patients want to avoid unnecessary ER evaluations, but they do not want to delay treatment when it is critical.

We need tools like a Stroke App for wherever a patient needs care.

The pipeline from pilot trial to pivotal study



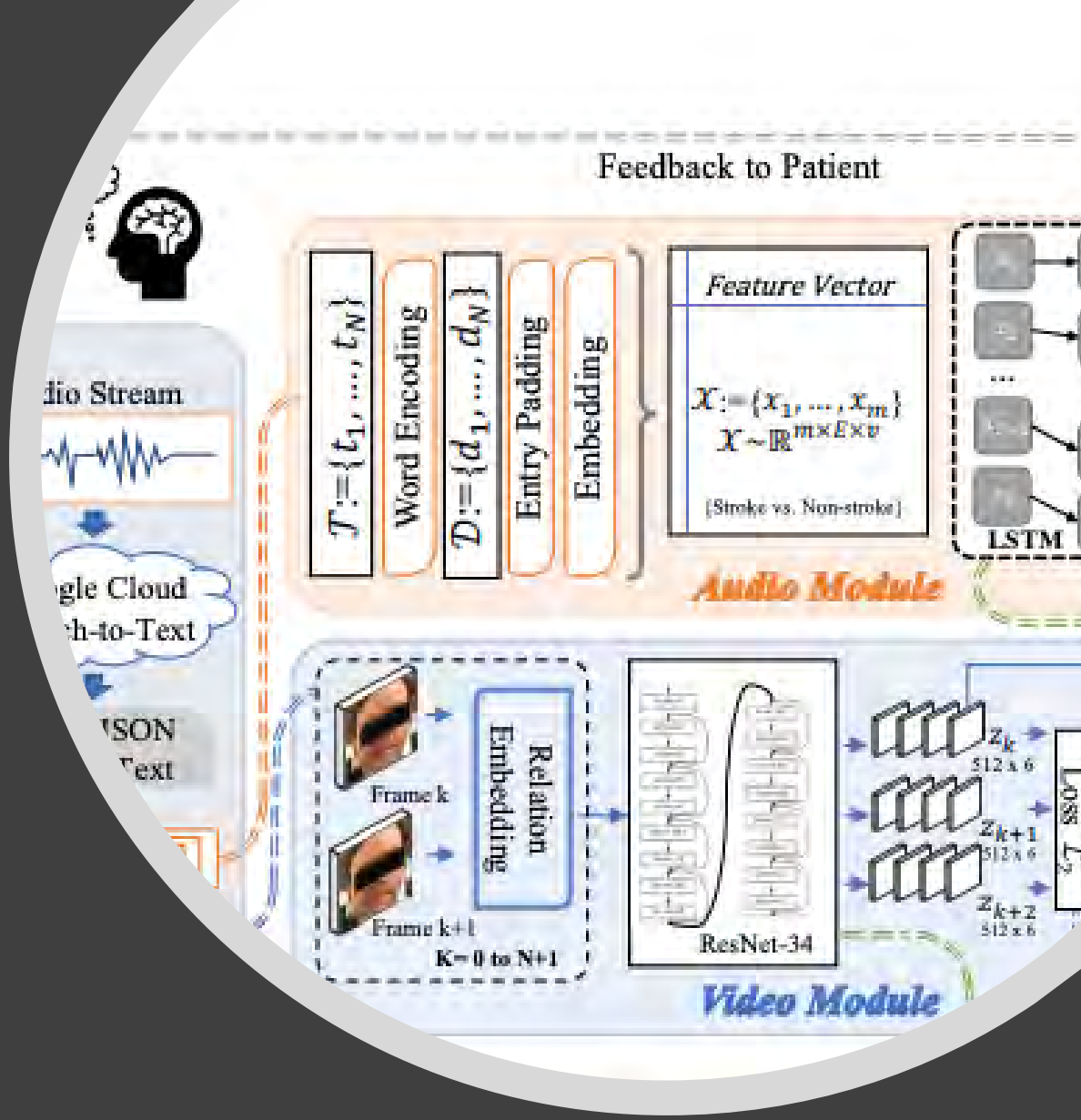
Tool Development

Our pilot study of 94 patients, using facial recognition alone versus the ER doctor.

Machine gets: ~30s video only

ER MD gets: patient, family, ***CT scan***, labs, vitals, chart full of information, med school, residency, experience, etc., etc.

How close do you think our process came to detecting stroke?

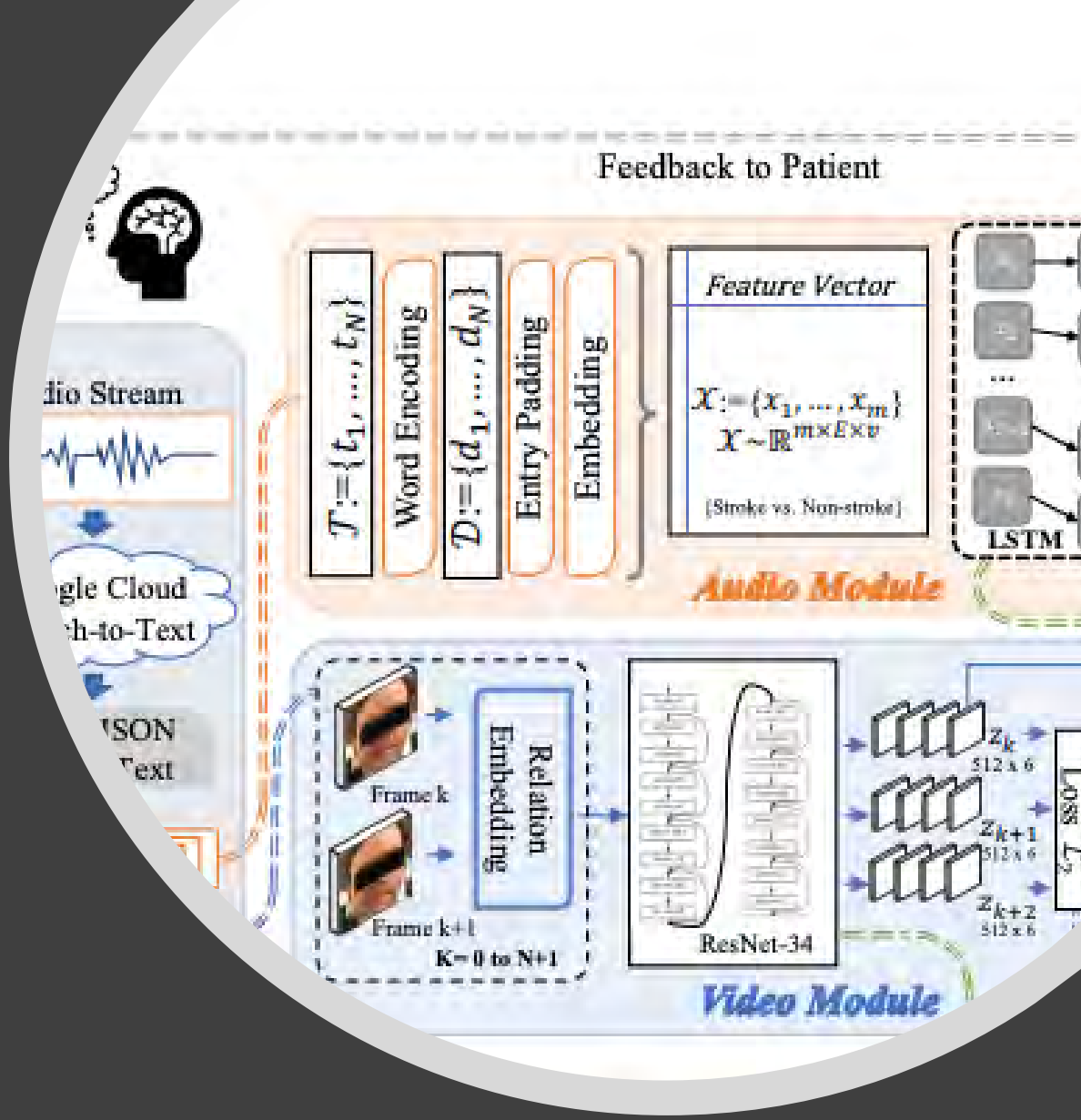


Tool Performance

Our First Prototype of Stroke App with video only proved:

93%

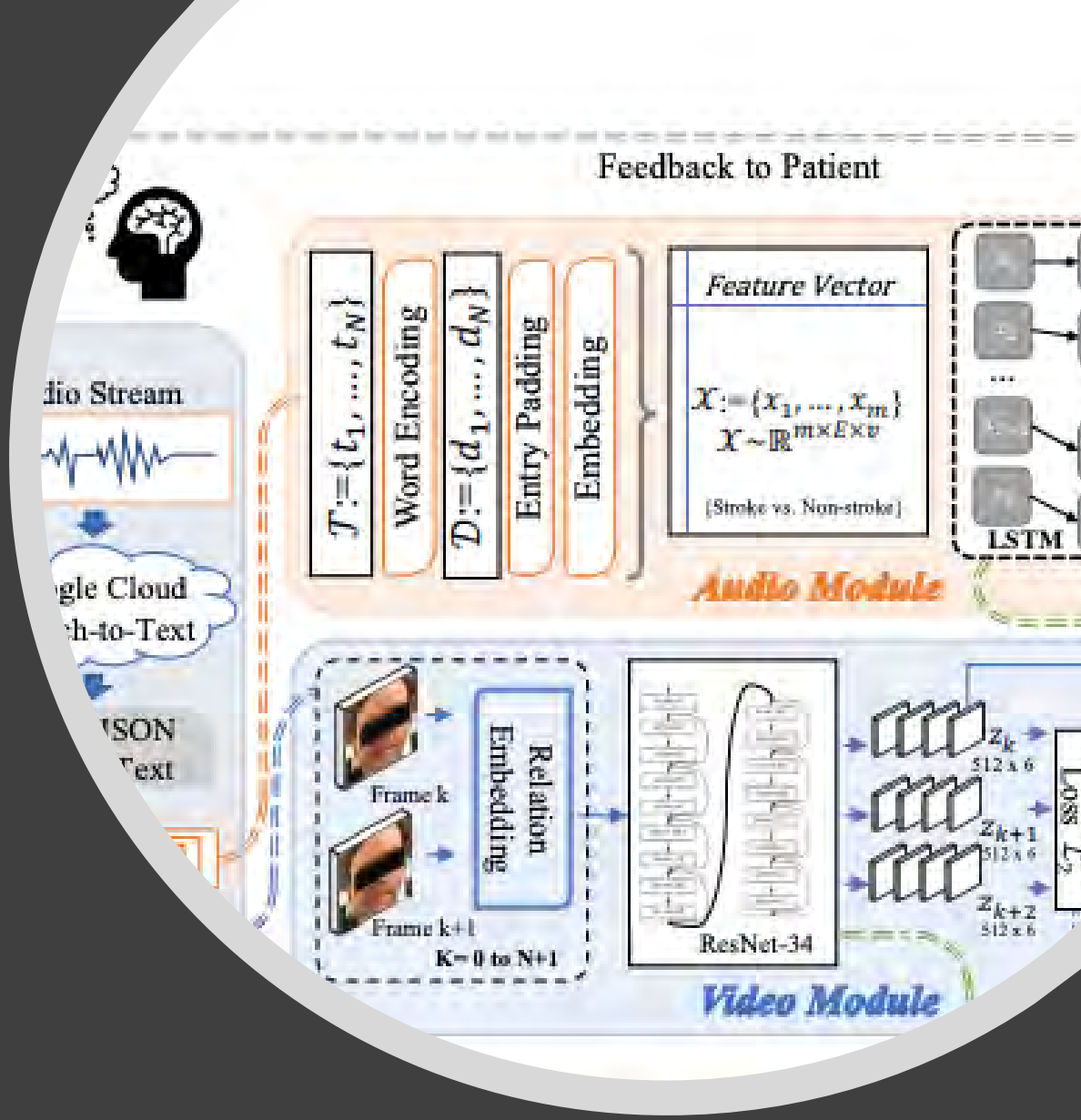
sensitive for detection of stroke



“Hot off the press”

Our First Prototype of Stroke App with video only proved equal in all patients:

93%



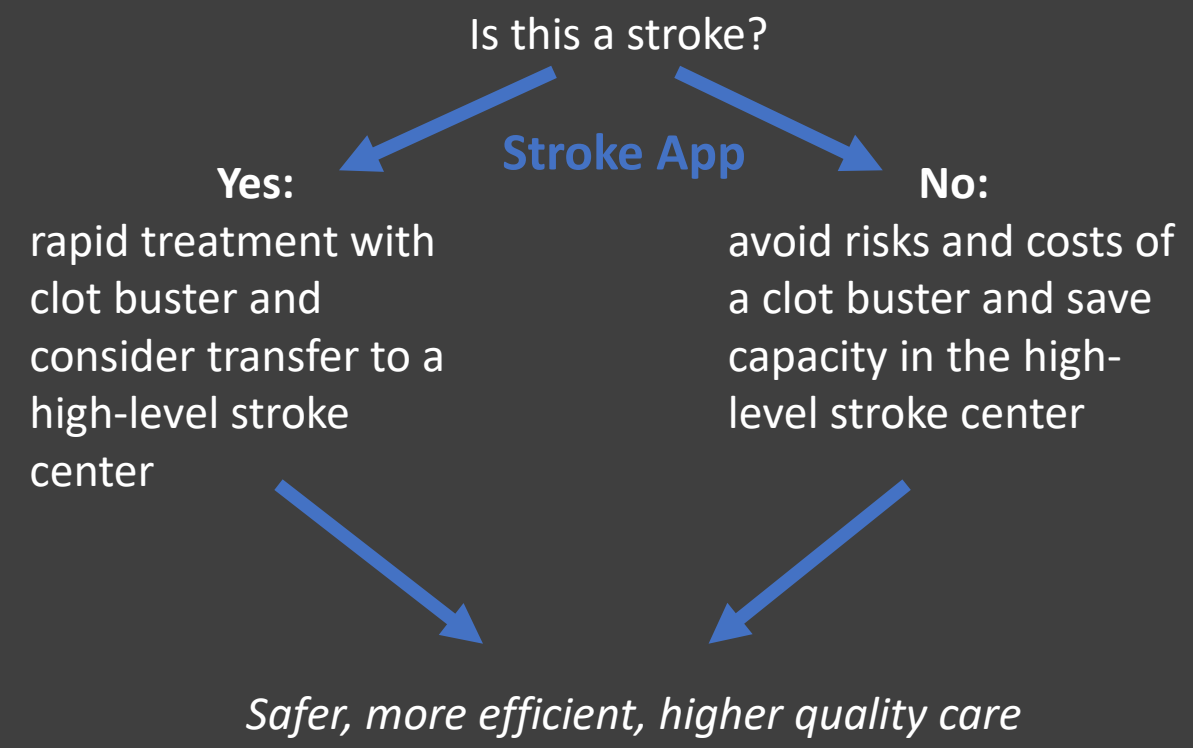
Toward Rapid Stroke Diagnosis with Multimodal Deep Learning

Mingli Yu[1], Tongan Cai[1⋆], Xiaolei Huang[1], Kelvin Wong[2], John Volpi[3], James Z. Wang[1], Stephen T.C. Wong[2]

[1] The Pennsylvania State University, University Park, USA
[2] TT and WF Chao Center for BRAIN & Houston Methodist Cancer Center, Houston Methodist Hospital, Houston, Texas, USA
[3] Eddy Scurlock Comprehensive Stroke Center, Department of Neurology, Houston Methodist Hospital, Houston, Texas, USA

The Future State:

A 58-year-old woman comes to the ER with dizziness and blurry vision.



Summary

Our group has accomplished:

- Best in class CT processing that achieves “MRI like” stroke detection to replace the “stroke clock”
- A library of over 300 acute stroke patient videos
- A successful pilot study of facial recognition for stroke detection with high fidelity
- Presentations and publications of our data in national and international forums

A model for integrating augmented intelligence into a typical stroke workflow

Future work

A bright future for *augmented intelligence* in healthcare and at Houston Methodist as a Center of Excellence:

- World class data science and imaging expertise
- Diverse patients
- 20+ years of leadership in stroke trials
- Extensive and detailed database
- Integrity in data stewardship
- Active clinicians at the largest stroke center in the region

A *platform technology* with applications in Parkinson's, Alzheimer's, depression, epilepsy, and many more.

Future work

Delivering rapid, unparalleled expertise to the patient, regardless of distance or time.

Integrate with telestroke and advances in virtual care.

Acute TeleStroke

Rajan Gadhia, MD

October 21, 2022

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Stroke Basics

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- Stroke is the fifth leading cause of death in the United States. More than 140,000 people die each year from stroke in the United States.
- Stroke is the leading cause of serious, long-term disability in the United States.
- About 795,000 people have a stroke in the United States each year.
- Strokes can and do occur at ANY age. Nearly one fourth of strokes occur in people under the age of 65.

Ischemic Stroke

- In the United States, majority (~87%) of strokes occur in the setting of lack of blood flow to a part of the brain.
- Etiologies of which vary, but could be thrombotic, embolic, hemodynamic, or a combination.
- HTN remains the leading modifiable risk factor for stroke.
- Encompasses acute ischemic infarcts as well as transient ischemic attacks.

Ischemic Stroke

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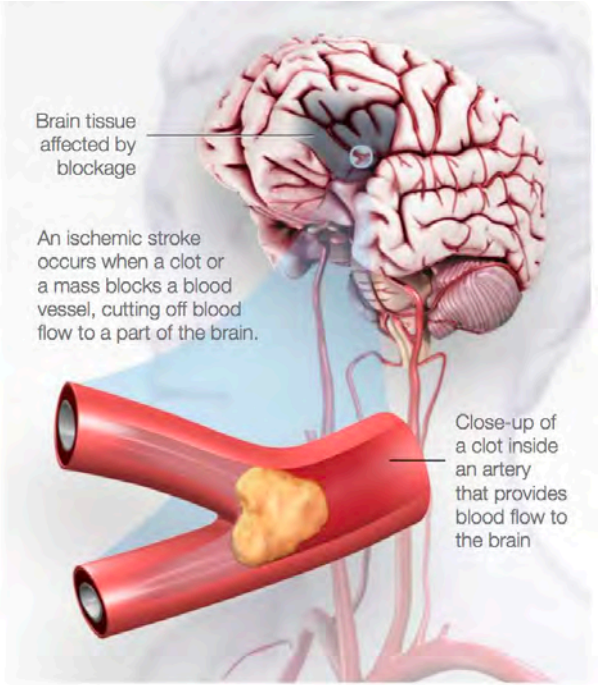

Case

- 58-year-old woman (Jane Doe) brought to ED after being found altered and unsteady in a parking lot.

Geographical Disparities in Care

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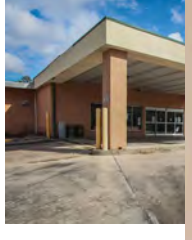
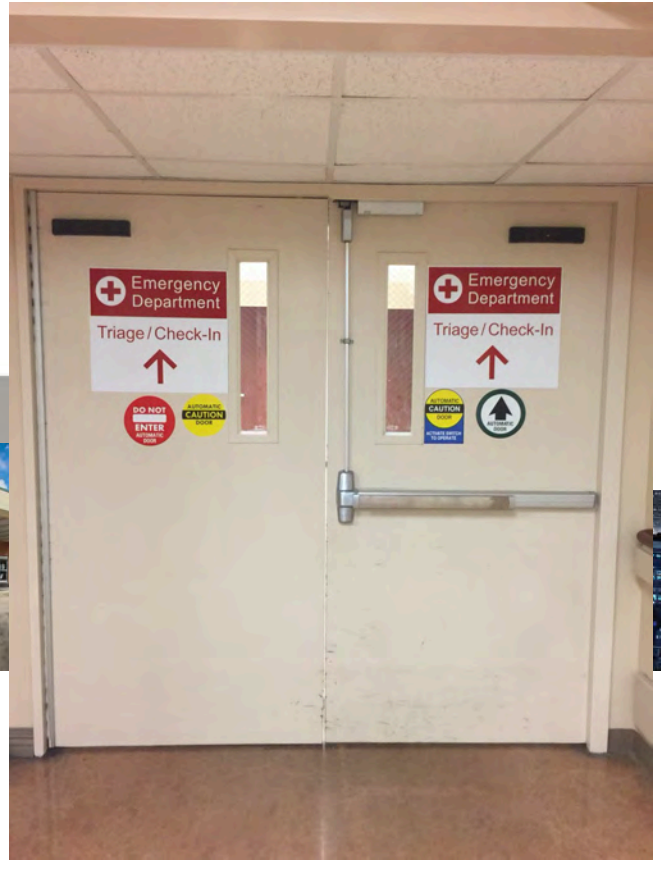
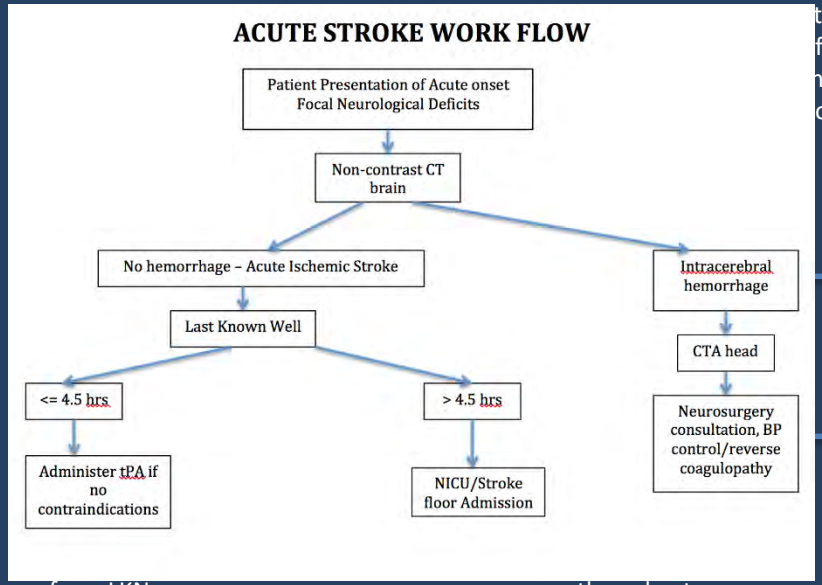




Timeline of Acute Stroke Therapy Trials

September 2008

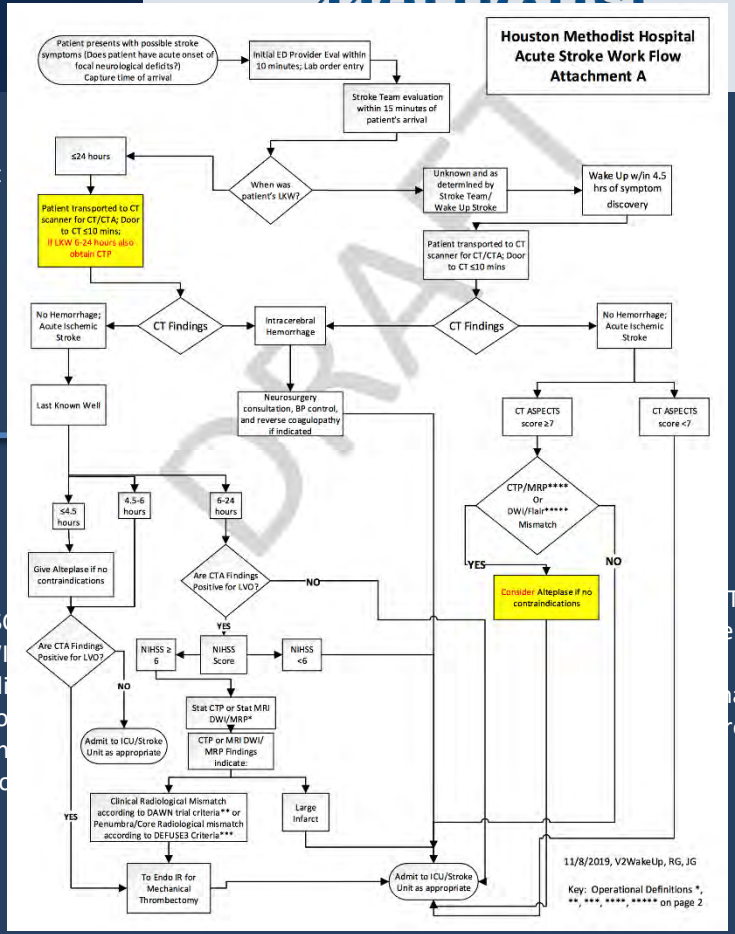


from LKN

thrombectomy with IV tPA vs. tPA alone

January 2015– MRCLEAN study shows added benefit of Endovascular thrombectomy within 6 hours of LKN

2015/2016– ESCAPE, EXTEND-IA, SWIFT, REVASCAT studies added benefit of Endovascular thrombectomy within 6 hours of



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Modified Rankin Scale Score

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Modified Rankin Scale (MRS)
0 No symptoms
1 No significant disability, despite symptoms; able to perform all usual duties and activities
2 Slight disability; unable to perform all previous activities but able to look after own affairs without assistance
3 Moderate disability; requires some help, but able to walk without assistance
4 Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5 Severe disability; bedridden, incontinent, and requires constant nursing care and attention
6 Death

Timeline of Acute Stroke Therapy Trials

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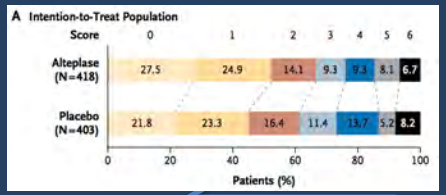
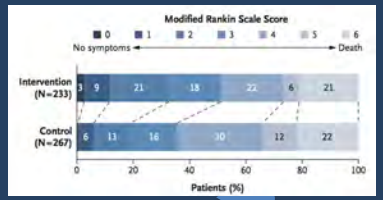
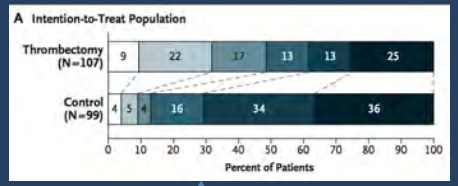
September 2008



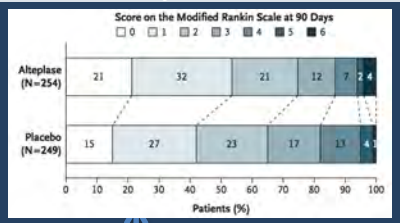
January 2015–



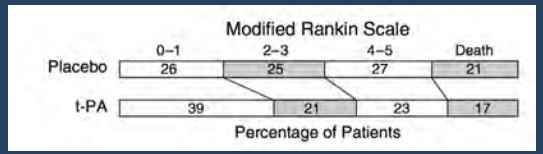
November 2017–



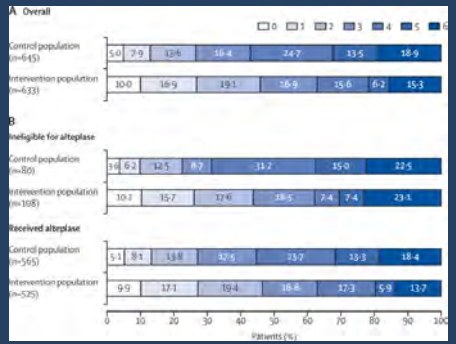
May 2018 –



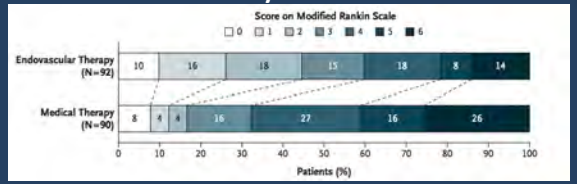
December 1995 –



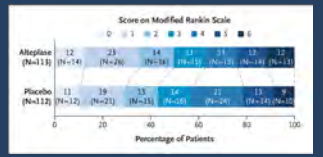
2015/2016–



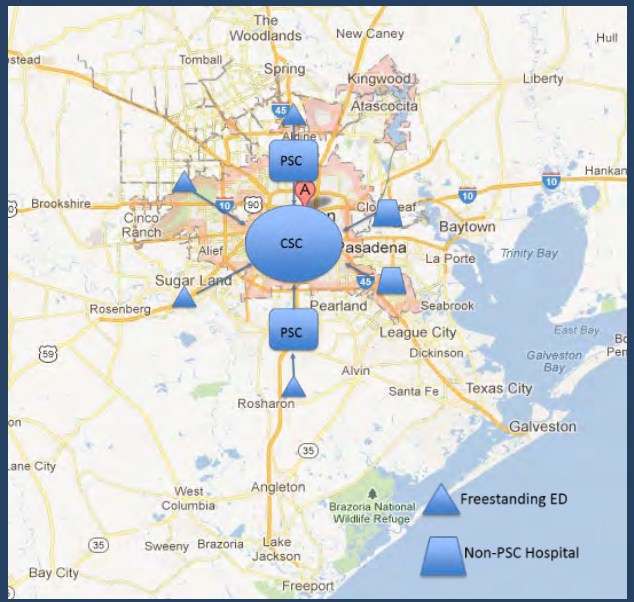
January 2018–

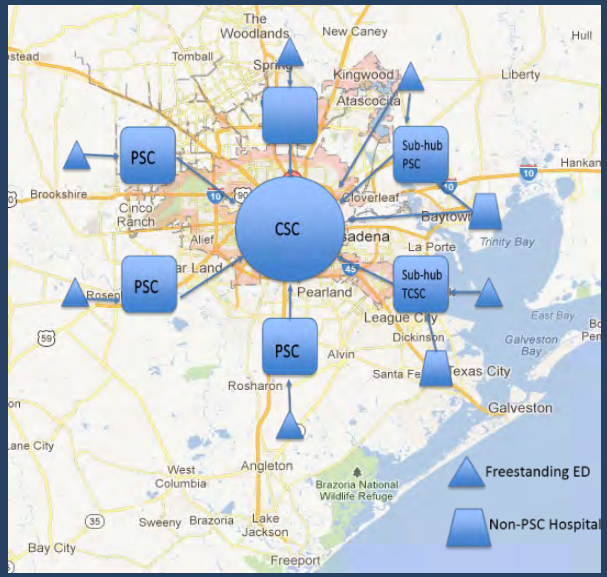


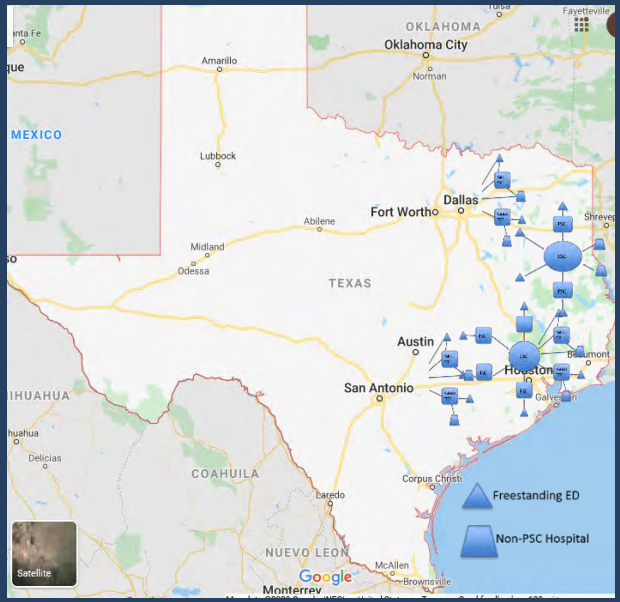
May 2019 –



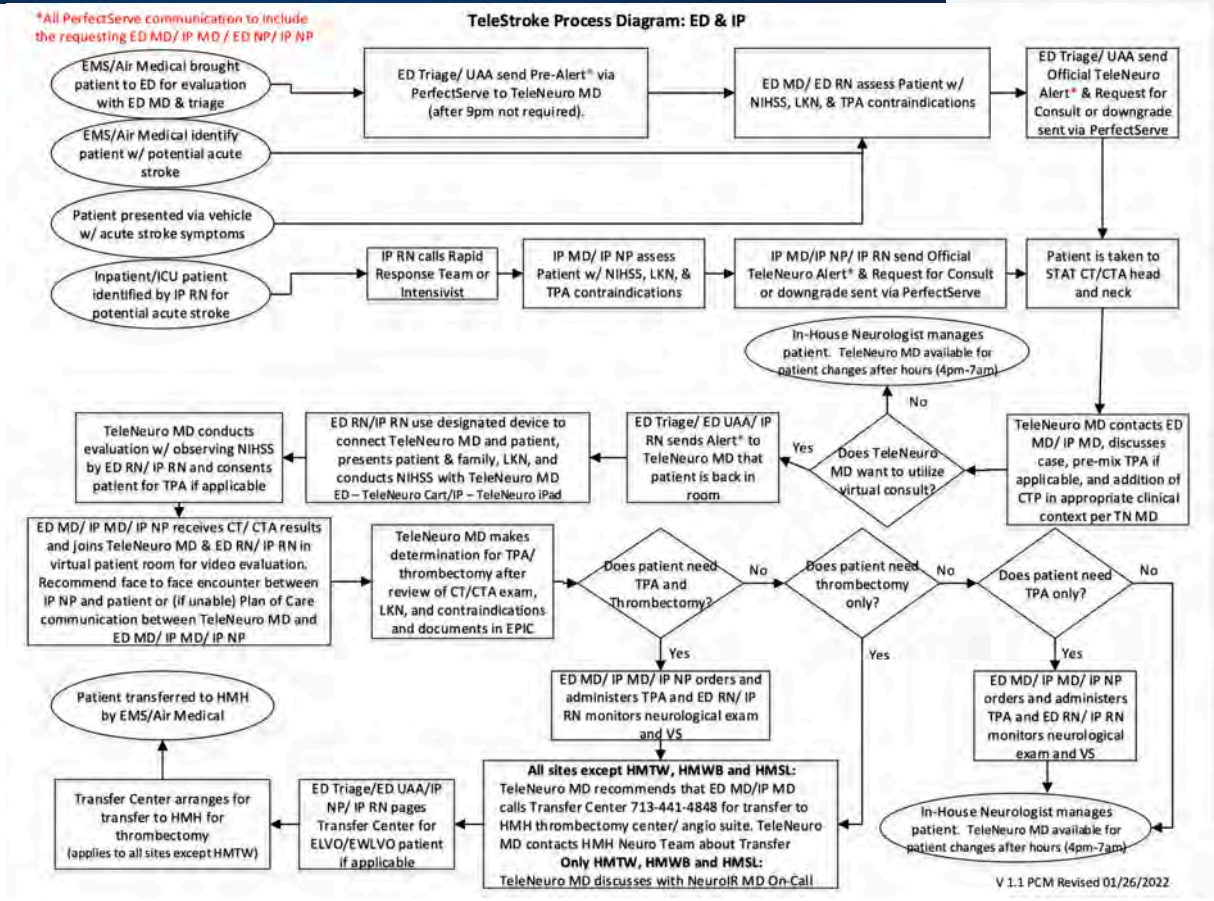
Evolution of Systems of Stroke Care







TeleStroke Implementation



Technology and…

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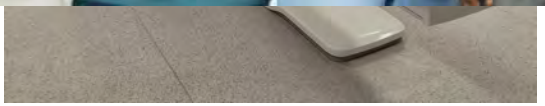

pulsara

TeleStroke Video Evaluation

Tele-Neurology
Go-Live Timeline, Consults & Coverage

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Tele-Neurology: Go-Live Timeline

6/26/2017

CSC: Houston Methodist The Woodlands

11/27/2017

PSC: Houston Methodist Willowbrook

9/17/2018

PSC: Houston Methodist West Houston

10/3/2019

PSC: Houston Methodist Sugar Land

3/10/2020

PSC: Houston Methodist Baytown

3/16/2020

PSC: Houston Methodist Clear Lake

6 ECC Locations: Sienna, Cinco Ranch, Cypress, Spring, The Woodlands, Deer Park (Added Dec 2020)

Tele-Neurology: Consults & Coverage

Tele-Stroke Consults & Patients

6,557 Consultations
June 2017 – YTD

3,815 Consultations
Jan 2021 – YTD

423 Patients
Transferred to a Comprehensive Stroke Center
June 2017 – YTD


Rajan Gadhia, MD

Tele-Stroke Coverage

7 Board Certified Physicians

Monday – Friday:
7am – 4pm (daytime)
4pm to 7 am (after hours)

Saturday, Sunday, & HM Holidays:
24 hour coverage

Acute and Tele-Neurology

Go-Live & Growth Timelines

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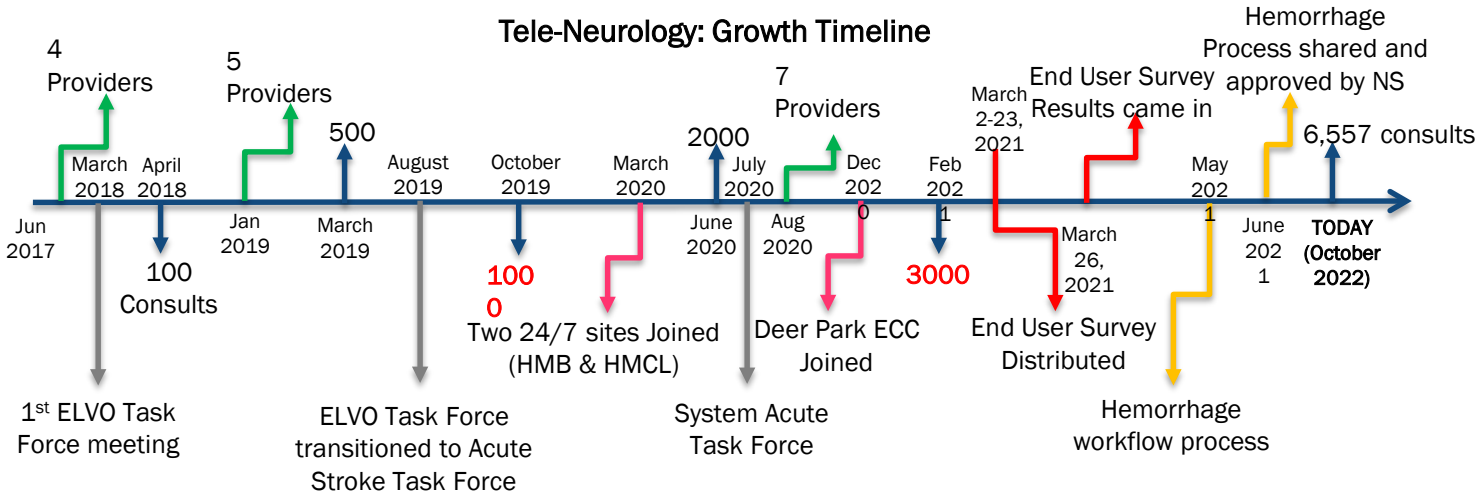
Tele-Neurology: Go-Live Timeline

Tele-Neurology: Growth Timeline



TeleStroke during COVID-19

Publication: Door to Needle (DTN)

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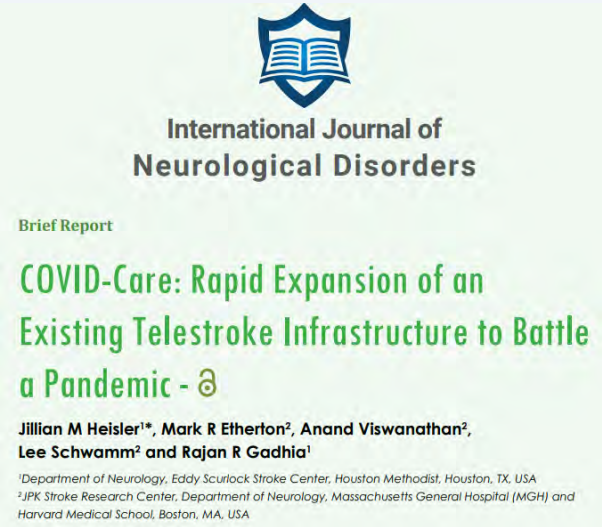

International Journal of Neurological Disorders

Brief Report

COVID-Care: Rapid Expansion of an Existing Telestroke Infrastructure to Battle a Pandemic -

Jillian M Heisler[1]*, Mark R Etherton[2], Anand Viswanathan[2], Lee Schwamm[2] and Rajan R Gadhia[1]

[1]Department of Neurology, Eddy Scurlock Stroke Center, Houston Methodist, Houston, TX, USA
[2]JPK Stroke Research Center, Department of Neurology, Massachusetts General Hospital (MGH) and Harvard Medical School, Boston, MA, USA

Table 1: Time to thrombolytic therapy at HMH in 2020

Door to Needle (DTN)

Month	Avg (Min.)	Median (Min.)	# of Patients
January	50.9	45.0	n = 14
February	42.3	43.5	n = 14
March*	63.0	67.5	n = 8
April**	57.6	45.0	n = 7

*First suspected cases of COVID in Houston, TX USA

**Implementation of a telestroke-based evaluation for all suspected acute strokes.

55% DTN increase with COVID (Median – Feb to Mar Month over Month)
33% DTN decrease with implementation of Tele-neurology (Median – Mar to Apr Month over Month)

Case

- 58-year-old woman (Jane Doe) brought to ED after being found altered and unsteady in a parking lot.

- ED triage team evaluates patient, and immediately suspects an acute neurological emergency, and acute TeleStroke team is activated as patient is transported to the CT scanner.

Acute Evaluation

perfectserve

Epic

Beyond Clinical Care – Research

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Music Therapy in Stroke Care

Maegan Morrow, Senior Music Therapist

October 20, 2022

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Center for Performing Arts Medicine Mission

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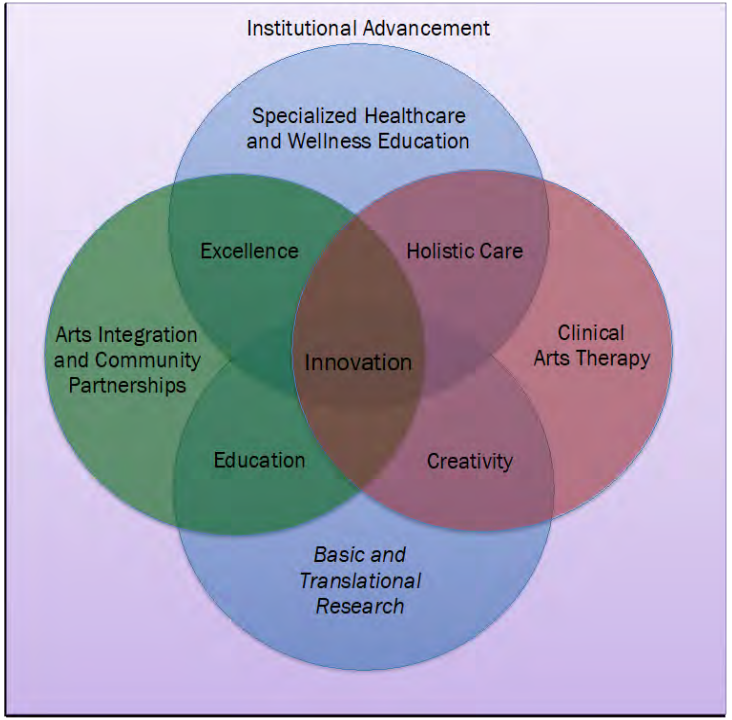
to effectively translate the collaborative potential of arts and medicine to the holistic healthcare environment of Houston Methodist

- Specialized health care and education for performing artists,
- Effective and meaningful integration of the performing and visual arts into the hospital environment,
- Creative Arts Therapy that utilizes the arts in support of patient goals, and
- Research that harnesses the broadest potential of the arts in therapy, rehabilitation and human performance.



Creative Arts Therapies

HMH (music and art therapy)

- Acute Psychiatry
- Outpatient Behavioral Health
- Inpatient Rehabilitation
- Outpatient Oncology
- BMT
- CVICU
- SLICU
- Palliative Care

HMB (music therapy)

- ICU (open position)

HMSL (music therapy)

- Cancer Infusion Center

HMWB (music therapy)

- Neonatal ICU

HMW

- ICU (open position)

HMTW (music therapy)

- Comprehensive Stroke Team

Music Therapy Credential

Music Therapy Degree
(Undergrad/Equivalency/Graduate from AMTA approved program)

1200 Clinical Fieldwork Hours
(from approved AMTA site)

Board Certification Exam

MT-BC Credential

What is Music Therapy?

- Music therapy is the clinical & evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an accredited music therapy program. (AMTA)

Not about teaching/developing musical skills

Concept of change

Social and humanistic psychological roots

Functional change

- Communication, cognition, physical, social, emotional and neurological functioning

All ages, groups, individuals

Medical Goals/Interventions

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Goals:

- Reduce anxiety/depression associated with medical trauma
- Promote reality orientation during ICU delirium
- Promote emotional processing of medical trauma
- Enhance respiratory strengthening in preparation for vent weaning
- Promote opportunities for family bonding through end-of-life legacy work

Interventions: songwriting, salient live music for orientation/grounding, music-assisted guided imagery, OMREX (oral motor and respiratory strengthening exercises) with harmonica, rhythmic diaphragmatic breathing, and heartbeat recordings.

The Power of Music

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- Is there a biological basis for the experiences that people talk about?
  - Heart rate increases, breathing deepens, their muscle tension increases
  - Human body falls into synchronism with a rhythmic phenomenon
  - Hormones and neurochemicals
    - Adrenaline, cortisol and ACTH
    - Prolactin, oxytocin, dopamine

The Power of Music

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- Specific parts of the brain are involved in perceiving different musical elements
  - Pitch, harmony, melody, dynamics, rhythm
  - e.g., specific neurons in the auditory cortex are tuned to perceive specific pitches
- Some of the areas involved: auditory cortex, motor cortex, prefrontal cortex, sensory cortex, the visual cortex, nucleus accumbens, and amygdala, hippocampus and so on

Music Listening

- Hearing music
  - Auditory cortex
    - Core: pitch and volume
    - Surrounding: timbre, melody and rhythm
- Imagining Music
  - Auditory cortex to a lesser magnitude
  - Inferior frontal gyrus (retrieving memory)
  - Dorsolateral frontal cortex (working memory)

Music Engagement

- Playing music
  - Auditory cortex (feedback system)
  - Visual cortex (reading a score)
  - Parietal lobe (e.g., computation of finger position)
  - Motor cortex
  - Sensory cortex
  - Frontal lobe
  - Cerebellum

Music as a Reward

- Emotional reaction to music
  - Reward structures such as ventral tegmental area (when you get chills!)
  - Same areas that get activated while
    - Eating
    - Sex
    - Using drugs
  - Pleasing song→ inhibition of amygdala

Paradigm Shift

From MT to NMT

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- Traditionally, music in therapy has been based on a model that uses music to facilitate concepts of well-being.
- Neuroscience research with the help of neuro-imaging has shifted the model to a perceptual model.
- They are based on how music perception and production engage the brain in ways translated to non-musical therapeutic learning and training.

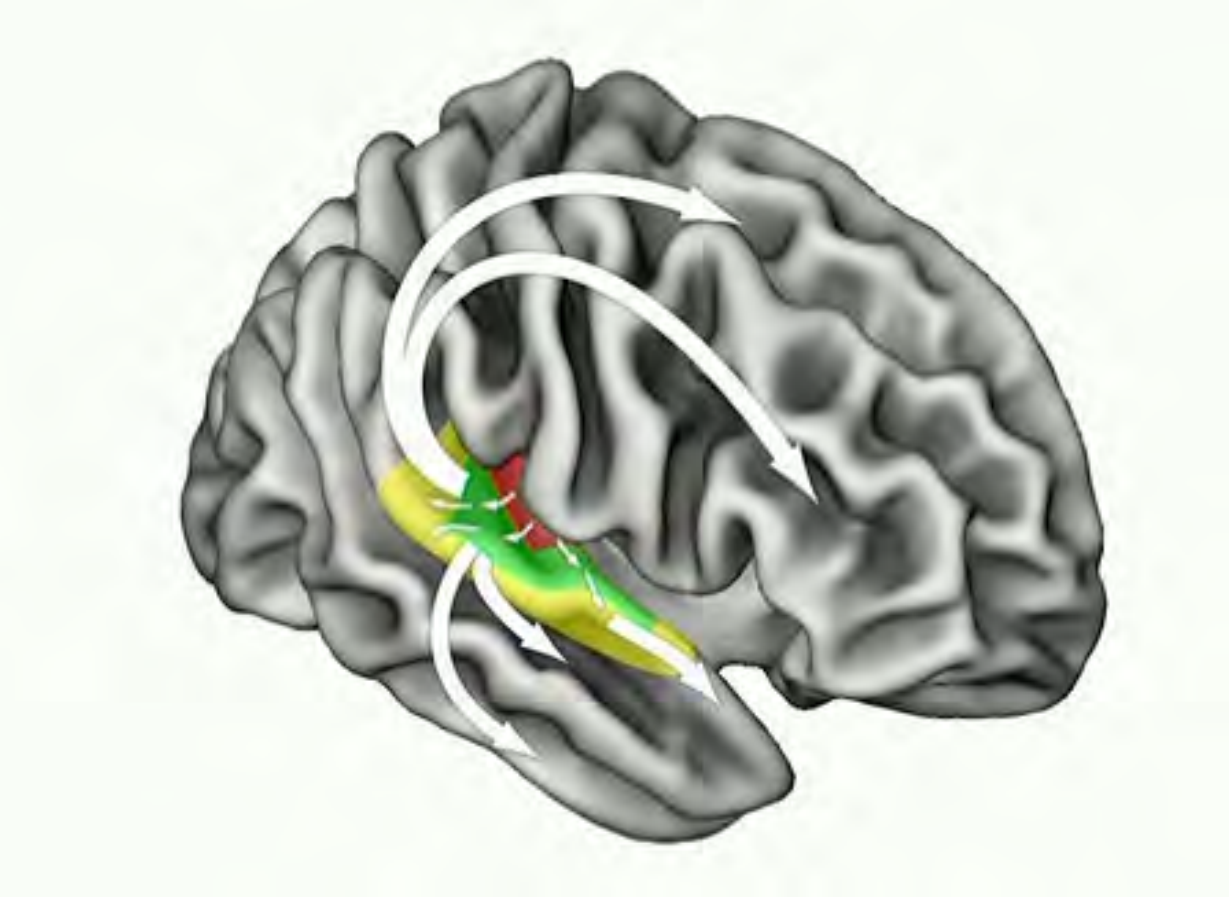
Neuroplasticity

- The essence of recovery

The brain's ability to reorganize itself by forming new neural connections throughout life.

Neuroplasticity allows the neurons (nerve cells) in the brain to compensate for injury and disease and to adjust their activities in response to new situations or to changes in their environment.

Auditory Cortex



Entrainment

Researchers demonstrated a relationship between neural processing of auditory stimuli and the arousal of the motor system, resulting in an entrainment effect.

Neurologic Music Therapy

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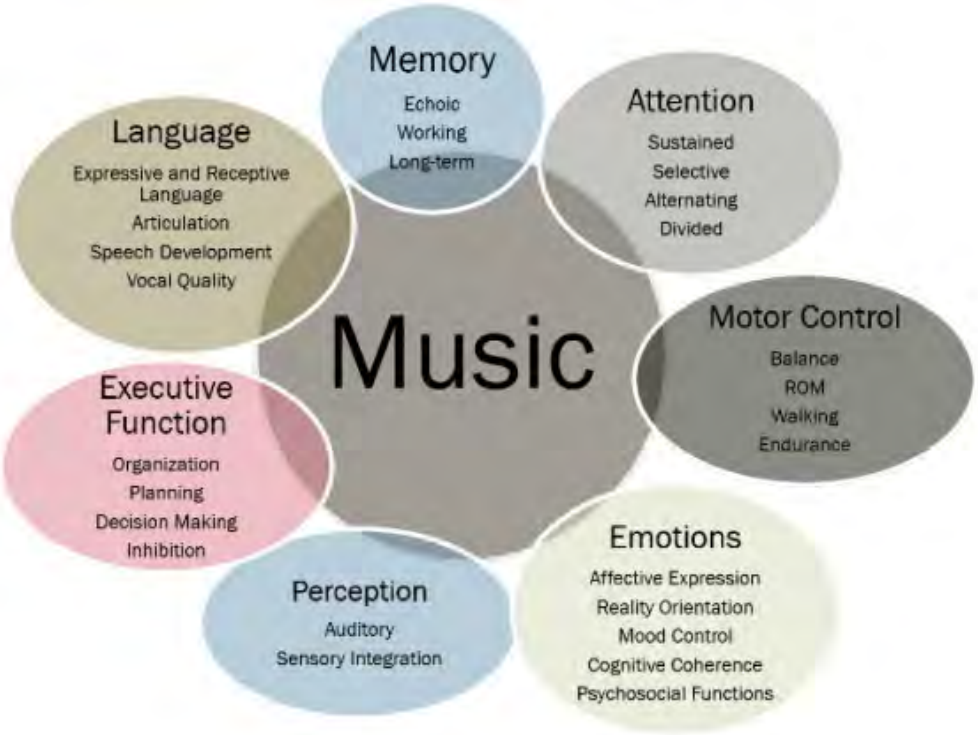
is the therapeutic application of music to **cognitive, sensory** and **motor** dysfunction due to neurologic disease of the human nervous system.

is based on a neuroscience model of music **perception** and **production**, and the influence of music on functional changes in the non-musical brain.

Shared Rehabilitation Goals



Rhythm and the Brain

RHYTHM IS PROCESSED SUBCORTICALLY

THE BRAIN PROCESSES THE SPACE *BETWEEN* THE BEATS

RHYTHM ASSISTS IN ANTICIPATION OF MOVEMENT AND FLUENCY OF MOVEMENT

RHYTHM ACTS AS A PRIMING MECHANISM TO THE MOTOR SYSTEM

NMT Techniques

- Sensorimotor Training

Rhythmic Auditory Stimulation

Patterned Sensory Enhancement

Therapeutic Instrumental Music Performance

NMT Techniques

Speech and Language Training

- Melodic Intonation Therapy (MIT)
- Musical Speech Stimulation (MUSTIM)
- Rhythmic Speech Cuing (RSC)
- Vocal Intonation Therapy (VIT)
- Oral Motor and Respiratory Exercises (OMREX)
- Developmental Speech and Language Training through Music (DSLM)
- Therapeutic Singing (TS)
- Symbolic Communication through Music (SYCOM)

NMT Techniques

Cognitive Training

- Musical Sensory Orientation Training (MSOT)
- Musical Neglect Training (MNT)
- Auditory Perception Training (APT) – 2 subcategories
- Musical Attention Control Training (MACT) – 4 subcategories
- Musical Executive Function Training (MEFT)
- Musical Mnemonics Training (MMT)
- Associative Mood and Memory Training (AMMT)
- Music Psychotherapy and Counseling (MPC)

Rhythmic Auditory Stimulation

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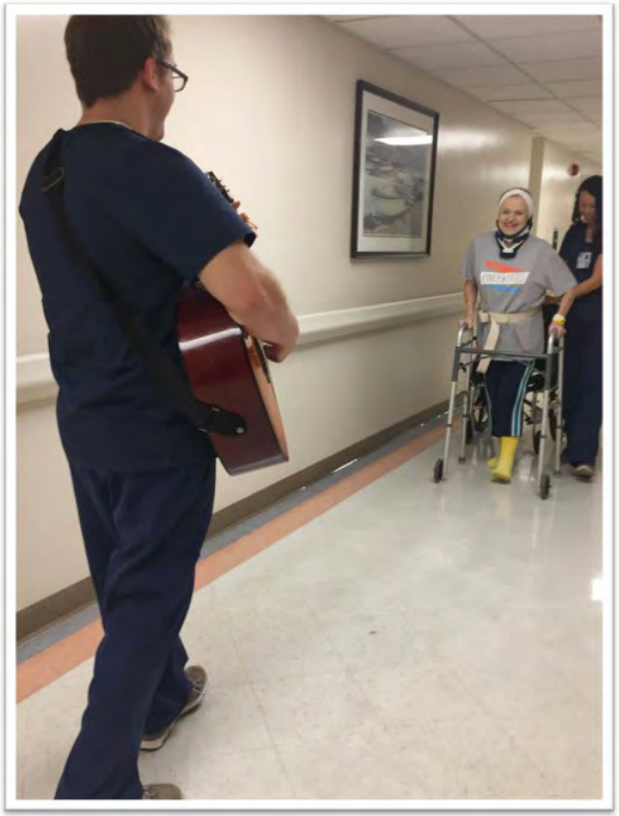
- Rhythm has physiological function to stimulate movement

Applies auditory sounds to movement (walking, stepping) 2/2, 2/4

Therapist gradually increases to form a pattern

Rhythmic entrainment, priming of auditory motor pathway, cueing of movement

Rhythmic Auditory Stimulation



Music Therapy in Rehabilitation

Goal: Increase endurance during ambulation

Intervention: Rhythmic Auditory Stimulation (RAS)

Best Practice

RAS has been included in the official Canadian Stroke Best Practice Guidelines

Clinical Practice Guidelines for the Management of Stroke Rehabilitation of the U.S. Veterans Administration and the Department of Defense

Therapeutic Instrumental Performance

Utilizes musical instruments to help patients to exercise impaired motor function and regain functional patterns of movement

Melodic Intonation Therapy

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- Utilizes a patient's unimpaired ability to sing to facilitate speech production
- Focuses on functional sentences and brief statements that are translated in melody
- Melody is developed based on inflection patterns
- Later stages of treatment the singing is reduced to "speech singing" and finally retranslated to normal speech prosody

Oral Motor Respiratory Exercise

- Addressing the improvement of articulatory control, respiratory strength, and function of the speech apparatus

- Using instruments such as:
  - Harmonica
  - Kazoo
  - Recorder

- Promotes improved walking (gait) patterns
- Improves affected limb functions (arms, hands, etc.)
- Helps improve speech (aphasia, apraxia, dysarthria)
- Improves cognitive functioning (attention, memory)
- Alleviates post-stroke anxiety and depression
- Promotes “massed practice” for neuroplasticity

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Reimbursement

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- 19 Current Procedural Terminology (CPT) codes that may be used for music therapy services.
- Medicare, Medicaid, Private Insurance, and Third-Party Payer.
- Most reimbursed services support children on the autism spectrum and those with developmental delays.
- Does not always impede clients from benefiting from other therapeutic services.

Community MT

The Harrison Center for Music Therapy

www.harrisoncentermt.com

Houston Aphasia Recovery Center HARC

www.harctx.org

Questions or Resources

mmmorrow@houstonmethodist.org

www.musictherapy.org

My Brain on Foo Fighters

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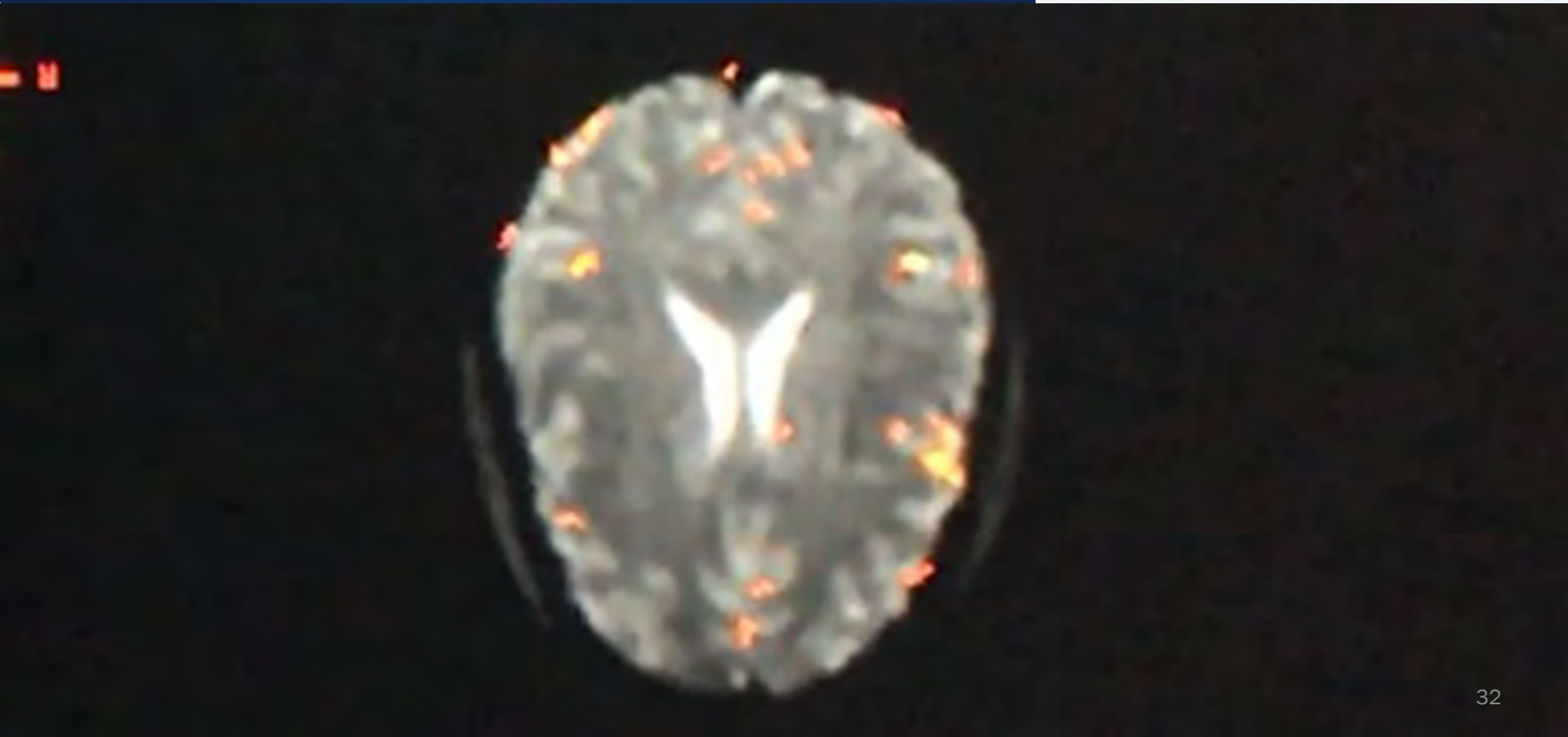

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Houston Methodist Update

Marc L. Boom, MD
President and CEO

October 20, 2022

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COVID-19 Viral Load Detected in City of Houston Wastewater

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HOUSTON

October 10, 2022

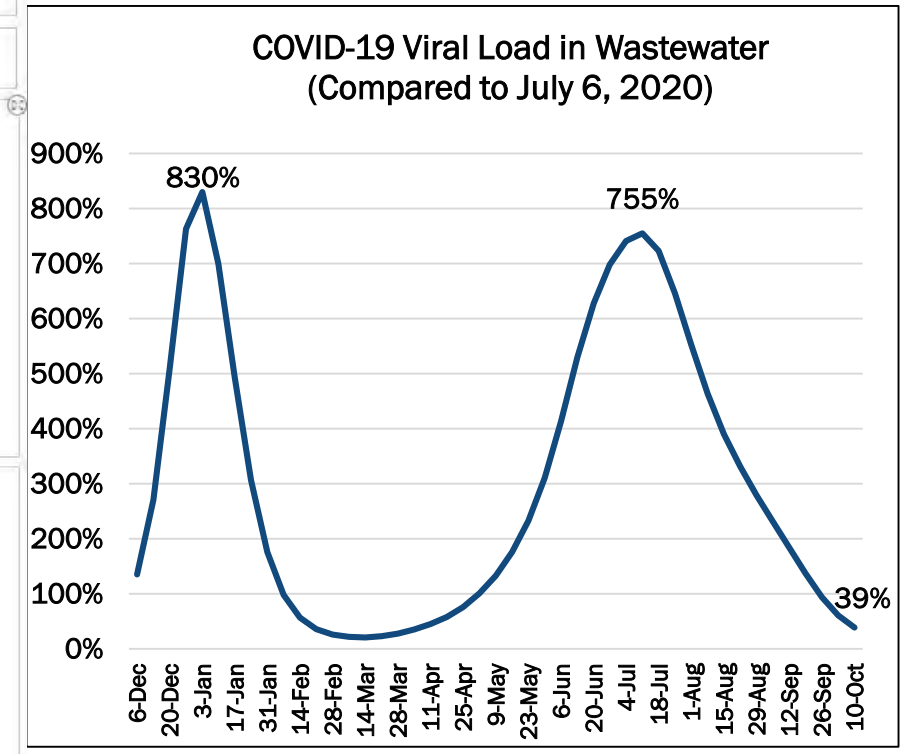
Viral Load:

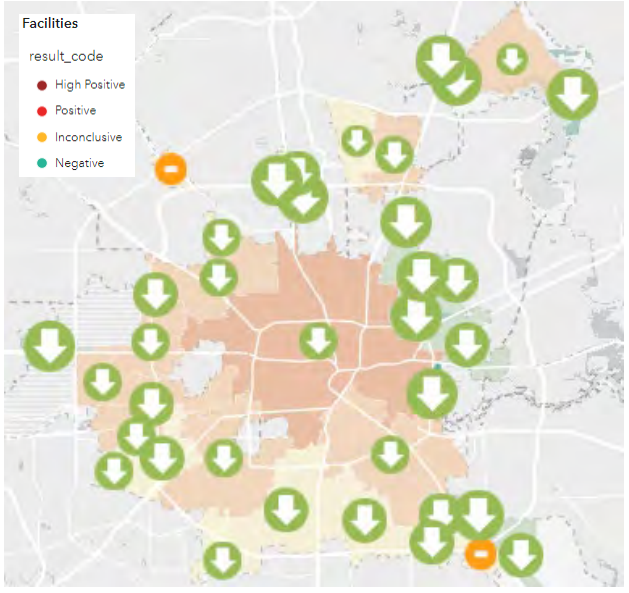
39%

In comparison to July 6, 2020

Positivity Rate:

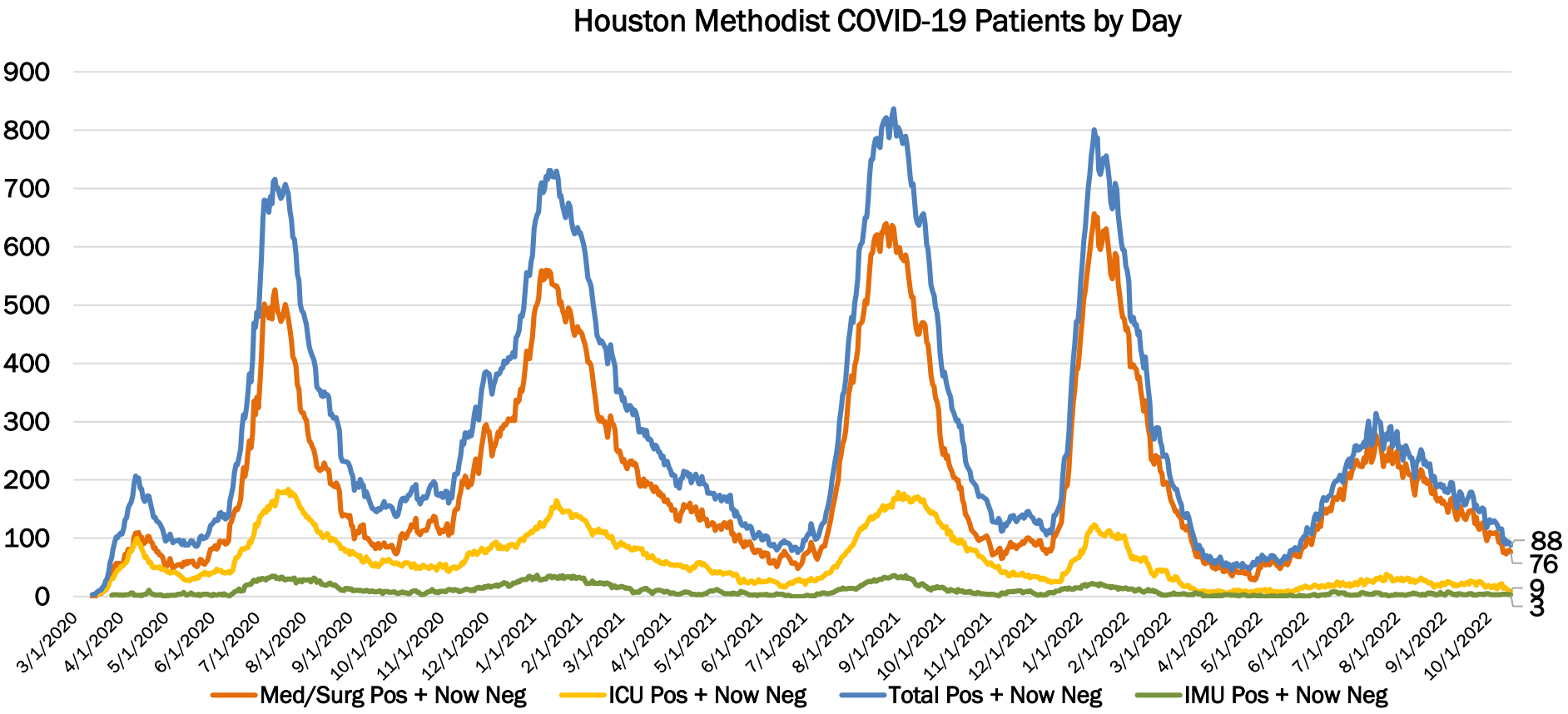
7%



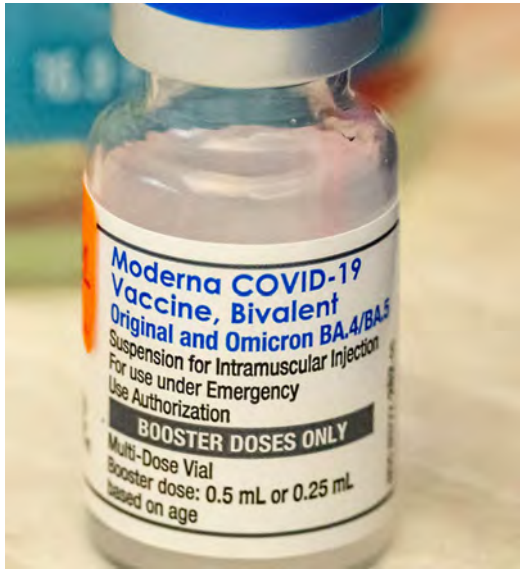


https://covidwwtp.spatialstudieslab.org/

Houston Methodist COVID-19 Cases By Day



Data as of October 16, 2022



If cases are down in my community, why should I get the new booster?

The virus that causes COVID-19 changes over time. Keep your protection against COVID-19 up to date by getting a bivalent COVID-19 vaccine booster dose.

How do the updated vaccines differ from the original one?

THE UPDATED (BIVALENT) BOOSTERS ARE CALLED “BIVALENT” BECAUSE THEY PROTECT AGAINST BOTH THE ORIGINAL VIRUS THAT CAUSES COVID-19 AND THE OMICRON VARIANT BA.4 AND BA.5.

https://www.houstonmethodist.org/blog/articles/2022/sep/how-effective-is-the-updated-booster-against-omicron-5-more-questions-answered/

How effective is the new booster against omicron?

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

A Bivalent Omicron-Containing Booster Vaccine against Covid-19

Chalkias S et al. DOI: 10.1056/NEJMoa2208343

CLINICAL PROBLEM

Covid-19 vaccines have had decreasing effectiveness against the omicron variant, with many breakthrough infections reported. Having the ability to boost immune response in the face of omicron is important.

CLINICAL TRIAL

Design: An ongoing, open-label, phase 2–3 trial examined the safety and immunogenicity of an omicron-specific booster vaccine in persons who were fully vaccinated against Covid-19.

Intervention: 819 participants who had received a two-dose primary series of the mRNA-1273 vaccine plus a booster dose at least 3 months earlier were given a second booster with either the bivalent mRNA-1273.214 vaccine (containing 25 μg each of ancestral Wuhan-Hu-1 and omicron B.1.1.529 spike mRNAs) or the monovalent 50-μg mRNA-1273 booster (containing Wuhan-Hu-1). The primary objectives were to assess the safety, reactogenicity, and immunogenicity of mRNA-1273.214 at 28 days, as shown by noninferior or superior neutralizing antibody responses against omicron and noninferior responses against ancestral SARS-CoV-2 with the D614G mutation.

RESULTS

Immunogenicity: In participants without previous SARS-CoV-2 infection, the bivalent booster prompted a superior neutralizing antibody response to omicron and was noninferior to the monovalent booster in generating neutralizing antibodies against ancestral SARS-CoV-2 (D614G). Higher neutralizing antibody responses against both omicron and ancestral SARS-CoV-2 were also observed in participants with previous SARS-CoV-2 infection who were given the bivalent booster.

Safety and Reactogenicity: Safety and reactogenicity were similar in the two groups.

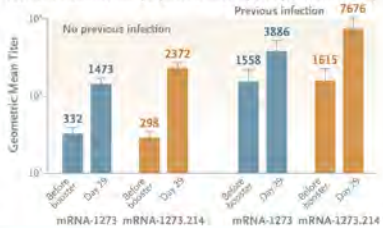
LIMITATIONS

- The trial was not randomized.
- Variant sequences were not ascertained among those infected with Covid-19.
- Follow-up was short, so it is not known how long antibodies persist.
- The trial was not designed to evaluate vaccine effectiveness.

Links: Full Article | NEJM Quick Take

Neutralizing Antibody Titers against Omicron Variant

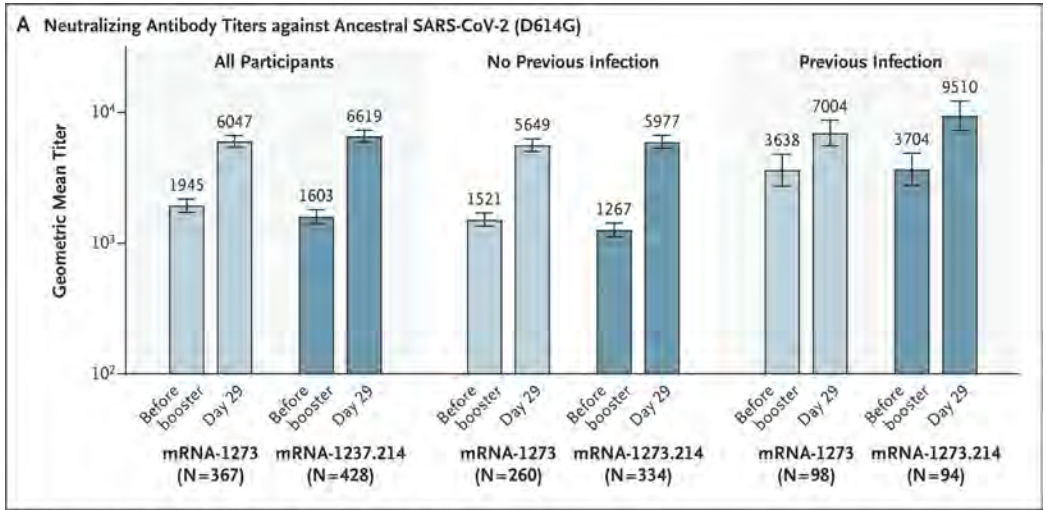
Geometric mean titer ratio (no previous infection), 1.75 (97% CI, 1.49–2.04)

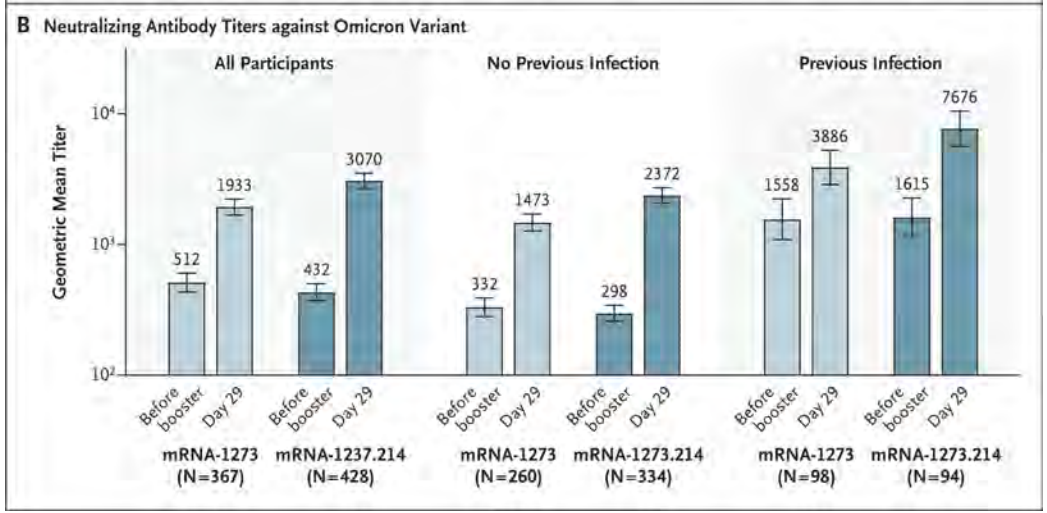


Solicited Local and Systemic Adverse Reactions

CONCLUSIONS

Among vaccinated persons who had received a booster against Covid-19, the bivalent omicron-containing mRNA-1273.214 vaccine had a safety and reactogenicity profile similar to that of the monovalent mRNA-1273 booster vaccine and was superior in eliciting a neutralizing antibody response against the omicron variant.



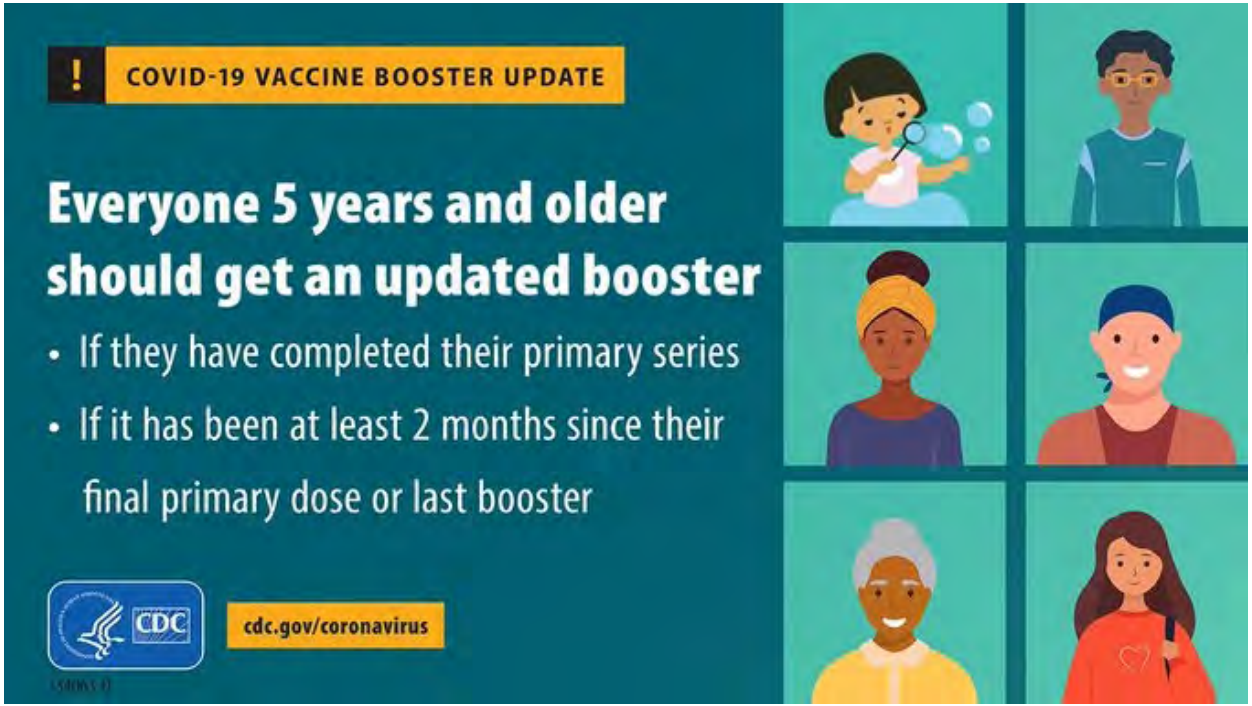


https://www.nejm.org/doi/full/10.1056/NEJMoa2208343

Who is eligible for the omicron booster right now?

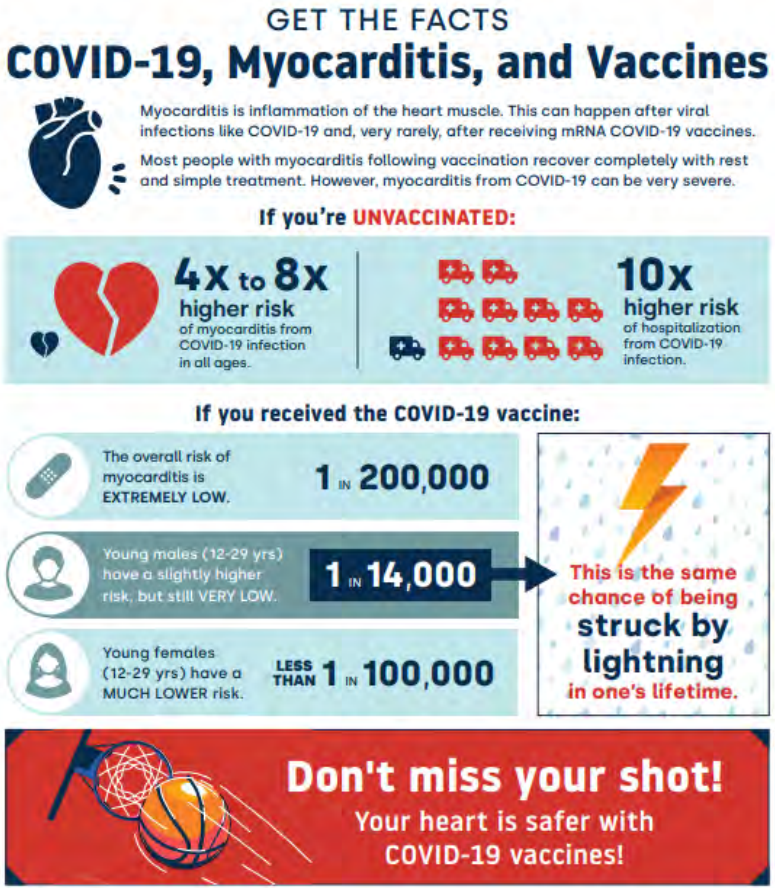
How long should I wait if I recently received a booster dose?

Do I need to get an updated booster if I just had COVID-19?



Vaccination history	→	Next dose
Primary series	At least 2 months →	1 bivalent booster dose
Primary series + 1 booster	At least 2 months →	1 bivalent booster dose
Primary series + 2 booster	At least 2 months →	1 bivalent booster dose

What about myocarditis?



https://www.idsociety.org/covid-19-real-time-learning-network/myocarditis-infographic/

NEW COVID-19 BOOSTERS FAQ

Q: Did the FDA and CDC approve this new booster?

A: Yes. They applied for EUA and were approved. Click here to see the fact sheet on the Pfizer bivalent vaccine booster, and click here to see the fact sheet on the Moderna bivalent vaccine booster.

Q: How do the new COVID-19 vaccine boosters differ from the existing vaccines and boosters?

A: These vaccines were specifically formulated to target the new COVID-19 variants. They are called bivalent because half of the COVID-19 vaccine booster targets the original COVID-19 virus, and the other half works against the Omicron variant, including the spike protein for BA.4 and BA.5 subvariants, which now account for nearly 100% of our positive COVID-19 cases.

Q: How do these new COVID-19 vaccine boosters work?

A: According to Pfizer, the bivalent vaccine contains mRNA encoding the original SARS-CoV-2 spike protein, which is present in the original COVID-19 vaccines, together with mRNA encoding the spike protein of the Omicron BA.4/BA.5 variants.

The booster stimulates the body's immune system and works by causing the body to produce antibodies against the virus that causes COVID-19. Similar to the original COVID-19 vaccines, this vaccine uses mRNA that carries instructions that cells in the body can use to make the spike protein, and the cells then make antibodies against the spike protein to help fight off the virus.

Q: Who is eligible for the new bivalent COVID-19 vaccine boosters?

A: The FDA granted EUA for the use of the Pfizer COVID-19 bivalent vaccine booster for individuals 12 years and older, while the Moderna COVID-19 bivalent vaccine booster received EUA for individuals 18 and older. The bivalent COVID-19 vaccine boosters are authorized as a single dose in people who have completed a primary vaccination series.

People who have already received the initial two-shot series of either vaccine are eligible, as well as those who have received the original vaccine plus one or two booster shots.

Q: How long should I wait if I just received the existing COVID-19 vaccine booster?

A: According to the FDA, you should wait at least two months following the primary vaccine series or booster vaccination.

Q: Does immunity still take two weeks to develop after this shot?

A: Antibody titers will start to rise within days after getting the shot, but it will probably take a couple of weeks to get the highest amount of antibodies, according to experts at Johns Hopkins School of Health.

Q: How long should I wait to get the bivalent booster if I just had COVID-19?

A: The FDA and CDC authorized the bivalent vaccine boosters for two months after previous boosters or infection. Some experts say it may be beneficial to wait a little longer.

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Q: Can I still get the original vaccine boosters?

A: No, the COVID-19 vaccine boosters that target only the original strain are no longer authorized as boosters in people 12 years old and older.

Q: How do I know these new COVID-19 vaccine boosters are safe since they were only tested on mice?

A: FDA officials say the public can rest assured that a great deal of care has been taken to ensure that these bivalent COVID-19 vaccine boosters meet the agency's rigorous safety, effectiveness and manufacturing quality standards for EUA.

According to the FDA, for each bivalent COVID-19 vaccine, the FDA based its decision on the totality of available evidence, including extensive safety and effectiveness data for each of the original COVID-19 vaccines in humans, safety and immunogenicity data obtained from a clinical study of a bivalent COVID-19 vaccine that contained mRNA specifically targeted to fight the omicron variant BA.1 variant in humans that is similar to each of the vaccines being authorized, and nonclinical data obtained using a bivalent COVID-19 vaccine that contained mRNA of the original strain and mRNA in common between the BA.4 and BA.5 lineages of the omicron variant. Human clinical trials of the bivalent vaccines targeting BA.4 / BA.5 are ongoing.

Based on the data supporting each of these authorizations, the bivalent COVID-19 vaccines are expected to provide increased protection against the currently circulating omicron variant. Individuals who receive a bivalent COVID-19 vaccine may experience side effects commonly reported by individuals who receive authorized or approved monovalent mRNA COVID-19 vaccines, according to the FDA.

FDA officials explained in a press conference that they have extensive experience with strain changes for annual influenza vaccines, which also do not require clinical trials. They are very confident that they will increase immunization to the new variants and reduce the risk of serious outcomes and hospitalizations.

Q: Why haven't these vaccine boosters been tested on humans?

A: The FDA studied mice trial data — and human clinical trial results from a similar vaccine that targets the original omicron strain (BA.1) and extensive research on mRNA technology — to evaluate the new shots in an effort to get them out as soon as possible, according to recent tweets from the FDA commissioner, Dr. Robert Califf. Both companies are currently conducting human clinical trials on the new bivalent vaccine boosters targeting BA.4/BA.5.

Q: If I got the Pfizer COVID-19 vaccine and booster, do I need the Pfizer bivalent shot or can I get Moderna?

A: No, according to the FDA, the updated booster you receive does not need to be from the same manufacturer that made the vaccine you received for your primary vaccination or previous booster.

Q: Why should I get the bivalent COVID-19 vaccine booster?

A: The BA.5 strain accounts for the vast majority of new COVID-19 cases in the U.S., according to the Centers for Disease Control and Prevention. These new vaccines are designed to significantly increase your immunity to the highly contagious virus and prevent severe disease.

Experts are predicting another wave of COVID-19 in the fall and winter, and the bivalent vaccine boosters will help protect you against serious outcomes in the future. FDA officials also say staying up to date on COVID-19 vaccines and boosters will also help prevent long COVID symptoms if you contract COVID-19 in the future.

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INTO *the* WILD

With Houston Methodist

MONDAY, NOVEMBER 7, 2022 | 6–8:30 P.M.

MASIHARA PAVILION *at the* HOUSTON ZOO

6200 Hermann Park Drive | Houston, TX 77030

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THANK YOU FOR ATTENDING OUR TOWN HALL CONVERSATION

If you would like more information about stroke prevention and treatments, please contact Emily Timm at **etimm@houstonmethodist.org**

If you would like more information about The Society for Leading Medicine, please contact Amanda Harris at **abharris@houstonmethodist.org**

Take care and be well