Amyotrophic lateral sclerosis care and research in the United States during the COVID-19 pandemic: Challenges and opportunities

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Abstract
Coronavirus disease 2019 has created unprecedented challenges for amyotrophic lateral sclerosis (ALS) clinical care and research in the United States. Traditional evaluations for making an ALS diagnosis, measuring progression, and planning interventions rely on in-person visits that may now be unsafe or impossible. Evidence- and experience-based treatment options, such as multidisciplinary team care, feeding tubes, wheelchairs, home health, and hospice, have become more difficult to obtain and in some places are unavailable. In addition, the pandemic has impacted ALS clinical trials by impairing the ability to obtain measurements for trial eligibility, to monitor safety and efficacy outcomes, and to dispense study drug, as these also often rely on in-person visits. We review opportunities for overcoming some of these challenges through telemedicine and novel measurements. These can reoptimize ALS care and research in the current setting and during future events that may limit travel and face-to-face interactions.

KEYWORDS
amyotrophic lateral sclerosis, clinical care, clinical trials, COVID-19, pandemic

1 INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic has created unprecedented challenges for neuromuscular clinicians and researchers working across several different diseases.1-5 The specific
impact on amyotrophic lateral sclerosis (ALS) care and research is illustrated in a recent survey of members of the Northeast ALS (NEALS) Consortium, a network of ALS clinical centers. Most of the 133 sites surveyed between April 21, 2020 and May 1, 2020 are affiliated with academic medical centers in the United States, have multidisciplinary care teams, see large numbers of patients, and participate in a variety of ALS research studies, including clinical trials. The survey itself is included in Figure S1 (see Supplementary Material online). Results from the 61 sites that responded are shown in Tables 1, 2, and 3.

2 | IMPACT OF COVID-19 ON ALS CLINICAL CARE AND RESEARCH

The first two survey questions asked about available options for the clinical evaluation of new and return patients (Table 1). One third of responding centers were no longer able to see new patients in-person. More than half of the responders were able to see new patients from their same state by video visit. Smaller numbers were able to offer video visits outside their state. Only 3% of responders were unable to see any new patients. With regard to follow-up patients, again a large number of responders (47%) were unable to see these in-person. Most could offer video visits to return patients in their same state, with smaller numbers being able see patients from other states. All responders were able to see follow-up patients in some manner.

Question 3 asked about evidence- and experience-based ALS measurements and treatments that may be challenging to obtain during the pandemic (Table 2). Spirometry was unavailable at most sites. Many sites reported difficulty getting feeding tubes, multidisciplinary team care, wheelchairs, home health/hospice, lifts, or hospital beds. Only 16% of responders reported being able to get everything they could for their patients before the pandemic.

Question 4 asked about available options for research participants (Table 3). Very few responding centers were able to enroll new participants into studies, either in-person or by phone or video. Most were unable to see participants for return in-person visits. About half the responders were able to see return participants virtually, even those residing in states beyond where the clinic was located. Twenty percent of responders were unable to see any research participants by any means during the pandemic.

3 | CHALLENGES TO ALS CLINICAL CARE AND RESEARCH

Our survey results confirm that COVID-19 has created specific challenges to ALS care and research in the United States. The first of these is making/confirming new ALS diagnoses. It is not clear how this may occur at sites that are now unable to offer in-person visits. Current ALS diagnostic criteria require a physical examination showing widespread upper and lower motor neuron signs. Although some aspects of a neurological examination can now be performed virtually, including measures of muscle bulk and power, assessment of muscle tone and tendon reflexes still cannot. This is likely to aggravate the already significant problem of diagnostic delay in ALS. Unfortunately, there may be no immediate way around it because previous work has shown that preliminary ALS diagnoses by nonexperts are inaccurate about 5% of the time. Even if a clinician could be certain of the findings documented by another provider, he or she may not feel comfortable breaking the news of an ALS diagnosis virtually. This idea is supported by a survey of clinicians.

### TABLE 1 Options for evaluation of new and return clinic patients at NEALS sites

|                      | New patients: number offering (%) | Return patients: number offering (%) |
|----------------------|-----------------------------------|-------------------------------------|
| In-person            | 41 (67%)                          | 32 (53%)                            |
| Video (in any state) | 18 (29%)                          | 24 (56%)                            |
| Video (in some but not all states) | 14 (23%) | 19 (31%) |
| Video (in my state)  | 38 (62%)                          | 42 (69%)                            |
| Phone                | 25 (41%)                          | 52 (87%)                            |
| Not able to offer    | 2 (3%)                            | 0 (0%)                              |

Abbreviation: NEALS, Northeast Amyotrophic Lateral Sclerosis.

### TABLE 2 Limitations on evidence- and experience-based ALS care options at NEALS sites

| Option              | Sites reporting difficulty (%) |
|---------------------|-------------------------------|
| Spirometry          | 42 (69%)                      |
| Feeding tubes       | 21 (34%)                      |
| Multidisciplinary team care | 20 (33%)     |
| Wheelchairs         | 14 (23%)                      |
| Home health/hospice | 11 (18%)                      |
| Ventilators         | 6 (10%)                       |
| Lifts               | 6 (10%)                       |
| Hospital beds       | 1 (2%)                        |
| None (can get everything I need) | 10 (16%)       |

Abbreviations: ALS, amyotrophic lateral sclerosis; NEALS, Northeast Amyotrophic Lateral Sclerosis.

### TABLE 3 Options for research patients at NEALS sites

|                               | Number offering (%) |
|-------------------------------|---------------------|
| New enrollments in person     | 12 (20%)            |
| New enrollments by phone or video | 15 (25%)         |
| Follow-ups in person          | 24 (39%)            |
| Follow-ups by phone or video (in any state) | 31 (51%)     |
| Follow-ups by phone or video (in some but not all states) | 11 (18%)   |
| Follow-ups by phone or video (in my state) | 28 (46%)       |
| Unable to see any research patients | 13 (21%)       |

Abbreviation: NEALS, Northeast Amyotrophic Lateral Sclerosis.
showing they felt that telemedicine visits lacked the emotional connection associated with in-person visits.

The second challenge relates to monitoring disease progression for clinical care and in trials. The most commonly used measure of ALS progression in clinics and in trials, the Amyotrophic Lateral Sclerosis Functional Rating Scale—Revised (ALSFRS-R), can be obtained reliably and easily over the phone or by telemedicine. Unfortunately, another important measure, spirometry, has recently been unavailable at almost 70% of NEALS sites. Even when patients can be seen in-person, use of spirometry has been cautioned by experts because it can stimulate a cough, which can aerosolize COVID-19 droplets and thus create an increased risk of spread. Spirometry is one of the main ways ALS clinicians determine prognoses, and make decisions about when to offer various evidence-based ALS care options, including noninvasive ventilation, invasive ventilation, feeding tubes, and hospice. It is also a key inclusion criterion for most ALS trials. With the restrictions placed on in-person visits at some sites, it is also not clear how key parts of safety monitoring in research participants such as blood draws and electrocardiograms can be performed.

A third challenge is the sudden unavailability of many key ALS treatment options. Multidisciplinary team care, which is associated with improved quality and length of life in people with ALS, is currently unavailable at one third of NEALS sites. Placement of feeding tubes, which are important for maintaining weight and improving survival in ALS patients, wheelchairs, which keep patients active and prevent falls; home health and hospice, which provide education as well as support and palliative care, are also all currently unavailable at some NEALS sites. These restrictions can also affect research studies. It has largely been assumed that baseline ALS care being provided at different sites of a multicenter trial is similar; this assumption is currently incorrect.

### TABLE 4 COVID-19 challenges and opportunities in ALS care and research

| Challenges                                                                 | Opportunities                                                                 |
|---------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| Inability to offer face-to-face clinic and research visits                 | • Capitalize on the large growth in telemedicine availability, at least for follow-up clinic patients and research patients |
| Inability to perform spirometry, including vital capacity which is used as an inclusion criterion in trials, and to plan timing of several care options (eg, NIV initiation) | • Use home-based spirometry<br>• Develop alternative measures that correlate well with spirometry but are simpler and carry no increases risk of infection (eg, counting out loud, vocalizing a sound) |
| Limited availability of several evidence- and experience-based ALS care options | • Capitalize on previous work showing that multidisciplinary ALS care is possible via telemedicine<br>• Account for variability in care options across different trial sites |

Abbreviations: ALS, amyotrophic lateral sclerosis; COVID-19, coronavirus 2019; NIV, noninvasive ventilation.

## 4 | OPPORTUNITIES FOR ALS CLINICAL CARE AND RESEARCH

The rapid expansion of telemedicine represents an exciting opportunity to improve clinical care and expand access to research opportunities for many patients (Table 4). At the beginning of 2020, a small but growing number of ALS centers were offering telemedicine visits to patients in their homes. Because no billing codes existed for this, it was supported by philanthropy, ALS nonprofits, or local institutions. Many states had laws restricting telemedicine visits to clinicians licensed in that state. The current pandemic has catalyzed the creation of new billing codes for telemedicine in the home, and many states have recently suspended their telemedicine licensure requirements. As evidenced by the NEALS survey, within a matter of weeks of the COVID-19 pandemic in the United States, more ALS centers were offering telemedicine for established patients than were offering traditional in-clinic visits. In medicine, where change is usually slow, the rapid acceptance and delivery of telemedicine is unprecedented. Although some patients still do not have internet access at home, that number is dwindling. In addition, hospital systems have invested in telemedicine teams to handle the massive increase in internet traffic to and from their institutions. Even as the COVID-19 pandemic resolves, partnering with patient advocacy groups will help ensure that telemedicine remains an effective tool to allow clinicians more effective care for patients for whom travel to the clinic is burdensome, fatiguing, or otherwise impractical.

We should also expand upon this new telemedicine infrastructure. First, we should increase the number of sites that can use it to provide multidisciplinary team care. Such care is known to improve quality of life and survival for people with ALS. During an in-person visit, the multidisciplinary providers generally see patients in succession while the patient remains in a single room for a multi-hour visit. Although this approach is still tenable for some teams using telemedicine, other approaches can also be successful. These can include hybrid models in which some clinicians see patients face-to-face and others see them virtually, models where the physician visit is scheduled and follow-up visits with the multidisciplinary team occur ad hoc over time, and asynchronous visits using recorded video for patients without access to internet. In the Veterans Affairs hospital system, one analysis demonstrated that quality of ALS care was independent of its delivery by telemedicine or in clinic.

Some measurements or evaluations will need to be altered to be administered via telemedicine. Although spirometry is generally considered a clinic-based assessment, it can also be done using a home spirometer and having a trained clinic staff monitor the patient as he/she performs the spirometry. Some home spirometers are approved by the US Food and Drug Administration (FDA) and web-connected, transmitting data directly to a central database. Ultimately, these devices could transmit data directly into the electronic medical record. Preliminary studies in the national Answer ALS program suggest app-based vital capacity can be monitored (unpublished observations).
Surrogates for spirometry could also be explored for ALS patients. These may include single-breath counting or vocalizing a sound; these have proven to correlate with spirometry in other study populations.31

When it comes to using telemedicine for research, remote or virtual consent platforms already exist. In fact, the FDA published a final guidance in December 2016 for institutional review boards, investigators, and sponsors.32 This can ease the hurdle of recruiting and enrolling people living with ALS into clinical trials. Another aspect of clinical trial design that can be improved is the frequency of in-person visits. It may be possible to conduct remote or virtual visits, conducting home safety measures by sending a service to the home to collect labs or electrocardiograms. Novel research outcomes are emerging that can be obtained virtually. Digital voice recordings and quantitative speech analysis can be evaluated through recordings from cellphone apps to monitor disease progression.33 Medical surveys can be deliv-
ered to people with ALS, and quantitative data about movement can be collected. As algorithms for processing data mature, passive cell phone data could be used to inform providers about patient well-being.34,35 Wearables may paint an even more detailed picture of patient function and behavior, although with the cost of requiring the patient to wear an additional device.35

5 | DISCUSSION

The COVID-19 pandemic has created an unprecedented challenges to ALS clinical care and research. The traditional face-to-face paradigm of medical decisionmaking and trial conduct have become difficult or impossible for many sites. An unexpected silver lining to these challenges is the development and maturation of a telemedicine infrastructure, providing clinicians and researchers with opportunities to fortify and even improve the way we approach ALS care and research. Our combined experiences of clinician-patient interactions during this pandemic will provide us with new paradigms that will likely improve the efficiency of clinical care and availability of research participation.

CONFLICT OF INTEREST

J.A. has consulted for Aveaxis, AL-S Pharma, Biogen, and Cytokinetics, and has received research grants from Neuraltus, Roche, Biogen, and Novartis. J.B. has consulted for Biogen, Clene Nanomedicine, and Alexion, and has received research support from Alexion, Biogen, MT Pharma of America, Amylyx Therapeutics, Anelixis Therapeutics, Brainstorm Cell Therapeutics, Genentech, nQ Medical, the National Instutes for Health/National Institute of Neurological Disorder and Stroke (NINDS/NIH), the Muscular Dystrophy Association (MDA), and ALS One. R.B. has consulted for Modulus Pharmaceuticals, Mitochondria in Motion, Accurastem, Sarepta, and Kite Pharma, and has received research grants from the NINDS/NIH, California Institute for Regenerative Medicine, Target ALS, Burroughs Wellcome Fund, the MDA, and the Charcot-Marie-Tooth Association. M.C. has consulted for Biogen, Cytokinetics, Sunovian, AL-S Pharma, Aveaxis, and Takeda. J.G. has research support from the NIH, ALSA, and the MDA, and clinical trial funding from Biogen, Genentech, Amylyx, Cytokinetics, and the Healy Center at Massachusetts General Hospital. N.M. has consulted for Orion, Apellis, Brainstorm Cell Therapeutics, and Clene Nanomedicine, and has received research support from the Department of Defense ALSRP, Answer ALS, the ALS Association, the NIH/NINDS, Biogen, and Clene. T.M.M. has licensing agreements with C2N and Ionis Pharmaceuticals, has served on advisory boards for and receives material support from Biogen and Ionis Pharmaceuticals, and is a consultant for Cytokinetics and Disarm Therapeutics. S.P. reports personal consulting fees for advisory panels from Orion Corp and reports research grant support from Amylyx Therapeutics, Revalesio Corporation, Ra Pharma, Biohaven, Clene, Prilenia, the ALS Association, the American Academy of Neurology, ALS Finding a Cure, the Salah Foundation, and the Spastic Paraplegia Foundation. J.R. has consulted for Expansion therapeutics and received research grants from the NIH/NINDS, the NIH/National Institute on Aging, the Department of Defense, the Chan Zuckerberg Initiative, the ALS Association, the MDA, Target ALS, F Prime, Travelers Insurance, American Airlines, ALS Finding a Cure, Answer ALS, Team Gleason, and Microsoft. Z.S. has consulted for Amylyx, Biogen, Biohaven, and Cytokinetics, and has received research support from Biogen, Biohaven, and Cytokinetics. M.W. has consulted for Biogen, Ra Pharma, and Argenx; is a speaker for Nufactor; and has received research support from ALSA and ALS Finding a Cure. R.B. has research support from ALSA and Orion, and consulting support from Amylyx, Alexion, ALSA, Biogen, Brainstorm Cell, ITF Pharma, Mallinkrodt, New Biotic, and Woolsey Pharma. N.C., B.D., and J.S. declare no potential conflicts of interest.

ETHICAL PUBLICATION STATEMENT

We confirm that we have read the Journal’s position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section at the end of this article.

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