ALSUntangled: Opening Up the X-Files of ALS

Richard S. Bedlack MD PhD FAAN
Duke University ALS Clinic
The Original X-Files

- TV show, 1993-2002; Movies
- Fox Mulder
  - Witnesses something strange
    - Disappearance of sister Samantha; Aliens?
  - Spends the rest of his life trying to investigate/understand it and similarly bizarre happenings
  - *Usually* finds a rational explanation

http://en.wikipedia.org/wiki/The_X-Files
Samantha

- 60 year old university professor, newly diagnosed with clinically definite sporadic ALS. She currently has minimal bulbar weakness, moderate arm and leg weakness. No obvious cognitive or behavior problems.

- Following education about the disease itself, she is presented with stage-appropriate, evidence-based management options including riluzole, multi-disciplinary team care
  - *Neurology* 2009;73:1218-1233

- She is also asked about participating in a research study
Samantha

- She opts for the first two, but declines the research study in favor of pursuing oral sodium chlorite

- Example of an alternative or off-label treatment (AOT, defined as non-mainstream therapy advertised to slow, stop or reverse ALS progression, without good evidence)
Common Decision?

• Survey of 350 patients with ALS
  – 50% responded
  – 54% admitted using at least 1 AOT
    – *J Neurol Sci* 2001;191:151-4

• Survey of 177 ALSRG clinicians
  – 23% responded
  – 50% stated they had patients using AOTs
    – *ALS* 2008;9:257-65
Why Try AOTs?

- ALS is a devastating, incurable, fatal disease with few proven treatment options
  - *Neurology* 2009;73:1218-1233
- Current treatments and those in foreseeable future *may slightly slow progression*
- 10% believe they will find a cure, 20% believe they will find something to make them better, 50% believe they will find something to slow progression
- “Peer pressure”
- “What further harm could come to me?”
  - *J Neurol Sci* 2001;191:151-4
Why Try AOTs?

• Many AOTs out there
  – Google search 3/11: 43M; 3/12: 80M

• Proponents of AOTs make attractive claims
  – “Clinically Proven”
  – “Perfectly safe”

- http://mototab.com/
Problematic?

• Information on AOTs ranges from absent to highly flawed to inaccurate
Ex. Absent Information

Welcome to mototab.com!

Most probably you are here in search of a treatment for Motor Neuron Disease. Rest assured that your search is now over!

Mototab is the world's most relied upon and clinically proven natural treatment for Motor Neuron Disease.

For more information on our fully guaranteed treatment, Mototab, please click here.

To view information on Motor Neuron Disease please click here.

Clinical Research on Mototab
Mototab is clinically proven to treat Motor Neuron Disease successfully. You may download a summary of our clinical study in Adobe's PDF format. Click here for details.

Mototab Guarantee
Mototab is a completely guaranteed treatment. You are at no risk for trying Mototab. Click here for details.

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Clinical Research Study

The unique formulation of Mototab is a result of extensive study and research. Mototab is clinically proven to be a safe and effective treatment for Motor Neuron Disease. To download the summary of a clinical research study on the effectiveness of Mototab please click the link below.

Clinical Study soon to be posted here (Size: 96 Kb)

Requires Adobe Acrobat Reader.

Click here to download Adobe's Acrobat Reader.

-http://mototab.com/
# DISCOVER AND COMPARE ALTERNATIVE HEALTH TREATMENT OPTIONS FOR Motor Neuron Disease

Sponsored by: The Society for the Promotion of Alternative Health (SPAH)
Suite 401, 302 Regent Street, London W1B 3WJ, United Kingdom

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## Effectiveness

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Hundreds of users rely upon these ratings daily to help them identify reliable alternative treatment options for their or a loved one’s Motor Neuron Disease condition.

Your participation in this poll is always a source of encouragement and a quick way for us to gain important feedback.

Please tell us how helpful you found our Motor Neuron Disease treatment ratings:
- Very Helpful
- Reasonably Helpful
- Not Helpful
- Can't Say

Submit
Ex. Flawed Information

Results from ALS treatment after 1 - 6 months (up to May 2008)

- Deterioration (17)
- No change (16)
- Improvement (19)
- Strong improvement (1)
- Cured (0)

© 2008 Xcell-center.com
Ex. Flawed Information

Details

- Investigators called patients and asked them to categorize themselves.

![Results from ALS treatment after 1 - 6 months (up to May 2008)](chart.png)
Ex. Inaccurate Information

For those who believe, no proof is necessary;  
For those who don’t believe, no proof is enough.

224

During her recovery, she had shared bits of the skepticism that had come her way from some of her doctors or people that didn’t believe in energy healing, and I had repeated these lines to her. I was deeply touched with this thoughtful and miraculously created gift, and realized its significance: All her recent extensive diagnostic tests from the same top hospitals and medical centers that had confirmed over and over that she was properly diagnosed with this killer disease now showed the disease was no longer present in her body. This was the first case on the medical books of Lou Gehrig’s ever going into a full remission. It was unequivocal proof that the laying on of hands can indeed reverse terminal illnesses that had no treatment, no cure, and no hope.
“Reversible ALS” Does Exist


Problematic?

• Potential Harms
  – Financial
  – Psychological
  – Physical
  – Scientific

Scientific Harms of AOTs

- **Enrollment** surprisingly low in ALS research studies
  - Less than 10% of PALS enroll in research studies
  - Literature review shows that ALS trial enrollment rate is 2 patients per site per month and not improving over time
  - “Doctor factors” and “patient factors” more important than “trial factors”
    - ALS 2008;9:257-65
    - ALS 2010;11:502-507
Doctor Factors

- Lack of awareness
- Loss of control/doctor-patient relationship
- Perceived increase in time and paperwork
- Doubts about protocols

96% physicians who treat PD believe trials are necessary, >60% have never referred a patient for one and most say they discuss trials with less than 10% of their patients

-Harris Poll 2005
Patient Factors

- Lack of awareness
- Concerns about burdens (time, travel)
- Fear of unexpected costs
- Fear of “being a guinea pig”
- Perceived loss of control over decision making
- Possibility of not receiving “best possible care” especially with placebo designs
- Confusion about research process, specifics
- Choosing an alternative therapy
  - According to ALS neurologists, 50% of eligible PALS decline research studies for this reason
    - *ALS 2008;9:257-65*
Scientific Harms of AOTs

• Consequences of lack of enrollment
  – She herself is being deprived of the benefits of being in trials (hope, altruism, “doing better” medically)
    – *Journal of Clinical Epidemiology* 2001;54:217-224
    – *Mov Disord* 2012;27:506-511
  – Trials take longer, are more expensive, may be terminated without a definitive conclusion
    – *Clinical Trials* 2010;7:312-321
  – Trial results may not be generalizable
    – *Neurology* 2011;77:1432
  – Unless this can be solved, it will take longer than it should to find a cure for ALS
What To Do?

• Models for Decision Making in Doctor-Patient Relationship

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<th>MD Obligation</th>
<th>Patient Autonomy</th>
<th>Patient Values</th>
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<tr>
<td>Paternalism</td>
<td>Parent or guardian</td>
<td>Define and promote goals</td>
<td>None</td>
<td>Defined by MD</td>
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<tr>
<td>Autonomy</td>
<td>Assent</td>
<td>Assist with procurement</td>
<td>Central and absolute</td>
<td>Assumed to be defined and reasonable</td>
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<tr>
<td>Consumerism</td>
<td>Technical expert</td>
<td>Provide relevant factual info</td>
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<td>Assumed to be defined and reasonable</td>
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<tr>
<td>Shared decision-making</td>
<td>Advisor</td>
<td>Provide info and opinion</td>
<td>Respected</td>
<td>Fluid</td>
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</table>
Paternalism

Strengths

• Physicians have many years of specialized training, experience, tools to critically evaluate treatment options according to efficacy and side effects

• Lasted a long time so there must be something about it that satisfies needs of both parties

Weaknesses

• Patient may not share same goals, values, acceptable benefits and risks

• Patients may want more or less than the physician is willing to give at particular time (active seekers, selective seekers, information avoiders)

  • *Br J Nurs* 2004;13:964-968

• Can be abused, at bedside and in clinical “research”
Autonomy

Strengths
• Respect for patient-defined values and goals is and should be paramount
• Allows patients to proceed with information gathering at their own pace (active seekers, selective seekers, information avoiders)

Weaknesses
• Underutilization of physician education, training and experience
• Patient values and goals may not be well-defined or stable over time
• Information patient is using may be flawed
“In Between” Models

**Strengths**
- Utilize physician talents and skills while still allowing patient to ultimately define values, goals, acceptable risks and benefits

**Weaknesses**
- In consumerism, the physician is reduced to a detached information source; patient values may be uncertain and may change
- Fine line between shared decision-making and paternalism
- Take more time
What To Do?

• Most patients (and doctors) prefer shared decision-making
  – *Patient Education and Counseling* 2007;65:189-196
  – *BMC Family Practice* 2007;8:10

• Shared decision-making is associated with improved compliance and health outcomes
  – *Med Care* 1989;33:s110-127
  – *Med Care* 1995;1176-1187
  – *BMJ* 2001;323:908-911

• But time in medicine is becoming more scarce...
Shared Shared Decision-Making

• Van den Berg
  – Systematically Investigated Beijing West Hill Hospital and Rehabilitation Center (OEC’s injected into brains of PALS)
    • Critiqued theory, “published data” claiming “safe” and “50-70% improved”
    • Visited clinic, interviewed physicians
    • Followed 7 PALS with validated ALS outcomes
  – Reported findings, advised against going
    • Very brief subjective benefit in 2 PALS
    • No objective evidence benefit
    • Documented harms (blood clot, respiratory failure & death)
    • $25,000

-2007 International Symposium Platform
-ALS 2010;11:328-330
ALSUntangled

• Started 2009 as ALSRG project
• Goal: develop group of clinicians/scientists that systematically assess AOTs, toward ultimately helping patients with ALS make more informed decisions
• Methods
  – Inputs from PALS
  – Investigations/Reviews
  – Outputs
Inputs

• Make it simple for PALS all over the world to access ALSUntangled with queries
  – Face to face meetings in clinics
  – Email: bedla001@mc.duke.edu
  – Twitter: twitter.com/#!/alsuntangled
    • Don’t need to remember specific email address, just key word
    • Everyone can see what is being asked about
  – Website www.alsuntangled.org
    • Describes program, email address, how to use Twitter
**Twitter Activity**

**FOLLOWERS**
- 3/10: 137
- 3/11: 363
- 3/12: 643
- 6/13: 1,127

**TWEETS**
- 3/10: monthly
- 3/11: weekly
- 3/12: daily
OPEN QUERIES

3/10: 26
3/11: 31
3/12: 40
6/13: 70

Open Reviews

- Accupuncture
- Alpenpark Clinic
- Ampyra
- AZ Stem Cell Center
- Baar Wet Cell
- Beike Clinic
- Biochromicium
- BuNaoGao (BNG)
- Cold Comfort
- Cupping
- Dr. Alice Fan
- Dr. David Steenblock
- Dr. Jason Williams, Precision Stem Cells
- Dr. Joseph Jemsek
- Dr. Maharaj
- Dr. Marvin Spounagle
- Dr. Savely Yurkovsky and Field Control Therapy
- Dr. Shahrar Vaziritebar
- Dr. Steve Ray, Natural Biosciences SA
- Dr. Warren Levin
- Dr. Zannos Grekos Stem Cell Clinic in Dominican Republic
- Dr. Zhu Ming at Huaihua Red Cross Hospital
- Embrel
- Equilibrium Therapy
- Eric is Winning
- Even Better Now
- Fry Labs
- Glutamate
- Glutamine
- Gluthione
- Hemp Oil
- Hippocrates Health Institute
- Huggins Applied Healing
- Hyperbaric Oxygen
- International Center for Cell Therapy and Cancer Immunotherapy
- Medra
- Mestinon
- Methylcobalamin
- Metronome
- Music Therapy
- Nepsis
- Normast
- Omental Transplants
- Perlmutter Clinic in Naples Florida
- Placebo Therapy
- ProTandim
- Regenocyte Clinic run by Dr. Grekos in Bonita Springs, Florida
- Repair Stem Cell Institute
- Resveratrol
- Sound Therapy
- Stem Cell Rejuvenation Center
- Stem Cells at Cell Medicine
- Stem Cells via TCA Cellular
- Stem-Kine
- Tamoxifen
- Tea
- The Bronx Project
- The Healing Code Solution
- Troneton
- UDCA/cyclosporine
- Ursodiol
- Vitamin C
- WF10
- Stem Cells
Reviews

• Team
  – Originally: 38 members, 4 countries
  – Today: 85 members, 10 countries (USA, Canada, Ireland, Israel, Spain, Thailand, Sweden, Poland, France, Russia)

• Platform for Interaction
  – NING (not used, now cancelled)
  – Email list serve (more than 100 emails in past year)
Reviews

• SOP
  – Multiple attempts to contact proponents
  – Materials from clinic (ex. Website)
  – PubMed Search (relevant publications)
  – Google Search (news, blogs)
  – Poll ALSUntangled Team (cases with objective measures)
  – Patients Like Me review (cases with subjective measures)
  – Visit Clinic
    • Review infrastructure
    • Interview proponents
    • Review records, interview “best successes”
Reviews

• Systematic Investigation Form
  – Clinic Name:
  – Location(s):
  – Advertising:
  – Name of Treatment Offered
  – Diseases Treated Besides ALS:
  – Detailed Description of Treatment:
  – Cost:
    • Amount Billed Each Visit:
    • Number of Visits Required:
      • Amount Paid By Insurance Companies (range):
  – Theoretical Benefits/Rationale:
  – Theoretical Risks:
  – Actual evidence of benefit (and type of evidence)
  – Actual List of AEs Encountered in Patients with ALS
  – Consent Process:
    • Inclusion/Exclusion Entry Criteria:
  – Outcome Measures Followed:
    • Efficacy:
    • Safety:
  – Facility Description:
  – Critique/Commentary:
Outputs

• Reports published “free open access” in journal Amyotrophic Lateral Sclerosis
• Group authorship
  – Members get minimum 48h to comment on draft
  – “Note: this paper represents a consensus of those weighing in. The opinions expressed in this paper are not necessarily shared by every investigator in this group.”
• 1000 words
• Standard format
  – What is the therapy being investigated?
  – Where did the idea for the investigation come from?
  – What is the rationale for using this therapy in PALS?
  – How is it obtained and delivered to PALS?
  – What are the efficacy data for this therapy in ALS?
  – What are the safety data for this therapy in ALS and in other relevant diseases?
  – How much does it cost?
  – Based upon the above, what are our recommendations?
Using Social Networking to Bring Patients, Clinicians and Scientists Together for Investigation of Alternative or Off-Label ALS Treatments.

Completed Reviews

1. Lyme Disease and Iplex
2. The Hickey Wellness Center
3. Stem cell transplants at the Hospital San Jose Tecnologico de Monterrey
4. The XCell-Center
5. The Stowe/Morales ALS Protocol
6. Marty Murray's Method
7. Hyperimmune Goat Serum for ALS
8. Low dose naltrexone for ALS
9. Spirulina (blue green algae) as a treatment for ALS
10. Luteolin and Lutimax
11. NuTech Mediworld
12. Dean Kraft, Energy Healer
13. Bee Venom
14. Mototab
15. Coconut Oil
16. Cannabis
17. "When ALS Is Lyme"
18. Apoaequorin (Prevagen)
19. Sodium Chlorite
20. Deanna Protocol
Lessons Learned
Lessons Learned

• It is rarely possible to know the motivation of the AOT proponent

• Larry Stowe (Stowe/Morales Protocol)
  – Impersonated physician
  – Lied about relationships with American Universities and Agencies such as FDA
  – Made impossible claims on hidden camera, later denied them
  – Currently arrested, awaiting trial
    – ALS 2010;11:414-416
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- **Over All Position**
  - 1st
  - 2nd
  - 3rd

- **Treatment Name**
  - Neurontin
  - Motoneurontin
  - Ramilin

- **Website**
  - Neurontin.com
  - Motoneurontin.com
  - Ramilin.com

- **Health System**
  - Herbal
  - Herbal
  - Homeopathy

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</table>
- **Traditionally Proven**
- **Clinically Tested**
- **Worldwide Usage**
- **Short Term Focus**

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- [Motor Neuron Disease Treatments - Windows Internet Explorer](http://motorneuron-options.com/index.html)

- [http://motorneuron-options.com](http://motorneuron-options.com)
Dr. Joe Hickey: A “True Believer”
-ALS2009;10:490-491
Lessons Learned

• AOT proponents do some things really well
  – I watched Dr. Hickey interact with his patients and then I interviewed them separately
  – Qualities he demonstrated that his patients said they did not find in their mainstream ALS doctors
    • Optimism
    • Respect
    • Responsiveness
Lessons Learned
Lessons Learned

• The most obviously flawed/bogus clinics/AOTs share things in common
  – Advertised as “dramatically effective” or “cure all” for multiple diseases with different pathophysiologies
  – Advertised as “perfectly safe”
  – Non-MD making medical recommendations
  – Lack of oversight/consent
  – Lack of standardized protocol
  – Large up front out of pocket cost
  – Subjective or no outcome measures
  – Lack of follow up
Lessons Learned

- Some AOTs warrant further study
  - Plausible mechanism
  - Either multiple positive animal studies, or published positive human study, or multiple case reports/blogs suggesting similar benefit
  - At least some human data available on safety and cost
CD 133+ stem cells from peripheral blood, injected into frontal motor cortex

Pilot trial
- 10 treated, 13 controls
- Improved survival and ALSFRS-R progression in treated patients
  - Non-randomized
  - Varying doses
  - Groups not balanced
    - Diagnosis-baseline
      » Treated 30m
      » Control 14m

“Safe and well tolerated”

Cost: $18,000 + travel
Aimspro

- Hyperimmune goat serum injected subcutaneously
- Single autobiographical case report, limited info on diagnosis
- Author performed his own PFTs, combined MEP, MIP, SNIP, FVC into one measure RFT
- Increasing dosages (intervals) appeared to result in improving, eventually reversing RFT decline; no effect on muscle strength
  - Bias, lack of validation of outcome, other therapies also used
- “No side effects” reported
- Cost: £19,000 per year

Fig. 1. The mean of four respiratory function tests (RFTs) (forced vital capacity, maximum mouth inspiratory and expiratory pressure and sniff nasal inspiratory pressure) per month, showing lines of best fit during each of four phases as a percentage of the predicted value showing changes over the course of treatment (Phase 1, untreated; Phase 2, first 13 months of second daily subcutaneous injection of 4 mg hyper-immune goat serum (Aimspro®); Phase 3, a further 23 months of phase 2 treatment; Phase 4, daily injection of an Australian source of Aimspro®).

Journal of Clinical Neuroscience 16 (2009) 1508–1511
Lutimax

- Combination of vitamins, flavonoids taken orally
- Video
- Pilot trial 25pts, 800mg daily, compared to Topiramate Placebo Group
- Slower progression in ALSFRS-R in Lutimax treated group
  - Not randomized, blinded
  - Large drop out rate
- Side effects include possible weight loss (carbohydrate restricted diet)
- Cost: $25-199 per month

**ALS 2011;12:235-237**
Coconut Oil

• Background

• Rationale(s) for Use in ALS
  - Converted into ketone bodies which may ameliorate energy production problems secondary to mitochondrial dysfunction
  - Source of fat calories, raises cholesterol
Coconut Oil

• Data
  – Animal (SOD1-G93A mice)
    • No trials of coconut oil
    • Ketogenic diet
      – Significantly better preserved rotarod function and motor neuron counts

• High fat diet
  – Significantly higher BMI, preserved motor neuron counts, improved survival
    » Lupuis L, Oudart H, Rene F, Gonzalez de Aguilar J, Loeffler J. Evidence for defective energy homeostasis in amyotrophic lateral sclerosis: benefit of a high energy diet in a transgenic mouse model. PNAS 2004;101:11159-11164
Coconut Oil

• Data
  – Human
    • No trials of coconut oil
    • No validated case reports
    • 6 PALS from web (5 from PLM)
      – Wide range of formulations, dosages, durations
        » “Optimal” dose unclear
      – 2/6 report improved muscle strength
      – Most common side effects are stomach upset, nausea, diarrhea (no discontinuations due to side effects)
      – Cost: $25-49 monthly
Challenges

• Widening gap between open and completed investigations
  • Rapid increase in twitter followers, requests
  • Lack of available information on some topics
  • Difficulty finding lead authors
  • Hard limit on number of ALS journal issues each year
• Limited opportunities for comments/rebuttals related to published investigations
• Difficult to measure “usefulness”
• No resources for follow up study of interesting AOTs
Opportunities, Next Steps

• Creating incentives for lead authors (meeting expenses)
  – 3 new lead authors in past month
• Publishing “early online” on ALS journal website
• Expanding our website to allow comments/rebuttals via twitter
• Allowing clients to vote for the open reviews they most want to see
Is ALSUntangled Useful?

### Top 50 Most Viewed Articles in Amyotrophic Lateral Sclerosis 2012

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<td>11</td>
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<td>ALSUntangled Update 4: Investigating the XCell-Center</td>
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<td>ALSUntangled No. 18: Apoaequorin (Prevagen)</td>
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-Source: ALS Editorial Board Meeting 2012
ALSUntangled: Conclusions

• Investigation of AOTs is timely and important
• “The Truth Is Out There” but it isn’t always easy to find
• ALSUntangled uses social networking to bring patients and clinician/scientists together to systematically review and report on AOTs
• Interesting lessons being learned (including ideas for future studies)
• Challenges are being addressed by incentivizing new authors, modifying website
• ALSUntangled reviews are being downloaded frequently
Where Does ALSUntangled Fit?

• Broad Goal: Cure ALS
• Why No Cure?
  – We don’t know what causes most cases
  – We don’t understand disease progression
  – It takes a long time to make a diagnosis
  – Our measurement tools are noisy and slow to change
  – It is a rare disease with limited resources available for study
  – **Enrollment in ALS research studies is surprisingly low**
    • My focus
    • Working with ALSRG, NEALS, WALS, Packard
Raise Awareness of Research Options

- Advertising via National ALS Registry
- Speaking to patient groups, writing in patient-centric literature
- Training research advocates (including patients and caregivers)
ALS Clinical Research Learning Institutes

• Modeled after successful programs in PD, cancer
• Lectures on research including ethics, informed consent, trial designs, statistics
• Lectures on advocacy including tips on public speaking, writing letters to the editor, writing letters to congress, internet tools, meeting with the press and congress
• Discussion and debate between faculty and attendees regarding research barriers and how to address them; both leave with new appreciation for the others’ issues

-Nat Rev Cancer 2005;5:73-78
<table>
<thead>
<tr>
<th>Outreach Efforts by NEALS Research Ambassadors</th>
<th>Number of Each</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speaking at a Fundraiser</td>
<td>0</td>
</tr>
<tr>
<td>Speaking at a Support Group</td>
<td>3</td>
</tr>
<tr>
<td>Speaking to a Congressman</td>
<td>2</td>
</tr>
<tr>
<td>Interview</td>
<td>5</td>
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<tr>
<td>Writing in a Newspaper</td>
<td>8</td>
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<tr>
<td>Writing in a Blog</td>
<td>0</td>
</tr>
<tr>
<td>Writing in a Website</td>
<td>20</td>
</tr>
<tr>
<td>Writing to a Congressman</td>
<td>3</td>
</tr>
</tbody>
</table>

This table shows the types of outreach efforts being undertaken by our NEALS Research Ambassadors. Through these, they are educating and advocating about ALS research to patients, clinicians, press and policymakers. We are very proud of them! If you would like to be a NEALS Research Ambassador please apply for the 2013 ALS Clinical Research Learning Institute [here](#).
Reduce Travel Burden

• Build more clinics
  • Clinic Mapping (ex. ALSA)

• Expand number of clinics with research studies
  • Consortia (ex. NEALS at 102 sites)

• Develop home based outcome measures
  • Ex. Arimoclomol trial for patients with FALS1 is underway using home spirometry, telephone ALSFRS-R scores
Optimize Study Presentations

• *Physicians* should present research option (not ancillary staff)
• Address misconceptions, AOTs
• Include video (ex. NEALS Ceftriaxone Study)
  – This approach improved patient knowledge and enrollment in cancer studies
    » J Thorac Oncol 2008;3:3-5
Samantha: One Resolution

- Patient given a copy of ALSUntangled 19: Sodium Chlorite (in press)
  - Rationale: sodium chlorite is the active ingredient in NP001, an IV treatment from Neuraltus Pharmaceuticals that inhibits macrophage activation
  - NP001 has shown efficacy in an ALS animal study
  - NP001 appeared safe and tolerable in a small human ALS trial; primary efficacy analysis was negative but post-hoc analysis suggested 27% of PALS on NP001 did not progress over 6m on ALSFRS-R, versus 10% of concomitant and historical controls. Further studies planned.
Samantha: One Resolution

• Patient given a copy of ALSUntangled 19: Sodium Chlorite
  – Only anecdotal evidence for oral sodium chlorite. PLM cohort on oral sodium chlorite had faster progression of ALSFRS-R scores compared to historical controls.
  – Not clear that oral sodium chlorite can be absorbed at levels that affect macrophage function, or that it is safe (reports of chlorine dioxide generation and hospitalizations).
  – ALSUntangled does not recommend further use or study of oral sodium chlorite unless it can be shown to be safe and act on a relevant mechanism.
Samantha: One Resolution

• Patient educated on option of participation in research studies, including clearing up misconceptions

• Decides to forgo oral sodium chlorite in favor of participation in new ALS clinical trial

• Attends ALS Clinical Research Learning Institute; becomes advocate for ALS Research
Thanks

- Patients
- Packard Center
- MNDA
- ALSRG
- ALSA
- MDA
- WFNALS
- ALS Journal
- 60 Minutes
- Quackwatch
- Patients Like Me
- ALS Worldwide
- ISSCR