Much more complex and controversial than reflexive use would suggest!

This topic was assigned by the organizers of the 2013 Charleston Swallowing conference.

It was delivered at that conference.

The conference was jointly sponsored by Medical University of South Carolina and Northern Speech Services.

Few of us would publically deny that practice based (in part) on evidence is a good idea.

Few of us have not seen patients in consultation with horror stories to tell about some of the things they had been asked to do in pursuit of enjoyable, safe, adequate nutrition and hydration.

“What was the clinician thinking?” we sometimes ask.

Other warnings about the risks of unexamined treatments abound.
Patient's are vulnerable

- Oliver Wendell Holmes: There is nothing people will not do, there is nothing they have not done, to recover their health, to save their lives. They have submitted to be half drowned in water, to swallow all sorts of abominations, and to pay for all this, as if to be singed and scalded were a costly privilege.

There are gaps in care

- The slow diffusion of empirically supported treatments and the rapid diffusion of treatments lacking empirical support play a significant role in the quality gap in the care of people...

It's part of a bigger societal problem

- Verifiable knowledge makes its way slowly and only under cultivation, but fable has feet and claws and wings and an indestructible sheath like weed seed, and can be carried almost anywhere and take root without benefit of soil or water.

  - Wallace Stegner
I wish

Despite the development of effective interventions to improve health care quality, most of these interventions have only been implemented in the academic settings in which they were developed.


17 to 25 years on average from time a treatment is conceived until it is widely and appropriately used in clinics

---

Enter evidence-based practice

Best available evidence

Clinician insight

Patient needs and values

---

A typical big idea

Helpfully organized into five steps

- Ask
- Access
- Appraise
- Apply
- Audit
The biomedical model
In its purest form it focuses on biologic factors in disease and minimizes the psychological, social or environmental

Three assumptions
• Illness has a single cause
• Disease or pathology is the cause
• Remove or reduce the disease or pathology and health results

“The biomedical model is the foundation upon which current evaluations in clinical practice are based. In the quest for objective evidence to support clinical interventions, the patient is reduced to a number of technologically generated variables that serve as a surrogate for the patient herself. One result may be that the lived experience of the patient is suppressed. The patient’s problem is seen as “a series of predetermined external events that dictate the patient’s affairs.”


Laboratory tests (always called “objective”) dominate outcome measurement

Patient reported outcomes are nearly inevitably secondary (always called “subjective”)
• And unless they correlate strongly and positively with laboratory findings they are likely to be dismissed as useless

Treatment efficacy is defined as a statistically significant effect on one or more of these objective values when two or more treatments or a treatment and standard of care are compared in a randomized group design
The outcome of greatest concern to the patient is ignored, suppressed or assumed to be captured by the objective measures. The evidence of these attitudes' inadequacies abound. For a primer read: Fleming & DeMets (1996). Surrogate endpoints in clinical trials: Are we being misled? Ann Int Med, 125, 605-613. Their answer, by the way, is YES, we are being misled.

A sample of their point of view

For RCTs they argue the primary endpoint should be the “true clinical outcome”

The true clinical outcome is

• That which is of greatest relevance to the patient
• Or the “event of which the patient is aware and wants to avoid”

The exception to above is when change in a surrogate or laboratory measure predicts the clinical outcome

• Actually fairly infrequent

Applied to swallowing

Outcomes patients want may vary

But usually have to do with some version of

• Enjoyable
• Often altered diets are not
• Efficient
• Slow eating is a frequent complaint
• Safe
• I don’t want to get pneumonia
Surrogates for what patients want

- What are the surrogates for safe, efficient and enjoyable?
  - Assumed surrogates
    - Quicker onset of swallow will be associated with more efficient eating
    - Aspiration means unsafe eating
    - Add your favorite
  - Most of these are in need of experimental verification

What does the evidence show?

- SWAL-QOL data are informative
  - The relationships among a host of physiologic variables and a host of symptom, functional and psychosocial variables are positive but modest
  - Relationship to pen-asp score one of smallest

Interpretation of these data

- Usual interpretation is that the patient data are unreliable and invalid
- Assuming you believe all these measures are sufficiently reliable and valid
- Then you may conclude as did the authors that the measures are
  - Complementary
  - And both offer important insights
The relationship of what the clinician believes from looking at an instrumented exam and what the person with dysphagia is feeling.

Knowing both makes a clinician better.

This borders on heresy in some circles but it just may be that a totally physiologic orientation to dysphagia is inadequate.

Not at all.

Physiologic are especially useful in pre-efficacy stages of method development as measures of a method's activity.

Patient-oriented variables such as SWAL-QOL domains are especially useful and appropriate in Phase III, efficacy research.


30 treated with EMST and 30 with sham.

Physiologic and QoL measures.

SWAL-QOL changed in both groups.

And differences in change were not significant.
Patients will say or believe anything is what some argue. Or—no need for the QoL outcome cause it is captured by the physiologic. Or treatment and sham both cause a placebo effect. Or the pathway(s) of EMST's action(s) are inadequately understood. Or active ingredient(s) of the treatment may be more than or different from "strengthening".

The last three points on that previous slide are the most interesting to me as a clinician. I also believe that our profession’s continued movement away from a strict medical model and toward a biopsychosocial model is to be encouraged.

A seminal reference is Engle (1978). The biopsychosocial model and the education of health professionals. Ann NY Acad Sci, 310, 169-81. Our educations should probably have included this article.
Principles of the model

“suffering, disease, and illness are affected by multiple levels of organization, from the societal to the molecular”

The model emphasizes “subjective experience as an essential contributor to accurate diagnosis, health outcomes, and humane care”


Evidence and clinical implications

This model supports two notions of clinical relevance

- Men and women with dysphagia are more than their bolus flow abnormalities
- Many clinicians know this and look for evidence about what these additions are
- Treatment is more than a focus on bolus flow abnormalities
- Changing bolus flow may not change these other variables
- Many clinicians want more evidence about what treatments change these other variables

And it supports

Patient-centered care

Typical article is

- Approach is called participatory medicine

Best practitioners have been doing for eons
And are probably most drawn to evidence collected under the notion’s orientation
**Bio is contained in the name**

**The biomedical model was a primary supporter of the notion of levels of evidence**

**In other words of the notion that all evidence is not equal**

---

**Small N and single-case designs**

**Meta analysis**

**Systematic review**

**Multiple RCTs**

**Single RCT**

**Cohort and case control**

**Small N and single-case designs**

**Clinical judgment**

---

**In one way gives the clinician an idea about the strength of data in support of a technique**

**Supports the notion that the absence of RCTs is not the absence of data**

**Allows for clinical experience**
There are dangers

- Inordinate—some would say—value placed on the RCT
- Forced to remind one’s self that RCTs can be poorly designed
  - Using unimportant or relatively insensitive outcome measures
- Individual differences among patients are so great “that testing (experimental medicines) in broad groups is doomed to create more frustration than knowledge”
  - Editorial, NYT, July 14, 2013

Another danger

- “An overemphasis on RCTs may create radical skepticism when this standard is not attained, and this in turn may lead to therapeutic nihilism” (p. X)
  - Montgomery & Turkstra (2003). Evidence-based practice: Let’s be reasonable. JMS-LP, 11, ix-xii
- Other evidence is ignored including single case design with replication
- Single subject designs defended

Another

- The design of the RCT is to produce the best possible internal validity
- External validity or generalizability can be threatened by high internal validity
- As but one example
  - Subject selection often results in participants being studied who fail to resemble many of the patients being treated by clinicians
  - This condition is at least part of the reason clinicians often argue that the literature lacks relevance to their practices
3/6/14

Said another way
- Increased precision comes with
  - Rigid subject selection
  - Tightly controlled interventions
  - Often *clinically unrealistic* durations and/or intensities of treatment
  - Clinically unrealistic schedules and intensities of testing
  - Clinicians often see more complex pts in more complex and limited environments

Another concern for clinicians
- Most of the data are related to treatment’s CONTENT
  - The method
    - Swallow normally and when you feel your voice box go up grab it with your throat muscles for a count of three before relaxing
    - Fill in any of your other favorites

What about PROCESS?
- What about the clinician’s
  - Warmth
  - Appropriateness of explanations
  - Type and timing of feedback
  - Pace and number of repetitions
  - Ability to know when to stop
  - Or change in some other way
  - Generally fewer data here
    - Which worries some of us who work clinically
Reason to believe that some of these variables may be among a treatment's ACTIVE INGREDIENTS

Most of us have had the experience of seeing two clinicians superficially doing the same thing but with different outcomes

This is not about warm fuzzies—its about the maximum amount of change most efficiently

And belief may be another active ingredient

“The physician's belief in the treatment and the patient's faith in the physician exert a mutually reinforcing effect; the result is a powerful remedy that is almost guaranteed to produce an improvement and sometimes a cure”

Skrabauck and McCormick. Follies and Fallacies in Medicine

What if that is true?

Let me quickly add

Of course we don't support people doing stupid stuff just because they believe in it but it is perhaps useful to remember that data can lead to stupid stuff as easily as can belief or even superstition
It is my contention that a major reason evidence works its way into clinics slowly and sometimes not at all. Is that process including that which comes from belief is inadequately studied. And of course there are other reasons for slow transfer.

Spent some time talking about the importance of evidence, models of care, and some general challenges of all this from the clinician's point of view.

Let's turn briefly to ASHA's attitudes and what we know about the difficulties of introducing evidence into the clinic.


• Time restraint ranks as first impediment to using evidence.
• Second was lack of requirements for EBP-OOPS.
• Especially important given the hierarchical structure in medicine.

98% of SLPs report using clinical experience in treating functional voice.

Tradition as a barrier

- Getting past “we have always done it this way”
- Few of us would admit it but I suspect we all get in ruts at least from time to time

Another useful reference


The data

- 240 of 488 questionnaires returned
  - Mean years of experience 12+ range 1-50
  - 90.8% had a master’s; 45.6% from schools
  - RESULTS
    - Generally positive attitudes about research and EBP
    - Best predictors of attitude were exposure to EBP in graduate training and during CFY
    - Clinical experience (99.6%) and opinions of colleagues (78.7%) most frequent sources of information in clinical decision making
Lack of time a variable

Only 13% felt they lacked skills and 17.6% lacked resources and 21.8% complained of quantity and quality of research.

Time
- When busy, searching for evidence is not a priority to me
- The time I have per patient is insufficient to also search for answers to my questions
- During consultations I have insufficient time to work according to EBM principles


Biggest is lack of time to read
Methodological inadequacies in studies as perceived by practitioner
Insufficient time to implement

ASHA has taken a stand with an official policy document advocating integration of EBP principles:
- Identified knowledge and skills related to EBP
- And recognized it as an important part of ASHA’s research mission

One is to summarize the best data into the format of clinical pathways:
- Reduces the individual clinician’s burden
- So how are extant guidelines faring?
Clinical practice guidelines

  - Used the IOM standards for evaluating guidelines called Clinical Practice Guidelines We can Trust
  - Found that “the vast majority of oncology CPGs fail to meet the IOM standards for trustworthy guidelines”

According to IOM they are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances”

Purpose: describe a range of generally accepted approaches for the diagnosis, management or prevention of specific diseases or conditions

Not fixed and responsible clinical judgment is critical

Report of the IOM, 3,23, 11

8 standards for evaluating CPGs

No time to go into all but they guide what we should do if we are to evaluate extant and develop new

As an example, Standard 5 Establishing evidence foundation for and rating strength of recommendations
Standard Five

- Provide for each recommendation
  - Clear description of potential benefits and harms
  - A summary of relevant available evidence (and evidentiary gaps) description of the quality (including applicability) quantity (including completeness) and consistency of the aggregate available evidence
  - An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation
  - A rating of the level of confidence in the evidence underpinning the recommendation
  - A description and explanation of any differences of opinion regarding the recommendation

Standard Seven

- External review
- External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations, agencies, patients and representatives of the public

Here is a good place for CPGs

- Nutrition and the elderly
- 731 of 1500 SLPs responded
- 42.1% felt moderately or well prepared to manage dysphagia
- 22.0 recognized that tube feeding is unlikely to reduce risk of aspiration pneumonia
- 50.2% recognized not likely to prevent uncomfortable death

731 of 1500 SLPs responded
42.1% felt moderately or well prepared to manage dysphagia
22.0 recognized that tube feeding is unlikely to reduce risk of aspiration pneumonia
50.2% recognized not likely to prevent uncomfortable death

Vitale et al cont
- 54.5 % realized unlikely to improve functional status
- 63.2 unlikely to enhance QoL
- Majority (70.0%) willing to consider oral diet even in presence of high risk of aspiration
- This 70.0 gave the highest percentage overall of data based answers
- Interestingly those self-identified as highly prepared had the most limited knowledge about aspiration pneumonia and QoL

54.5 % realized unlikely to improve functional status
63.2 unlikely to enhance QoL
Majority (70.0%) willing to consider oral diet even in presence of high risk of aspiration
This 70.0 gave the highest percentage overall of data based answers
Interestingly those self-identified as highly prepared had the most limited knowledge about aspiration pneumonia and QoL

Data specific to dementia
- 34% of 186,835 NH demented patients were tube fed
- No evidence of increased QoL Or improved nutritional status
- “May actually increase the risk of developing pneumonia”

Data specific to dementia
34% of 186,835 NH demented patients were tube fed
No evidence of increased QoL Or improved nutritional status
“May actually increase the risk of developing pneumonia”
Recent US data

- 53.6% of 1,000 pts in US NHs have tubes
- 68.1% placed during acute hospitalization
- Admitted with pneumonia, dehydration, dysphagia
- Mortality at one year = 64.1%
- Median survival 56 days
- Median time to revision is 145 days

State data

- Proportion of NH pts tube fed
  - 64% in DC
  - Six southern states have the next highest percents
  - Florida has 40%
  - Maine, NH, VT have lowest at 9%
- So something is clearly influencing decisions
  - Mitchell et al. JAGS, 51, 75-79

Quality homes

![Map of quality homes in the US](image)
Two NHs in south Carolina with 41.8% of residents on tube in one and 10.7 in other
Low
- Homelike atmosphere
- Food important part of socialization
- Trained staff at mealtimes who valued hand feeding
- Advance care planning with family
- Palliative care options

Questionable practices have been with us forever and will remain so—but perhaps in reduced numbers
And it is not just dysphagia
Indeed it is all of health care
But this is not about bad practitioners
No one comes into healthcare to do a bad job
So where does the fault lie?
There is blame enough to go around

We know that persons educated to respect and use data do so
- So educators have responsibility
We know that clinicians identify lack of time as a barrier
- So administrators have responsibility
We know that evidence is often irrelevant to daily practice
- So researchers have responsibility
Practice improves by fixing problems rather than fixing blame.

So what can be done?

Embrace as a profession the science of dissemination.

Avoid unidirectional thinking about the direction of action in moving evidence into the clinic.

Remind ourselves of the inadequacy of evidence as the sole guide of practice.

Evidence based practice should be complemented by evidence based implementation.


Ask yourself: Have you heard as much about this as about evidence based practice?
A critical step is dissemination. Profession has, for the most part, relied on traditional (and relatively easy) mechanisms - meetings, journal articles, conventions, presentations of the sort you are listening to today. Data confirm these traditional mechanisms are generally ineffective. (Oxman et al. 1995). No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. CMAJ, 153, 1423-1431)

That is not to say that all these methods are to be abandoned.

It is to say that they are insufficient. In part because clinicians are not the only ones needing to buy in to new evidence for treatment programs.

Consider an example:

- Lets say you want to introduce Expiratory Muscle Strength Training (EMST).
- This method for respiratory muscle strengthening requires a calibrated pressure valve device.
- Clinicians have to be trained.
- Decisions have to be made about who will purchase a device for each patient.
- And you can imagine other necessary steps.
Clinicians are going to have to be convinced that doing EMST is more effective than doing what they have always done. Administrators are going to have to be convinced of a return on investment. Will we be able to see more patients, more efficiently?

Invention is hard, but dissemination is even harder.

So if anyone listening is worried about less than best practice in his or her part of the world, and is willing to work more and differently to make things better, then we have the power to make changes. We have to add The Science of Dissemination to our present science.

A planned process that involves consideration of target audiences and the setting in which research findings are to be received, and where appropriate, communicating and interacting with wider policy and health service audiences in ways that will facilitate research uptake in decision-making processes and practices.

Adoption of a **theoretically informed** approach to dissemination

- Three predominate
  - Persuasive communication
  - Diffusion of innovations
  - Social marketing

**Consider one**

- The aptly named, persuasive communication
- Components of the dissemination framework
  - Source of communication
  - Message to be communicated
  - Channels of communication
  - Characteristics of audience(s)
  - Setting in which communication is received

**Data in support of this model**

- Every component has been studied
- Time prohibits full discussion
- Two examples will serve
  - For administrators profit from new program must equal or exceed profit from traditional ones
  - Clinicians see lack of time and inadequate explanation of method(s) as main barriers thus time for learning and effective learning strategies must be created
A set of steps

- One of many informed by data
  - Develop a concrete proposal for change
  - Identify target settings and groups and the obstacles to change
  - Link intervention to needs, facilities, and obstacles
  - Develop an implementation plan
  - Monitor progress and maintenance


Supporting tools and procedures

- Toolkits
  - Written materials
  - Web-based activities, eg. Announcements of new findings
  - One on one and small group training
  - Follow-up consultation and measurement

- Pilot introduction into selected sites, such as selected swallowing centers

- Sponsorship ($$$) of efforts is critical

- Torrey et al. (2001). Implementing evidence based practices for persons... Psychiatriq Bull, 52, 45-50

A modest proposal

- We can do this

- Not all of us and perhaps not all parts, and not immediately

- But the skills are present in this profession's members in those listening to this presentation

- What is necessary in addition is the will
Another way forward

- Would be rethinking notions that create unidirectional titles such as the one for this talk
- Remember it after all these minutes?
- Evidence to Clinical Practice

This title implies clinicians are receivers

- I think this is wrong
- Practitioners are not merely receivers
- Some of the best research questions come from practitioners
- And perhaps even some of the best (most useful) data

A better title

- Evidence (insight, intuition and what patients and caregivers want) to (and from) Clinical Practice
We must resist the tyranny of the randomized clinical trial.

And it behooves us to remember Einstein:

- Everything that can be counted does not necessarily count.
- Everything that counts cannot necessarily be counted.

Remember, data have no frontal lobes.

But you do.
Thank you