

**PROACTIVE AOPA STEPS –
THE SURVIVAL IMPERATIVES**

O&P Leadership Conference
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The Genesis of the Survival Imperatives

Setting: AOPA Board meeting in July 2012 with invited guests from the healthcare legal, payer and consulting worlds.

Theme: The New World of Healthcare Reimbursement: Incenting Patient Centric, Value-Based Care

Key Challenges: How to:

- ✓ Improve the outcome ,
 - ✓ Enhance patient satisfaction,
 - ✓ Reduce per capita cost?
- 

The System Change Prediction

- New delivery and payment models will emerge,
- Payment schemes designed merely to trim costs or to address inefficiencies in the current fee-for-service system will not survive,
- Clinical care and risk management will be critical,
- Beneficiaries will be assigned to large provider networks to gain scale; therefore the complexity of managing infrastructure will increase,
- Population health management will be all about the data,
- Payers will retool regulatory/enforcement apparatus.



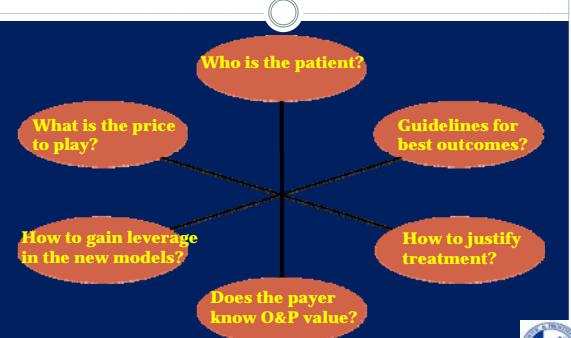
Overarching Conclusions

You must be able to track your patient population,
You must be able to prove the efficacy of your device selections and treatment protocols,
You must have data to prove your outcomes and value.,
You must be a team player adding value to participate,
You will need leverage to negotiate with larger players for a piece of the check,
You may have to risk some of your reimbursement based on the consolidated outcome.

Note the importance of data, outcomes and teamwork!



What are the Critical Questions?



Who is the patient?
What is the price to play?
Guidelines for best outcomes?
How to gain leverage in the new models?
How to justify treatment?
Does the payer know O&P value?



Stream	Objective
1	Develop a longitudinal patient database with uniform health and functionality data to track treatments and outcomes
2	Develop clinical practice guidelines for decision-making which will provide a scientific evidence base for O&P practice
3	Demonstrate the efficacy of O&P products and services in cost effectiveness, improved outcomes and patient satisfaction
4	Understand current payers' knowledge of O&P, then launch a program to properly educate/inform the payer and constituent communities
5	Identify other healthcare providers to be allies in the new care delivery models such as ACO's, bundled payments, etc.
6	Understand the various types of payment methodologies being used or contemplated by health care systems which share risk/reward among all the participants.



Stream 1

- Understanding our patient

- We know very little about the patients we treat
 - * What is the average age of a dis-vascular amputee
 - * What percentage of trans-tibial amputees progress to a tran-femoral amputation
 - * On average at how many days post stroke is an AFO fitted
- We must *begin to collect data in a collaborative way* in order to make educated decisions regarding strategy, market scope, size and trends that we can validate



Patient Intakes, Outcomes, and Data Collection

- Develop Longitudinal Patient Database via Uniform Patient Intake Data to Track Treatments and Outcomes.

- Implementation seeks incorporation of the basic intake forms into existing O&P software programs
- A working draft of the survey form was developed
 - * This data can be a tool for developing best practices leading to better outcomes
 - * Establish a data repository that can be referenced as new questions arise.



Patient Intakes, Outcomes, and Data Collection

- Road blocks-

- System was discussed that employed a third party that would manage, analyze and protect the data
- In spite of that the perceived value has not overcome issues related to sharing of data and funding of the endeavor



Stream 2

- Validating what we do

- Our payers really don't care what we do or why we do it. They just want to know that the procedure is medically necessary and that there are validated outcomes to measure success
- Payers define successful outcomes as those that reduce morbidity and mortality because that saves them money



Outcomes/Evidence-Based Practice

- Create a Process for Studying Outcomes for Specific Diagnoses to Develop a Series of Best Practices/Practice Guidelines

- Two specific areas were targeted, trans-tibial prosthetics and the orthotic management of stroke
- An ambitious program that commissioned systematic reviews of the literature and the development of Clinical Practice Guidelines was undertaken



Outcomes/Evidence-Based Practice

- Under the able leadership of Jim Campbell PhD both of these projects progressed nearly to completion.

- Both the trans-tibial and stroke systematic reviews have recently been submitted for publication and the Clinical Practice Guidelines will be released this year.
- This should lead to the development of outcome measurements based on these CPG's



Scientific Evidence Base

The Evidence Pyramid

The Evidence Pyramid Orthotics and Prosthetics

- There is an obvious lack of high quality meta analyses.
- Systematic reviews of Randomized Controlled Trials are uncommon.
- There are few high quality systematic reviews of case control or cohort studies.



The Evidence Pyramid diagram illustrates the hierarchy of evidence types:

- Top Level (Red):** Meta-analysis, Systematic Review
- Second Level (Yellow):** Gradient-Aggregated Evidence (e.g., Case Series and Substudies)
- Third Level (Green):** Case Report, Individual Article (Expert Consensus)
- Fourth Level (Blue):** Randomized Controlled Trials (RCTs)
- Fifth Level (Orange):** Cohort Studies
- Sixth Level (Light Green):** Case-Control Studies (Case Series Reports)
- Bottom Level (Light Blue):** Background Information / Expert Opinion

On the right side of the pyramid, there are three boxes representing the flow of information:

- FILTERED INFORMATION** (top box)
- UNFILTERED INFORMATION** (middle box)
- IMPROVED INFORMATION** (bottom box)

The Evidence Pyramid Orthotics and Prosthetics

- We have mainly relied upon case control or cohort studies (with a higher risk of confounding or bias) and non analytical studies, e.g. case reports and case series **to form our scientific base.**
- Personal Clinical experience

The diagram illustrates the Evidence Pyramid for Orthotics and Prosthetics. The pyramid is divided into four horizontal layers, each representing a different type of study design:

- Top Layer (Red):** Systematic Review
- Second Layer (Yellow):** Critically Appraised Individual Article (Single Session)
- Third Layer (Green):** Randomized Controlled Trials (RCTs)
- Bottom Layer (Orange):** Case Controlled Studies (Case Series Reports)

On the right side of the pyramid, there are two vertical columns representing the flow of information:

- Top Column (Labeled 'FILTERED INFORMATION'):** A downward arrow connects the top layer to the second layer.
- Bottom Column (Labeled 'UNFILTERED INFORMATION'):** A downward arrow connects the bottom layer to the third layer.

At the very bottom of the pyramid is a green box labeled "Background Information / Expert Opinion".

Two Projects, Funded 2 systematic reviews

Description of the Process We Adopted

- The best evidence is usually found in clinically relevant research that has been conducted using sound methodology.
- The evidence, by itself, does not make a decision for you, but it can help support the patient care process essentially the EOC.
- The full integration of these three components (*clinical expertise, patient values and best evidence*) into **clinical decisions** enhances the opportunity for optimal clinical outcomes and quality of life. *It will also significantly enhance our chances of being paid!*

Prosthetic Interventions for the Transtibial Amputee

A Systematic Review and Meta-analysis of High Quality, Prospective Literature and Systematic Reviews from 1997 to 2012

31 Evidence Statements Have Been Made

- 22/31 were supported by level 2 evidence
- and the remaining 8 by level 1 evidence
- In Summary, this is very positive
 - evidence to support the use of rigid dressings
 - evidence to support the use of ES feet
 - evidence to support the use of VSP
 - evidence to support the use of liners
 - evidence to support the use of vacuum suspension
- Following article synthesis, several empirical evidence statements were made:

Statements, Feet and Ankle

- In community ambulating persons with transtibial amputation:
- ESAR feet:
 - increase prosthetic propulsion and stability and minimize intact joint compensations during gait compared with FK feet
 - improve stair ambulation
 - decrease fatigue compared with SA and MA feet
 - reduce walking energy cost, and increase gait efficiency and stride length compared with SACH

Statements Regarding Interfaces

- In persons with transtibial amputation: use of gel liners could:
 - decrease walk aid dependence.
 - improve prosthetic suspension.
 - improve load distribution.
 - decrease pain and increase comfort.

Orthotic Management of Stroke Patients

- Three elements:
- Systematic Review
 - Clinical Practice Guideline, 90% complete
 - Treatment Pathways, 7 algorithms have been formulated and are being finalized

Our Most Important Goal

- The most important goal of the Clinical Practice Guideline for the Orthotic Management of Stroke Patients is to provide a scientific evidence base for orthotic practice and interventions.
- This guideline is being developed to assist clinicians and health care providers implement orthotic management processes that are evidence based and designed to achieve maximum functionality, independence as well as improve patient and family quality of life.

Method

- Recommendations for the performance of orthotic procedures or services *have been* derived through a rigorous methodological approach that includes: determination of appropriate criteria such as *effectiveness, efficacy, population benefit, patient satisfaction*
- Comprehensive systematic literature review to determine the strength of the evidence in relation to these criteria.



As it Relates to Orthotic Management

- Development of treatment pathway algorithm.
- This algorithm will serve as a guide to help clinicians determine the best interventions and timing of care for their patients and optimize healthcare utilization.
- If followed this guideline is expected to have a positive impact on multiple measurable patient outcome domains.



Summary of Statements

- Strong (level 1a) evidence to support the use of AFO's to improve gait in stroke patients
- Moderate evidence to support the use of AFO's to decrease energy cost of walking post stroke
- Moderate evidence that an AFO when combined with posterior tibial nerve de innervation improves gait outcomes in hemiplegic stroke patients
- Conflicting evidence on the use of AFO's to improve balance in patients post stroke



Summary of Statements (cont'd)

- Functional Electrical Stimulation combined with gait training improves hemiplegic gait
- There is strong (level 1a) evidence that FES and gait re training results in improved hemiplegic gait.
- There is strong (level 1a) evidence to support the use of FES to improve gait speed in patients post stroke
- There is moderate evidence that FES improves cadence post stroke
- There is limited evidence that FES improves gait symmetry post stroke



Stream 1, Longitudinal Data Base Demand for Registry

- Several developments in healthcare, such as progress in information technology and **increasing demands for accountability**, have led to an increase in the number of medical registries over recent years.
- We define a medical registry as a systematic collection of a clearly defined set of health and demographic data for patients with specific health characteristics, held in a central database for a predefined purpose (based on Solomon et al.). The specific patient characteristics (e.g., the presence of a disease or whether an intervention has taken place) determine which patients should be registered.



What is a Registry and Why is it so Important?

- Perhaps the most straightforward definition of a patient registry describes it as a prospective, observational cohort study of patients with a particular disease and/or receiving a particular treatment/intervention.
- Registries are, in fact, typically categorized as either disease or product registries.
- Indeed, objectives for initiating a registry range along a continuum from learning more about a product's real-world performance to gathering additional safety data; in all cases, though, **the registry seeks to advance science by spotlighting what really happens in actual medical practice, in contrast to the artificial environment of a controlled clinical trial**



Current Status

- Issue RFP for additional systematic reviews. Need to determine topics, process.
- Identify topics and fund additional CES
- Publication of stroke and TT reviews.
- Once stroke review is published complete and disseminate practice guideline and treatment pathway/algorithm.
- Advance the prosthetic registry project, to do so requires creation or **adoption** of measured outcomes.



Stream 3

- Demonstrate that Orthotics and Prosthetics is one of the most cost effective modalities in rehabilitation today.
- Do we bring value to the rehabilitative process or are we a luxury
- Began the process of developing research questions that will help validate our effectiveness AND our value
- Demonstrate that advanced technology reduces morbidity and conserves resources



Cost & Comparative Effectiveness

- Fund a study of the Medicare database analyzing the cost effectiveness of O and P
- Commission studies of the comparative effectiveness of MPK's –vs.- hydraulic knees and dynamic response –vs.- non dynamic response feet



Cost & Comparative Effectiveness

- The Dobson-DaVanzo Study proves conclusively that timely appropriate prosthetic & orthotic care saves payers' money because Medicare data establishes that costs for co-morbid conditions of less mobile, untreated patients exceed the cost of the O&P intervention, demonstrating the value and return of your work.
- The Dynamic Foot comparative effectiveness study at BCIT showed better, reproducible patient outcomes in both lab and daily living, as contrasted to Sach feet.



Stream 4: Payer Education

A survey of the payers was conducted and it revealed that on the whole they know very little about who we are , what we do or how we bill.

We launched a comprehensive communication effort via multiple channels to fill these voids and extended it to the membership, the payers, the referral sources, the policymakers and the regulators.

The effort is known as "Mobility Saves, Lives and Money"



Stream 5: Health Care Alliances

We needed to identify important allies in new health care delivery models including ACO's, insurance companies and other provider groups.

These alliances can help leverage and master the new health care models emerging from commercial and government payers. Strategic alliances can mitigate the threats posed by the new health care models.



Stream 5: Health Care Alliances

The payers responded in the survey that they considered these fields adjacent to O&P:

- Physical/ occupational therapy
- DME
- Home Health
- Chiropractic
- Podiatry

Once the models mature, we will commence a reach out plan to discuss the benefits of working together in new payment relationships.



Stream 6: Risks/Reimbursements

Payers, including CMS, are all about sharing risk with providers, and are willing to reward favorable shared risk patient outcomes. We have studied the various types of payment methodologies being used or contemplated by health care systems to share risk among all the participants

O&P profession needs to be prepared to participate in new risk sharing models being implemented in the new accountable care climate



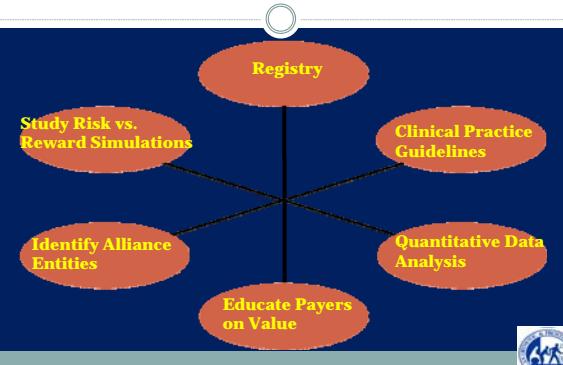
Stream 6: Risks/Reimbursements

The existing risk sharing models have not been accepted by the provider entities. Many groups (mainly hospitals and doctors) have withdrawn from participation and O&P has not yet been included in these prototypes.

New legislation introduced (not enacted) at the end of the last Congress contained provisions for bundled payments for certain types of procedures such as implants and for all subsequent care for a period of 90 days, and AOPA has gained some support for excluding O&P patient care from these bundles, but this fight is still going on.



Survival Answers



Building a Solid Communications Mechanism-

Mobility Saves – Lives & Money

Originally conceived as a way to spread the exciting conclusions of the Dobson- DaVanzo study, Mobility Saves has developed into a multi-faceted tool to educate and to reinforce the achievements, progress and most importantly the value of the O&P profession to:

- Payers
- Policymakers
- Regulators
- Referral Sources
- O&P Professionals



The Dimensions of the Program

The Elements

- The web site,
- all of the social media channels,
- patient testimonials and documentaries,
- a tool box with support materials and local use,
- site visits to national payers, policymakers and regulators,
- and an ongoing effort to broadcast new findings.



Dobson-DaVanzo Cost Effectiveness Study

CASE FOR O&P CARE BUILDS

- ▶ October, 2013 NEJM article demonstratively proved favorable impact of orthotic braces for scoliosis.
- ▶ Colorado state study showed costs of O&P more than offset by savings.
- ▶ An entry level Masters requirement raises the bar on training/expertise.
- ▶ Twelve dedicated schools assuring optimal expertise of trained professionals.



Dobson-DaVanzo Cost Effectiveness Study

Cost Effectiveness of Orthotic & Prosthetic Interventions in Reducing Total Medicare Expenditures

A study conducted using, with the permission of the Medicare system, a custom cohort database of Medicare by Dobson-DaVanzo

Commissioned by the Amputee Coalition, with grant support from the American Orthotic & Prosthetic Association



Dobson-DaVanzo Cost Effectiveness Study

WHAT'S NEW? -- O&P CARE SAVES \$\$\$

The Dobson-DaVanzo Study proves conclusively that timely appropriate prosthetic & orthotic care saves payers' money because Medicare data establishes that costs for co-morbid conditions of less mobile, untreated patients exceed the cost of the O&P intervention, demonstrating the value and return of your work.



Dobson-DaVanzo Cost Effectiveness Study

O&P CARE IS NOT A COSTER

- ▶ For the First Time Solid Empirical Data Demonstrates that O&P Care is Cost Effective—Generally Saving Payers Money and Is Not a Coster.
- ▶ Today's New Entry: *K2 amputees who receive K3 prosthetics cost less in total than if they receive K2!*



Dobson-DaVanzo Cost Effectiveness Study

O&P DELIVERS ROI TO PAYERS WITHIN 12-18 MONTHS

In addition to economic comparisons of the costs of their Medicare services, indicators of enhanced recovery, risk reduction and lifestyle factors were also examined. The hypothesis was that the cost of treatment would be cost justified thus providing the payer a return on his investment.



Dobson-DaVanzo Cost Effectiveness Study

MEDICARE DATA PROVES O&P VALUE

These conclusions are **extraordinarily significant** in that for the first time actual data prove the value of an O&P intervention based on economic criteria. In addition, there are other soft benefits in the form of: quality of life, enhanced mobility and the opportunity to more fully participate in earning a living and enjoying life.



Social Media:

Outlets & Statistics

Outlet	Statistic
Facebook	3,100 followers, 28k messages
Twitter	361 following
LinkedIn	2,400 following
Constant Contact	12,500 subscribers
Website	9,000 page views
Paid Website Searches	>1 million impressions
You Tube	Up to 1,000 views



Relationships:

Example Partners

- Amputee Coalition
- Cerebral Palsy
- Multiple sclerosis
- Easter Seals
- State and Federal Agency heads
- HAB coalition
- ITEM coalition
- Brain Injury Association



Presentation

National Payers

- Background of O&P
 - definitions
 - market size, number of clinicians, evolution
 - Education, training, certification, role in the continuum of care
- The process –
 - First encounter thru invoicing (difference between DME and O&P)
 - Billing & documentation.



Presentation cont'd

National Payers

- Deciding what to do
 - clinical pathways- episodes of care
 - comparative effectiveness
 - clinical studies
- Value of the O&P Intervention- Dobson DaVanzo
- Future research directions
- How O&P can be an effective partner



Future Directions

Work in Progress

- Blog
- K level study
- Impact of spinal orthosis on surgery
- Custom vs. Prefabricated braces
- Local toolbox

