

Public Written Comments

Submitted to PCAST

September 14, 2015 to November 17, 2015

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RE: PCAST Meeting, Fri, Sep 18 - hearing technology

From: "Alissa Parady" [REDACTED]

Date: Tue, September 22, 2015 2:09 pm

To: "Predith, Ashley" [REDACTED]

Please see the attached comments from the International Hearing Society on the topic of hearing aid technology for older adults, which was discussed at the 9/18 PCAST meeting, for the Council's consideration.

Many thanks,

Alissa Parady

Director of Government Affairs

International Hearing Society

[REDACTED]
[REDACTED]
[REDACTED]; www.ihsinfo.org

From: Predith, Ashley [REDACTED]

Sent: Saturday, September 05, 2015 11:27 AM

To: Predith, Ashley [REDACTED]

Cc: 'pcast@ostp.gov' <pcast@ostp.gov>

Subject: PCAST Meeting, Fri, Sep 18 - hearing technology

Dear Colleague:

The President's Council of Advisors on Science and Technology (PCAST) has been studying how technology can assist older Americans with living at home as they age. At the next PCAST meeting on Friday, September 18th, the Council will discuss how technologies and policies for hearing aids affect older Americans.

The meeting is open to the public, and details on how to attend in person are available on the website. A link will to the live webcast will be available from the site below on the day (no registration required). Written comments to PCAST may be submitted at any time to pcast@ostp.gov, and members of the public may register to comment orally at the meeting, subject to the available time. Requests for oral comments and registrations by noon ET, Monday, September 14th will be prioritized.

<https://www.whitehouse.gov/administration/eop/ostp/pcast/meetings/future>

Best regards,

Ashley Predith

Ashley Predith, PhD

Assistant Executive Director

President's Council of Advisors on Science and Technology

Executive Office of the President

[REDACTED]
[REDACTED]

September 22, 2015

President's Council of Advisors on Science and Technology
Executive Office of the President
Sent via email: pcast@ostp.gov

Re: PCAST Report on how the technologies and policies of hearing aids affect older Americans

Members of the Council:

On behalf of the International Hearing Society (IHS), we applaud the PCAST for examining the issue of hearing technology and the value of amplification for older adults who have mild to moderate hearing loss. We agree with the Council that this is an important health care issue worthy of examination. Considering and expanding methods to encourage the millions of people who are currently not using hearing aids to use them can drive acceptance and adoption, drive innovation, and provide an increased quality of life for those with hearing loss, and the lives of those around them.

Founded in 1951, the International Hearing Society, is a professional membership organization that represents hearing aid dispensing professionals, including the more than 9,000 hearing aid specialists who practice in the United States. Hearing aid specialists dispense and provide professional services to approximately half of the non-VA hearing aid market. IHS promotes and maintains the highest possible standards for its members in the best interests of the hearing-impaired population they serve by conducting programs in competency accreditation, testing, education and training, and encourages continued growth and education for its members through advanced certification programs.

IHS stands in strong agreement with remarks made during the Council's 9/18/15 meeting that recognized hearing aids as amazing technical devices. Truly, they have transformed over the years from more of a one-size fits all, perhaps clunky instrument, to the small, sleek, and advanced instruments we know today. We do feel, however, that such an emphasis on the device falls short of understanding that the device is just one piece of the identification and rehabilitative process, which also includes the expertise of the hearing healthcare professional, selection of the most appropriate device for a person's hearing loss, and ongoing counseling and support for both the person with hearing loss and his/her loved ones.

It is the position of IHS that the public is best-served by adherence to existing Federal and State laws which require that consumers receive a hearing evaluation and be fitted and dispensed a hearing aid only by a properly-licensed hearing aid provider – a hearing aid specialist or audiologist. Purchasing a hearing aid over the internet or through the mail without personal and continued involvement by a hearing health professional places consumers at risk of: missed pathology, which can be very serious in nature; purchasing a hearing aid unnecessarily; purchasing a suboptimal device; further hearing damage due to an improperly programmed device; and little to no consumer protections or support/counseling services. There is a reason the FDA requires pharmaceutical and device manufacturers to insert cautionary language into their labeling regarding the issue of ongoing (or worsening) difficulties; *i.e., if your symptoms do not improve within 7-10 days, consult your physician.* Medications, if not properly prescribed and monitored, can mask existing and worsening symptoms. Similarly, improper use of a hearing aid (or PSAP) could easily mask pathology that in the best case would go untreated and in the worst case put the user's life at risk.

Hearing aid specialists conduct in-person, comprehensive hearing evaluations to determine the nature of one's hearing loss and affirm that hearing loss can be aided through the use of hearing aids, as well as screen for "Red Flag" conditions that require referral to a physician as prescribed by the FDA Rules at 21 CFR § 801.421. Detection of the "Red Flags" require on-site visual observations and testing procedures (i.e. bone conduction) that can only be conducted by a trained professional in person. Hearing loss may be the symptom of a condition such as acoustic neuroma, Meniere's disease, infection, or obstruction of the external ear canal, and may be sensorineural (cochlear and/or neural damage), conductive (obstruction, perforation, or bone-related), or mixed – none of which can be self-identified by a consumer.

We often hear the comparison of hearing aids to reading glasses – an "over-the-counter" solution to age-related vision loss. Reading glasses will not correct vision if they are not appropriate for an individual's impairment, so he/she will know whether professional consultation is necessary. That is not the case with hearing impairment. The use of a PSAP or hearing aid can mask underlying conditions, which can delay medical or surgical treatment. Therefore, to ensure proper treatment and rehabilitation for hearing loss, as well as referral when necessary, consumers must have a comprehensive hearing evaluation, including a visual examination of the ear, air and bone conduction hearing tests identification of the possibility of a medically-correctable condition, and patient history performed by a properly-licensed professional.

Personal sound amplifiers and over the counter hearing aids are not the solution. In 2014, IHS conducted a Medical Referral Survey to learn more about specific cases of clients who came to hearing aid specialists after having purchased a PSAP. The following are a few of the many experiences shared, which were tied to underlying pathology that would have gone missed without intervention, and for some of which, delaying care could have and did result in death:

- An eighty year old lady, came into my office with her son. He had purchased her over-the-counter amplifiers (hunters ears). The complaint was her hearing had gone completely out. When I tested her, she had an air bone gap with zero speech discrimination score and conductive hearing loss. I referred her to an ENT. CAT scan & MRI revealed tumor on 8th CN. She died 6 months later.
- The patient came in for help with an OTC amplifier that was purchased at a local retail store off the shelf (not a hearing aid). The patient was still having difficulty hearing and felt had to change to volume too often. After speaking with them, I discovered there was an untreated balance issue with vertigo-like symptoms and possible fluctuating hearing loss. The patient was ultimately diagnosed with Meniere's Disease.
- We routinely find that people who have purchased personal sound amplifiers without proper testing have various "red flags." The most recent was a patient who complained of tinnitus, balance issues, and lack of hearing "clearly." Testing revealed an asymmetrical hearing loss and poor word recognition scores - requiring referral for MRI and possible retrocochlear disease or possible auditory neuroma. Possibly a life-saving referral.
- Air-bone gap; it was the result of fluid in the middle air and could be resolved by the ENT via tubes. Patient still needed hearing aids, but at a much lower volume.
- I have seen several patients with severe cerumen impaction who wore personal amplifiers and needed medical attention. One in particular had a perforated tympanic membrane. Fortunately the physician saw this after cleaning the ear out, and the patient received the appropriate treatment.
- Impacted cerumen; the patient actually had asymmetric hearing levels. The seller of the PSAP told him he needed only one device and sold him a unit for the ear with the worse hearing. Medical referral and audiologic evaluation revealed an acoustic neuroma in the ear that was recommended for the PSAP.

- Patient purchased a PSAP for sudden hearing loss. Three weeks later the patient came to me. It was too late for sudden loss treatment; he lost 60% of his hearing.

These real stories underscore the need for an appropriate fitting, follow up services, and counseling on use of the device by a licensed hearing healthcare professional. Ultimately, these consumers were lucky to suspect a problem and seek help. They were also fortunate that the hearing health professional that saw them had the skill set to identify a potential problem and refer them to a physician. Melodramatic as it may sound, hearing health professionals can and do save lives. What is not accounted for are those consumers who did not self-refer for an examination, and whom may be currently and perhaps unknowingly dealing with the consequences of missed medical pathology, or be using PSAPs when their hearing difficulty may simply be a case of impacted cerumen. Further, based on the stories presented, it is reasonable to believe that some PSAP purchasers may have had even more serious consequences, and as a result of forgoing a professional hearing evaluation have already died.

IHS strongly urges PCAST to use caution on the idea of making sweeping recommendations that are unproven and do not get at the root of the problem, specifically proposals to change the federal mechanism that controls hearing aid manufacturing regulation and sales via the Food and Drug Administration. These mechanisms provide an important safeguard for consumers by ensuring hearing aids meet important quality standards and standards for sale.

As you work towards developing your report, we ask that you please consider the following points:

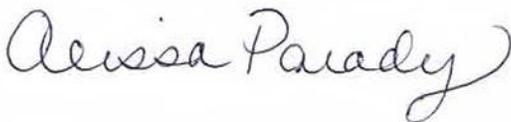
- Hearing aids are medical devices. Comparisons were made during the meeting between hearing aids, which are medical devices, and electronic devices like smartphones. To suggest that a hearing aid should be comparable in any way to a smartphone disregards the fact that a hearing aid is an individualized medical device that is designed and programmed by a professional to replicate the perception of sound and help the brain process that sound. The process of interpreting sound is unique to each individual, with the hearing aid essentially acting as a prosthetic nerve – which is in no way equivalent to a consumer electronic device or smartphone.
- There are plenty of entry level hearing aids that are available through a health care professional that can compete on the same price point as many of the personal sound amplifiers available on the market today – despite the fact that this may not be well-known to the public or online retailers may suggest the contrary.
- According to Hearing Industries Association, who represents hearing aid manufacturers in the United States, the average cost of “a hearing aid” dispensed through the traditional model is \$500-\$3,000. However, it is important to understand that this cost encompasses not only the hearing aid itself, but the hearing aid providers’ services as well, such as the hearing test, fitting services, counseling, follow-ups, repairs, and a warranty on the hearing aid. Bundling the services into the cost promotes better aftercare, increases hearing aid usage, and leads to more satisfied consumers – the latter being a critical component to expanded acceptance of addressing hearing loss.
- There are many other reasons people go untreated. Price is one factor, but by and large not the only factor. Vanity, social acceptance, and perceptions – not only of how one will be perceived if they wear hearing aids, but also their perception that a hearing aid won’t work or that they are still very much like the hearing aids their grandfather used to wear – play a big factor in making a decision to purchase a hearing aid. And for someone whose hearing has slowly declined over time, they likely do not know the extent of what they are missing and are not feeling the need. Market forces, once hearing aid use is more accepted and they are more widely used, will hopefully drive the costs down, but getting at the root of the psychology behind these purchases is the first step towards getting to the proper outcome.

IHS hereby recommends the following for your consideration, each of which could increase the adoption of hearing aids and help drive down cost, all while maintaining essential safety standards that protect the public:

- Launch a national public campaign to encourage annual or biennial hearing checks, and educate the public about the impact of untreated hearing loss. IHS recommends a partnership with Curtis Alcock of Audira, who is leading the charge in the U.S. and Great Britain about the need for the conversations to change from those that create negative associations about hearing ability to those that are productive and encourage action. At a recent meeting of the Institute of Medicine, he presented a concept of partnering with the Ad Council on such a campaign.
- Encourage primary care physicians to perform regular hearing screenings as part of their annual physical examinations and become aware of the staggering facts regarding co-morbidities associated with hearing loss so they recognize hearing loss as an important health issues.
- State Departments of Motor Vehicles can also be a useful avenue for screening the public for hearing loss, which would be particularly useful due to the risk to public safety if those with hearing loss go untreated yet operate vehicles on public roads.
- We agree with the Hearing Loss Association of America's comments that support the expanded adoption and use of hearing assistive devices like hearing loops in public places. As you may know, the use of hearing aids does not return one's hearing ability to 100%; oftentimes assistive devices like FM systems and hearing loops that utilize features of a hearing aid help bridge that gap in difficult listening situations. This will increase the value and promote greater use of hearing aids in the general population.

We thank you for your consideration and for the important work you are doing. The International Hearing Society would be pleased to participate on any working groups or in future discussions on this topic. With any questions or to discuss further, please feel free to contact me at any time at [REDACTED]

Sincerely,



Alissa Parady
Government Affairs Director

Chess In Schools

From: "raymond burwell" [REDACTED]

Date: Thu, October 15, 2015 8:31 am

To: pcast@ostp.gov

Dear members of PCAST, I read your recommendations to the President!

And found it lacking in the basic and fundamental skill sets that the students will need in the future.

See: Chess Players' Thinking (A cognitive psychological approach) (Pertiti Saariluoma). The research has been done (400 years+)

Solution Recommendations: Chess Education at all levels (spatial awareness, logical thinking, social stability, etc...)

Implemented from the Presidential Office: Cost effective! You could test MOOCs (Massive Open Online Courses).

There is ELO: An accurate measure of progress and proficiency

Implementation: CHEAP ...long term benefit to the nation Massive.

Respectfully,

Raymond Burwell ($mc^2=E$)

Discrete Event System Specification Framework for Self-Improving
Healthcare Service Systems

From: "Bernard Zeigler" [REDACTED]
Date: Sun, October 25, 2015 12:23 pm
To: pcast@ostp.gov

FYI

See attached

A Healthcare Service System is made of humans and technology where for the foreseeable future, *value* self-improvement will be primarily based on human understanding rather than machine learning. Therefore, for such a system to continually self-improve it must provide the right data and models to support human decisions on selection of alternatives likely to improve the quality of its services. Our focus in this paper is to show how modeling and simulation can help design service infrastructures that introduce coordination and bring into play the conditions for learning and continuous improvement. To do this, we discuss the application of the Discrete Event System Specification formalism within System of Systems Engineering to develop coordination models for transactions that involve multiple disparate activities of component systems that need to be selectively sequenced to implement patient-centered coordinated care interventions. We show how such coordination concepts provide a layer to support a proposed information technology for continuous improvement of healthcare as a learning collaborative system of systems.

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http://en.wikipedia.org/wiki/Bernard_P._Zeigler

Computer Simulation Pioneer:
<http://d.lib.ncsu.edu/computer-simulation/videos/bernard-p-zeigler-interviewed-by-richard-e-nance-zeigler>

SOSE 2015 - Bernard P. Zeigler (Keynote Speaker) : [Modeling and Simulation for Engineering of Self-Improving Service Systems of Systems: Barriers and Prospects](#)

Discrete Event System Specification Framework for Self-Improving Healthcare Service Systems

Bernard P. Zeigler‡

RTSync Corp. and Arizona Center for Integrative Modeling and Simulation, AZ, United-States of America, Email: [REDACTED].

Abstract- A Healthcare Service System is made of humans and technology where for the foreseeable future, *value self-improvement* will be primarily based on human understanding rather than machine learning. Therefore, for such a system to continually self-improve it must provide the right data and models to support human decisions on selection of alternatives likely to improve the quality of its services. Our focus in this paper is to show how modeling and simulation can help design service infrastructures that introduce coordination and bring into play the conditions for learning and continuous improvement. To do this, we discuss the application of the Discrete Event System Specification formalism within System of Systems Engineering to develop coordination models for transactions that involve multiple disparate activities of component systems that need to be selectively sequenced to implement patient-centered coordinated care interventions. We show how such coordination concepts provide a layer to support a proposed information technology for continuous improvement of healthcare as a learning collaborative system of systems.

I. Introduction

Modeling and Simulation (M&S) have been applied to a variety of levels of analysis in medicine and healthcare (1,2). However, M&S has had little impact at the level of reform involving radical restructuring of the ways in which multiple systems interact to deliver healthcare (3). Indeed, healthcare delivery can be regarded as a *service system* that comprises service providers and clients working together to coproduce value in complex value chains. Following Spohrer et al (4) we raise the question: Under what conditions does a Healthcare Service System (HSS) improve itself, and how can we design such a system to improve in this manner?

Roughly our argument is as follows: A HSS is made of humans and technology where for the foreseeable future, self-improvement will be primarily based on human understanding rather than machine learning. Artificial intelligence and cognitive computing, such as IBM's WatsonPaths (5), will be increasingly better at generating and evaluating hypotheses about improved treatments and other interventions. However, humans must make decisions about protocols, processes, and procedures to actually put in place to improve healthcare

delivery. Therefore, in order for a HSS to continually self-improve it must provide the right data and models to support human selection of alternatives likely to improve the quality of its services. It follows that:

- a) There must be working definitions of *the quality of services* (6),
- b) There must be *systems implemented to measure*, in an ongoing manner, the elements of clinical and extra-clinical interventions that can be aggregated to compute quality of service as defined,
- c) Likewise, there must be implemented systems that allow *alternative component configurations* (protocols, processes, procedures) to be continually tested (7), and
- d) There must be systems to *correlate measured quality* with component configurations to provide evaluations that humans can employ to help select the most promising options.

A prerequisite for such conditions to prevail in a HSS is that sufficient organization and infrastructure exists to support their implementation. Currently, most national healthcare systems do not meet this prerequisite. At the high end is healthcare delivery in the United States. Although the most costly in the world, it focuses on medical services and fails to include social services that are equally important in achieving good health outcomes (8). U.S. healthcare has been diagnosed as consisting of loosely-coupled, fragmented systems that are not sufficiently integrated or coordinated to provide high quality of service (9) or to enable self-learning (10). At the low-end, some national healthcare infrastructures are both underdeveloped and uncoordinated so that leap-frogging into 21st century learning systems is critical to meeting the challenges of burgeoning populations (Traore, personal communication). In the middle, nationalized systems are better organized from the top down but still lack the infrastructure to experiment, measure, and evaluate on the large scales required to implement self-improving HSSs.

Our focus in this paper is to show how M&S can help design service infrastructures that introduce coordination and bring into play the conditions a) through d) for a self-improving HSS. To do this, we discuss the application of the Discrete Event System Specification (DEVSS) formalism (11) to design of self-improving healthcare service systems. Systems theory, especially as formulated by Wymore (12-14), provides a conceptual basis for formulating the coordination problem of interest here. In particular, we discuss a concept of coordination

models for transactions that involve multiple activities of component systems and coordination mechanisms implementable in the DEVS formalism. We show how System of Systems Engineering (SoSE) concepts (15,16) enable formal representation that combines Porter’s (6) value-based care concepts with Pathway Community HUB care coordination (17, 18) to enable implementation of criteria for measurement of outcome and cost. This leads to a Pathways-based approach to coordination of HSSs and to a proposed mechanism for continuous improvement of HSSs as learning collaborative system of systems.

The framework will be expressed at the fine grained level in which individual patents are explicitly represented because this is level of analysis at which the metrics of quality and cost are fundamentally measured. However, means for aggregation of data to more abstract levels of analysis are also included to support generalization and quality improvement. In the sequel we will point out the technical benefit that DEVS offers over other approaches. Finally, we will suggest how the paper offers a fertile framework for healthcare service system of system engineering that can stimulate further research in both the underlying theory and its application.

A. Overview of DEVS Methodology for Coordination Modeling

In this section we provide a brief overview of the coordination methodology in order to provide an initial point of departure for later detailed elucidation (Please see Refs. 11, 21, and 22 for details outside the scope of this paper.). Italicized words denote relations in Figure 1. A System of Systems (SoS) is a system *composed* of multiple complex systems. The SoS can be *abstracted* to a simulation model in a manner that is sketched in Figure 1.

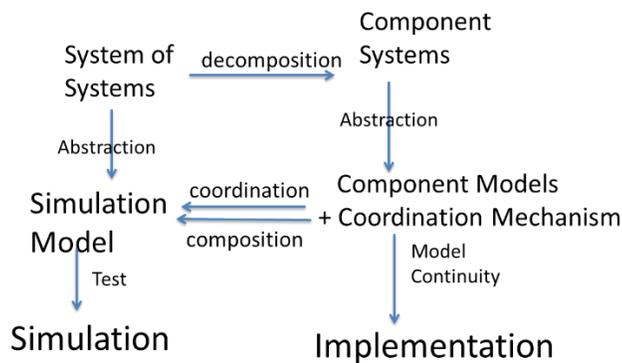


Figure 1. Modeling and Simulation Methodology for Coordination Systems Engineering

The SoS model is obtained by coupling together component models that are DEVS models that represent the system’s components. Such component models can be derived by abstracting the features (activities, services, etc.) of the component systems that are relevant to defining *coordination* mechanisms for cross-system transactions of interest (19). The component models together with the coordination mechanism, expressed as a DEVS, constitute a simulation model (by

composition) that can be used to *test* the quality of coordination. The computational framework for performing the composition and abstraction processes just described is provided by the System Entity Structure (SES.) This is a hierarchical system representation framework that supports automated generation of the SoS simulation model by coupling together all component system and coordination mechanism models that have been selected from component models in a model base (20). Then after virtual testing in the SoS simulation, the same models can be implemented in net-centric information technology using the *model-continuity* properties of the DEVS framework. Such model-continuity allows simulation models to be executed in real-time as software or hardware by replacing the underlying simulator engine (20, 21.) Several modeling and simulation environments based on DEVS support design, testing, and implementation of coordination mechanisms in a SoSE approach (22, 23.) .

B. Healthcare as a Learning Collaborative System of Systems

On the US national level a Learning Health System is being envisioned that lays out several requirements including one for a stable, certifiable, adaptable, and self-improving system. A workshop on the topic raised such questions as: What is the relationship between health care delivery innovations, such as team practice and patient engagement, and the extent and quality of learning in such a system? (10) Porter and Teisberg (24) advocate radical reform of health care that requires that physicians re-organize themselves into Integrated Practice Units (IPUs) moving away from care that is currently based on specialties with associated hospital departments. An IPU is centered on a medical condition defined as an interrelated set of patient medical circumstances best addressed in an integrated way. Porter’s formulation for an IPU emphasizes knowledge acquisition and continuous improvement based on measurement of outcomes but does not provide a mechanism to do this. We will discuss a generalization of Porter’s IPU concept based on DEVS and SoS concepts that lays the groundwork for application of DEVS to continuous improvement of HSS.

First we summarize and review some of the basic concepts required to formulate the continuous improvement problem for collaborative HSS (25). Table 1 defines features characteristic of continuous improvement and exemplifies them for multi-disciplinary physician teams characteristic of IPUs. as a “slot” in which interchangeable variations can be “plugged-in.” Component systems have variants that are interchangeable in the slot represented by the component. This is referred to as **specialization**. The variants are available for substitution alternatives in the component slots. **Outcome** variety will be created due to the composite effect at the SoS level of an assignment of alternatives to component slots. This is the global behavior of the enclosing system that is the healthcare outcome to be evaluated. The analogy with genetic evolution is noted and discussed in Muzy and Zeigler (25.) A decision must be made on **what constitutes a single trial** - this is the time interval

Table 1. Exemplifying Features Characteristic of Continuous Improvement in Multi-disciplinary Physician Teams

Characteristic feature	Definition	Multi-Disciplinary Physician Team Manifestation
Enclosing System	SoS for which goal requires collaboration, may enclose components of more than one identified system	Integrated Practice Unit
Component System	A component that participates in the Enclosing System	Physician
Collaboration requirement	Description of the goal that requires collaboration	Each physician must provide his/her service to the assure successful treatments
Modularity	Component system has well defined interfaces and its own contained state	Physicians within the same discipline can be interchanged to play the same role in a team
Specialization	Component Systems have variants that are interchangeable in the slot represented by the component. Typically, the variants represent the behavior characterized by the component in specialized manners	Physicians specialize via disciplines to play specific roles in a team
Variety at component level	The variants available for substitution alternatives in the component slot	Physicians schedules and participation in multiple teams provide variety in components
Outcome Quality of Service	Composite effect at the SoS level of an assignment of alternatives to component slots. This is the global behavior of the Enclosing System that is health care outcome to be evaluated	Some physicians work well with others, some do not. So selecting the best team composition for a given full cycle of patient care is a challenge
What constitutes a single trial	The time interval during which activity of components, global outcome and their correlation are evaluated as a single instance	Time spent by physician in full cycle of care rendered to a patient
Evaluation of trial	The evaluation of activity of components, global outcome and their correlation for a trial instance	Healthcare Value (outcome per unit cost as will be defined in text)

during which the activity of system components and the global outcome are measured. At the end of a trial, the correlation of component activity and global outcome in such time series is computed as the result of the trial (how **evaluation of a trial** occurs will be explained in detail below.)

While the table shows the elements needed for implementing continuous improvement strategies, it does not show how to employ these elements in a manner to implement such a strategy. We now turn to a proposal for such a strategy and its implementation.

In the traditional formulation of the coordination problem, each system has a goal and often the goal of the SoS conflicts in part with those of the components. Coordination is then conceived as a mechanism to achieve optimal alignment of component goals to the overall goal (26). In contrast, as mentioned above, our concern here is the organization of activities among individual clients and service providers to coordinate the appropriate delivery of services. Although salient in healthcare,

this concept of coordination is applicable to many situations where multiple providers offer multiple services to multiple clients.

In the sequel we show how the DEVS formalism provides a clear and precise way to define and implement coordination mechanisms in systems of systems.

II. DEVS Coordination Pathways

Craig et al (27) present a care coordination framework aimed at improving care at lower cost for people with multiple health and social needs. Although such a framework provides a starting point, it does not afford a rigorous predictive model that takes account of emerging health information networks (HIN) and electronic health records (EHR). The Pathways Community HUB Model is a delivery system for care coordination services provided in a community setting (28). The model is designed to identify the most at-risk individuals in a community, connect them to evidence-based interventions, and measure the results

(17). Community care coordination works at the SoS level to coordinate care of individuals in the community to help address health disparities including the social barriers to health.

The Pathways Community HUB model is a construct that enforces threaded distributed tracking of individual clients experiencing certain pathways of intervention, thereby supporting coordination of care and fee-for-performance based on end-to-end outcomes (28). As an essential by-product, the Pathway concept also opens up possibilities for system level metrics that enable more coherent transparency of behavior than previously possible, therefore greater process control and improvement re-engineering.

Zeigler (19) developed a *Coordination Model* that abstracts essential features of the Pathways Community HUB Model so that the kind of coordination it offers can be understood and employed, in a general SoS context. This allows development of a M&S framework to design, test, and implement such coordination models in a variety of SoS settings, exemplified by healthcare, that present the issues that such coordination models address. Formalization provides a firm basis for capitalizing on the transparency that is afforded by the Pathways Community HUB Model (29). Such pathways were represented as DEVS atomic models with implementation in the form of an active calendar that combines event-based control (30), time management, and data architecture capabilities (31). Further, such DEVS Pathways can become components of coupled models thereby enabling activation of successors and sharing of information. Such pathway models represent steps in a Pathway as states that can constrain steps to follow each other in proper succession with limited branching as required; external input can represent the effect of a transition from one step to next due to data entry. Moreover, temporal aspects of the Pathways, including allowable duration of steps can be directly represented by the DEVS atomic model's assignment of residence times in states.

A. Individual-Based Coordination of Cross-System Transactions

In the kind of coordination considered here, there are multiple service providers (component systems) whose activities must be brought together in different ways to serve different clients. In the as-is situation, a client is to a large extent responsible for selecting, sequencing, and scheduling encounters with providers. Since multiple activities are located in different component systems, the client needs to traverse several activities across different systems to complete a *cross-system transaction*. Thus an adequate coordination model is characterized by the following requirements:

- Coordination design must define cross-system transactions and criteria for their successful completion
- One or more cross-system transactions may be assigned to a client
- A coordination agent must aim to assure that clients will successfully complete their assigned transactions
- Coordination tracks the completion state and provides accountability for success/failure of the client and

coordination agent in completing assigned transactions

- Coordination allows the costs of sets of cross-system transactions by accumulating the costs of activities involved in such sets

B. Pathways as Coordination Models

Viewed as coordination models as just defined, Coordination Pathways provide concrete means to:

- Define steps in terms of goals and subgoals along paths to complete cross-system transactions
- Test for achievement and confirmation of pathway goals and subgoals
- Track, and measure progress of, clients along the pathways they are following
- Maintain accountability of the compliance/ adherence of the individual and responsible coordination agent

An information technology implementation of such Pathways can provide abilities to:

- Query for the state of a client on a pathway
- Query for population statistics based on aggregation of pathway states for individuals
- Support Time-Driven Activity-based costing (32) based on pathway steps and their completion times

Atomic Pathways Models

Three aspects of Atomic Pathway models to note are: *Their primary role* is to request and receive data about a main goal and benchmarks (or subgoals) accomplishment – we will call these Questions and Answers.

Bounded times are given for answers to be received.

Accomplishment of the main goal is decidable after a finite time in the sense that the model is guaranteed to wind up (and remain) in one of three classes of states: *known success, known failure, or incomplete*. In the last type, the model explicitly reports that it is unknown whether the goal has been achieved or not.

In the following, we illustrate how Atomic Pathway models are formally defined as a class of DEVS models:

An Atomic Pathways model is a DEVS (11):

AtomicPathway = (X, Y, S, δ_{ext} , δ_{int} , λ , ta)

where

X is the set of inputs;

Y is the set of outputs;

S is the set of sequential states;

$\delta_{ext}: Q \times X \rightarrow S$ is the external state transition function;

$\delta_{int}: S \rightarrow S$ is the internal state transition function;

$\lambda: S \rightarrow Y$ is the output function;

$ta: S \rightarrow \mathbb{R}_0^+ \cup \infty$ is the time advance function;

with $Q = \{ (s, e) \mid s \in S., 0 \leq e \leq ta(s) \}$ is the set of total states and e is the elapsed time when the input occurs.

Table 2 gives the definition of the sets and functions in the specification. An example of an Atomic Model representing a Pathway with one goal is given in Figure 2. The model starts in state WA (for waitForActivate) which is passive (its time advance, ta is infinity). When an Activate is received (input ports are noted by ?, output ports by !), the model transitions to the Initialization state, I which is a transient state (ta = 0).

Table 2 Definition of the sets and functions in Atomic Pathway Model

Set and Functions	Explanation
$X = Answers \cup \{ Activate \}, Y = Queries \cup \{ Activate \}$	Inputs are answers received by sending out queries plus the ability to send and receive an activation signal
$S = \{s_0, s_1, s_2, s_3, \dots s_N\} \cup \{Success, Failure, Incomplete, End\}$	The states form a sequence starting with subscript 0 and ending with subscript N where N is an even integer. In addition there are states for successful and unsuccessful completion, as well an incomplete state (see text.)
$ta(s_0) = \infty$	The starting state is a passive state (waits for input)
$\delta_{ext}(s_0, e, Activate) = s_1$	Upon receiving an activation signal the initial state goes to the first indexed state
$\delta_{int}(s_i) = s_{i+1} \quad ta(s_i) = 0 \quad \lambda(s_i) \in Queries$	The first indexed state and all odd indexed states immediately output queries and transition to the next even indexed state
$\delta_{ext}(s_{i+1}, e, ans) = s_{i+2}$ for $ans \in Answers$ $ta(s_{i+1}) = T_{i+1} \quad \delta_{int}(s_{i+1}) = Incomplete$	An even indexed state waits for a specified time interval (parameter of the model); if it receives an expected answer within that time, it transitions to the next odd indexed state; otherwise (a timeout situation) it transits to the incomplete state
$\delta_{ext}(s_N, e, ans) \in \{ Success, Failure \}$ $ta(s_N) = T_N, \delta_{int}(s_N) = Incomplete$	In the last state of the sequence and answer indicates either success or failure. Timeout is again to the incomplete state.
$ta(Success) = 0 \quad \lambda(Success) = Activate$ $\delta_{int}(Success) = End \quad ta(End) = \infty$ $ta(Failure) = \infty \quad ta(Incomplete) = \infty$	Success outputs an activation signal and transitions to the passive end state. Failure and incomplete states are passive. None of these states accept input.

This state immediately outputs the question, GoalReached and transitions to the state WG (waitForGoal.) In this state, the model can receive answers Yes or No and eventually enter passive states S (Success) and F (Failed) resp. (S is entered after an Activate output is generated from state SY.) However, WG has a finite time advance, TN, so that it transitions to states Inc (incomplete) if it does not receive one of the Yes or No answers within this interval. Since Inc is a passive state, it is easy to see that, as required, this simple model always winds up (and remains) in one of the three states S, F or Inc.

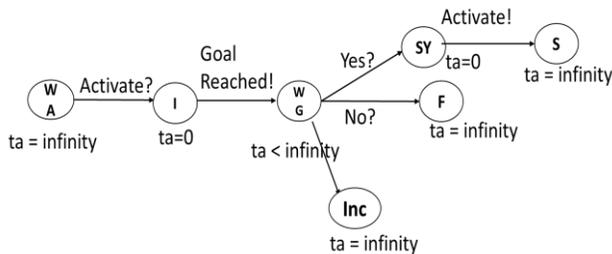


Figure 2. A Single Question Pathway Atomic Model

Following the methodology in Figure 1, such a specification can be automatically transformed into a component of a simulation model and tested through simulation as well as implemented in actual software to function in an actual HSS setting.

Coupled Pathways Models

Coupling atomic pathway models to compose coupled models enables us to coordinate the behavior of multiple concurrent pathways. For simplicity in exposition, coupling will be limited to activations by one pathway of one or more others. The DEVS formalism’s closure under coupling will assure that the resultant is a DEVS model. More than that, we can show that the resultant is also expressible as an atomic pathway model, establishing closure under coupling when restricted to the subset of DEVS defined as pathway models. The following property is essential to such closure:

Finite Termination Property:

1. For any atomic pathway model, there is a finite time T , such that the model reaches, and passivates, in any one the three types of states: Success, Failed, or Incomplete within time T after initialization.
2. For any coupled pathway model, there is a finite time T , such that all the components of the model reach, and passivate, in any one the three types of states: Success, Failed, or Incomplete within time T after initialization.

Zeigler (19) proved the Finite Termination Property and the closure of under coupling of pathway models. Examples of coupled pathway models are presented in the upcoming discussion.

Many of the features discussed above are common to both coordinated care and clinical pathways commonly employed in hospital settings (33, 34). However, coordinated care pathways are focused on accomplishment of steps, with associated

accountability and payment schemes. Consequently, they specify tests for accomplishment and time bounds within which such tests must be satisfied (18.)

III. Quality of Service Measurement

As indicated we must have working definitions of *quality of service* and there must be *systems implemented to measure*, in an ongoing manner, the elements of clinical and extra-clinical interventions that can be aggregated to compute quality as defined. We turn to formalizing quality as the quotient of health value delivered divided by cost to deliver it.

A. Porter’s Integrated Practice Unit

As indicated, Porter and Teisberg (24) advocate radical reform of health care that requires that physicians re-organize themselves into Integrated Practice Units (IPUs) moving away from care that is currently based on specialties with associated hospital departments (geriatrics, obstetrics, etc.) As formulated by Porter and Lee(35, 36) an IPU is centered on a medical condition defined as an interrelated set of medical circumstances best addressed in an integrated way. Examples of IPUs are those centered on asthma, diabetes, congestive heart failure, and so on. These target a cluster of related adverse health conditions that includes the most common co-occurring complications. As such, the IPU may bring together a host of specialists and services needed to treat the target in an integral manner – as a team rather than as a collection of individual entities. This assemblage of individual independent entities into a single collaborative organization fits the pattern of system of systems and motivates research to provide a firm basis for such integration. The IPU delivers all the services needed for the target condition which are organized into an *end-to-end interaction* with the patient called a full cycle of care covering a Care Delivery Value Chain (CDVC). Here “Value” is defined as health outcome achieved per dollar of cost. The critical requirement is that such a metric be quantifiable so that it can be compared by the patient – or surrogate payer such as insurance company - to the equivalent number offered by the competition. Much like the increase in value in a manufacturing process, the Value Chain is a linked set of activities that increase value (i.e., contribute to the outcome) from the initiation of the care cycle to its termination.

B. Formal Representation for Care Value Delivery Chain

The CDVC is formulated as a chain of activities that constitutes the architectural blueprint of the integrated team-based practice unit. From a SoS perspective, the CDVC specifies the organization of its components and their coupling. Adopting this perspective allows us to generalize the application of the CDVC concept to HSSs beyond the IPU. To do this, we interpret Porter’s discussion of requirements for a properly constituted CDVC as:

- The set and sequence of activities are aligned with value. Generally, value should increase, i.e., later activities cannot have lesser value than precursors. Taken together, the activities must achieve the desired outcomes.

- The activities have the right scopes to cover the target cluster of conditions and to minimally overlap.
- The activities form a coherent whole with seamless hand offs from one to the other – this will ultimately minimize process delays and “dropping the baton” (37.)

Porter provides examples of CDVCs for particular targeted medical conditions following the template below. The main value-producing activities are shown along the bottom row (Preventing, Diagnosing, Preparing, Intervening, Recovering/Rehabilitating, and Managing are kinds of activities that contribute directly to treatments and outcomes.) Supporting activities are shown in the first column (Knowledge Development, Informing, Measuring, Accessing, and Monitoring are kinds of activities that contribute indirectly to increase in value by providing necessary infrastructure.) In principle any of the supporting activities can be paired with the main activities (e.g. we should be able to *measure* the cost of *preventing* a sickness e.g., vaccinating). Further, supporting activities can also operate across the full care cycle, e.g., knowledge development can apply to each of the value-producing activities and concern their coordination as well.

Template for Instantiating a Care Delivery Value Chain

Knowledge Development						
Informing						
Measuring						
Accessing						
Monitoring						
	Preventing	Diagnosing	Preparing	Intervening	Recovering/Rehabilitating	Managing

The template will be illustrated in relation to the design of a coordinated care HSS for HIV-AIDS.

C. Pathways-based Outcome Measurement

As indicated, the CDVC enables computing the numerator in the Value definition by defining how outcomes are produced. As shown in the template, the CDVC also includes measurement and other activities that cut across the outcome producing activities and that are capable of observing the behavior of the outcome producing activities. The key guiding principle is that “whatever is measured tends to improve” (36). The denominator in the value quotient is the cost attributable to the activities that produced an outcome. This requires that the activities are sufficiently granular to support activity-based cost analysis. We now consider how both numerator and denominator are formalized in our DEVS-based approach.

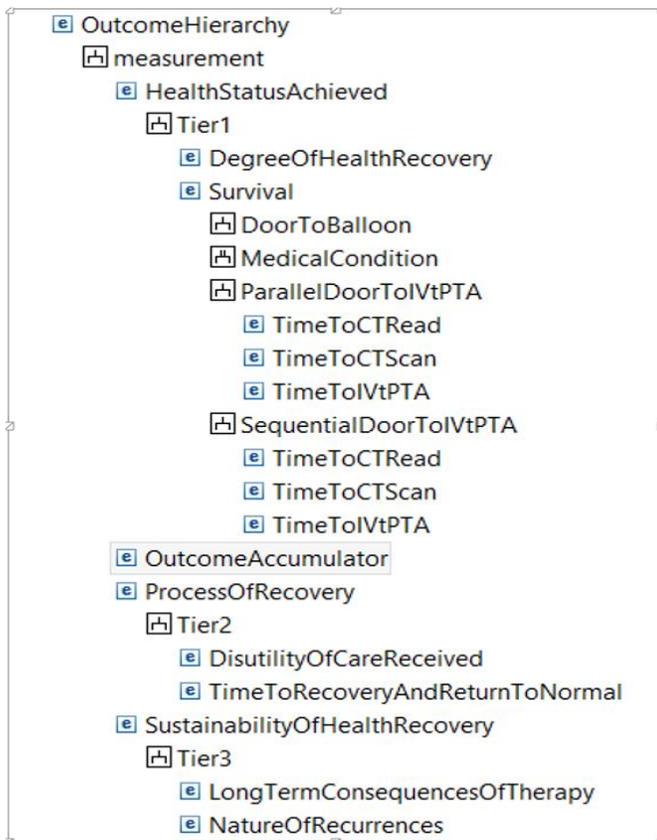


Figure 3. System Entity Structure for Outcome Hierarchy

Porter’s Outcome Measurement Hierarchy (35,36) provides a comprehensive basis for the measurement system. The hierarchy has three tiers relating to health status, process of recovery, and sustainability of health. Each tier has two parts. Tier 1 concerns survival and degree of health or recovery; Tier 2 concerns time to recovery and disutility of care or treatment process; and Tier 3 concerns sustainability of health or recovery including nature of recurrences and long-term consequences of therapy. Measuring the full set of outcomes that matter is indispensable to better meeting patients’ needs and a powerful vehicle for lowering health care costs. As illustrated in Figure 3, the form of the SES shows the HealthCare System composed of three components: Health Status Achieved, Process of Recovery, and Sustainability of Health. Following Porter’s approach, each of these are decomposed into the two types of measures illustrated in the figure. The basic event-based Pathways models implement specific measures into the 6 slots to flesh out the full measuring system. Before discussing the SES in more detail we note that we employ the DEVS Pathway representation for the Measurement System along the lines of Porter’s Outcome Hierarchy design approach. We can define a comprehensive set of outcome dimensions, and specific measures based on the event-based experimental frame methods implementable using DEVS. *Following the Pathways Coordination Model, allows tracking patients through the full cycle of care to accumulate actual costs of care (not how they are charged, currently often done in arbitrary fashion).*

D. Pathways-based Cost Measurement

Qualitatively, an activity is a label assigned to a state trajectory over an interval. Events that start and end of such activity cause

discrete changes in the state of the system when formulated in discrete event terms. A quantitative measure of activity was provided by the framework presented (38). In this approach, the *activity* of a DEVS model is simply measured by the count of its state transitions. Thus as a DEVS model, activity of a pathway over a time interval is measured by the number of state transitions that occurred in the interval. The activity of the overall system is estimated by the aggregation of all individual pathway activities. When activity is aggregated over all individuals that traversed a component, we get an estimate of the component’s activity. These measures can be sub-indexed by pathway to rank the overall system activity from most active to least active pathway, thereby providing insight into how the system is being utilized. Further sub-indexing by factors such as condition treated, patient attributes, source of client referral, enable analysis of the variation due to such factors (28). Pathway activity can be correlated to personnel and resource expenditures to calculate costs using time-driven activity-based costing (37.) Distributions of activity such can be used to inform continuous improvement as will discussed soon.

E. Alternative Component Configurations

As indicated, there must be implemented systems that allow *alternative component configurations* (protocols, processes, procedures) to be continually tested. The SES Outcome Hierarchy of Figure 3 offers an example of alternative architectures for so-called “door-to-critical-interventions.” These are shown as specializations for Survival in Figure 3 that can be selected as appropriate for different medical conditions. For example, a heart attack implementation (39) might use only a single atomic pathway model to measure door-to-balloon times and survival rates. In contrast, a stroke implementation might employ one of the sequential or parallel alternative architectures for its time-lost-is-brain-lost interventions. The SES supports automated generation of the SoS model once all selections have been made from component models in a model base.

IV. Example: Coordinated HIV-AIDS Care System Model

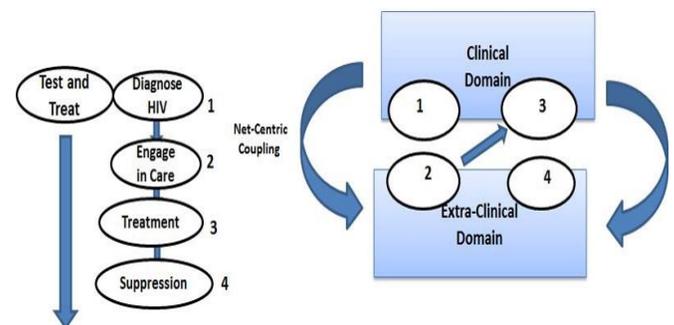


Figure 4. HIV-AIDS Continuity of Care Pathway Model

The continuity spectrum of HIV-AIDS intervention spans HIV diagnosis, full engagement in care, receipt of antiretroviral therapy, and achievement of complete viral suppression (Figure 4). However, Gardner et al, (40) estimate that only 19% of HIV-infected individuals in the United States have been treated to

the point where their virus is undetectable. This occurs because achievement of an undetectable viral load is dependent on overcoming the barriers posed by patients “falling through the cracks” in traversing each of the sequential stages shown in Figure 4. The authors conclude that recognition of the “pipeline” and support for successful handoff of patients from stage to stage is necessary to achieve a substantial increase in successfully treated HIV population. Figure 4 depicts the stages of care continuity roughly assigned to both clinical and extra-clinical domains and that they alternate between the two domains (shown cycling from 1 to 4).

Here we consider the approach of formulating the DEVS Pathways discussed above for stages 1 and 3 to form an Integrated Practice Unit. Also DEVS pathways are proposed for stages 2 and 4 which are similar to those of the Pathways Community HUB. Using a DEVS coupled model, the clinical domain pathways are interfaced to the extra-clinical ones. The objective is that patients are handed-off from one DEVS Pathway to the next without being dropped from care. Such cross-organization care pathways require sufficient electronic health record system and health information technology networking support to track and monitor patients as they traverse the treatment pipeline (41, 37). Recall that this will require definition of goals and subgoals along paths to complete cross-system transactions, testing for achievement and confirmation of pathway goals and subgoals, tracking, and measuring progress of, patients along the pathways they are following, and maintaining accountability of compliance and adherence. The implementation of such IT can then provide a “dashboard” for viewing the overall disposition of patients through the complete cycle of continuity of care required for successful HIV-AIDS treatment.

Table 3. Illustrating Criteria for Well-Specified CDVC for HIV-AIDS

Criteria for CVDC	Application to HIV-AIDS
The set and sequence of activities are aligned with value	Set: Diagnosis, Engagement, Treatment, Suppression Sequence: shown in Figure 4 Earlier stages must be completed before later stages. All 4 stages must be completed for positive outcome
The activities have the right scopes to cover the target medical cluster of conditions and to minimally overlap	Diagnosis determines presence of HIV HIV presence triggers engagement Engagement enables treatment Treatment enables suppression
The activities form a coherent whole with seamless handoffs from one to the other – minimize process delays and “dropping the baton”	The sequence in Figure 4 is minimal connection at Pathway level Must be implemented faithfully with minimal delays at service level <i>Must assure transfer without dropping patient</i>

Although formulated for IPU the criteria for a well specified CDVC apply generally to health care system of systems. Table 3 applies the criteria to provide a basis for achieving a CDVC for the HIV-AIDS example in Figure 4. The main value chain

activities appear in this example as Diagnosis, Engagement, and Treatment, Suppression. They are organized in a sequence and must satisfy the criteria given for well-defined CDVCs in order to support value-based healthcare.

The generalization of value chain concepts from IPU to HSS in general allows us to achieve a synthesis that applies to HSS with both clinical and extra-clinical aspects. The synthesis combines Porter’s Value-based concepts of CDVC and Outcome Hierarchy with Pathways concepts that support implementation capabilities such as individual end-to-end goal-based tracking.

V. Pathways-Based Learning System Implementation

Returning to the conditions that allow a HSS to continually self-improve, we have laid the foundation with a working definition of quality of service, DEVS Pathway models for systems implemented to measure and compute quality of service in an ongoing manner, as well as systems that allow alternative component configurations (protocols, processes, procedures) to be continually tested. Finally, we noted that there must be systems to *correlate measured quality* with component configurations to provide evaluations that humans can employ to help select the most promising options. In this regard, continuous improvement in healthcare can be productively viewed as a specific kind of adaptation over time of a collaborative system whose components can take on alternative variants (42). The goal is to keep improving the value (outcome/cost) of the system’s CDVC by finding combinations of component variants that produce high value outcomes. In the following we present an approach based on the application of credit assignment and activity-based selection of component alternatives to successively increase the level of collaboration needed to produce progressively higher valued outcomes. In this regard, Muzy et al (43) identify three layers of an activity-based adaptive system:

1. *Time-Driven Activity-Based Costing* using a built-in system for measurement of component activity and performance (outcome value)
2. *Activity Evaluation and Storage*: using the built-in detection mechanisms of level 1, activity can be measured as the fractional time that a component contributes to the outcome. Correlating contribution with outcome, a credit can be attributed to components. Such a measure of performance of components can be memorized in relation to the experimental frame, or context, in which it transpired
3. *Activity awareness*: feedback of the activity-outcome correlation to inform the selection of combinations of component variants so as to drive the system toward increased performance

This kind of adaptive system differs from other simulation-based optimization systems (see e.g. 44.) It also differs from supervised learning (e.g., 45) in that here learning is based on correlation between the activity of component systems and the behavior achieved at the SoS composition level.

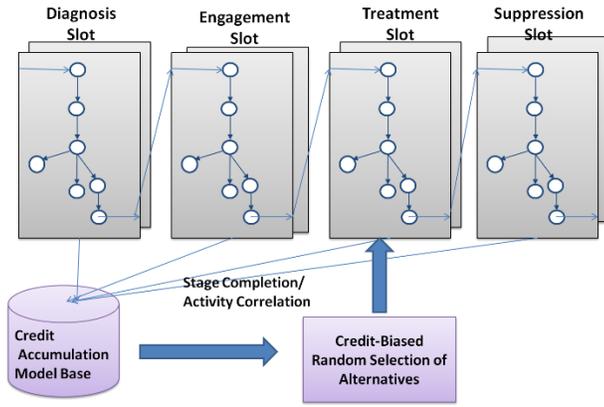


Figure 5. Illustrating Implementation Activity-based credit assignment in the HIV-AIDS SoS

Muzy and Zeigler (25) describe a system that implements these layers in a simulation that involves finding winning combinations of players on a hockey team. A simulation-based stochastic search is achieved based on the performance model-base. Correlation between the activity of a component and corresponding composition outcome is referred to the credit assignment problem. The credit of components is used to bias their selection. Activity-based credit assignment (ACA) was shown to 1) apply to any level in the hierarchy of components within any experimental frame, 2) converge on good compositions much faster than a repository-based random search, and 3) automatically synthesize an SoS from a model-base thus enabling reusability of highly rated components in compositions.

Pathway coordination models lend themselves to support critical features of such learning systems. As mentioned before, DEVS Pathways enable time-driven activity-based costing based on pathway steps and their completion times. Recall that, as a DEVS model, the activity of a pathway over a time interval is measured by the number of state transitions that occurred in the interval. We can estimate a component’s activity by aggregating the pathway activities over all individuals that traversed the component during an interval. Moreover, since pathways include outcome measurement they enable correlation of activity and performance (CDVC value) for each individual. Aggregation over individual traversals of components yields estimates of activity–outcome correlation for components. Components or variants that do not perform well in this measure are candidates for replacement by other alternatives that can replace them. Such activity-based performance correlation and feedback exhibits the continuous improvement characteristic of an evidence-based learning healthcare system advocated by Porter and others.

F. Activity-based Credit Assignment Applied to HIV-AIDS Example

Table 4, exemplifying features characteristic of continuous improvement in collaborative healthcare, sets up the basis for application of the ACA-based continuous improvement to the case of the HIV-AIDS continuity of care. As indicated the stages of Continuity of Care (Diagnosis, Engagement,

Treatment, and Suppression) form a pipeline in that each stage must follow the prior one and set up the next one. As in Figure 5, the stages can be viewed as component systems coupled together in the overall SoS which represents the pipeline. The stages are distinct from each other having different goals with alternative processes for stages being specialized to support the goals of the stage. Not all combinations of pipeline component variations will work to achieve the overall SoS goal of enabling patients to traverse the full pipeline, i.e., to receive the complete intervention required by continuity of care. Each patient constitutes the basis for a trial with the evaluation of a trial being the how many stages the patient successfully traversed. The overall objective of continuous improvement is to increase the number of successful patient pipeline traversals, ideally to reach 100%, but with an objective of reaching a level of 65% (40). Muzy and Zeigler (46) consider a family of pipeline coupled models with alternatives selected from an independent identically distributed random process. They proved that for such a pipeline, the activity-based credit assignment converges to an equilibrium distribution in which the best alternative at each stage has a credit that exceeds the others at that stage. This result offers an analytic confirmation to support the simulation results of Muzy and Zeigler (25) and a basis to propose that the implementation of a continuous improvement strategy based on ACA such as discussed above will prove successful in real application.

Table 4. Exemplifying Features Characteristic of Continuous Improvement in Continuity of Care

Characteristic feature	HIV-AIDS Continuity of Care Manifestation
Component System	Stage of Continuity of Care (Diagnosis, Engagement, Treatment, Suppression)
Collaboration requirement	Stages form pipeline, each stage must follow the prior one and set up the next one
Modularity	Stages are distinct from each other having different goals and (conceptually) well- defined interfaces
Specialization	Alternative processes for stages are specialized to support the different goals of the respective stages
Variety at component level	A continuous improvement approach would seek to alter sub-processes and/or internal couplings (information flows) to provide requisite variety
Outcome Quality of Service	Not all combinations of pipeline component variations will work together
What constitutes a single trial	Time consumed by a stage in patient traversal of the pipeline
Evaluation of trial	The number of stages successfully traversed by a patient.

VI. Current State of DEVS Framework for a Coordinated Learning Healthcare System

At least three types of users for M&S environments can be distinguished: M&S Developers, general M&S users, and M&S Expert Professionals (22). For M&S Developers, DEVS-based methodology offers a comprehensive approach to SoSE that other simulation languages and tools do not provide (Mittal & Risco-Martin (21) and Denil (47).) General M&S users are interested in using the models and associated products of environments not necessarily in how they were produced.

Specialized simulation packages for particular world views (48,49) are able to quickly synthesize usable models. However, the capabilities of such tools fall short as their styles and domains of application are exceeded. On the other hand, in new domains such as HSS and other service systems, generic DEVS environments, such as MS4 Me (50), enable development of novel concepts and mechanisms with accompanying user interfaces that meet the new challenges but also take more time to mature. M&S Expert Professionals are interested in the internals of models and in research and development of new technologies. As an open formalism DEVS fosters environments that support transparent model presentation and comprehension as well as scrutiny of the environment's features and the theory that supports them.

The DEVS comprehensive methodology, illustrated in Figure 1, underlies the development of Pathways-based self-improving HSS architecture models. It proceeds along parallel paths of HSS simulation model development, coordination and learning sub-models, testing of the sub-models in the simulation model, and implementation of the sub-models within actual healthcare environments. Progress in the development can proceed independently along segments where the paths do not intersect. As of this writing, development of the simulation is in process where initial steps have taken the form of formalization of the basic Pathways concept and analysis of real data using this formalization. The formalization in terms of DEVS provides enabled temporal analysis that would difficult to undertake with conventional biostatistics (50). The development of HSS simulation models is proceeding with focus on West Africa (personal communication) Ebola is a non-standard infectious disease, due to its very high contamination potential – simple contact is enough, unlike HIV-AIDS which requires fluid transmission inside the body. Such models are not easily analyzed using conventional simulation languages and require DEVS-based methodologies. Hierarchies of scale for both systems (e.g., local units, regional centers and organization; cell, individual, population) and processes (e.g., contamination, disease, epidemic) were designed using the SES. Couplings among system components within and between levels implement cross-aspect interactions along the lines defined by Seck and Honig (51). Development of this model family is in process and will be employed to test Pathway coordination approaches to Ebola outbreak control in West Africa.

Finally, the model continuity path shown in Figure 1 was used to partially automate the mapping of Pathway models into Web-based implementation. Figure 6 shows the browser interface that supports selection of SES documents such as the one for HIV-AIDS as shown, pruning by making selections from the alternatives for each slot, and executing the model to obtain activity-based credit evaluations of alternatives (23). The Web-based system is currently being tested in a real application of patient-centered coordinated care in the public health care setting of Prince Georges County, Maryland, USA.

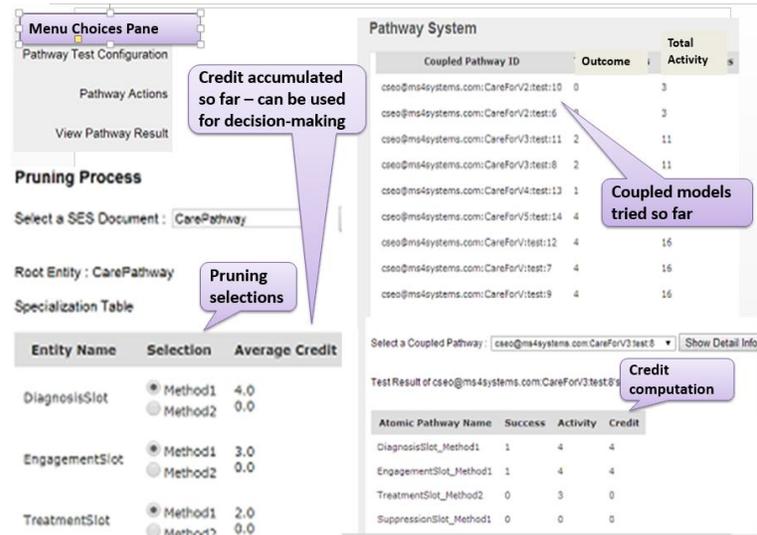


Figure 6. Web-based Implementation of Pathways

VII. Conclusions and Further Research

An AHRQ/NSF workshop (9) envisioned an ideal health care system that is unlike today's fragmented, loosely coupled, and uncoordinated assemblage of component systems. Improving the health care sector presents a challenge in that optimization cannot be achieved by sub-optimizing the component systems, but must be directed at the entire system itself. On the other hand, healthcare has been compared to manufacturing with the premise that many of the same techniques can be transferred to it. However, complex patient flows, numerous human resources, dynamic evolution of patient's health state motivated Augusto and Xie (2) to develop Petri-net-based software for modeling, simulation, and activity planning and scheduling of health care services. Their goal was to provide a mathematical framework to design models of a wide range of medical units of a hospital in order to model and simulate a wide range of healthcare services and organizations and to support such design with a Unified Modeling Language (UML) / business process modeling (BPM) interface for decision-makers. In contrast, our concern here is not within the hospital but at the System-of-Systems (SoS) level where hospitals interact with other components such as physicians, community workers, social services and health plan payers.

At the SoS level, care coordination is the organization of all activities, both clinical and extra-clinical, among the individual patient and providers involved in the patient's care to facilitate the appropriate delivery of health care services. In this paper, we expanded upon a System of System Engineering formalization and simulation modeling methodology for a more in-depth application of DEVS Coordination Pathways to re-engineer healthcare service systems.

Space limitations prevent more-in-depth discussion of human characteristics in the proposed self-improving system and the prospect of including agent-based representations to capture these characteristics. On the one hand, fallibility of patients (e.g., in adhering to prescribed care plans) is a prime concern in coordination of care and presents a challenge to agent-based modeling (18,19). Error tendencies of care coordinators are

another source of concern that can be accounted for in measurement and ameliorated through incentives for pathway completion success (28, 29,31,) Furthermore, humans are prone to unintentionally misuse decision support systems or even may intentionally circumvent a self-improving system for various reasons – an example pointed out by a reviewer is being actively explored in the security domain (53) On the other hand, as another reviewer points out, the agents underlying the proposed coordination can learn and provide for systems that are “antifragile,” i.e., get better under stress over time. A challenge presented by these realities is to include models of such behavior to predict and manage as needed, both negative and positive effects. Agent-based modeling methodology within the context of the more encompassing SoS M&S framework is a promising means to do so (22.)

The US President’s Council on Science and Technology (52) advocates that the U.S. health care industry adopt a systems-engineering approach used in other industries to improve the health data infrastructure and boost overall quality and delivery of care. Our results support the contention that understanding health care as a HSS and applying SoSE methods based on simulation modeling helps to address these recommendations. The Pathways and activity-based evaluation of components provides a basis for aligning payment incentives for subgoal completion. Distributed individual-based tracking enabled by Pathways provide a basis for effective design of a health data infrastructure. Increased data supply on the community level enabled by extra-clinical Pathway Hubs and the analysis supported by modeling and simulation will enable better understanding of health care delivery as a self-improving service system.

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Bernard P. Zeigler is Emeritus Professor at Arizona Center of Integrative Modeling and Simulation and Chief Scientist at RTSync Corp, Arizona and Maryland. He is internationally known for his seminal contribution to M&S theory

STEM - Ysen Educational Systems (Technology Perspective)

From: "Pamela Langford" [REDACTED]

Date: Tue, October 27, 2015 11:28 am

To: pcast@ostp.gov

Name/Organization: BLIT Services, LLC (A Veteran-Owned Business)

Date of event: (Whenever someone is available)

Format of event: Conference Call

Contact person and email address: Pamela V. Langford [REDACTED]

My name is Pamela Langford. I have designed an Artificial Intelligence System that effectively tutors children grades 3 through 12. I am also enrolled in a Technology BS program at Strayer University and now see why Information Technology employers will not hire Information Technology college graduates. I have designed a knowledge base system that can be used to redesign U.S. undergraduate college programs so graduates will marketable; and, they will have knowledge & experience in applying the SDLC.

The attached presentation provides an overview of the Ysen Educational System, which I believe will make the United States a leader in designing & developing innovative technology systems.

Pamela Langford
[REDACTED]

<http://bussystemanalysis.blogspot.com/>

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[REDACTED]

STEM: Teaching Our Society of Tomorrow, Technology & Engineering Today

Pamela V. Langford,
Sr. Systems Analyst



Agenda

- **About Pamela V. Langford
(Creator of the Yson Artificial Intelligence Educational Systems)**
- **STEM Overview & Goals**
- **Introducing the Yson I Educational System**
- **Introducing the Yson II Educational System**

About Pamela V. Langford

17 Years of Information Technology Experience	Roles	Industries	Undergraduate Education
	Project Manager	Defense/Aerospace	Strayer University, BS, Computer Systems Concentration: Database Management Systems (130 of 180 Credits Completed)
	Team Lead	Biotechnology	
	Business Systems Analyst	Education	
	Sr. Systems Analyst	Health Care	
	Developer	Federal Government	
	Tester	Systems Integration & Automation	
	Technical Writer	Manufacturing	
	Deployment Manager	Automotive	
		Telecommunications (Mobile Devices, Network Security, Routing)	
	IT Consulting		
	Accounting		

STEM Overview & Goals

- “The health & longevity of our Nation’s citizenry, economy and environmental resources depend in large part on the **acceleration of scientific and technological innovations**, such as those that improve health care, inspire new industries, **protect the environment**, and **safeguard us from harm.**”

- Federal Science, Technology, Engineering, & Mathematics (STEM) Education 5-Year Strategic Plan, “*A Report from the Committee on STEM Education National Science and Technology Council*”, Executive Office of the President – National Science and Technology Council , MAY 2013

- “The need for high quality science, technology, engineering, and mathematics (STEM) education has been touted by numerous **reports that link our Nation’s future economic success and security to a highly skilled STEM workforce.**”

- The Federal Science, Technology, Engineering, & Mathematics (STEM) Education Portfolio Report

STEM Overview & Goals

- **President Obama's goal for STEM**
 - **The U.S. will have the highest proportion of college graduates in the world by 2020,**
 - **The Federal Government will work with education partners to improve the quality of science, technology, engineering and math (STEM) education at all levels to help increase the number of well-prepared graduates with STEM degrees by one-third over the next 10 years,**
 - **The United States institutions of higher education will increase the number of students who receive undergraduate STEM degrees by about 34 % over current rates by 2020.**
- **Goal Leader: Joan Ferrini-Mundy, Assistant Director, Education and Human Resources, National Science Foundation**

STEM Overview & Goals

- **Federal Government Investments**
 - The CoSTEM released the Federal Science, Technology, Engineering, and Mathematics (STEM) Education Portfolio report that describes how 13 Federal agencies utilize \$3.4 billion to support STEM education.
- **A gap analysis of current investments shows none collectively bring the following:**
 - Present an Artificial Intelligence Educational System that teaches children 3rd grade – High School IT concepts based on the SDLC
 - Present content & provide practice sessions with lessons based on a real IT project;
 - Uses a strategy to teach all U.S. children Information Technology industry best practices to increase the number of IT graduates & professionals
 - Present a branch, in IT Education, that takes into consideration concept changes by IT Industry

Introducing the Yson I Educational System

- Goals established for Yson I (Artificial Intelligence System) and Yson II (Knowledge Base for Higher Education Curriculum Development):
 - Develop basic knowledge on how to create technology products by applying the “same work processes used in the real world”
 - Initiate Information Technology education at the 3rd Grade Level.
 - Help the U.S. have the highest proportion of college graduates in the world by 2020.
 - Make college graduates marketable right out of school.
 - Increase the # of people who know how to build technology products (to increase the # of technology products developed in the U.S.)
 - Improve the U.S. economy & way of life (increasing the # of technology products mean an increase in the #of software development companies, which increases the # of high-paying jobs in the U.S.)

Introducing the Yson I Educational System

- What U.S. Public Schools “Are” Teaching Grade & Middle School Kids vs. What We “Could” Be Teaching

Information Technology Skills Developed in Many Classrooms Today (Grades 3 – 8)	Information Technology Skills Developed Using Yson I (Grades 3 – 8)
<ul style="list-style-type: none">• How to turn on a device, laptop or computer	<ul style="list-style-type: none">• The basics of the Software Development Life Cycle (SDLC)
<ul style="list-style-type: none">• How to launch a software application from a device, laptop or computer	<ul style="list-style-type: none">• The basics of the artifacts created to support an IT project that follows the SDLC
<ul style="list-style-type: none">• How to use software applications (i.e., educational tutorials, games, etc.)	<ul style="list-style-type: none">• The basics on using industry best practices to test a software or hardware product.
<ul style="list-style-type: none">• How to shut down a device, laptop, or computer	<ul style="list-style-type: none">• An overview of how a software or hardware product is delivered to the end user.

Introducing the Yson I Educational System

- The Yson Educational Systems present a modified, lightweight Software Development Life Cycle that:
 - Improves the IT Project success rate
 - Introduces the Requirements Definition phase
 - Breaks the Requirements phase into manageable phases for greater precision
 - Ensures customer requirements are properly defined, managed and analyzed

Step 1: Planning

**Step 2: Requirements
Definition**

Step 3: Design

Step 4: Development

Step 5: Integration & Test

Step 6: Implementation

Introducing the Yson I Educational System

- Yson includes 3 Educational Systems as follows:
 - Yson I Educational System (YES I)
 - An Artificial Intelligence System that targets Grades 3 – 12.
 - Increases in detail and complexity as the children move from one grade to the next
 - Includes industry branches that develop the skills of a Jr. Systems Analyst.
 - Yson II Educational System (YES II)
 - A knowledgebase that provides IT content with examples so course designers can revamp the BS in Computer Science degree programs.
 - Yson III Educational System (YES III)
 - An Artificial Intelligence System that targets low –income and upward mobility veterans

Introducing the Yson I Educational System

- Yson I is an Artificial Intelligence Educational System
- Yson I does the following:
 - Enables students to receive one-on-one technology education – **Quality**
 - Enables students to practice anywhere that has a computer or device with access to the internet – **Availability**
 - Enables students to repeat tutorials & practice sessions until content is learned (student does not have to keep up with the class) - **Personalized**

The screenshot displays the Yson I Educational System interface within a web browser window. The browser address bar shows 'http://localhost:49251/'. The page title is 'Project Management Plan'. The interface features a red header with the 'Yson I Educational System' logo and a navigation bar with 'HELP', a gear icon, and 'End Session'. The main content area is divided into sections: 'Role: Project Manager' with a cartoon bee character, 'Learning Objectives' with a list of topics, 'Site Words' with a robot icon, 'Tools' with a robot icon, 'Activities' with a robot icon, and 'Tutorial Session' with the subtitle 'SDLC Phase: Planning'. The 'Tutorial Session' section includes a list of tasks: '- Project Manager', '- Create Project Management Plan', '- Microsoft Office Project', and '- Project Plan'. Below this, there is a paragraph of text and a photograph of three children talking on mobile phones. At the bottom, a partially visible sentence reads: 'To build a cell phone or tablet you need to have things: hardware and software. Hardware is always'.

Introducing the Yson I Educational System

- With Yson I students can:
 - Advance at their own pace
 - Play games, via the Practice module, to create software artifacts or write software code (Games are popular among most children & can compel them to practice more than writing exercises.)
 - Use real world projects to teach technology concepts
 - Develop skills that enable them to effectively interview & complete work in the real world



Introducing the Yson I Educational System

- Yson I includes the following modules:
 - The Tutorial Module
 - The Review Module
 - The Practice Module
 - The Assessment Module
 - The Reporting Module
 - The Administration Module



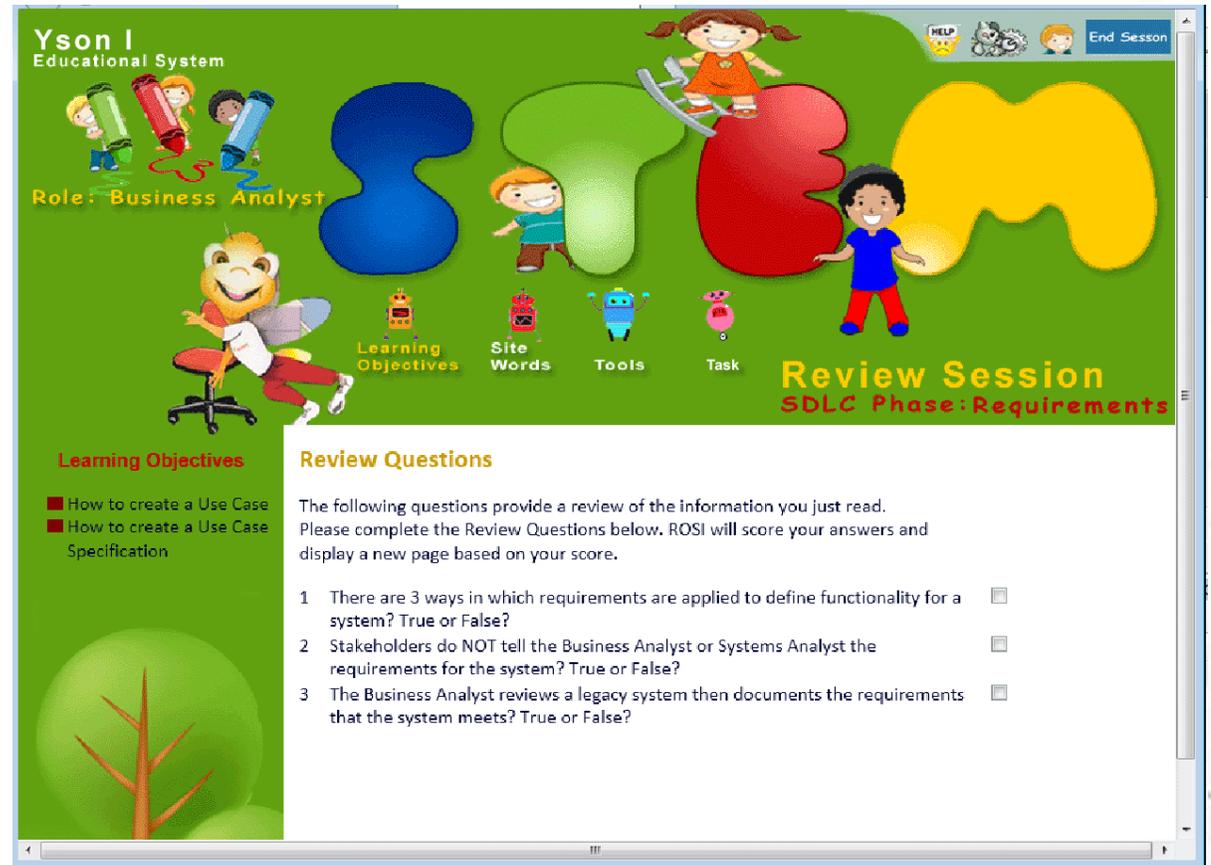
Introducing the Yson I Educational System

- The Yson I Tutorial Module delivers a series of Tutoring Sessions that:
 - Present Information Technology concepts using common terms
 - Define the relevant Roles & Software Development Life Cycle Phases along with the corresponding tasks & tools
- Each Tutoring Session includes the following content:
 - Learning Objectives - Presents Concepts & Content that kids should learn
 - Site Words – Presents IT terms kids should recognize
 - Tools – Presents tools used to perform the tasks in an SDLC Phase
 - Tasks – Explains the work (i.e., test software, write test plan, meet with stakeholders, etc.) performed in an SDLC phase



Introducing the Yson I Educational System

- The Review Module presents a series of Review questions that gauge users' comprehension & knowledge of the content in the Tutorial Session.
- Students answer the Review Questions & Yson directs students as follows:
 - If students pass the Review the student is directed to the next learning objective in the Tutorial Session
 - If students fail the Review, they are presented additional content on the same learning objective & retested.



Yson I Educational System

Role: Business Analyst

Learning Objectives Site Words Tools Task

Review Session
SDLC Phase: Requirements

Learning Objectives

- How to create a Use Case
- How to create a Use Case Specification

Review Questions

The following questions provide a review of the information you just read. Please complete the Review Questions below. ROSI will score your answers and display a new page based on your score.

- 1 There are 3 ways in which requirements are applied to define functionality for a system? True or False?
- 2 Stakeholders do NOT tell the Business Analyst or Systems Analyst the requirements for the system? True or False?
- 3 The Business Analyst reviews a legacy system then documents the requirements that the system meets? True or False?

Introducing the Yson I Educational System

- Yson I presents Practice Sessions that use the Yson Game Module
- Playing games to reinforce IT content:
 - Keeps kids engaged
 - Reinforces what was learned in the Tutorial Module.
 - Provides details for a “real world” project.
 - Provides “real world” experience as children build artifacts or write code for a software project.
- The Practice Module develops knowledge & skills that can be “directly” applied to a real world project.
- The Game Score drives where the student is directed to:
 - If the child gets a high score the child progresses to the Assessment Module.
 - If the child gets a low score the child returns to the Tutorial Module or the Practice Module.



Introducing the Yson I Educational System

- The Yson I Assessment Module:
 - Presents questions that cover the content from the Tutorial Session
 - Confirms that students understand the concepts presented in the Tutoring Module & practiced in the Practice Module.
 - Uses the Assessment Score to drive what content is presented next:
 - If the child gets a high score the child progresses to the next Tutorial Session.
 - If the child gets a low score the child returns to the Tutorial Module or the Practice Module.

The screenshot shows the 'Yson I Educational System' interface for an 'Assessment Session' on the 'SDLC Phase: Planning'. The page is bright yellow and features large, colorful letters spelling 'STEM' with cartoon characters. Below the letters are icons for 'Learning Objectives', 'Site Words', 'Tools', and 'Activities'. The 'Assessment Questions' section contains five questions with True/False options.

Learning Objectives

- What is a Project Plan
- How to Create a Project Plan
- How to Read a Project Plan
- How a Project Plan Can Help Make a Cell Phone or Tablet Work
- When to Create a Project Plan

Assessment Questions

Please complete the Assessment Questions below. All questions require a True or False response. ROSI will score your answers and display a new page based on your score. The passing score for this assessment is over 60 higher. If your score below is over 60; but, below 70 ROSI will display the Tutorial section. This will allow you to review the material associated with the questions below. If your score is over 70 but below 75 ROSI will display the Practice Game so you can practice Project Planning. If your score is over 75 the Congratulations page will display. You can then proceed to the next tutorial.

	True	False
1 To build a cell phone or tablet you need to two key components: hardware and software ?	<input type="checkbox"/>	<input type="checkbox"/>
2 Team members view the Project Management Plan to learn four things as follows: 1) What task to work on, 2) How much time they have to finish the task (duration), 3) When to start the task, and 4) When to finish the task?	<input type="checkbox"/>	<input type="checkbox"/>
3 The Project Manager must figure out how long it will take to build the software or hardware?	<input type="checkbox"/>	<input type="checkbox"/>
4 Just as you complete tasks to clean up your room, people from the IT Department complete tasks to create hardware or software?	<input type="checkbox"/>	<input type="checkbox"/>
5 If you download a game from the internet to a computer, you can	<input type="checkbox"/>	<input type="checkbox"/>

Introducing the Yson I Educational System

- The Yson Reporting Module lets users, parents & teachers generate reports to determine:
 - Where a child is in the learning process
 - Problematic areas (based on how many times a child repeats a Tutorial Session)
 - Assessment scores by IT Task & Student
 - Top 100 Ranking IT Students in the country – Will include Maintenance [Future] (If launched nationally)
 - Top 100 Ranking IT Students by School (If launched nationally)
 - Top 100 Ranking Development Students (If launched nationally)
 - Top 100 Ranking Systems Analyst Students (If launched nationally)
 - Top 100 Ranking Students by Industry (if launched nationally)
 - Adhoc Reporting Feature Can Be Made Available

Introducing the Yson II Educational System

- Yson II addresses the following short-comings in our current undergraduate Bachelors, Computer Science Education programs:
 - Students do not complete assignments using an IT Project methodology; thus they are not familiar with real world IT project documents.
 - Exercises are not presented using an IT project so the homework results in building samples for a professional portfolio.
 - Schools do not use pre-requisites to ensure reading & homework assignments are presented in the order in which work is done in the real world (this is why BS, Computer Science graduates cannot perform as part of a team in the real world).
 - IT content presented does not delve into the detail needed for Computer Science graduates to effectively pass an interview for a junior IT position.
 - Note: Most employers will not hire graduates without experience; but will take experience without a degree.
 - Social Studies courses and electives are not designed to further nurture a clear understanding of related Industries so students specialize in an industry (i.e., Systems Integration & Automation, Space Engineering, Automotive, etc.)

Introducing the Yson II Educational System

- Yson II provides the information needed to make the BS in Computer Science degree programs more useful:
 - Provides a searchable system that professional curriculum design professionals can review to create Computer Science Programs that enable graduates to get a job with the BS, in Computer Science
 - Provides a real world project with exercises that can be easily tailored by curriculum design professionals to ensure Computer Science graduates have a basic portfolio of samples to show recruiters upon graduating
 - Presents the educational material in the order that it should be presented to students so course pre-requisites can be established

Contact

Pamela V. Langford

CEO

BLIT Services, LLC

“A Veteran-Owned Small Business”

www.blitservllc.com

From: Paul Dybala, PhD [mailto: [REDACTED]]
Sent: Tuesday, November 10, 2015 6:35 PM
To: [REDACTED]
Cc: pcast@ostp.gov
Subject: Mr. President, your advisers were wrong about hearing aids

Paul Dybala, PhD
Healthy Hearing
PO Box 515381 #42919
Los Angeles, CA 90051-6681

November 10, 2015

The President
[REDACTED]

Dear Mr. President,

As a licensed audiologist and the president of Healthy Hearing (www.healthyhearing.com) it was with great anticipation that I looked forward to the President's Council of Advisors on Science and Technology's (PCAST) initial report on *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*.
(https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf)

After reading the report, I was disappointed and concerned to see that the recommendations made by PCAST completely missed the mark.

Summary of the PCAST report on hearing aid technology

The council reported hearing loss as a major health and social problem; and left untreated, hearing loss is associated with social isolation, falls, depression and cognitive decline. They cited two factors as the major barriers to treatment: the cost of hearing aids (approximately \$2400 per device) and the lack of coverage by Medicare and insurance. The study proposed the following recommendations to reduce cost to consumers, increase the number of people who use hearing aids and stimulate innovation and technology development:

1. Designation of a basic, over-the-counter (OTC) hearing aid category which would not require being dispensed by a credentialed dispenser.
2. The FDA's withdrawal of draft guidance regarding Personal Sound Amplification Devices (PSAPs) and labeling requirements that exclude the use of PSAPs by persons with more severe hearing loss.
3. A new requirement that hearing care professionals share results of hearing tests with other providers.
4. A new requirement that hearing care professionals provide a copy of hearing test results to the patient at no additional cost.

What the PCAST committee got wrong about hearing aids

I do appreciate the work of PCAST and it's encouraging to see hearing health being considered a serious matter. However, as a professional in the audiology field for almost 20 years, I can confidently say these recommendations will accomplish none of the stated objectives, for the following reasons:

1. OTC hearing devices (such as PSAPs) generally contain comparatively poorer levels of sound processing technology to modern hearing aids. Persons who would use these OTC devices would be less likely to have a satisfactory experience due to the lower levels of technology. The analogy comparing PSAPs to reading glasses is flawed. Treating farsightedness involves refocusing an image on a retina that is still intact. Most hearing loss is sensorineural, which means that the hearing organ has been damaged and/or non-functional. Therefore, the job of a hearing aid is more complex than just increasing the volume of the sounds sent to the ear (Clason, 2015) as it is sending amplified sounds to a hearing organ that is not fully intact.
2. The labeling of OTC hearing devices (such as PSAPs) is essentially a non-issue for consumers. Most consumers purchasing PSAPs are not aware of the exact amount of hearing loss they have, so the current system of warning consumers to avoid use with severe hearing loss is somewhat meaningless to start with.
3. The vast majority of hearing care professionals already provide a copy of the hearing test results upon request. Those results can be taken to another clinic for hearing aid purchase and fitting. It is common practice for the second clinic to repeat the testing to confirm results, especially if the results are older than 6 to 12 months. This is part of the professional's due diligence to provide the best hearing aid programming for the patient.
4. As stated above, it is standard clinical practice for professionals to provide a copy of the hearing test to the patient at no additional cost. Spending taxpayer dollars to institute legislation to enforce what is already occurring as standard practice would be a waste of time and money.

It does not surprise me that I do not agree with the committee's recommendations, as this specific PCAST committee

(https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_letter_report_0ct_meeting.pdf) was comprised of a large number of computer technologists, biologists and physicists, with some additional experts on aging. There were no committee members who had any extensive experience in the hearing loss or hearing aid fields from industry, clinical, research or consumer perspectives. The PCAST committee therefore lacked any applied or scientific experience with hearing loss and treatment.

My recommendations for improving access to hearing aid technology

I respectfully suggest the following recommendations would make a more positive impact on persons with hearing loss and their families. These recommendations are based on scientific and economic data, as well as my experience as a practitioner and researcher in the hearing healthcare field.

1. **Mandate all health insurance to cover hearing aids as a preventative care measure.** Untreated hearing loss has been linked to several other disorders, such as depression (Li, et al., 2014; NCOA, 1999), anxiety (NCOA, 1999), cognitive decline (Amieva, 2015) and heart disease (Bishop, 2012; Friedland, et al., 2009; Hull, et al., 2010). Insurance companies should include hearing health as part of their preventative health initiatives, as treating hearing loss early can improve the overall health of the insured, saving money in health care costs the long run.
2. **Support initiatives to promote hearing aids as a healthy choice.** Hearing loss is a major health issue, as described above. While affordability is a barrier to hearing aid use, it is not the largest one. The negative perception that the general public has towards hearing aids, a.k.a the stigma surrounding hearing aids, is the largest barrier. A review of hearing aid adoption rates in

countries that subsidize or provide free hearing aids to patients show roughly the same hearing aid adoption rates as the United States (HIA, 2015). Therefore, reducing the cost of hearing aids is not likely to increase hearing aid adoption (Amlani, 2010). We have to work together to change the public's attitude toward hearing aids and their perceived value (Amlani, et al., 2011) in order to increase hearing aid adoption rates. The general public needs to understand that hearing aids are a healthy choice that treats hearing loss and promotes general wellness.

3. **Mandate a national best practices protocol for hearing aid fittings.** An individual's success with hearing aids depends on the appropriate fitting and proper verification (Abrams, et al., 2012). Recent surveys of professional practices (Mueller & Picou, 2010) have shown that best practices for hearing aid fittings are not always followed by professionals. Additionally, the typical "first fit" algorithm from the hearing aid manufacturer generally needs to be adjusted using those best practices (Abrams, et al., 2012; Sanders, et al., 2015). OTC hearing aids with self-fit protocols are even less likely to be fit properly.
4. **Mandate package labeling for risk of hearing loss.** If you want to update the label on something that will make an impact, add hearing loss risk labels to speakers at concert venues. Add hearing loss risk labels on the outside of the boxes of the millions of iPods and iPhones sold every year versus being where they currently are; buried in the user manuals that no one reads. Require leaf mower, leaf blower, chain saw and other related power tool sales to include protective earmuffs and regulate the sale of excessively noisy toys. Support initiatives that build awareness of hearing loss by informing consumers when they will be exposing themselves to potentially dangerous noise levels. Americans currently value their hearing, but do little to protect it and this needs to change (Packer & Dybala, 2015).

I am thankful for the initial work PCAST has done to shed light on hearing loss awareness. I would like to see the discussion reframed with input from practicing hearing care professionals, experts in the field of auditory research and persons with hearing loss. Together, we can recommend policy on this important health issue that could actually improve the lives of over 30 million Americans with hearing loss.

Most respectfully,

Paul Dybala, PhD
President, Healthy Hearing
www.healthyhearing.com

cc: PCAST Aging and Technology Study Full Working Group

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Comments re: PCAST Report "Aging America & Hearing Loss: Imperative of Improved Hearing Technologies"

From: "Marcinko, Megan" [REDACTED]

Date: Thu, November 12, 2015 1:46 pm

To: "pcast@ostp.gov" <pcast@ostp.gov>

Cc: "Marcinko, Megan" [REDACTED]

Dear PCAST Members:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), please accept the attached comments regarding the October 2015 PCAST report entitled “Aging America & Hearing Loss: Imperative of Improved Hearing Technologies.”

For more information, please contact us at legfederal@entnet.org.

Best regards,

Megan K. Marcinko, MPS

Director, Congressional Affairs

American Academy of Otolaryngology—Head and Neck Surgery



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Comments re: October 26, 2015, PCAST report to the President on *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*.

Drs. Holdren and Lander:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), please accept the following comments regarding the recently released report to the President on *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*.

As background, the AAO-HNS is the world's largest organization representing specialists who treat the ear, nose, and throat, and related structures of the head and neck. The Academy represents approximately 12,000 otolaryngologist—head and neck surgeons who diagnose and treat disorders of those areas. The medical disorders treated by our physicians are among the most common that afflict all American, young and old. They include chronic ear infection, sinusitis, snoring and sleep apnea, hearing loss, allergies and hay fever, swallowing disorders, nosebleeds, hoarseness, dizziness, and head and neck cancer.

Given the specific expertise of our Membership, we have been watching closely, and appreciate, the efforts of PCAST and other entities, such as the Institute of Medicine (IOM), to study, and hopefully mitigate, some of the ongoing issues faced by the nation's senior population in regards to the access and affordability of hearing aids, and their applicable services.

For ease of review, the following comments are organized in the context of the PCAST's formal recommendations. However, they may also reference, refute, and/or articulate concern regarding statements included

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in the general PCAST analysis/report.

Open up the market for innovative hearing technologies:

PCAST Recommendation 1. *FDA should designate as a distinct category (“basic” hearing aids) non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss and adopt distinct rules for such devices.*

(a) FDA should approve this class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser. FDA should also approve for OTC sale, both in stores and online, tests appropriate to the self-fitting and adjustment of these OTC devices by the end user. Such hearing treatments and tests meet the FDA requirements for OTC products, which are that consumers should be able to self-diagnose, self-treat, and self-monitor the condition.

(b) FDA should exempt this class of hearing aids from the QSR regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer-electronics industry, developed by an appropriate third-party organization and approved by FDA. Similar actions should be taken with respect to diagnostic hearing tests used to dispense and fit Class I hearing aids.

The AAO-HNS is generally supportive of the concept of denoting a “basic” category of hearing aids, which would be more easily available for purchase by seniors. Although the AAO-HNS believes that providing access to a lower-cost or “basic” hearing aid could/would likely benefit a large portion of the senior population, we caution that specific action should first be taken to ensure that a particular individual/patient’s condition actually falls into the category where non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss would be of value. **As such, we assert it is an overstatement to conclude that patients/consumers could or would be able to self-diagnose, self-treat, and self-monitor their particular hearing loss.** For example, an individual living alone may personally evaluate his/her hearing loss as only mild or moderate, not realizing that another individual with normal hearing would not be able to tolerate the excessive television, etc. volume used to compensate for the person’s hearing loss.

Therefore, the AAO-HNS recommends the retention of a medical evaluation by a physician, followed by a standardized hearing test (via a hearing health professional or appropriate online/technological source), BEFORE an individual could seek purchase of a “basic” hearing aid or other FDA-regulated assistive hearing device. Even if the resulting end-product is purchased OTC, a patient will still benefit, and will certainly not be harmed, by receiving an appropriate evaluation of their actual hearing loss. In general, the PCAST report makes light of the potential *medical* issues associated with hearing loss. However, a large percentage of Medicare beneficiaries (the general population discussed in the PCAST report) have multiple and complex medical conditions. For example, according to a 2014 U.S. Department of Health and Human Services report¹, in 2011-2013, the most frequent occurring conditions among the senior population included: hypertension (71%), diagnosed arthritis (49%), heart disease (31%), cancer (25%), and diabetes (21%). Of the five



aforementioned medical conditions, three have correlations to hearing loss. In addition, ototoxic and vestibulotoxic drugs can have a direct correlation with hearing loss; a factor exacerbated by advanced age (over 65).ⁱⁱ

As such, any changes to current regulations regarding the availability and/or access to hearing aids must be accompanied by parallel efforts to ensure said changes aren't viewed by the public as a means to disregard the *medical* issues that *can* be associated with hearing loss. The PCAST report seeks to classify such occurrences as “extremely rare,” by focusing on the incidence of patients who are diagnosed with acoustic neuroma. In reality, there is a broad range of medically-related issues associated with hearing loss. Furthermore, the Report (perhaps inadvertently) lumps together “sudden” and “unilateral” onset of hearing loss. These are two separate hearing-related issues. “Sudden” hearing loss (SHL) is defined as rapid-onset, occurring over a 72 hour period, of a subjective sensation of hearing impairment in one or both ears.ⁱⁱⁱ The occurrence of SHL should be viewed as a medical emergency, requiring immediate evaluation by an MD/DO physician. By receiving prompt evaluation, diagnosis, and treatment of SHL by a physician, patients have a greater chance of recovery.

Ensuring patients/consumers continue to receive proper evaluations before purchase of a hearing-related device will also help mitigate the instances where such a device isn't actually needed. For example, the AAO-HNS generally disagrees with PCAST's assessment that “...ear-wax removal at a clinic or local drugstore...” is an adequate means for cerumen management. The AAO-HNS position statement regarding cerumen management states, “...removal requires mechanical or chemical manipulation of the external auditory canal and such manipulation may result in traumatic and/or inflammatory lesions to the external auditory canal, tympanic membrane, and/or middle ear conduction mechanism.”^{iv} The AAO-HNS believes mechanical and/or chemical manipulation of the external auditory canal in an effort to remove cerumen should only be performed by or under the supervision of a qualified physician (MD or DO). Allowing and advocating for the non-professional or personal management of cerumen may create complications for a patient/consumer that would have otherwise not required ANY additional treatment, service, or intervention.

Beyond the aforementioned medically-related concerns, we agree with the PCAST's assertions in its report that the costs associated with hearing aids remain prohibitive for a large population that could benefit from receiving some form of assistive hearing device. In addition, we agree that for a variety of reasons, hearing aids (and their associated costs) have not necessarily benefited from the vast technological advances that have occurred since hearing aids (in various forms) entered the market. It is in this context that the AAO-HNS urges interested parties to differentiate between the “access” issues associated with the cost of hearing aids, versus alleged “access” issues to qualified hearing-healthcare professionals (e.g. otolaryngologist—head and neck surgeon, primary care physicians, audiologists, etc.) which tend to offer hearing aid services in the same urban and rural areas. While patients/consumers will undoubtedly benefit from the creation of additional pathways for hearing loss treatment or mitigation (e.g. PSAP, “basic” hearing aid, or other “hearable” device), it remains critically important that the same patients/consumers are, from the first step (evaluation) pointed in the right direction. If not, the effort is done in vain. It is for those reasons that the AAO-HNS supports efforts to *pragmatically* deregulate the availability of various assistive hearing



devices, while still retaining requirements for a patient to receive the appropriate medical evaluation and hearing screening.

Ideally, commonsense efforts to *deregulate and thereby increase access to “basic” hearing devices and “hearables”* will spur additional technological innovations – naturally driving costs down, much like what has been seen in regards to smart phones.

PCAST Recommendation 2. *FDA should withdraw its draft guidance of November 7, 2013 on Personal Sound Amplification Products (PSAPs). PSAPs should be broadly defined as devices for discretionary consumer use that are intended to augment, improve, or extend the sense of hearing in individuals. PSAP manufacturers should continue to be able to make truthful claims about their use in normal settings. FDA should not require language in PSAP labeling or advertising that excludes their use by individuals with age-related hearing loss no worse than mild-to-moderate.*

The AAO-HNS agrees with PCAST’s recommendation that the FDA withdraw its draft guidance regarding PSAPs. In many cases, patients/consumers may view PSAPs as a market-entry device. And, if they have a positive experience with a PSAP, but eventually believe they could benefit from greater hearing assistance, a patient/consumer may be more apt to transition to a standard hearing aid if medically necessary. In addition, the AAO-HNS supports the assertion that PSAP manufacturers should have the opportunity to market their products as capable (in general terms) of providing hearing assistance in a variety of settings. **However, the AAO-HNS also believes that consumers would benefit from the inclusion of or information on the “red flags”^v associated with ear disease in all PSAP and/or potential “basic” (OTC) hearing aid packaging. The standardization of such packaging and inserts is a critical aspect of any effort to deregulate, on any level, PSAPs and/or a potential “basic” hearing aid device.**

Increase opportunities for consumer choice

PCAST Recommendation 3. *Analogously to its “Eyeglass Rule,” FTC should require audiologists and hearing-aid dispensers who perform standard diagnostic hearing tests and hearing aid fittings to provide the customer with a copy of their audiogram and the programmable audio profile for a hearing aid at no additional cost and in a form that can be used by other dispensers and by hearing-aid vendors. Also analogously, the availability of a hearing test and fitting must not be conditioned on any agreement to purchase goods or additional services from the provider of the test.*

As previously stated, the AAO-HNS supports continuing to require consumers/patients to receive a medical evaluation and appropriate hearing test prior to the purchase of any potential OTC “basic” hearing aid device. **After having received such an evaluation, the AAO-HNS sees no reason why a patient/consumer should not be able to “shop around” for their own most cost-effective solution.** Based on a standard evaluation, a skilled otolaryngologist—head and neck surgeon or audiologist should be able to assist, and make recommendations regarding, the best course of action for the patient—even if that means directing them to a high-quality PSAP. Conversely, the same dialogue will also enable the



hearing healthcare provider to fully explain why a PSAP (or other applicable device) may not be appropriate, or helpful, for a person’s particular hearing loss. Ultimately though, the decision to purchase *any* hearing-related device would be left to the patient/consumer, and in whatever setting they chose (clinic/office, online, etc.)

PCAST Recommendation 4. *Similarly in effect to its “Contact Lens Rule,” FTC should define a process by which patients may authorize hearing-aid vendors (in-state or out-of-state) to obtain a copy of their hearing test results and programmable audio profile from any audiologist or hearing-aid dispenser who performs such a test, and it should require that the testers furnish such results at no additional cost. While FTC has the authority to issue new regulations of this sort, action can be accelerated and strengthened by legislative direction. We urge the Administration to work with Congress to initiate bipartisan legislation that would instruct FTC to issue a rule for hearing aids and PSAPs similar to the eyeglass and contact lens rules.*

The AAO-HNS agrees with PCAST’s recommendation regarding the portability of hearing test/audiogram results. **And, theoretically, the AAO-HNS would support legislation instructing the FTC to issue a rule for hearing aids and PSAPs similar to the eyeglass and contact lens rules.** However, and with all legislative matters, the AAO-HNS strongly feels that the “devil is in the details.” Any future legislation proposed to address/mitigate the issues discussed in the PCAST report would require careful analysis by the AAO-HNS. The inclusion of provisions regarding the requirement of appropriate hearing evaluation/testing would be critical.

Summary

The AAO-HNS appreciates PCAST’s analysis of the barriers faced by older Americans in terms of hearing loss and access to appropriate hearing-created services and/or devices. The PCAST report offers several tangible recommendations to help mitigate these issues for a potentially large portion of the older population. While more extensively elaborated above, the AAO-HNS reiterates its support for the following:

- **The availability of a “basic” and/or OTC hearing aid, intended for patients/consumers categorized to benefit from non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss. In order to identify individuals who actually fall into this category, the AAO-HNS stresses the importance of retaining requirements for a medical evaluation by a physician and appropriate (high-quality and standardized) hearing test.**
- **The withdrawal of draft FDA guidance and concurrent deregulation of PSAPs, thereby increasing the availability of basic or market-entry assistive hearing devices. Said devices should, however, include standardized information regarding the “red flag” warnings associated with ear disease.**
- **The availability of portable hearing test/audiogram results following the provision of a medical evaluation and standardized hearing test. Such flexibility**



will encourage consumer choice and hopefully spur technological advances and natural downward market changes regarding the cost of various hearing-related devices.

- **The potential for future legislation relating to the portability of hearing test/audiogram results and access to various hearing-related devices.**

The AAO-HNS looks forward to working with PCAST and other relevant stakeholders regarding efforts to mitigate the barriers associated with access to appropriate hearing-healthcare devices (and services) in the United States. If you have any questions or would like additional information regarding these comments, please contact legfederal@entnet.org.

Sincerely,

James C. Denny III, MD
Executive Vice President/CEO

ⁱ http://www.aoa.acl.gov/Aging_Statistics/Profile/2014/docs/2014-Profile.pdf

ⁱⁱ <http://www.audiologist.org/ada-resource-library/diabetes-hearing-loss-resources>

ⁱⁱⁱ <http://www.entnet.org/sites/default/files/SHL-talking-points-physicians.pdf>

^{iv} AAO-HNS Position Statement: Medical Role in Cerumen Management. <http://www.entnet.org/?q=node/926>

^v AAO-HNS Position Statement: Red Flags-Warning of Ear Disease <http://www.entnet.org/?q=node/912>