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Agency for Healthcare Research and Quality
Scientific Resource Center
Portland VA Research Foundation
3170 SW U.S. Veterans Hospital Road
Mail Code: R&D 71
Portland, Oregon 97239

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The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a national membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA appreciates the opportunity to provide comments on the key questions that will be used by the Agency for Healthcare Research and Quality (AHRQ) as part of its systematic review of the available clinical evidence that “defines practices, evaluates the association between assessment techniques and tools and functional measures used in the care of beneficiaries who require lower limb prostheses (LLP), and the associations between LLP (components) and patient centered outcomes, including patient expectations regarding expectations, satisfaction with accessing LLPs, and use (or non-use) of the prostheses.” AOPA is pleased to provide the following general comments on the systematic review as well as specific comments regarding each of the key questions on which the AHRQ has invited comments. In addition to its comments below, AOPA joins in and supports the comments being submitted by the Orthotic and Prosthetic Alliance, which AOPA participated in preparing. AOPA has tried to avoid redundancy by focusing most of the attention in these comments in areas distinct from those being submitted on behalf of the Orthotic and Prosthetic Alliance, of which AOPA is a member.

General Comments Regarding the AHRQ Systematic Review

AOPA supports a systematic review of the clinical literature that addresses the relationship between assessment techniques and functional measures that are used to determine the most clinically appropriate lower limb prosthesis that best meets the clinical and functional needs of the individual patient; at the same time we believe that the ongoing work nearing completion by the Rand Corporation, and its systematic literature review relating to identifying the comprehensive, value-based economic approach and model to prosthetic services, has likely captured most of said literature. While significant research exists on this topic, it must be reviewed and compared in an effort to improve assessment techniques to ensure that amputees have access to lower limb prostheses that offer the opportunity for a successful patient outcome. A preliminary report of the progress of the RAND Corporation on this important study is appended to these comments for reference and review.

In addition to the extremely valuable research currently underway by the RAND Corporation, existing research by the health economics firm Dobson DaVanzo examined the overall cost effectiveness of the provision of orthotic and prosthetic services through the use of a retrospective study.¹ For lower limb prostheses, the study showed that post amputation healthcare expenditures were no greater for those patients who received a prosthesis than those that did not. Further, the trends identified in the study indicated that if patients continued to be tracked for more than the 18 month period included in the study that overall healthcare costs were likely to be lower for those patients who received a lower limb prosthesis compared to those that did not.

Another valuable study by Highsmith et al.² reviewed existing literature on the cost effectiveness of prosthetic intervention for transtibial amputees in an effort to determine whether “there is sufficient evidence to conduct a formal systematic review or meta-analysis in any particular prosthetic intervention area and to determine if any evidence statements could be synthesized relative to economic evaluation of interventions provided to patients with trans-tibial amputation” This study should be considered by AHRQ when performing its systematic review

AOPA has long supported clinical research that focuses on patient centered outcomes to determine the most appropriate lower limb prosthesis to meet their reasonable functional expectations. While the longstanding benchmark for coverage of lower limb prostheses has been the five tiered (K0-K4) functional level assessment system created

¹ Dobson, PhD., A; El-Gamil, BA, A; Shimer, PhD., M; DaVanzo, PhD., J; Economic Value of Prosthetic Services Among Medicare Beneficiaries: A Claim-Based Retrospective Cohort Study; Military Medicine, Supplement Relating to Proceedings of December, 2015 AMSUS Meeting, Volume 181, No. 2, February, 2016, pp. 18-24.

² *Economic Evaluations of Interventions for Transtibial Amputees: A Scoping Review of Comparative Studies.* CPT. M. Jason Highsmith et al. *Technology & Innovation, Volume 18, Numbers 2-3, September, 2016, pp. 85-98.*

by the Medicare program, times, technology and patients have changed in the many years since this assessment system was created. For example, there is strong economic data pointing to the fact that when K2 assessed patients receive a more expensive K3 prosthesis, their **total health costs decline** to the lower level of K3 patients, in lieu of the higher total health costs that are typical for K2 patients. There are also indicators that the K-level coding criteria may have things upside down—there is a solid prospect that giving more advanced technologies, like K3 components, lowers the risk of very costly falls and their sequelae in patients who begin at a significantly lower level of balance and mobility on their prosthesis³. The evolution of clinical research has shifted toward a more patient centric, outcome based assessment, warranting additional review to ensure that outcomes are considered when prescribing and providing a lower limb prosthesis.

A consideration that AOPA believes is extremely important to the AHRQ systematic review is the number of Medicare amputee beneficiaries who are under age 65 and are eligible for Medicare coverage as a result of classification as permanently disabled. This population, measured from Medicare's data to actually represent 33.9% of all amputees enrolled in traditional (fee for service) Medicare in 2012⁴ represents more than one third of the Medicare covered amputee population and will likely have clinical needs related to lower limb prostheses that are unique compared to those amputees who are eligible for Medicare as a result of their age (65 or older). Contrary to the reflexive sense by those familiar with Medicare generally who demand data must relate to patients over 65, prosthetics is very different—and one-third of beneficiaries requires a broader look at those both younger and older than the standard 65-year benchmark. This percentage is disproportionate to the percentage of all Medicare enrolled beneficiaries who were under the age of 65 (18.1%) in 2012⁵. Certainly, studies relating to cohorts of patients who are younger than 65, as well as those who are age 65 and older must be considered as part of the AHRQ systematic review.

AOPA believes that consideration of existing systematic reviews is an integral part of the AHRQ process and would like to ensure that AHRQ is aware of and considers the publication by Highsmith et al.⁶ entitled *Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews*. This systematic review was published in the *Journal of Rehabilitation Research and Development* 2016; 53(2): 157-184... This publication

³ Kannenberg A, Zacharias B, Pröbsting E: Benefits of microprocessor prosthetic knees to limited community ambulators: A systematic review. *J Rehabil Res Dev* 2014;51(10):1469-1495.

⁴ Dobson DaVanzo analysis of Medicare Custom Cohort Dataset, 2011-2014, currently in progress, see Addendum

⁵ Dobson DaVanzo analysis of Medicare Custom Cohort Dataset, 2011-2014, currently in progress, see Addendum

⁶ *Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews*. *Journal of Rehabilitation Research and Development*, Volume 53, number 2, pages 157-184

comprised a systematic review of the literature relating to post-amputation treatment of patients following trans-tibial amputation, which is exceedingly germane to the inquiry on lower limb prosthetics now being undertaken by AHRQ. It may actually represent the most comprehensive, reasonably current systematic review of the scientific literature relating to lower limb prosthetics, and so, as such, must be considered as very strong primary resource in any systematic review of the AHRQ.

AOPA recommends the consideration of studies that move beyond the reliance on Medicare Functional Classification Level (K-level) as the sole source for determining the most appropriate lower limb prosthesis for an amputee beneficiary. As noted above, while functional level assessment and classification has traditionally been used as the sole determining factor in coverage decisions by Medicare, recent research indicate that the provision of lower limb prosthetic components that exceed those covered based on the patient's functional level assessment result in improved outcomes and cost savings through a reduction in overall healthcare cost for the specific patient.

The health economics firm Dobson DaVanzo conducted an additional study “to determine if patients who received prosthetic devices beyond their reported functional limitation assessment indicated on the claims achieved different clinical outcomes and/or Medicare payments over 18-months compared to patients who received the prosthetic devices (i.e., a prosthetic device that matched the patient's reported functional level).” Dobson DaVanzo also tested the “proposition that the cost of higher (more functional) K-level devices is offset by overall lower health care utilization, resulting in lower Medicare payments.”⁷ Results from this study indicate that overall healthcare costs for amputees who were fit with prostheses that exceeded their functional level assessment were lower than those that were fit with prostheses consistent with their functional level assessment. In the broader Dobson-DaVanzo study, patients with K2 prostheses had higher total health costs, more ER visits, and more SNF admissions than patients with K3 prostheses, while the K3s had greater PT costs, emblematic of greater mobility.⁸ A second, study, published at present solely in abstract form was presented during the 2016 AOPA National Assembly in Boston, Massachusetts that analyzed the number of falls and six month associated healthcare costs that occurred among a study group of 77 trans-femoral or knee disarticulation amputees residing in Olmstead County Minnesota.⁹ The study determined that the average cost of healthcare treatment related to falls in patients with trans-femoral or knee disarticulation exceeded the cost of the provision of a micro-processor controlled prosthetic knee component which could significantly reduce the number of falls based on its ability to allow the amputee to recover from stumbles.

⁷ Dobson DaVanzo Summary of Findings: K-Level Analysis

⁸ Dobson, PhD., A; El-Gamil, BA, A; Shimer, PhD., M; DaVanzo, PhD., J; Economic Value of Prosthetic Services Among Medicare Beneficiaries: A Claim-Based Retrospective Cohort Study; Military Medicine, Supplement Relating to Proceedings of December, 2015 AMSUS Meeting, Volume 181, No. 2, February, 2016, pp. 18-24.

⁹ *Direct Medical Costs of Accidental Falls for Adults with Above Knee Amputations: Benjamin Mundell, Hilal Maradit Kremers, Sue Visscher, Kurtis M. Hoppe, Kenton R. Kaufman*

A third study, also presented at the 2016 AOPA National Assembly, discussed the clinical benefits of the provision of a micro-processor controlled prosthetic knee to amputees who were classified as functional level 2 ambulators.¹⁰ Reported study results included a reduction in stumbles and falls among study participants, significantly less “sitting time”, and less overall frustration among study participants. This presentation was selected for the prestigious Howard R. Tranhardt award during the 2016 AOPA National Assembly. In addition, a recently published systematic review of six studies with microprocessor controlled knees in patients with transfemoral amputation and functional level 2 mobility found a significant reduction in uncontrolled falls by up to 80% as well as significantly improved indicators of the risk of falling. Performance-based outcome measures suggest that persons with K2 mobility may be able to walk up to 25% faster on level ground, about 20% quicker on uneven surfaces, descend a slope almost 30% faster and significantly improve quality of stair descent when using a microprocessor knee¹¹.

A fourth study that AOPA believes warrants strong AHRQ consideration when performing its systematic review examined the likelihood of a patient receiving a prosthetic prescription based on pre-amputation characteristics. This study, entitled *Predictors of Receiving a Prosthesis for Adults with Above-Knee Amputations in a Well-Defined Population*¹², reported that patients who ambulated independently prior to amputation were 30 times more likely to receive a prescription for a prosthesis than those who did not ambulate independently. Overall, only about 50% of the amputees in the study ever received a prescription for a prosthesis, far below the levels of prescription in European studies marking similar measurements in Sweden and Scotland, and the likelihood that a patient in the U.S. population received a prescription for a prosthesis declined by roughly 50% for each ten years of additional age in the amputees. Studies such as this are invaluable when reviewing the clinical literature related to provision of lower limb prostheses in the United States, pointing to a remarkable access issue among an underserved population in the general Medicare-eligible contingent.

Beyond specifically citing any particular study deemed relevant, a few methodologic considerations bear mention here. For example, when reviewing an entire body of literature as comprehensively as has been proposed here by AHRQ, several methodologic factors should be considered. For example, a standard 10 year search window may be excessively narrow. One example of this is in regard to outcome measures. The Socket Fit Comfort Score (SCS) was first shared in the literature in

¹⁰ Functional Assessment and Satisfaction in K2 Transfemoral Amputees Receiving MPK Knees-Initial Findings: Kenton R. Kaufman, Kathie Bernhardt, Kevin Symms

¹¹ Kannenberg A, Zacharias B, Pröbsting E: Benefits of microprocessor prosthetic knees to limited community ambulators: A systematic review. *J Rehabil Res Dev* 2014;51(10):1469-1495.

¹² *Predictors of Receiving a Prosthesis for Adults With Above-Knee Amputations in a Well-Defined Population* Benjamin F. Mundell, PhD, Hilal Maradit Kremers, MD, Sue Visscher, PhD, Kurtis M. Hoppe, MD, Kenton R. Kaufman, PhD, PE. *PM&R, Volume 8, Issue 8, August 2016, pp 730-737.*

2003¹³. Similarly, the widely popular Activities Specific Balance Confidence Scale was first disseminated regarding its use with patients with amputation in 2002¹⁴. Thus, a 10 year search may miss important publications. **We recommend a search window greater than 10 years.** Further, it is common for the prosthetic literature to make use of methods suitable for patients with conditions of chronicity such as amputation. For example, given the great difficulty in studying the effects of new therapies and components on “new” amputee patients along with the confounding of healing and steadily improving function, scientists make use of cross-over and repeated measures methodologies in patients who are ‘experienced’ or ‘established’. These methodologic decisions assist in several ways such as: 1) improving statistical power with fewer subjects, 2) affording completion of study objectives with smaller samples, 3) affording more measurement opportunities. As a result, **we recommend inclusion of studies that use repeated measures and cross-over methodology. We further recommend that sample size not be an eligibility factor (i.e. all study designs be included if topically eligible).** It is widely recognized that blinding is difficult or impossible in physical medicine and rehabilitation studies. This applies to prosthetic research. **Thus, we recommend that blinding not be considered as a study eligibility criteria but rather as a factor in rating the quality of a study.** The latter criteria are commonly considered as eligibility criteria for pharmacologic trials which are able to be blinded and also far less burdensome in terms of the time necessary to participate in the research. Also in regard to methodologic considerations, the AHRQ public comment document suggests in one place that therapy will be considered and contradicts this point in another. This review is more about prosthetic intervention and not therapy. Thus, **we recommend that so long as functional outcome(s) following a prosthetic intervention is reported, that the use of therapy, accommodation, acclimation or any other “training” not be cause for exclusion but rather a factor for rating the quality of a study.**

In summary, while AOPA supports the AHRQ systematic review of clinical literature related to lower limb prostheses, it is crucial that AHRQ recognize and consider all of the existing and ongoing research regarding lower limb prostheses.

AOPA Comments Relative to the Key Questions Being Considered by AHRQ

The comments below are in direct response to the AHRQ request for feedback on the key questions it will consider when performing its systematic review. When appropriate, AOPA will identify existing clinical literature that relates to each of the key questions.

¹³ Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. Disabil Rehabil. 2003 Nov 18;25(22):1278-80.

¹⁴ Miller WC, Speechley M, Deathe AB. Balance confidence among people with lower-limb amputations. Phys Ther. 2002 Sep;82(9):856-65.

1. What assessment techniques have been used for evaluation of functional ability of patients prior to prescription of a new or replacement lower limb prosthesis (LLP)?

Response: Assessment techniques that have been used for evaluation of functional ability of patients prior to prescription of a new or replacement lower limb prosthesis vary, with some techniques based on a combination of clinical experience and patient reported expectations, goals, vocational needs, and their potential physical abilities; and other techniques that include post-amputation measures of mobility and balance. While both of these techniques have been widely accepted, many other variables exist that may have an impact on the individual patient's ability to successfully use a lower limb prosthesis. These variables include, but are not limited to patient age, gender, length of residual limb, patient co-morbidities, cognitive abilities, and patient motivation. All of these variables factor in the true assessment of an individual patient's prosthetic needs and therefore must be considered when conducting an assessment regardless of the chosen technique. In the study referenced above by Mundell et al., common reasons why patients did not receive a prescription for a lower limb prosthesis included mobility, co-morbidities, mental status, and frailty or weakness. Proper assessment for prosthetic intervention must consider the overall condition of the patient and their likelihood of successful prosthetic intervention.

1a. In studies that use an assessment technique in people being evaluated for lower limb prostheses who are also assessed using the prosthesis, what are the characteristics of included study participants in terms of?

Response: While each of the characteristics listed in question 1a. may impact the patient's ability for success using a prosthesis, the most important characteristics that must be considered are level of amputation (remaining residual limb), the impact of the amputation on the remaining limb relative to tissue, bone, nerves, etc., co-morbidities, whether the amputation is unilateral or bilateral, the patient's cognitive ability, and the expectation of functional abilities after prosthetic intervention.

1c. What is the Association between prescription assessment techniques and outcomes with the LLP?

Response: While pre-prescription assessment is critical to determine the expected prosthetic needs of the patient, the vast number of variables that can impact the patient outcome once they are fit with a prosthesis make it very difficult to quantify any direct association between pre-prescription assessment and prosthetic outcomes.

Relevant Existing Clinical Literature *Predictors of Receiving a Prosthesis for Adults With Above-Knee Amputations in a Well-Defined Population* Benjamin F. Mundell, PhD, Hilal Maradit Kremers, MD, Sue Visscher, PhD, Kurtis M. Hoppe, MD, Kenton R. Kaufman, PhD, PE. *PM&R, Volume 8, Issue 8, August 2016, pp 730-737.*

Functional Assessment and Satisfaction in K2 Transfemoral Amputees Receiving MPK Knees-Initial Findings: Kenton R. Kaufman, Kathie Bernhardt, Kevin Symms...
Presentation at the 2016 AOPA National Assembly, September 2016, Boston, MA

Direct Medical Costs of Accidental Falls for Adults with Above Knee Amputations: Benjamin Mundell, Hilal Maradit Kremers, Sue Visscher, Kurtis M. Hoppe, Kenton R. Kaufman. *Presentation at the 2016 AOPA National Assembly, September 2016, Boston, MA*

2. What tools to predict outcomes have been used prior to prescription of a new or replacement LLP?

Response: A number of assessments are highly regarded in the literature for the assessment of the patient with lower limb amputation using a prosthesis. Clinical outcome measure requires quantifiable patient activity system for Activities of daily living. The new objective measurements needs to be determined by medical necessity and clinical outcome. The Amputee Mobility Predictor (AMP)¹⁵ is frequently used to assess the ability of an individual with lower limb amputation to ambulate. The AMP is a 20-item scale that includes progressively harder tasks including sitting, balance, transfers, and an ability to negotiate obstacles. The AMP is administered both with a prosthesis (AMP-PRO) and without a prosthesis (AMP-noPRO). The AMP is widely accepted as a reliable test to predict patient functionality with a lower limb prosthesis. Other tools that are commonly used include the Patient Assessment Validation Evaluation Test (PAVET) and the Prosthesis Evaluation Questionnaire (PEQ).¹⁶ Finally, walking tests such as the 6MWT are also considered reliable assessments of functional capacity in persons with lower limb amputation¹⁷.

Relevant Existing Clinical Literature

The Amputee Mobility Predictor: An Instrument to Assess Determinants of the Lower-Limb Amputee's Ability to Ambulate: Robert S. Gailey, PhD, PT et al. *Archives of Physical Medicine and Rehabilitation. Volume 83, May 2002*

Prosthesis Evaluation Questionnaire for Persons with Lower Limb Amputation: Assessing Prosthesis-Related Quality of Life. Legro, MW et al. *Archives of Physical Medicine and Rehabilitation, Volume 79(8), August 1998, pp. 931-938*

¹⁵ *The Amputee Mobility Predictor: An Instrument to Assess Determinates of the Lower-Limb Amputee's Ability to Ambulate.* Robert S. Gailey, PhD, PT et al. *Archives of Physical Medicine and Rehabilitation, Volume 83, May 2002*

¹⁶ *Prosthesis Evaluation Questionnaire for Persons with Lower Limb Amputation: Assessing Prosthesis-Related Quality of Life.* Legro, MW et al. *Archives of Physical Medicine and Rehabilitation, Volume 79(8), August 1998, pp. 931-938*

¹⁷ Lin S-J, Bose NH. Six-minute walk test in persons with transtibial amputation. *Arch Phys Med Rehabil* 2008;89:2354-9.

Lin S-J, Bose NH. Six-minute walk test in persons with transtibial amputation. *Arch Phys Med Rehabil* 2008;89:2354-9.

3. What functional outcome measures have been used to assess ambulation with LLPs?

Response: There are a number of instruments which assess lower extremity function. These include both questionnaires designed to obtain subjective feedback directly from the amputee themselves, and objective measures of functional capability that are based on the individual amputee's ability to perform certain tasks under observation. The questionnaires include tools such as the Locomotor Capability Index (LCI), Prosthetic Limb User Survey of Mobility (PLUS-M), the Patient Specific Functional Scale (PSFS), and the Amputee-Specific Balance Confidence (ABC) scale.

Objective measures include the Timed Up and Go (TUG), the L-Test, and the Four Square Step Test (FSST), and other timed walk tests (2-minute or 6-minute walk test). The TUG is designed to objectively measure functional capabilities of K1 and K2 amputees. It records the time a person takes to rise from a chair, walk three meters, turn around, walk back to the chair, and sit down. The FSST evaluates dynamic balance and mobility through observing a patient step over an object while moving forward, backward, and sideways. The L-Test is used to assess mobility and balance and records the amount of time it takes a patient to rise from a chair, walk to a mark 3-meters away, turn 90 degrees, walk to a second mark, which is 7 meters from the chair, and return to the chair. Timed walk tests are used to assess the distance walked in 2 or 6 minutes, which allows for conclusions on endurance, cardiovascular capacity, and overall walking capabilities.

Relevant Existing Clinical Literature

Dobson DaVanzo Summary of Findings: K-Level Analysis

Biomechanical characteristics, patient preference and activity level with different prosthetic feet: A randomized double blind trial with laboratory and community testing: Silvia Raschke, PhD et al. *Journal of Biomechanics*, Volume 48, Issue 1, pp. 146-152

Functional Assessment and Satisfaction in K2 Transfemoral Amputees Receiving MPK Knees-Initial Findings: Kenton R. Kaufman, Kathie Bernhardt, Kevin Symms. *Presentation at the 2016 AOPA National Assembly, September 2016, Boston, MA*

4. How do the effects of the different components vary based on the characteristics listed in KQ 1A?

Response: When considering this key question, it is important to understand the significant impact that using the proper prosthetic componentry will have on the quality of life of the amputee. Factors to consider when reviewing this question include the length of time the patient will live with their prosthesis, the anticipated amount of daily use of the prosthesis, and the ability of the prosthesis to assist the patient in their activities of daily living. While over-utilization is a concern, the potential for under-utilization must be considered as well. The studies referenced below highlight the potential overall cost savings that may be achieved by ensuring that amputees receive prosthetic componentry that best meets their functional needs, or in some cases provide additional benefits that may reduce additional healthcare cost through events such as preventable falls.

Relevant Existing Clinical Literature

Dobson, PhD., A; El-Gamil, BA, A; Shimer, PhD., M; DaVanzo, PhD., J; Economic Value of Prosthetic Services Among Medicare Beneficiaries: A Claim-Based Retrospective Cohort Study; Military Medicine, Supplement Relating to Proceedings of December, 2015 AMSUS Meeting, Volume 181, No. 2, February, 2016, pp. 18-24.

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5. How do the patients pre-prescription expectations of ambulation align with their functional outcomes? How does the level of agreement vary based on the characteristics listed in KQ 1A and level of componentry incorporated into their lower limb prosthesis?

Response: Patient expectations are inherently subjective and therefore can be difficult to use as a predictor of outcomes. While positive patient expectations may certainly have an impact on outcomes as a source of motivation, the same may be said for negative or unrealistic expectations. Areas of importance regarding how a patient's expectation may impact their outcome include the overall fit of the prosthesis, the mechanical capabilities of the prosthesis, the overall appearance of the prosthesis, and the patient's ability to adapt to life with limb loss. In a study by

Kahle, Highsmith et al.¹⁸ results indicated increased patient satisfaction and function with the use of a microprocessor knee over a mechanical knee. This study identified the importance of patient perception in achieving a positive outcome.

6. What is the level of patient satisfaction with the process of assessing a lower limb prosthesis (in terms of experiences with both providers and payers), how does the level of patient satisfaction vary based on the characteristics listed in KQ 1A and other report characteristics?

Response: Patient satisfaction with the overall process of obtaining a lower limb prosthesis is crucial to ensuring an overall positive experience. Patient outcomes can be negatively impacted by a bad experience with either their provider or their insurance provider (payer). When interacting with both prosthetic care providers and insurers, patients have a reasonable expectation that they will be treated with respect, have the opportunity to provide input on the level of care they receive, and how that care is delivered. Increased patient satisfaction may lead to better outcomes through increased function, patient motivation, and the ability to adjust to potential complications.

Twenty years of technology advances since the K-levels were developed have highlighted deficiencies of the K level (K0-K4) assessment of amputee activity and explain in more detail the need for an objective assessment. K functional level indicator has fulfilled its purpose for subjective assessment established in 90s and provided clinician a guide to assess and prescribe. There are strong arguments for moving away from functional assessment based on old K level, and support further investigation onto more advance objective assessment of medical necessity and quantifiable outcome measure. Patients may need to be segregated based on their own merit, (this is a multi-component, and requires analysis suitable to accommodate all the different variables, different comorbidity, etc... such outcome feeding to prescription assessment by clinician. In the absence of data based on stratified information, the outcome needs to provide statistically valid analysis... (e.g. drug prescription).

EQ5D is cost utility analysis for medical healthcare economic analysis and other measuring systems may not provide data associated with health care economic outcome. Interpretation of assessment methods such as EQ5D with other patient reported outcome (indicating comfort, and Confidence) is a key objective for any future work to correlate the outcome to health economics. Studies refereeing to different componentry, are primarily based on previous generation products. Today's

¹⁸ Kahle JT, Highsmith MJ, Hubbard SL. Comparison of Non-microprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, Stumbles, Falls, Walking Tests, Stair Descent, and Knee Preference. J Rehabil Res Dev 2008;45(1):1-14.

modern prosthetic sciences are already providing evidences that integrated whole limb system, catering for functional interrelation of joint components and their interaction with each other must be considered for dealing with a dynamic system, which is pertinent to the overall outcome achieved. There are international efforts in stratification of amputees to determine the overall rehabilitation directive, using objective measurements in order to determine quantifiable guideline to be used by Multi-Disciplinary Team (e.g. ISPO) and liaison with these group enables provision of new international standards replacing the current functional level indicator.

Relevant Existing Clinical Literature

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7. At six months, one year, and five years after receipt of a prosthesis, accounting for intervening mortality, subsequent surgeries or injuries what percentage of individuals . . . ?

Response: While research on the long term use of a lower limb prosthesis is relatively limited, four studies may be useful in the AHRQ systematic review. A study by Roffman, Buchanan et al.¹⁹ reviewed predictors of non-use of a prosthesis following discharge from rehabilitation. A systematic review by Highsmith et al.²⁰ explored the economic impact of prosthetic intervention in trans-tibial amputees. Another systematic review performed by Sansam, Neumann et al.²¹ explored existing clinical literature that predicted walking ability following lower limb amputation. Finally, Blough et al. modeled costs of service members with major amputations who use prostheses and compared costs between those from the Vietnam era with Veterans from the recent wars in Iraq and Afghanistan. Inclusion

¹⁹ *Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules.* Roffman, Buchanan et al. *Journal of Physiotherapy, Volume 60, Issue 4, December 2014, pp. 224-231*

²⁰ *Economic Evaluations of Interventions for Transtibial Amputees: A Scoping Review of Comparative Studies.* CPT. M. Jason Highsmith et al. *Technology & Innovation, Volume 18, Numbers 2-3, September, 2016, pp. 85-98.*

²¹ *Predicting walking ability following lower limb amputation: A systematic review of the literature.* Sansam, Neumann et al. *Journal of Rehabilitation Medicine, Volume 41, Number 8, 2009, pp.593-603*

of these four studies in the AHRQ systematic review are relevant to the key question above.

In individuals with LLP, how is function impacted (adversely or beneficially) by the level of componentry in their given LLP?

Response: The Medicare based functional level classification system has long been used as the sole guidance in determining what lower limb prosthetic components a patient is eligible to receive. Several recent studies however have explored the potential benefits and overall cost savings that may be achieved by fitting patients with specific components that may exceed their functional level assessment.

In addition to some of the benefits of advanced (K3-K4) prosthetics noted both above and by the Dobson-DaVanzo data, more advanced components may reduce falls and low back pain, slow down disease progression like osteoarthritis (All other chronic), and possibilities of tissues damage due to incorrect distribution of interface loading conditions. There is significant research that indicates that patients with greater impairment and medical need may actually benefit the most from advanced prosthetic technology such as microprocessor controlled knees. The more advanced technology should be prioritized to those individuals with more need (more impairment = more need = more advanced technology) i.e – Recent and emerging research indicates that the K2 individual likely has as much, if not even more need and higher priority and more use for a microprocessor knee than a K3 individual.

Studies that should be considered as part of the AHRQ systematic review include, but are not limited to the following:

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Dobson DaVanzo Summary of Findings: K-Level Analysis

Conclusion:

In summary, AOPA is very appreciative of the opportunity to comment on the proposed process and key questions that will be utilized in performing its systematic review of clinical literature relative to lower limb prostheses, AOPA must stress the importance of the work of the RAND Corporation on this specific issue and believes that AHRQ will be best served by allowing the RAND corporation to be completed and considered by the

ARHQ in its entirety. Failure to consider this comprehensive work as part of the AHRQ process would be a very unfortunate oversight.

There are several very important addenda being included with these comments:

- (a) A preliminary report on the Rand Study comprised of three specific items:
 - (i) A Preliminary Report on their work.
 - (ii) the bibliography (i.e., the collection of the manuscripts comprising their systematic literature review); and
 - (iii) comment on some of the questions from AHRQ as appropriate) which, at minimum, we will be submitting to AHRQ as an attachment/addendum to the AOPA comments; and
- (b) A very rough preliminary report from Dobson-DaVanzo on its initial work on the 2011-14 custom cohort of data from Parts A, B, and D.

We see these two preliminary reports on scientific work in progress/nearing completion as critically important, perhaps among the most important portions of AOPA's comments. Both RAND and Dobson-DaVanzo have been working full bore on providing data to RAND needed for the RAND work, so their review and evaluation of new data, is extraordinarily timely and germane to AHRQ's inquiry and work.

Once the RAND work is completed, over roughly the next 60 days, RAND has committed to early sharing of its report directly to AHRQ. Following up on these comments, AOPA intends to communicate with AHRQ project officer about this. It is possible that RAND may want to communicate directly with the lead AHRQ researcher to offer a briefing and in-depth analysis of its results once available.

Respectfully Submitted

A handwritten signature in blue ink, appearing to read "M. Oros", with a stylized flourish at the end.

Michael Oros, CPO, FAAOP
AOPA President

A handwritten signature in blue ink, appearing to read "Thomas Fise", with a stylized flourish at the end.

Thomas Fise, JD
Executive Director