Final Deliverable

PSAS PROGRAM EVALUATION
PATIENTS WITH AMPUTATIONS STUDY

Department of Veterans Affairs

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Introduction

The purpose of the patients with amputations study is to evaluate the functional outcomes for VA patients who have received a lower extremity amputation

The Department of Veterans Affairs (VA) contracted Booz Allen Hamilton (Booz Allen) to conduct a program evaluation of services provided to veterans who utilize Prosthetics and Sensory Aids Services (PSAS). The main PSAS Program Evaluation study questions evaluate "to what extent is VA achieving its program outcomes for patients requiring prosthetics based on a continuum of care?" This portion of the Program Evaluation concentrates on specific study questions listed below. Analysis metrics were developed in the course of this study to best address these questions based on existing VA data.

Patients with Amputations Study Questions

1. For VA patients undergoing amputation treatment, when risk- and age-adjusted:

   1a-Do they have discharge to community rates the same as or greater than comparable non-VA patients?

   1b-Do they return to their former physical functional capacity to the maximum extent possible at the same rate compared to non-VA patients?

2. Are VA patients, when risk- and age-adjusted, provided properly prescribed and fitted prostheses and orthoses at equal or better rates compared to non-VA patients?

Summary of Findings

Our findings indicate that veterans undergoing amputation have appreciable improvements in functional capacity after discharge and are well support by VA. VA patients had higher FIM motor scores at admission and discharge than non-VA patients (i.e., VA patients had better functional status than non-VA patients). Both VA and non-VA patient populations show improvement in motor function following amputation; however, non-VA patients tended to gain slightly more motor function. VA patients perceived their functional capacity, quality of life and participation in life situations slightly worse than non-VA patients. Physical functioning was more affected than mental functioning. Based on the data available it is not possible to conclude whether these differences were attributable to selection bias, factors unique to VA's patient population, factors unique to VA's operating environment, or other factors.

The majority of VA patients[1] and the majority of non-VA patients[2] returned home following discharge. Our findings indicate comparable discharge-to-community rates between VA and non-VA patient populations.

Comparison data in non-VA populations for properly prescribed and fitted devices was not available. The majority of surveyed VA patients were satisfied with the quality of their prosthetic device, according to

[1] *Q. 1a: FSOD (FIM) database was used.*

[2] *Q. 1a: UDSmr FIM database was used.*

National Prosthetic Patient Satisfaction Survey (NPPSS). However, approximately half of the responding patients also reported problems with their prosthetic device. Addressed in a separate question, half the veterans reported their prosthetic device helped them meet their rehabilitation goals.

In this report, the methodology presented is used to assess VA and non-VA patient populations, as well as our findings and analyses. The Booz Allen team collaborated with VA to develop an analysis plan for the study population. Several VA databases were utilized, as well as non-VA databases, to conduct the analyses. The findings and analyses focus on patient functionality, patient and family education, quality of life, referrals and prescriptions for prostheses, and patient satisfaction.

Methodology

The Booz Allen team utilized several databases and tools to perform the analyses necessary to answer VA's study questions

This section of the report provides an overview of the methodology, a detailed explanation of various clinical assessment tools and a description of the data extraction process. A detailed description is provided of the differences in methodology utilized for each study population group within the respective chapters. Several tools were used to measure and quantify patients' functional ability and quality of life. These tools are described in detail below and were used throughout the study to answer the analysis questions.

A listing of all databases used in this study, as well as summaries of all analysis metrics and the accompanying results are provided in Appendix A—Patients with Amputations Analysis Metrics.

Booz Allen measured the functional capacity and quality of life of VA patients with amputations

The assessment of a patient's functional capacity and quality of life after amputation must be determined using available tools since there are no direct measurements available. The Functional Independence Measure (FIM), for example, is a widely accepted clinical measure based on clinicians' ratings of a patient's performance of motor and cognitive activities to assess the patient's "need for assistance" with performance of common daily activities. The FIM is typically administered to a patient at the beginning and end of medical rehabilitation.

Another accepted method of quantifying a patient's functional ability is through administration of patient self-reported, health-related quality of life (HRQL) surveys such as the SF-36. Such surveys capture the perception of the patient's functional ability by assessing pertinent elements of general health including physical and mental functioning (Ware 1993). Both the FIM and SF-36 are considered "gold standards" for measuring clinical outcomes — FIM for functional assessments and SF-36 for generic HRQL assessments of health status.

The FIM has thirteen motor items and five cognitive items, each rated on a one (total dependence) -to seven (indicating total independence) scale. Trained practitioners of any discipline can administer the FIM. There are no able-bodied population norms for the FIM, which was designed to assess function of patients, as opposed to the SF-36, which was designed to assess HRQL for people both with and without disease or medical conditions (Ware 1992).

The SF-36 allows self-assessment of physical (general health, physical functioning, role physical, bodily pain) and mental (mental health, role emotional, vitality, social functioning) elements of HRQL. The SF-36 facilitates comparisons of functional abilities between VA patients with DM and/or PVD and lower extremity amputations and the following comparison samples:

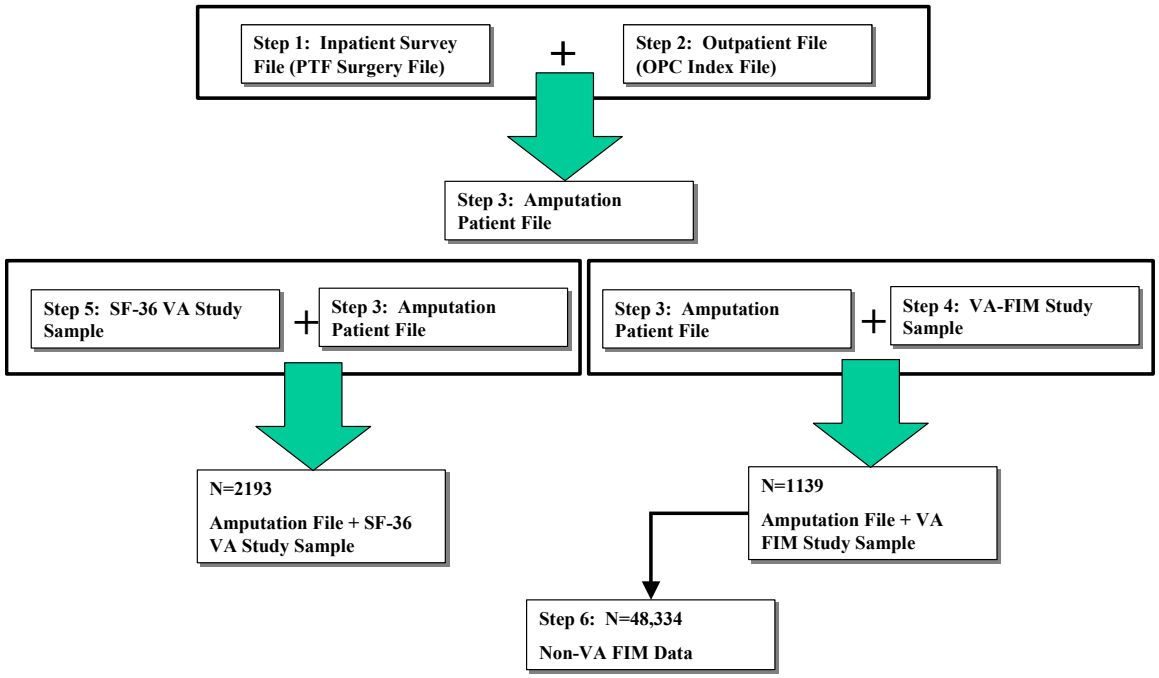
- MOS-36 US normative sample (Ware, 1993)
- Non-VA patients with Type II diabetes (Ware, 1993)
- Non-VA patients with prostheses after lower extremity amputation (Hart, 1999)

Norms ("normative values") for SF-36 have been published for the U.S. population as a whole and for populations with various diseases and conditions, which were developed through (Ware 1993) the Medical Outcome Study (MOS). Data were collected as part of the National Survey of Functional Health Status in 1990 using personal interviews, rather than self-administered questionnaires (Ware 1992; Ware 1993). Respondents were drawn from the General Social Survey in 1990, which surveyed 2,474 non-institutionalized adults in the United States (Ware 1993). Norms for patients with Type II diabetes have been published from the MOS SF-36 study, without data specifically addressing amputations. The average age for that sample was 60 years of age with 38% over 65 years of age. Females comprised 56% of the sample.

Another comparison group is a sample of non-VA patients who completed an HRQL survey containing SF-36 elements before and after their receipt of prostheses for lower extremity amputations (Hart, 1999). Completed SF-36 physical functioning and bodily pain scales (Ware, 1993) were included in the HRQL survey, which allows these two elements to be extracted and compared with VA patients. In that sample (n=840), 70% of patients were males, 56 (Standard Deviation 17; range 14 to 90) years old, with trans-tibial (73%), trans-femoral (19%), or ankle/foot/toe (3%) amputations, seen in 56 orthotic and prosthetic facilities in 25 states in 1998 and 1999. Their amputations were a result of peripheral vascular disease (PVD) (31%), trauma (29%) and DM (27%). In this sample, 32% of patients were receiving their first prosthesis, while the remaining patients were receiving replacement prosthesis.

The patients in the three comparison samples are not exact matches for patients in VA sample for this study, but they include patients to which VA sample can be compared. However, limitations of these comparisons should be taken into consideration.

A multi-step process was used to extract data from VA databases for this study question



Data Extraction Requirements and Techniques

Step 1. Extract Amputation Records from VA Inpatient Surgery File

An electronic file was developed from the inpatient surgery Patient Treatment Files (PTF) for study years 1997 through 2000 from which records were selected if they had lower extremity amputations codes. This file contained 25,444 records, representing 16,890 patients.

Step 2. Extract Demographic and Clinical Information from VA Outpatient File

An electronic file was developed from the Outpatient Care File (OPC). Each record was selected if, on the first outpatient visit, a patient had ICD-9 diagnostic codes for DM or PVD affecting the circulation of the lower extremity. Demographic and additional clinical information is also gained about each patient. Patients were excluded if they: (1) died before study period started or (2) were less than 19 years old. This file contained 452,000 records, one record for each patient.

Step 3. Merge and Match Inpatient Surgery File and the Outpatient File to Obtain Relevant Demographic and Clinical Information

The Inpatient Surgery File was matched to the Outpatient File so patients with diabetes or peripheral vascular disease who had amputations of the lower extremity could be identified with their demographic data. This Amputation Patient File contained 16,890 patient records.

Step 4. Merge Amputation Patient File with VA FIM Data File—VA-FIM Study Sample

A file containing FIM data was developed from the Functional Status and Outcomes Database for Rehabilitation (FSOD) File. A record was selected if a patient was 19 years old or older, had a lower extremity amputation, complete FIM record, and a length of stay between 4-120 days. The FSOD file was then matched with the Amputation Patient File (Step 3) to obtain surgery and demographic information. Patient records were kept only if their dates of surgery preceded dates of rehabilitation admission. This VA FIM Study Sample resulted in 1,139 VA patients.

Step 5. Merge Amputation Patient File with SF-36v—SF-36 VA Study Sample

A file containing veterans' quality of life data was developed from the SF-36v File (SF-36v: Short Form Functional Status Assessment for Veterans). Records were selected if patients were 19 years old or older, had any lower extremity amputations, complete SF-36 responses, and lengths of stay between 4-120 days. The SF-36v file was then matched with the amputation file (Step 3) to obtain surgery and demographic information. Patients were excluded if their dates of surgery followed completion of the SF-36 survey, or if the patients had more than one surgery. This SF-36 VA Study Sample contained 2,193 patients[3].

Step 6. Extract Non-VA FIM Data—Non-VA Sample

Non-VA FIM data were obtained from Uniform Data System for Medical Rehabilitation (UDSmr). Patients were selected if they had FIM scores for calendar years 1997 to 2000, lower extremity amputations and complete FIM data. Limited demographic and programmatic variables were included. All patient

[3] *Few patients had complete data for independent variables.*

identification information was removed. The UDSmr calculated patient age. This Non VA Sample file contained 48,334 patient records.

Booz Allen determined that there was no difference in functionality results between males and females; therefore, female patients were included in our analysis of the non-VA population

The nature of and extent of gender differences in functional status among medical rehabilitation patients was explored using a large sample reported to the Uniform Data System for Medical Rehabilitation in Buffalo, New York. UDSmr maintains the largest database nationwide for medical rehabilitation facilities; its functional status measure, the FIM instrument, is also part of the VA's FSOD. Heinemann and colleagues (1994) used data from 27,699 patients.[4] Collected were patients' functional status at admission to and discharge from medical rehabilitation, along with a variety of demographic and impairment characteristics. Women comprised 53% of the sample; 90% were Caucasians; 44% were married; and the mean age was 62 years. The most important predictor of discharge functional status was admission functional status for each of 12 impairment groups (stroke, brain injury, neurological disorders, amputees, arthritis, etc.), for motor and cognitive function predicted separately. Age, interrupted stays and time from disability onset to rehabilitation admission were also consistent predictors, though they accounted for considerably less variance. In general, greater admission functional status, younger age, shorter time from disability onset to admission and uninterrupted stays was associated with greater function at discharge. In a few analyses, various predictors accounted for a statistically significant but clinically unimportant amount of the variance in functional status. Gender was not consistently related to any of the measured outcomes for any impairment group.

The demographic and clinical characteristics were analyzed for patients with amputations receiving rehabilitation

The study population extracted from VA databases totaled 1,139 patients and the non-VA population totaled 48,334 patients. These patients had functional status information before and after amputation rehabilitation treatment. Table 1 shows the characteristics of both VA FIM study sample (under the FSOD column) and non-VA amputation sample (under UDSmr column).

[4] *Heinemann AW, Linacre JM, Wright BD, Hamilton BB, Granger CV: Prediction of rehabilitation outcomes with disability measures. Archives of Physical Medicine and Rehabilitation, 75, 133-143, 1994.*

Table 1. Summary of Patients with Amputations Receiving Inpatient Rehabilitation

	n=1,139				n=48,334			
Characteristics	**VA FSOD n**	**Summary**	**Number of respondents**	**Missing data**	**Non-VA UDSmr n**	**Summary**	**Number of respondents**	**Missing data**
Gender			971	168			48,334	0
Male	964	99.3%			27,972	57.9%		
Female	7	0.7%			20,362	42.1%		
Ethnicity			1,083	56			46,758	1,576
Caucasian	620	57.2%			32,052	68.5%		
African American	289	26.7%			11,600	24.8%		
Hispanic	164	15.1%			2,479	5.3%		
Native American	8	0.7%			350	0.7%		
Asian	2	0.2%			277	0.6%		
Marital Status			1,114	25			47,079	1,255
Single	121	10.9%			6,704	14.2%		
Married	471	42.3%			23,396	49.7%		
Widowed	136	12.2%			11,259	23.9%		
Divorced	308	27.6%			4,869	10.3%		
Separated	78	7.0%			851	1.8%		
Pre-Hospital Living Setting			1,108	31			46,682	1,652
Home	1048	94.6%			44,921	96.2%		
Board & Care	8	0.7%			475	1.0%		
Assisted Living	5	0.5%			278	0.6%		
Acute Unit	17	1.5%			939	2.0%		
Sub acute Setting/SNF	30	2.7%			69	0.1%		
Amputation Code (Rehabilitation Category)			1,139	0			48,334	0
5.3 (Single AK)	262	22.0%			12,081	25.0%		
5.4 (Single BK)	658	55.2%			27,651	57.2%		
5.5 (Double AK/AK)	33	2.8%			1,207	2.5%		
5.6 (Double AK/BK)	42	3.5%			1,216	2.5%		
5.7 (Double BK/BK)	72	6.0%			2,254	4.7%		
5.9 Other	72	6.0%			3,925	8.1%		
Year of Rehabilitation			1,139	0			48,334	0
1997	101	8.5%			10,994	22.7%		
1998	424	35.5%			11,294	23.4%		
1999	342	28.7%			11,608	24.0%		
2000	272	22.8%			14,438	29.9%		
Length of Stay (days)	22 ± 14				18 ± 11			
Age (yrs - M±SD)	66 ± 10				66 ± 13			

Table 1 presents a comparison of VA and non-VA patients with amputations who received rehabilitation care in an inpatient setting. The majority of patients in both study populations are married, Caucasian males living at home. The most frequent type of rehabilitation for both groups occurred for those who had a single below-knee amputation. There was no difference in age between VA and non-VA patients; there were differences in length

of stay and admission and discharge FIM scores.

- VA patients' lengths of stay were longer than non-VA patients (22 vs.18 days, $t_{(d.f.=1169)}=10.08$)
- VA patients had higher FIM motor scores at admission and discharge than non-VA patients (i.e., VA patients had better functional status than non-VA patients) (See Table 3 under Q.5A)
- When comparing the rehabilitation admission status (i.e., the "admission class" variable), 84.7% of VA and 86.5% of non-VA patients were classified as initial rehabilitation admission
- 1.3% of admissions were classified as "short stay for evaluation" for both groups
- There was a 0.1% unplanned discharge rate for VA and 0.3% for non-VA patients
- Readmission rate was 12.2% for VA and 11.3% for non-VA patients
- The continued rehabilitation rate for VA was 1.7% compared with 0.6% for non-VA patients

Limitations

There are several limitations to this study that should be considered when reviewing the findings

To answer each study question for the Patients with Amputation Study, different data extraction techniques were used, which are described in each section of text. There are limitations in both the data as well as the methods for each of the study populations. The details of these limitations are provided in the text. The limitations are summarized at a high level below.

- Data fields changed over time within and across data sets
- Data were frequently incomplete
- Comparison non-VA samples were difficult to identify and contained different demographic variables
- Exact dates of survey completion and pertinent events (e.g., surgery or rehabilitation) were not recorded in non-VA and VA samples
- Multiple patient records with limited common variables existed for rehabilitation and surgery files
- Privacy and confidentiality constraints made age calculation impossible
- Inconsistent demographic variables existed in VA comparison data sets
- Compliance with treatments or interventions was unknown
- Direct measures of quality of life, functional abilities and participation in life situations were not available
- There was concern for general integrity of data analyzed
- Differences exist between functional abilities and HRQL measures
- Details of rehabilitation were not available
- Potential for sampling bias exists

Findings

VA and Booz Allen collaboratively developed specific analysis metrics to address the main study questions

The Booz Allen team collaborated with VA to develop and further refine analysis metrics to evaluate the program outcomes. Our findings are organized in correspondence with each analysis metric. The metrics are presented below and labeled to match the November 9, 2001, *Refined Project Plan* of the Program Evaluation of Prosthetics and Sensory Aids Services. These multiple metrics are divided into the following four sections: Discharge Rates, Functional Capacity & Quality of Life, Prescriptions for Prostheses and Patient Satisfaction.

Discharge Rates

- 4. What are the discharge-to community rates for VA and non-VA patients, when risk-and age-adjusted (sorted by discharge location)?

Functional Capacity & Quality of Life

- 5A. What is the functional capacity before and after amputation for VA patients? Compare with non-VA patients.
- 5B. How do VA patients perceive their functional capacity after amputation?
- 5D/E. What training did VA patients receive after amputation?

Prescriptions for Prosthesis

- 6A. What VISN/VAMC guidelines exist regarding qualifications of individuals making referrals for VA patients?
- 6B. What credentials do associations specify for prescribing and fitting prostheses and orthotics?
- 6C. What percent of prostheses were repaired/remade?

Patient Satisfaction

- 7A. How do VA patients perceive their quality of life after amputation?
- 7B. What percent of VA patients had ADL equipment delivered before discharge from hospital?
- 7E. How do VA patients perceive the quality and appropriateness of their prosthesis?
- 7F. How do VA patients rate their ability to participate in life situations?
- 7G. What are the wait times VA patients experience for clinic appointments?
- 7H. How long do VA patients with amputations wait to see a provider?

DISCHARGE RATES

Question 4: What are the discharge-to-community rates for VA and non-VA patients?

- 73.1% of VA patients returned home after hospitalization compared to 77.9% of non-VA patients.
- There were differences in the frequencies of VA and non-VA patients discharged to: home (χ^2= 14.1), skilled nursing facility (χ^2= 6.4) and intermediate care facilities (χ^2= 78.8).
- There were differences in frequencies between VA and non-VA patients discharged to: home (χ^2= 27.8) and skilled nursing facilities (χ^2= 13.7), after age-adjustment. (See Tables 4 and 5).
- There were no differences in frequency between VA and non-VA patients discharged to acute units, sub-acute, or other settings. Table 2 presents the details on discharge living settings.

Table 2. Discharge Living Setting In VA And Non-VA Patients With Amputations

Discharge Living Setting	VA (n=1,139)	Summary	Missing data	NON-VA (n=48,334)	Summary	Missing data
	n		15	n		700
Home	833	73.1%		37,661	77.9%	
Board & Care	9	0.8%		303	0.6%	
Assisted Living	9	0.8%		342	0.7%	
Acute Unit—Own	69	6.1%		2,009	4.2%	
Acute Unit—Other	4	0.4%		1,743	3.7%	
Sub-acute Setting	10	0.9%		794	1.7%	
Skilled Nursing Facility	123	10.9%		4,153	8.7%	
Transitional Living	13	1.2%		94	0.2%	
Alternative Level of Care	7	0.6%		119	0.2%	
Intermediate Care Facility	41	3.6%		277	0.6%	
Chronic Hospital	1	0.1%		50	0.1%	
Rehabilitation Facility	5	0.4%		89	0.2%	

Both VA and non-VA patients were discharged to a variety of locations, with the majority of patients discharged to the home. The second most frequent discharge living setting for both groups was a skilled nursing facility (SNF).

To determine whether differences existed in discharge locations between VA and non-VA patients after rehabilitation stay, Chi-square tests were conducted[5]. After adjusting for age, differences were noted in the frequency of patients discharged to home and skilled nursing facilities (χ^2=27.8, 13.7 respectively). Table 3 and Table 4 show the frequencies of the six most common locations patients were discharged.

[5] *Chi-square is the statistical test used to evaluate the difference in distribution across samples. For example, to compare home discharge rates for VA and non-VA patients, the 74% home discharge rate (within the VA group) is compared with the 79% home discharge (within the non-VA group). Chi-square analysis shows that these two percentages are significantly different.*

Table 3. Discharge Location By Age Group In VA Patients With Amputations (n=1,125)

	HOME	TRANSITIONAL LIVING	INTERMEDIATE CARE FACILITIES	SUB-ACUTE NURSING FACILITIES	ACUTE UNITS	REHAB FACILITIES	MISSING DATA
Age							14
0-54	147	1	5	16	10	1	
55-64	211	4	8	25	18	0	
65-74	329	4	15	52	26	2	
75 and Above	146	4	13	30	19	2	
Total	833	13	41	123	73	5	
%	75.0%	1.2%	3.7%	11.1%	6.6%	0.5%	

Table 4. Discharge Location By Age Group In Non-VA Patients With Amputations (n=48,001)

	HOME	TRANSITIONAL LIVING	INTERMEDIATE CARE FACILITIES	SUB-ACUTE NURSING FACILITIES	ACUTE UNITS	REHAB FACILITIES	MISSING DATA
Age							333
0-54	8,307	19	24	416	591	18	
55-64	9,147	11	50	663	888	13	
65-74	12,076	29	78	1,394	1,252	31	
75 and Above	8,131	35	125	1,680	1,021	27	
Total	37,661	94	277	4,153	3,752	89	
%	79.0%	0.2%	0.6%	8.7%	7.9%	0.2%	

The majority of VA and non-VA patients were discharged home, but differences in frequency (or “rate”) were found in VA and non-VA patients discharged home.

FUNCTIONAL CAPACITY & QUALITY OF LIFE

Question 5A: What is the functional capacity before and after amputation for VA patients? And compared with non-VA?

Both VA and non-VA patients improved in motor function during rehabilitation. On average, VA patients improved 13 Rasch-transformed points whereas non-VA patients improved 15 points. The difference in improvement between the VA patients and non-VA patients was statistically significant.

The FIM ratings were transformed into equal-interval, log odd units ("logits") using Rasch Rating Scale Analysis. The logits were then transformed into a 0-100 point scale for ease of interpretation: "0" represents the lowest observed level of functioning (dependent on all items) and "100" the highest observed level of functioning (independent on all items). Raw data as well as Rasch-transformed measures ("measure" is used in the Rasch model to distinguish itself from "score" which is used to indicate "raw" data) for admission and discharge FIM data are summarized in Table 3. Admission and discharge data were used to calculate change scores or "gains." Only Rasch-transformed measures are used for the FIM-related analyses in this section.

Table 5 shows that at admission, the total (both motor and cognitive) FIM score for VA patients was 88 (based on a total of raw score of 126, higher score means better function), while the total FIM score for non-VA patients was 78; the positive T-value indicates that VA patients had better functional status at admission than non-VA patients. VA patients also had better function at discharge than non-VA patients. However, VA patients made smaller functional gains than non-VA patients. When examining motor and cognition separately, VA patients had better motor function than non-VA patients; no difference was found in their cognitive abilities.

Table 5. Functional Status In Patients With Amputations Before And After Rehabilitation

	VA (N=1,139)	NON-VA (N=48,334)	T*
	Mean (Standard Deviation)		
Raw FIM Total[1] at Admission	88 (18)	78 (16)	19.1
Raw FIM Total[1] at Discharge	104 (17)	96 (18)	13.9
Raw FIM Gain	16 (11)	19 (11)	-9.5
Motor FIM[2] (Raw Score) at Admission	58 (15)	47 (12)	23.5
Motor FIM[2] (Raw Score) at Discharge	72 (14)	65 (14)	18.1
Raw Motor Gain	14 (10)	18 (10)	-10.9
Cog FIM[3] (Raw Score) at Admission	30 (5)	30 (6)	NS
Cog FIM[3] (Raw Score) at Discharge	31 (5)	31 (5)	NS
Raw Cog Gain	1 (3)	1 (3)	NS
Rasch Transformed Motor Measure at Admission[+4]	44 (14)	34 (11)	22.0
Motor Measure at Discharge[+4]	57 (13)	50 (13)	18.1
Gain in Motor Measure	13 (10)	15 (10)	-7.4

**Unequal variances were found in all variables between the two groups due to large discrepancy between sample sizes.*

[+]Rasch transformed measures.

NS= Not Significant

[1]Based on 0-126, higher score means better function.

[2]Based on 0-91, higher score means better function.

[3]Based on 0-35, higher score means better function.

[4]Based on 0-100, higher score means better function.

Analysis of Data

Descriptive analyses of discharge locations and functional status at admission, discharge, and functional gain are presented. Risk-adjustment was not possible because pertinent risk-adjustment variables were not available in both samples. Patients were lost when the two samples were merged because they did not have similar descriptive data. Few cases increase the potential for sample bias and can make comparisons difficult. For example, data extracted from FSOD were matched with the PTF-surgery files, so patients who were classified as "amputee" by the Impairment Group variable had an amputation surgery. We included only those patients whose surgery date was before rehabilitation admission date. Similar data required for matching surgery data with UDSmr data were not available. Therefore, it was not possible to know if all patients in the UDSmr data set classified in the "Amputee" Impairment Group had a recent surgery. There was no data to describe the treatment received, and comparisons between groups should be interpreted with caution.

In light of these differences, functional status improved in both groups following amputation with larger gains observed in motor function than in cognitive function. VA patients made smaller gains, on average, than did non-VA patients. These findings are consistent with patient self-report of functional abilities reported below. These results are consistent with earlier research on non-VA patients (Hart 2000).

Although there were gains in functional status, neither the cause of the gain nor the difference in the gains across groups could be attributed to specific causes due to the study design limitations. VA vs. non-VA differences in improved function might be related to several factors, possible examples are listed below.

1. The samples may be different in terms of co-morbidities or other demographic characteristics
2. Treatment presence, type, frequency, duration, intensity or timing of treatment may be different
3. Different financial or management incentives/disincentives may confound the results. VA facilities do not have incentives for clinicians to "influence" their ratings of the patients' functional status at either intake or discharge to maximize reimbursement or management recognition. Therefore, differential gains in function would be expected.
4. Case-mix differences could result in apparent differential gains
5. Differences in treatment frequency, focus or guidelines could account for the results
6. If clinician-rated FIM measures were lower at admission and higher at discharge than actual functional status of the patient, rate gain would be artificially higher

In summary, this study demonstrated:

- VA patients have a longer length-of-stay compared to non-VA patients,
- higher motor FIM functional status at admission and at discharge for VA patients compared to non-VA patients,
- lower functional gains (difference between admission and discharge) for VA patients compared to non-VA patients, and

- differences in home and nursing home discharge between VA and non-VA patients (a larger proportion of VA patients were discharged to skilled nursing homes, a larger proportion of non-VA patients were discharged home).

Whether these differences are related to differences in actual functional abilities of the patients could not be determined given the nature of the data sets.

Questions 5B and 7F: How do VA patients perceive their functional capacity after amputation? How do VA patients rate their ability to participate in life situations?

The methodology used to determine both how VA patients perceived their functional capacity after amputation and how VA patients rate their ability to participate in life situations follows the steps outlined in the Methodology section. Data is not available in existing VA data sets that allow direct assessment of life situation participation. However, assessment of the SF-36 constructs of HRQL (Ware, 1993, p 9:22-25) permits estimation of participation in life situations. Self-reported HRQL reflects extent of patients' participation in life activities, though perceptions and actual participation cannot be distinguished. Patient self-report surveys capture the perception of the patient's functional ability by assessing pertinent constructs of general health including physical and mental functioning (Ware, 1993).

Use of the SF-36 facilitates comparisons of functional abilities for patients 1) in the VA system with DM and/or PVD and a lower extremity amputation, 2) in the MOS SF-36 US normative sample (Ware, 1993), 3) not in the VA system who have Type II DM (Ware, 1993), and 4) with lower extremity amputation who were receiving lower extremity prostheses as part of their rehabilitation (Hart, 1999).

The methodology for data extraction involved selecting patients from SF-36v database and reviewing the data files for dates of surgery occurring after the completion of the SF-36v. We excluded those patients who had more than one surgery and those who had surgery after the completed SF-36v. This left a sample size of 2,193 patients, consisting of those with diabetes mellitus (DM) or PVD, a lower extremity amputation and a completed SF-36v (Table 6). Sample sizes varied for each characteristic. Descriptive statistics for the patients answering the SF-36 are shown in Table 6 below.

Table 6. Characteristics Of Patients With SF-36v (n=2,193)

Characteristics	n	Summary	Missing Data
Gender			877
Male	1,303	99%	
Female	13	1%	
Ethnicity			121
Caucasian	1460	70%	
African American	420	20%	
Hispanic	150	7%	
Native American	40	2%	
Asian	2	1%	
Age (yrs - mean±standard deviation)	1,309	64.2±10, 34 to 89	884

Characteristics	n	Summary	Missing Data
Type of amputation			0
Above knee	327	15%	
Below knee	550	25%	
Ankle, foot, forefoot or toe	1,316	60%	
Employment status			62
Employed for wages	52	2%	
Self-employed	25	1%	
Looking for work >1	19	1%	
Looking for work <1	11	1%	
Homemaker	3	<1%	
Student	3	<1%	
Retired	624	29%	
Disabled	1,394	65%	
Year of amputation			0
1997	780	36%	
1998	785	36%	
1999	622	28%	
2000	6	<1%	
Comorbidity (Collected via patient recall)			
Hypertension or high blood pressure	1,591	74%	43
Diabetes or high blood sugar	1,366	64%	59
Arthritis	1,201	58%	122
Angina or coronary heart disease	844	41%	134
Congestive heart failure	831	40%	116
Heart attack or myocardial infarction	776	38%	151
Depression	776	38%	151
Chronic low back pain	701	34%	131
Stroke	576	28%	136
Benign prostatic hypertrophy	441	21%	93
Chronic lung disease	415	20%	118
Post-traumatic stress disorder	336	17%	217
Cancer	258	13%	208
Spinal cord injury with quadriplegia or paraplegia Schizophrenia	124	6%	126
Schizophrenia	72	4%	393
If your doctor told you that you had diabetes, how long ago were you first told?			576
<1 yr ago	61	4%	
1-3 yrs ago	125	8%	
4-10 yrs ago	371	23%	
11-20 yrs ago	521	32%	
>20 yrs ago	539	33%	
			55

Characteristics	n	Summary	Missing Data
Do you now smoke cigarettes?			
Every day	514	24%	
Some days	168	8%	
Not at all	1,456	68%	
Marital status			359
Married	760	58%	
Divorced	268	20%	
Separated	0	0	
Widowed	103	8%	
Never married	159	12%	
Lives alone	544	27%	
How many times during past month did you have 5 or more drinks on an occasion?			146
Never or less than once per month	1,659	81%	
1-3/month	133	7%	
1/week	45	2%	
2-4/week	61	3%	
5-6/week	57	3%	
1/day	20	1%	
>1/day	72	3%	

In summary, the majority of patients are Caucasian males with amputation procedures performed in VA at the ankle, foot, forefoot or toe level. The majority of amputation procedures were performed in 1998 to disabled veterans who also suffer from hypertension or high blood pressure.

Figure 1. Frequency Of Patients With Lower Extremity Amputations By Age (n=1,309)

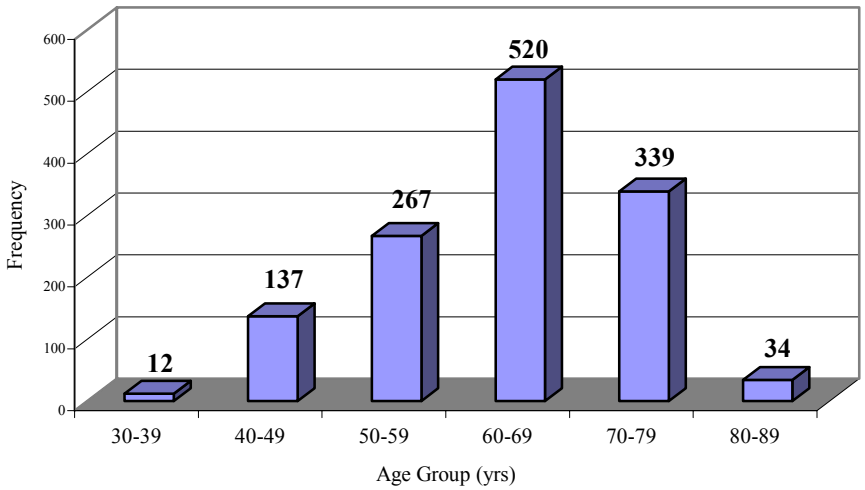


Figure 1 demonstrates that the incidence of patients' aged 30-90 undergoing lower extremity amputations follows a normal (or Bell curve) distribution.

Comparison Groups

Three groups were used for comparison: (1) SF-36 norms from the male US population, (2) patients with Type II diabetes from MOS, and (3) patients with lower extremity amputations from FOTO, Inc.

MOS SF-36 Sample

Two samples from the MOS SF-36 study (Ware, 1993) were selected for comparison with the VA sample. First, male patients from the normative sample of the MOS SF-36 study were selected (n=1,055). Average age was not reported, but ranged from 18 to greater than 75 years. Second, patients (n=541) with Type II diabetes were selected. The data did not imply that these patients with DM had amputations, but mean age was 60 years, with 38% over 65 years and 56% female.

FOTO, Inc. Sample

The non-VA patient population obtained from FOTO, Inc. consisted of the 767 patients with above knee (AK), below knee (BK) or foot/ankle/toe amputations. Of this sample, 242 of 767 patients were selected because they had DM and/or PVD and had HRQL data at the time of their prosthetic fitting. Descriptive statistics for these patients are shown in Table 7.

Table 7. FOTO, Inc. Patients (n=242)

Characteristics	n	Missing data	Summary
Age (yrs)	239	3	63±13, 21 to 90
Gender		0	
Male	158		65%
Female	84		35%
Type of amputation		3	
Above knee	38		16%
Below knee	193		81%
Ankle, foot, forefoot or toe	8		3%

Discussion of Data Analyses

SF-36 data for VA patients were collected using the Health Survey of Veterans (Veterans SF-36 & Health Behaviors). Extracted data contained 35 items from the SF-36 representing eight functional scales (Ware, 1992 & 1993, McHorney, 1993 & 1994). Eight SF-36 constructs were evaluated: general health, physical functioning, role physical, bodily pain, mental health, role emotional, vitality and social functioning.

Role physical (RP) and role emotional (RE) constructs used rating scales that deviated from published algorithms (Ware, 1993), so item responses were transformed using VA algorithms. The constructs used five response categories rated from high functioning to low functioning (No, none of the time; Yes, a little of the time; Yes, some of the time; Yes, most of the time; Yes, all of the time). The responses were used

to generate scales ranging from 0 to 100. However, for these two scales, the scores were subtracted from 100 to reverse the final scale score, so high scores represent higher function.

The difference between role functioning and physical/mental functioning lies in the difference between a task limitation and a limitation in the performance of work-related tasks affected by the task limitation. For example, a person may be limited in lifting and carrying, but if the job or work around the home does not require lifting and carrying, their role functioning may not be limited (Ware 1993). Role limitations, whether physical or emotional, assess limitations in the 1) kind of, 2) amount of time spent in, and 3) difficulty performing work or other usual activities (Ware 1993).

The responses for the other six functional scales were transformed following published algorithms (Ware, 1993, p 6:17), so the scores ranged from 0 to 100. Hence, the resulting 0 to 100 scores for all eight scales could be interpreted similarly to published interpretations: 0 reflects low functioning, and 100 reflect high functioning (Ware, 1993). The scores have been interpreted as percentages of functioning and health and well-being. Physical Component Summary (PCS) and Mental Component Summary (MCS) SF-36 scores were calculated following published algorithms (Ware 1994). PCS and MCS use different scoring algorithms than the constructs above. PCS and MCS algorithms produce scores with an expected average of 50 and standard deviation of 10, which are the mean and standard deviations for a normal USA population (Ware 1994). In this way, the PCS and MCS are norm-referenced and can be interpreted in relation to standard deviation units (multiples of 10) away from the expected normal value (i.e., 50).

Only VA patients with complete data were assessed. Descriptive statistics were used to estimate the patient's ability to function as well as to estimate quality of life for each of the eight SF-36 constructs. Results can be compared to normative values from the male patients in the MOS SF-36 study by age (Ware, 1992 and 1993; McHorney, 1993 and 1994), patients with Type II diabetes in the MOS SF-36 study, and data from patients with diabetes or PVD with similar amputations as the VA sample that received prosthetic devices (Hart, 1999).

For comparisons between the VA population and normative data, patients with Type II diabetes and patients receiving prosthetic devices, each pair of scores was transformed into an effect size (Cohen, 1988). Effect sizes quantify the magnitude of the difference between the two groups and can be interpreted as follows: 0.2 to 0.4 is small, 0.5 to 0.7 is moderate, and greater than 0.7 is large (Cohen, 1988). Effect sizes are standardized change scores, which allow direct comparisons of magnitudes of change across studies. The Booz Allen team calculated the effect size by subtracting the comparative score from the VA score and dividing the result by the standard deviation of the comparative score (Jette, 1996). For example, on average, the 2,156 VA patients reported their physical functioning as 24 out of 100. The 1,055 males used in the MOS SF-36 normative study reported their physical functioning as 87 out of 100 with a standard deviation of 21. The effect size would be [(24-87)/21] = -3 standard deviation units. An effect size was calculated for each available SF-36 scale for an appropriate age-adjusted group. In the example on physical functioning, the magnitude of the effect size of –3 is large, and the direction means the VA patients reported less physical functioning than the normative males.

Effect of amputation type (AK, BK, foot or distal) on each SF-36 functional scale and effect size (comparison to normative SF-36 values) was assessed by one-way analysis of variance (ANOVAs) in the VA sample. Effect size for this analysis was calculated on a patient-by-patient basis using the MOS SF-

36 means and standard deviations by construct. If amputation type was significant, differences between levels of amputation type were assessed using Scheffe post hoc analyses. Probability level was set at .001 to adjust for the multiple ANOVAs conducted.

The MOS SF-36 male norms are grouped by age so VA patients could be compared to age-adjusted norms. The SF-36 PCS and MCS data are normed to a mean of 50 (normal population, males and females) with a standard deviation of 10. PCS and MCS data can be compared as a group, but were not age-adjusted.

Tables 8 and 9 demonstrate that VA patients with DM and/or PVD lower extremity amputation reported low functional capacity in all eight SF-36 scales. These patients reported less function in the physical constructs and social functioning compared to the mental constructs.

Table 8. Functional Health Status Statistics For All VA Patients Regardless Of Amputation Type

PHYSICAL CONSTRUCTS					
	General Health [a]	*Bodily Pain* [a]	*Physical Functioning* [a]	*Role Physical* [b]	*PCS* [a]
N	2,165	2,165	2,156	1,277	1,991
Minimum	0	0	0	0	4
Maximum	100	100	100	100	58
Median	30	31	10	13	24
Mean	34	39	24	22	26
Standard Error	0.5	0.6	0.6	0.7	0.2
Standard Deviation	22	27	28	26	9

[a] *Values calculated using algorithms from MOS SF-36 (Ware, 1993)*

[b] *Values calculated using algorithms from VA*

Table 9. Mental Construct Results

MENTAL CONSTRUCTS					
	Mental Health[a]	*Role Emotional*[b]	*Social Functioning*[a]	*Vitality*[a]	*MCS*[a]
N	2,152	1,277 [b]	2,151	2,165	1,991
Minimum	0	0	0	0	6
Maximum	100	100	100	100	77
Median	60	33	38	35	40
Mean	59	43	40	35	41
Standard Error	0.5	1.0	0.7	0.5	0.3
Standard Deviation	24	36	32	23	13

[a] *Values calculated using algorithms from MOS SF-36 (Ware, 1993)*

[b] *Values calculated using algorithms from VA*

Table 10 demonstrates, as expected, that VA patients reported lower functioning as the level of amputation increases, i.e., foot/ankle to BK to AK.

Table 10. Effect of Amputation Type of SF-36 Functional Scales for VA

PHYSICAL CONSTRUCTS				
SF-36 Scale	*AK*	*BK*	*Foot/Ankle*	*Post Hoc***
General Health (n=2,134)	33(1.3)	34(1.0)	34(.6)	NA
Bodily Pain* (n=2,165)	34(1.5)	37(1.2)	41(.8)	1
Physical Functioning* (n=2,156)	14(1.5)	19(1.2)	28(.8)	1,2
Role Physical* (n=1,277)	15(1.9)	18(1.4)	25(.9)	1,2
PCS* (n=1,991)	24(.5)	25(.4)	27(.3)	1,2
MENTAL CONSTRUCTS				
Mental Health* (n=2,152)	53(1.4)	58(1.0)	60(.7)	1
Role Emotional* (n=1,277)	32(2.7)	40(2.0)	47(1.3)	1,2
Social Functioning* (n=2,151)	33(1.8)	38(1.3)	43(.9)	1,2
Vitality (n=21,65)	35(1.3)	37(1.0)	35(.6)	NA
MCS (n=1,991)	40(.8)	42(.6)	42(.4)	NA

AK=Above knee amputation

BK=Below knee amputation

Foot/Ankle=Amputations from the ankle distal

Post Hoc=Scheffe post hoc analyses

PCS=SF-36 Physical Component Summary Scale (50±10 (mean±Standard Deviation) is considered the norm)

MCS=SF-36 Mental Component Summary Scale (50±10 (mean±Standard Deviation) is considered the norm)

**Main effect significant (p<.001)*

***1=AK less than Foot/Ankle*

***2=BK less than Foot/Ankle*

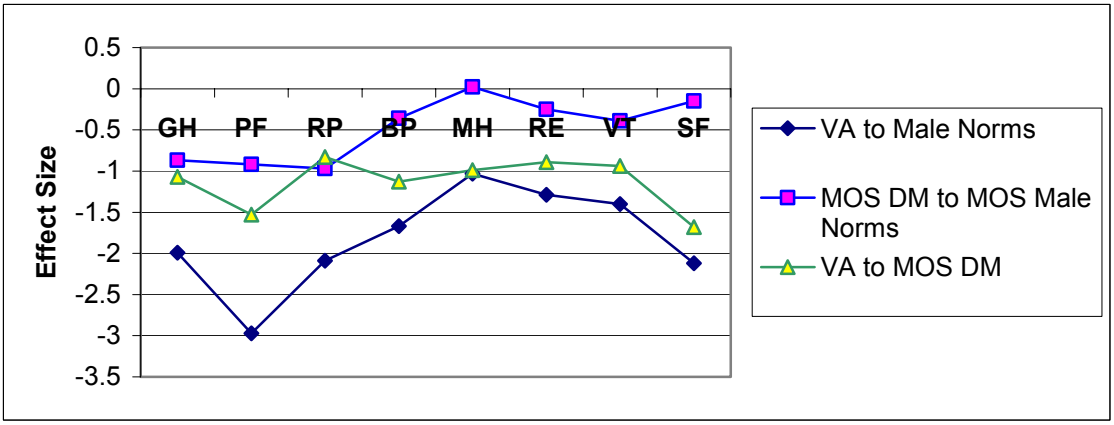
Type of amputation affects the ability of VA patients to participate in life situations in expected ways. VA patients with higher amputations (foot ankle lowest; BK middle; AK highest) reported lower functioning or participation for the constructs of physical functioning, but not for mental functioning. As the level of amputation rises, VA patients reported more difficulty participating in life situations in all constructs except general health and vitality.

SF-36 scales from VA patients with amputations (regardless of amputation type) were compared to normative values for men (Ware 1993 p 10:14) and values for patients who received a prosthetic device for a lower extremity amputation for the bodily pain and physical functioning scales (Hart 1999) using effect sizes (Cohen 1988). In this way, differences between VA patients and the two comparative samples were transformed into standardized differences (Figures 2 and 3).

The lower line in the figure below represents the magnitude of the difference between perceived functional abilities of male VA patients regardless of age or amputation type, compared to normed males

in the MOS SF-36 study (0 line on figure) (Ware 1993). The upper line in the figure below represents the magnitude of the difference between perceived functional abilities of male and female patients in the MOS SF-36 study with Type II diabetes regardless of age, compared to normed males in the MOS SF-36 study without diabetes (0 line on figure) (Ware 1993). The middle line in the figure below represents the difference between functional abilities of male patients in the VA system, regardless of age or amputation type, compared to male and female patients in the MOS SF-36 study with Type II diabetes (Ware 1993).

Figure 2. Differences In Functional Abilities Across Samples



GH = General Health, PF = Physical Functioning, RP = Role Physical, BP = Bodily Pain, MH = Mental Health, RE = Role Emotional, VT = Vitality, SF = Social Functioning

Effect sizes are in units of standard deviations. The 0 value (y-axis) represents the normative value for the US male population (Ware 1993 p 10:14). As the patient becomes less functional (x-axis), the effect size becomes more negative. As the patient becomes more functional, the effect size becomes more positive (y-axis). The data demonstrate that, in general, VA patients with DM or PVD and a lower extremity amputation perceive lower functional abilities than patients with Type II diabetes or normative males. The magnitude of the comparisons is in standard deviation units, so on average, as an example, VA patients with DM or PVD and a lower extremity amputation perceive their physical functioning worse by three standard deviations than the average normed male in the US.

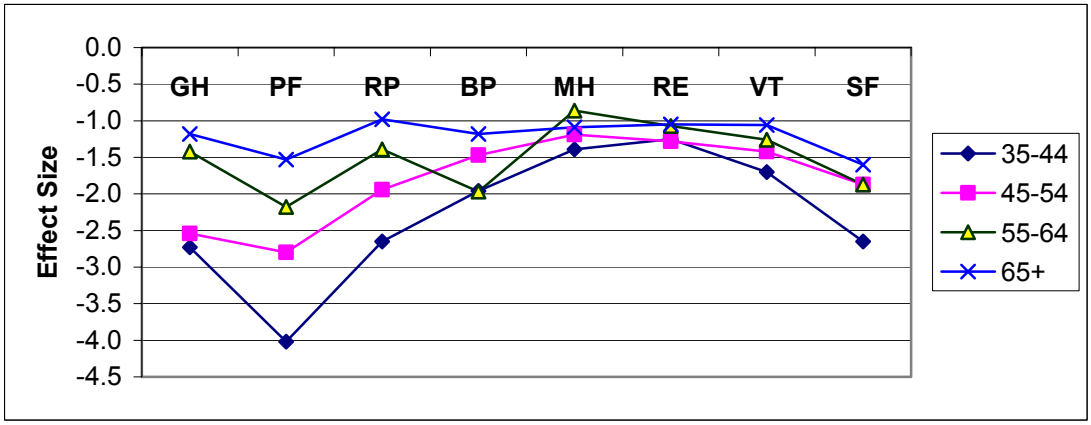
As another comparison, 453 patients with lower extremity amputations from DM or PVD who were measured for prosthesis had effect sizes of -0.6 and –2.3 for intake MOS SF-36 bodily pain and physical functioning scales, respectively, from the FOTO, Inc. data (Hart 1999). Therefore, VA patients reported worse physical functioning and bodily pain compared to patients surveyed by FOTO, Inc.

In general, VA patients demonstrate considerably (Cohen, 1988) lower function in all SF-36 scales, and dramatically lower scores on the four physical functioning scales (GH, PF, RP and BP) and social functioning (SF) compared to the normative sample of males. Social functioning represents both mental and physical constructs (Ware, 1993). VA patients reported lower functioning compared to patients with diabetes as well, but the difference was not as dramatic as the comparison with the normed males. VA patients reported lower bodily pain (more pain and interference of physical activities because of pain) and physical functioning compared to FOTO, Inc. patients.

Figure 3 below represents comparisons of SF-36 functional constructs of male VA patients regardless of amputation type and MOS SF-36 normed males by age group. The figure presents an age-adjusted

comparison of functional abilities. In general, the physical functioning constructs (general health, physical functioning, role physical and bodily pain) and social functioning are the lowest. Most importantly, the younger VA patients have the largest difference in functioning compared to normed males.

Figure 3. Differences In Functional Abilities By Age



GH = General Health, PF = Physical Functioning, RP = Role Physical, BP = Bodily Pain, MH = Mental Health, RE = Role Emotional, VT = Vitality, SF = Social Functioning

Effect sizes were calculated using the MOS SF-36 means and standard deviations, and effect of type of amputation was assessed (Least squares means (standard error) from one-way ANOVAs). Table 11 shows the effect size for each of the mental and physical constructs measured by they SF-36 for the three amputation groups.

Table 11. Differences In SF-36 Constructs Compared To SF-36 Norms

PHYSICAL CONSTRUCT EFFECT SIZES				
SF-36 Scale	*AK*	*BK*	*Foot/Ankle*	*Post Hoc***
General Health (n=1,277)	-2.2(.09)	-2.1(.07)	-2.1(.04)	NA
Bodily Pain (n=1,277)	-2.0(.09)	-1.8(.07)	-1.7(.05)	NA
Physical Functioning* (n=1,277)	-3.7(.1)	-3.3(.07)	-2.9(.05)	1,2,3
Role Physical* (n=1,277)	-2.2(.06)	-2.1(.05)	-1.8(.03)	1,2
MENTAL CONSTRUCT EFFECT SIZES				
Mental Health (n=1,277)	-1.1(.09)	-.9(.07)	-.8(.05)	NA
Role Emotional* (n=1,277)	-1.5(.08)	-1.2(.06)	-1.0(.04)	1
Social Functioning* (n=1,277)	-2.4(.11)	-2.2(.08)	-1.9(.05)	1
Vitality (n=1,277)	-1.3(.08)	-1.2(.06)	-1.3(.04)	NA

AK=Above knee amputation

BK=Below knee amputation

Foot/Ankle=Amputations from the ankle distal

Post Hoc=Scheffe post hoc analyses

**Main effect significant (p<.001)*

***1=AK less than Foot/Ankle*

***2=BK less than Foot/Ankle*

***3=AK less than BK*

VA patients with higher amputations (foot ankle lowest; BK middle; AK highest) reported lower physical, role physical, role emotional and social functioning.

Table 12 displays the SF-36 summary component scales compared to MOS SF-36 norms regardless of amputation type.

Table 12. SF-36 Component Scores

	PCS	MCS
Norms General US Population (n=2474)*	50±10	50±10
Norms for Males US Population (n=1055)*	51.1±9.4	50.7±9.6
VA Males (n=1991)	26.1±8.9	41.4±13.3

**MOS SF-36 Study (Ware, Kosinski, Keller, 1994)*

Figure 4 below shows comparisons between values of the SF-36 PCS and MCS by age group regardless of amputation type (normed with a mean=50, standard deviation=10).

Figure 4 and 5 demonstrate comparisons between normed (mean=50, standard deviation=10) values of the MOS SF-36 PCS and MCS by age group regardless of amputation type. There were 782 males from the MOS SF-36 study, 157 males from the FOTO data set, and 1,299 males from the VA data set; all with DM and/or PVD. Figure 4 demonstrates the differences in Physical Component Summary Scores by age. Figure 5 demonstrates the differences in Mental Component Summary Scores by age.

Figure 4. Differences In Physical Component Summary Scores By Age

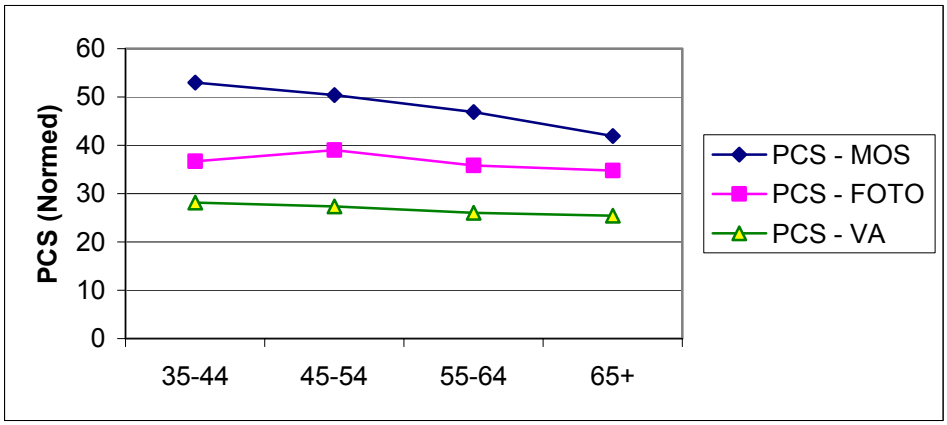
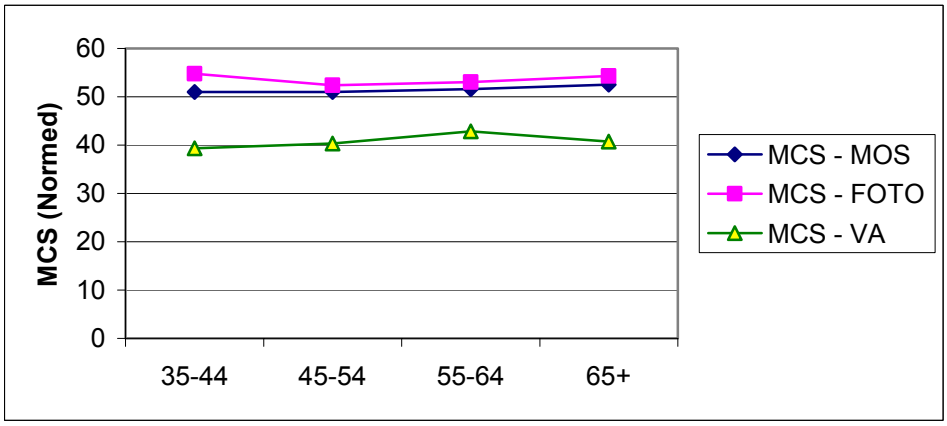


Figure 5. Differences In Mental Component Summary Scores By Age



These findings indicate that as VA patients got older, they reported more dysfunction in their physical capabilities. Mental functioning of VA patients tends to remain steady overtime.

Effect of amputation type across SF-36 component scales for 1,175 VA males and 125 males at discharge from FOTO data set is as follows (Least squares means (standard error) from two-way ANOVAs).

Table 13. Effect Of Amputation Type On SF-36 Component Summary Scores

SF-36 SCALE	AK	BK	FOOT/ANKLE	POST HOC**
VA PCS*	23.2(0.7)	24.9(.5)	26.9(0.3)	1,2
VA MCS	38.8(1.1)	41.1(0.8)	41.7(0.5)	NS
FOTO PCS*	32.2(1.8)	36.2(0.8)	41.7(3.7)	1
FOTO MCS*	50.9(1.8)	55.0(0.8)	39.5(3.8)	1,2

**Main effects significant (p<.001)*

***1=AK less than Foot/Ankle*

***2=BK less than Foot/Ankle*

***3=AK less than BK*

VA patients with higher amputations (foot ankle lowest; BK middle; AK highest) reported lower physical functioning using the SF-36 Physical Component Summary Score. VA patients with higher amputations did not report low mental constructs for the Mental Component Summary Score. However, non-VA patients receiving a prosthesis for a lower extremity amputation reported lower functioning with higher amputations for the physical and mental constructs using the SF-36 Physical and Mental Component Summary Scores.

Discussion of Results

VA patients with lower extremity amputations from DM and/or PVD reported low functional capacity in all eight SF-36 scales. In addition, they reported less function in physical and social functioning compared to mental functioning capability. This result is understandable since lower extremity amputations affect physical functioning more than mental functioning (see FIM data above). Functional abilities for patients

in the VA sample were lower than for comparison groups of normal males in the US (Ware, 1993), patients with Type II diabetes (Ware, 1993), and non-VA patients with lower extremity amputations receiving prosthetic devices (Hart, 1999). Age affects the comparisons with younger people reporting less function compared to older people per construct.

Male VA patients with lower extremity amputations from DM and/or PVD reported lower functional capacity in the mental and physical functioning compared to US population norms. The reduction is more pronounced for physical scores than mental scores. This result is consistent with the physical and mental differences reported above. Patients with AK or BK amputations reported lower physical functioning compared to patients with foot or ankle amputations. These findings were different than findings from the FOTO data set, where patients with foot or ankle amputations had lower mental component scores compared to patients with BK or AK amputations. FOTO data was similar to VA data for physical component scores.

The two comparison groups differed from the VA sample, so interpretations should be made with caution. Similar demographic data were not collected for all patients across comparison groups, so only age risk-adjustments were possible between VA and MOS SF-36 samples.

References for SF-36 are annotated below with complete annotations in the Bibliography

Binkley JM et al, 1999
Cohen J., 1988
Hart DL, 1999
Jette DU et al, 1996
McHorney CA et al, 1994
McHorney CA et al, 1993
Ware JE et al, 1992
Ware JE et al, 1993
Ware JE et al, 1994

Question 5D/E: Did VA patients receive training after amputation?

The Booz Allen team utilized specific variables in the NPPSS for patients using AK and BK prostheses (n=866) to answer this question. Only valid percents (i.e., based on non-missing responses) are reported.

> ***Q.32 (n= 490) asked "When you asked questions, did you get answers you could understand? ":*** *457 (93.3%) patients answered 'Yes'*
>
> ***Q.33 (n= 490) asked "During your most recent device-related visit, did someone teach you how to use your prosthetic device in a way that you could understand?":*** *280 (57.1%) answered 'Yes'* ***[241 (49.2%) answered 'Yes', 39 (8%) answered 'Yes, somewhat']*** *20 (4.1%) answered 'No', 185 (37.8%) reported that they already knew how to use their prosthetic device, and no teaching was needed*

Q. 34 (n= 493) asked "During your most recent device-related visit, did someone teach your family or friends how to help you use your prosthetic device in a way that they could understand?": *97 (19.7%) answered 'Yes', 65 (13.2%) answered 'No', and 95 (19.3%) stated that no teaching was needed because they already knew how to use their prosthetic device*

Q 35 (n= 492) asked "Did you get as much information about your device as you wanted from your provider?": *468 (95.1%) responded 'Yes'*

The majority of respondents (>93%) reported satisfaction with understanding the answers to questions asked and the amount of information about their device given by their provider. Questions 33 and 34 are worded in an ambiguous manner. It is unclear if patients were responding to whether teaching was adequate or whether they could understand the teaching, or both.

Question 7A: How do VA patients perceive their quality of life after amputation?

Quality of life cannot be measured directly, but can be estimated by calculating relations between assessments of general health and other constructs of HRQL (Ware, 1993, p 9:22-25). We utilized patient self-report HRQL from the SF-36v survey from which correlations can be assessed. HRQL surveys assess pertinent constructs of general health including physical and mental functioning (Ware, 1993). Many clinicians consider the SF-36 the "gold standard" of generic HRQL assessments of health status (Ware, 1992 & 1993; McHorney, 1993 & 1994; Hart, 1999; Binkley, 1999). The SF-36 allows assessment of physical (general health, physical functioning, role physical, bodily pain) and mental (mental health, role emotional, vitality, social functioning) constructs of HRQL.

Norms for the SF-36 constructs were generated for the Medical Outcome Study (MOS) SF-36. Data were collected as part of the National Survey of Functional Health Status in 1990 using personal interview, not self-administered questionnaire (Ware, 1992; Ware, 1993). Respondents were drawn from the General Social Survey in 1990, which surveyed 2,474 non-institutionalized adults in the United States (Ware, 1993).

Quality of Life After Amputation Analyses

Quality of life was assessed by correlating seven of the SF-36 scales with the SF-36 general health scale for VA patients with amputations associated with DM and/or PVD. In this way, the relation between perceived health and HRQL were estimated.

Comparison Group

SF-36 norms from the general US population were used for comparison. The comparison group consisted of 2,474 people from the general US population in the MOS SF-36 study (Ware, 1993). Use of this group provided a comparison population for VA patients with DM or PVD and an amputation.

Discussion of Data Analyses

SF-36 data for VA patients were collected using the Health Survey of Veterans (Veterans SF-36 & Health Behaviors). Extracted data contained 35 items from the SF-36 representing eight functional scales (Ware, 1992 & 1993, McHorney, 1993 & 1994).

Role physical (RP) and role emotional (RE) constructs used rating scales that deviated from published algorithms (Ware, 1993), so item responses were transformed using VA algorithms.

The responses for the other six functional scales were transformed following published algorithms (Ware, 1993). As in Question 7A, the constructs used five response categories rated from high functioning to low functioning, so the scores ranged from 0 to 100. Eight SF-36 constructs were evaluated: general health, physical functioning, role physical, bodily pain, mental health, role emotional, vitality and social functioning.

Discussion of Results

A total of 1,286 patients had complete data from which analyses could be performed. All correlations were positive, of considerable magnitude and significant ($p<0.01$), thus supporting the relation between health and quality of life. The correlations were similar to those published for the general population (Ware, 1993 p 9:24) with the exception of the physical functioning and role physical scales, which were less for VA patients with amputations compared to the general US population.

Table 14. Associations Between SF-36 Scales and the General Health Scale

SF-36 SCALES	VA SAMPLE R[a]	GENERAL US SAMPLE R[b]
Bodily Pain	0.51	0.58
Physical Functioning	0.36	0.69
Role Physical	0.46	0.69
Mental Health	0.56	0.49
Role Emotional	0.42	0.43
Vitality	0.66	0.65
Social Functioning	0.58	0.57

[a] *n=1,286*

[b] *n=2,474 (Ware, 1993 p 9:24)*

Table 14 demonstrates that:

- Quality of life can be assessed by using the SF-36,
- VA patients reported low quality of life in physical constructs,
- VA patients reported low functioning for most constructs, particularly physical functioning and role physical, and
- Best constructs to use to assess quality of life are social functioning, vitality, mental health, role emotional, and bodily pain.

VA patients who have lower extremity amputations associated with DM and/or PVD perceived their quality of life after amputation as low for the constructs of physical functioning and role physical as compared to the general population. The physical functioning and role physical constructs pertain to the physical abilities of individuals. Physical functioning assesses functional tasks, whereas role physical pertains to health-related limitations in the type or amount of work performed because of the physical limitations. VA patients perceive a reduction in their quality of life associated with physical functioning and work-related tasks after amputation compared to the general population.

There is no limitation in quality of life associated with mental constructs after amputation compared to the general population. Previous studies on patients with lower extremity amputations also found limitations were primarily physical when assessed with HRQL tools (Hart, 2000).

References for Quality of Life are listed below with complete annotations in the Bibliography

Binkley JM et al, 1999
Hart DL, 1999
McHorney CA et al, 1994
McHorney CA et al, 1993
Ware JE et al, 1992
Ware JE et al, 1993

PATIENT SATISFACTION

Question 7B: What percent of VA patients had ADL equipment delivered before discharge from hospital?

Refined Methodology

The Booz Allen team could not determine the percent of patients that had ADL equipment delivered before discharge from VA data. There is not specific information in FSOD or PTF regarding the distribution of ADL equipment — we identified the types of equipment provided to patients for ADL. A wider "window" for equipment delivery was established to capture equipment information since it may take more time for items to be delivered or installed: 5 days before and 30 days after the date of discharge.

From PTF-FSOD, we identified 1,139 patients with amputations who received medical rehabilitation. We were able to match 1,134 patients with the NPPD file and 16,872 equipment records. We first deleted records that had a missing value of "delivery date" (n=1,680), and those with a "delivery date" prior to rehabilitation admission date (n=5,449), which left 9,743 equipment records for 5,449 patients. We then selected records that had a delivery date 5 days before and 30 days after discharge, which resulted in 3,003 records for 94 patients. We computed the frequency of these records and grouped them in NPPD line categories. Table 15 shows the largest and most relevant categories out of these 3,003 pieces of equipment, which were issued to the 94 patients before, during, and soon after discharge. Home safety equipment such as shower or tub grab-bars accounted for 711 items. Walking aids such as crutches or walkers accounted for 245 items, 158 items were wheelchair accessories, 149 were wheelchairs, and 148 were wheelchair cushions. These items appear tobe relevant for patients discharged from rehabilitation.

Table 15. Major Categories Of Equipment And ADL Devices Patients With Amputations Received At The Time Of Discharge Of Rehabilitation

NPPD ITEM CATEGORIES	DESCRIPTION	n OF RECORDS
500A - 500F	Shoes and/or Inserts	38
900G	Bed Accessories	49
900C – 900F	Beds, Mattresses	73
100E, 100F	Wheelchair Cushions	148
100B	Manual Custom Wheelchairs	149
100D	Wheelchair Accessories	158
900A	Walking Aids	245
900K	Med Equip / All Others (incl. ADL Equip)	323
999A-Z	All Other Equipments	431
900I	Home Safety Equipment	711

**We only listed categories that are relevant for this population, therefore the total number of records is greater than what is listed in the table.*

Booz Allen utilized specific variables in the NPPSS for patients using AK and BK prostheses (n=866) to answer questions 7E, 7G, and 7H. Only valid percent (i.e., based on non-missing responses) are reported.

Question 7E: How did patients perceive quality and appropriateness of their prosthetic device?

Q. 4 (n= 510) asked "Overall, how would you rate the quality of this device?": *430 (84.3%) of patients were satisfied with the quality of their prosthesis device (Combination of "excellent", "very good" and "good" to define "satisfied")*

Q 5 (n= 486) asked "Did you have a problem with your prosthetic device?" *252 (51.9%) said they had a problem*

Q. 24 (n= 495) asked "Did the prosthetic device help you to meet your goals?": *234 (47.3%) answered 'Yes, completely', 166 (33.5%) said it somewhat met their goals*

In summary, more than 80% of VA patients were satisfied with the quality of their device. Approximately 50% said the device helped them meet their goals and 52% of patients reported a problem with a device.

Question 7G: What are the wait times VA patients experience for scheduling clinical appointments?

The majority of VA patients reported that they scheduled appointments when they wanted, and approximately half reported that did not wait long for their appointments.

Q.11 (n= 370) asked "Were you able to schedule this visit as soon as you wanted?": *300 (81.1%) said 'Yes'*

Q 12 (n= 360) asked "How long did you wait from the day you scheduled this visit until the day you were seen?": *51 (14.2%) said they did not have to wait, 184 (51.1%) waited for 1-14 days, 72 (20%) 15-30 days, 29 (8.1%) waited 1-2 months, 11 (3.1%) 2-4 months, and 7 (1.9%) waited longer than 4 months.*

Question 7H: How long did the patients with amputation wait to see a provider on the day of the appointment at the clinic?

More than one third of VA patients reported that they did not wait to be seen by a provider. More than 18% did not wait to be seen by their provider and 80% reported waiting less than 30 minutes.

Q. 16 (n=491) asked "On the day of your most recent device-related visit, how long did you wait in line to check in?" *184 (37.5%) said they did not have to wait at all, 181 (36.9%) waited 1-15 minutes, 73 (14.9%) waited 16-30 minutes, and 44 (9%) waited more than 30 minutes*

Q. 19 (n= 492) asked "On the day of your most recent device-related visit, how long did you wait to be seen by your provider after you checked in?": *90 (18.3%) did not have to wait, 150 (30.5%) waited 1-10 minutes, 104 (21.1%) waited 11-20 minutes, 80 (16.3%) waited 21-30 minutes, 37 (7.5%) waited 31-60 minutes, 14 (2.8%) waited more than one hour*

Most patients responding to the NPPSS reported satisfaction with the quality of their device; however, 52% reported that they had a problem with their device. The majority of respondents were able to get a clinic appointment when they wanted and 80% reported waiting less than 30 minutes to see a provider.

PRESCRIPTIONS FOR PROSTHESES

Question 6A: What VISN/VAMC guidelines exist regarding the qualifications of individuals making referrals for VA patients?

There are no definitive guidelines regarding the qualifications of individuals making referrals for VA patients. However, from our VAMC site visit findings, interviewed staff stated the following individuals refer patients for AK prostheses:

- Hines: Chief of PACT and/or physiatrist
- Atlanta: Any physician in Amputee Clinic (anyone, non-physician, can make a referral)
- Miami: Any physician
- New York: Anyone from a clinical service
- Richmond: It is unclear who can refer
- Seattle: Any physician
- West Palm: Any physician or the PACT Coordinator

Question 6B: What credentials do associations specify for prescribing and fitting prosthesis and orthotics?

Provider certification standards from the two American certifying bodies, American Board for Certification in Orthotics and Prosthetics (ABC) and Board of Orthotist/Prosthetist Certification (BOC) require orthotists and prosthetists to be certified to be able to fit prostheses and orthotics.

Associations such as American Orthotic and Prosthetic Association (AOPA), American Academy of Orthotists and Prosthetists (AAOP) and NAAOP (National Association for the Advancement of Orthotics and Prosthetics) all support ABC certification. The International Association of Orthotics and Prosthetics (IAOP) also support professional certification but do not specify a certifying body.

Physicians are medically licensed to perform certain medical procedures including prescribing prosthetics and orthotics. From our site visit findings, the individual position referring and/or prescribing for orthotics and prosthetics varies among VAMCs. The VAMCs visited reported the following physicians write prescriptions for orthotics and prosthetics in their facility(s):

- Atlanta – Physiatrists and orthopedists
- Miami- Physiatrists
- Richmond-Any physician
- New York- Physiatrist
- Seattle- Physiatrist
- West Palm- Any physician in Amputee Clinic

Question 6C: Percent of prostheses that were redone/repaired?

The percent of prosthesis that were redone or repaired could not be determined by VA databases. The NPDD has a data field for repairs, however this field is not used by orthotists or prosthetists to capture information on the amount of prosthetic devices that had to be reworked due to staff error. Although this would be valuable information to obtain, it would be difficult to set a performance target considering that prosthetic devices are fitted, over time, to individual patient requirements. It would be difficult in many cases to determine whether a rework could have been avoided or whether it was necessary due to patient physical adjustment.

The Booz Allen team asked VAMC staff during interviews if they captured information on rework. Although many Orthotist/Prosthetist Supervisors stated that this would be useful information, no one was collecting rework information at that time.

VAMCs may consider collecting rework data for ongoing management review. There will need to be available data collection tools that would allow stratification of the responses by reason, such as workmanship-related issues, physiological issues (such as wound healing), and changes in patient's clinical condition causing variations in the size of the residual limb.

Conclusions

VA patients were discharged home at a rate somewhat lower than their non-VA counterparts

Veterans included in this study experienced a slightly lower discharge to home rate than the non-VA population. Veterans also experienced a higher discharge rate to skilled nursing facilities and intermediate care facilities. There are several possible explanations for the differences in veterans' discharge rates. The first is that the veteran population may have more co-morbidities and different socio-demographic characteristics than the non-VA population that may lead to a need for a higher level of care after discharge.

In addition, there are also operational differences between VA and the public- and private sector facilities. For example, the private-sector is highly influenced by managed care requirements and reimbursement arrangements, placing critical pressure both on healthcare facilities and on patients to be discharged to home as early as possible. On the other hand, VA has made more progress towards standardization of care and capacity for uniform data sets. The care of analogous patients in non-VA settings is directed, typically without algorithms or closely followed guidelines, by individual independent practitioners and uncontracted vendors.

Finally, VA offers a continuum of care related to patients with amputations, which most of the non-VA sectors do not offer. VA has its own skilled nursing home units and other facilities that provide veterans easy access to additional care and treatment.

VA patients with amputations have appreciable improvements in functional capacity after discharge and are well supported by VA

By most study measures, veterans' functional status after amputation improved after discharge from VAMC facilities, though at a rate somewhat less than their non-VA counterparts. It is important to note however that VA patients had better functional status at admission and at discharge than the non-VA patients.

- VA patients had a higher FIM motor score at admission and discharge that non-VA patients
- Raw FIM scores, motor FIM scores, and motor measures improved in both populations, though somewhat more so for non-VA patients.
- Cognitive FIM scores were effectively unchanged in both populations.

Veterans report a high satisfaction of the services and devices received from VA Medical Centers

VA patients report a very high satisfaction rate with the devices provided to them from VA and with the training and education on the devices. The majority of patients also reported that the devices provided to them helped in meeting their goals.

- 93% of patients acknowledged having their questions answered regarding their use of prosthetics or assistive devices.
- 57% acknowledged that they received specific instructions on use of their prosthetic device (37.8% reported that they already knew how to use their device).
- 95% stated they were satisfied with the amount of information they received.
- 81% stated their prosthetic device helped them reach their functional goals.

Recommendations

VA should conduct a multi-disciplinary initiative to develop data elements and performance measures needed across the continuum of limb-preservation and post-amputation care

During this study, it became apparent that services providing care to veterans are dependent on data and information generated by other services. For example, a PACT program reviewing its success rate for limb-preservation may be reliant on data generated by surgery and PSAS to determine successful and unsuccessful factors and strategies in preventive care. It is clear that, though independent databases are well maintained by different services, other services involved in the care process will profit from knowledge of that data.

Accordingly, the Booz Allen team recommends that VA convene a multi-disciplinary group to:

- Determine additional data needs
- Identify opportunities for various services along the continuum to share data and information in order to enhance each department's quality improvement efforts
- Develop strategies for unification of database elements
- Devise an ongoing mechanism to ensure that changing data needs are discussed by all relevant services

VA should consider an enhanced program of database education for VA staff to increase the accuracy and comprehensiveness of its patient care data

Due to the size of its patient population and its database capacities, VA is in the privileged position to set national directions for the medical care of patient sub-groups through rigorous patient care research. Part of the difficulty in finding appropriate non-VA patient populations for comparison purposes was the unavailability of private sector and non-VA public databases and, consequently, the inability of those sectors to perform rigorous statistically based research.

During this study, the Booz Allen team encountered incomplete, conflicting, and sometimes inaccurate data that required creating statistical surrogates and modifying assumptions, to make the available data as meaningful and useful as possible.

The VA should focus on enhancing the accuracy, comprehensiveness, and reproducibility of data entry and collection processes by VA staff to improve the ongoing monitoring of patient clinical outcomes. Improving data quality would provide VA the opportunity to better support its patient care quality and performance improvement and its funding requests.

VA should develop a uniform, standardized set of patient, environmental and program characteristics that can be used to study clinical outcomes for veterans with lower extremity amputations

Assessment of clinical outcomes and tracking change over time was problematic in this study due to the inconsistencies in data collection for multiple data sets (i.e., FIM, SF-36). VA should consider developing a new initiative to: 1) identify pertinent patient (physical and psychological), environmental, and program characteristics that should be collected during prevention treatment programs, pre-surgery treatment programs and post-surgery treatment programs, and 2) co-calibrate appropriate data into a computerized adaptive testing process to monitor veterans throughout their medical rehabilitation process in a seamless manner. Results would produce one consistent, mathematically sound data collection process that would collect precise data over the continuum of care.

VA should use computerized adaptive testing (CAT) to determine if there is a difference in functional outcomes across VAMCs. CAT enables greater precision and efficiency in assessment by first estimating an examinee's clinical condition, and then adapting to it, presenting only those questions that are expected to give the most information about that individual. CAT mimics what a skilled test administrator does by using algorithms to characterize the test taker after each question and determining the most appropriate question to administer next. CAT would provide a more precise, standardized method of outcomes data collection that would allow the identification of VAMCs that obtain better clinical outcomes than other VAMCs. The VAMCs with better outcomes could then be studied to determine the patient, environmental, program and clinician characteristics related to better outcomes. Results of the new project would be the foundation of future clinical guidelines to improve treatment of veterans with lower extremity amputations.

The Booz Allen team recommends specific performance measures related to functional status, quality of life, customer service and management of patients with amputations

The Booz Allen team has recommended a set of performance measures that would support CARF (The Rehabilitation Accreditation Commission) accreditation. The recommended performance measures are listed in Table 16, on the next several pages. Several clinical assessment tools may be utilized to facilitate the evaluation of amputation patients in the future. These tools are listed below.

Northwestern University OPUS

The Northwestern University OPUS LE Prosthesis Functioning Module can be used to assess patient's perception of his or her functioning and quality of life using the prosthesis. The Northwestern OPUS Patient Assessment also allows prosthetists to generate a score for their patient's functional abilities.

FOTO OPOT

The FOTO OPOT allows prosthetists to generate a score for their patient's functional abilities with or without a prosthesis. The FOTO OPOT can be used to assess patient self-report of quality of life. This tool measures the constructs of physical functioning and mental health.

McHorney & Cohen

An Activities of Daily Living (ADL) tool for patients not in rehabilitation (McHorney & Cohen 2000) could track individuals over time to determine how their functional abilities related to changes in performance of ADLs or to determine how successfully rehabilitation has influenced functional abilities related to performance of ADLs. Examples include moving from bed to chair, carry small bag of groceries, wash your feet, etc.

Table 15. Recommended Performance Measures for Amputation Patients

PERFORMANCE MEASURE CATEGORY	PERFORMANCE MEASURE/METRIC	DATA SOURCE
Functional Status	**Inpatient** ➢ Functional assessment – average changes in motor functioning over time (total FIM score) annually (*or VA chosen timeframe) ➢ Discharge location compared to admission location of residence ➢ Severity-adjusted percent of patients (with amputation) who improve functional status from admission to discharge1 ➢ Severity-adjusted distribution of discharge functional status1 Utilize the FIM for people in inpatient rehabilitation to track individuals over time. The FIM will allow VA to determine how patient's functional abilities change over time, therefore providing the ability to determine how successfully rehabilitation has influenced motor functioning. The FIM motor scores would be transformed to measures ranging from 0 to 100 with higher scores suggesting better function or health. Change scores from admission to discharge, either regular (discharge – admission) or standardized [(discharge – admission)/(standard deviation at admission)] could be calculated.	FIM (for inpatient rehabilitation)
	Outpatient – Lower Extremity Prosthetic Users Develop or utilize an assessment tool to capture functional status information on outpatients with lower extremity prosthesis in the following areas: ➢ Ambulation ➢ Pain ➢ Satisfaction with fitting ➢ Skin breakdown	New Tool

PERFORMANCE MEASURE CATEGORY	PERFORMANCE MEASURE/METRIC	DATA SOURCE
Quality of Life	Measure the eight functional scales from the SF-36 to assess patient self-report of quality of life. The eight scales include: ➢ general health, ➢ physical functioning, ➢ role physical, ➢ bodily pain, ➢ mental health, ➢ role emotional, ➢ social functioning and ➢ vitality. The SF-36 scores per construct would be transformed to measures ranging from 0 to 100 with higher scores suggesting better function or health. Change scores from admission to discharge, or any other two time intervals, either regular (discharge – admission) or standardized [(discharge – admission)/(standard deviation at admission)] could be calculated.	SF-36
Customer Service	**Access** ➢ Percent of amputation patients within travel time and distance requirement --- ➢ Average wait time (in minutes) for amputation patients to be seen by a provider after check in ➢ Percent of amputation patients satisfied with the ease of making appointment ➢ Average wait time (in days) for amputation patients to get an appointment	Zip Code File matched with amputation patients from PTF/OPC or Patient Satisfaction Survey --- Patient Satisfaction Survey
	Education ➢ Percent of patients that state they received education and training on prescribed medical equipment ➢ Percent of time patients state they received understandable instructions for prescribed medical equipment	Patient Satisfaction Survey
	Customer Satisfaction ➢ Percent of patients satisfied with processes of care received at a VA Medical Center or clinic[1] ➢ Percent of patients (who were prescribed a new prosthesis) that report satisfaction with the prosthetic device ➢ Percent of patients reporting satisfaction with results of care[1]	Patient Satisfaction Survey

PERFORMANCE MEASURE CATEGORY	PERFORMANCE MEASURE/METRIC	DATA SOURCE
Management/ Operational	**Utilization** ➢ Number of prescribed prosthesis per year (facility, VISN, national) *workload indicator – not performance based --- ➢ Percent of prosthetic patients using prosthesis at 6 month and 1 year follow up ➢ Hospital admissions for lower extremity amputations in patients with diabetes per 100,000 population[2]	NPPD --- CPRS or new tracking software
	Cost ➢ Average cost of services per patient/year (Facility, VISN, national)[1] --- ➢ Average cost of prosthesis (facility, VISN, national)[1] ➢ Comparison of average cost of VA produced prosthesis and commercial produced prosthesis Review over time as an indicator of cost only, not performance related	DSS --- NPPD

[1]. Similar to CARF performance measures. (13)

[2]. Similar to AHRQ measures. (14)

Appendix A—Patients with Amputations Analysis Metrics

PERFORMANCE MEASURE	ANALYSIS METRIC/ DATABASE(S) UTILIZED	RESULTS
Discharge to Community Rates	4. What are the discharge to community rates for VA and non-VA patients when risk and age adjusted? Use: setting the patient goes to at discharge and who the patient will live with at discharge **FSOD**	**n= 1,139 (VA)** **n=48,334 (non-VA)** 883 (73%) of VA patients have been discharged to community 37661 (78%) of non-VA patients have been discharged to the community
FIM scores before and after treatment, both VA and comparable non-VA patients	5a. What is the functional capacity before and after amputation for **VA patients**? **FSOD**	**n= 1,139** Table 5. Functional Status In Patients With Amputations Before And After Rehabilitation
	5a1. What is the functional capacity before and after amputation for **non-VA patients**? **UDSmr** **FOTO**	**n= 48,334** Table 5. Functional Status In Patients With Amputations Before And After Rehabilitation
Patients' perceptions of quality of life	5b. How do VA patients perceive their functional capacity after amputation? **SF-36v**	**n=2,193** Table 8. Functional Health Status Statistics For All VA Patients Regardless Of Amputation Type Table 9. Mental Construct Results
Patient and family education, wound care, dressing and cast care, training in wheelchair safety, crutch safety	5d/e. Did VA patients receive training after amputation? **National Prosthetic Patient Survey**	n= 490 to 493 280 out of 490 (57%) patients were taught how to use their prosthetic device in a way that they could understand (37.8% stated they already knew how to use their device) 97 out of 493 (19.7%) patients' family or friends were taught how to help the patient to use the prosthetic device in a way that they could understand (13.3% stated that no teaching was needed) 468 out of 492 (95%) patients received as much information about the device that they wanted from the provider

PERFORMANCE MEASURE	ANALYSIS METRIC/ DATABASE(S) UTILIZED	RESULTS
Referral for placement and prosthetic appliance made by a qualified person	6a. What VISN/VAMC guidelines exist regarding the qualifications of individuals making referrals for VA patients? **Site Visits**	Physician referrals from PM&R, Vascular and Orthopedic Surgery for prosthetic limbs
	6b. What credentials do associations specify for prescribing and fitting prosthesis and orthotics?	Medical Doctor prescribes fitting prosthesis and orthotics
Percentage of prostheses and orthotics that must be redone	6c. What is the percent of prostheses that were re-done or repaired? **NPPD**	VA staff does not track re-dos or repair data for prostheses; therefore, we are unable to answer this question.
Patient's perceptions of quality of life	7a. How do VA patients perceive their quality of life after amputation? **SF-36v**	Patients from VA who have lower extremity amputations associated with diabetes or PVD perceive their quality of life after amputation as low for the constructs of physical functioning and role physical. The constructs of physical functioning and role physical pertain to the physical abilities of individuals. Physical functioning assesses functional tasks, whereas role physical pertains to health-related limitations in the kind or amount of work performed because of the physical limitations. Table 8. Functional Health Status Statistics For All VA Patients Regardless Of Amputation Type Table 9. Mental Construct Results Table 14. Associations Between SF-36 Scales and the General Health Scale
Necessary equipment for ADL delivered to home before disc	7b. What percent of VA patients had ADL equipment delivered before discharge from hospital? **NPPD** **PTF**	ADL equipment provided to VA patients is listed in Table 15.

PERFORMANCE MEASURE	ANALYSIS METRIC/ DATABASE(S) UTILIZED	RESULTS
Technical quality and appropriateness of assistive device	7e. How do VA patients perceive the quality and appropriateness of their prosthetic device? **National Prosthetic Patient Survey**	**n=486 to 510** 430 out of 510 (84%) patients were satisfied with the quality of their prosthesis device 231 out of 486 (47.5%) patients had no problems with their prosthetic device 400 out of 495 (81%) patients' prosthetic devices helped meet their goals
Ability to perform ADL and IADL. Participation in life situations	7f. How do VA patients rate their ability to participate in life situations? **SF-36v**	Type of amputation affects the ability of VA patients to participate in life situations in logical ways. VA patients with higher amputations (foot ankle lowest; BK middle; AK highest) reported lower functioning or participation for the constructs of physical functioning, but not for mental functioning. As the level of amputation rises, VA patients reported more difficulty participating in life situations in all constructs except general health and vitality. Table 8. Functional Health Status Statistics For All VA Patients Regardless Of Amputation Type Table 9. Mental Construct Results

PERFORMANCE MEASURE	ANALYSIS METRIC/ DATABASE(S) UTILIZED	RESULTS
Time patient waits to receive procedure	7g. What are the wait times VA patients experience for clinic appointments? **National Prosthetic Patient Survey**	**n=370** 300 out of 370 (81%) patients were able to schedule their visit as soon as they wanted. **n=360** 51 out of 360 (14%) did not need to wait for a scheduled appointment 184 (51%) waited for 1-14 days 72 (20%) waited 15-30 days 29 (8%) waited 1-2 months 11 (3%) waited 2-4 months 7 (2%) waited longer than 4 months

PERFORMANCE MEASURE	ANALYSIS METRIC/ DATABASE(S) UTILIZED	RESULTS
	7h. How long do patients with amputations wait to see a provider? **National Prosthetic Patient Survey**	**n=491** 184 (37.5%) patients did not need to wait for a clinic appointment related to the most recent device-related visit 181 (36.9%) waited 1-15 minutes 73 (14.9%) waited 16-30 minutes 44 (9%) waited more than 30 minutes **n=492** 90 (18.3%) patients did not have to wait to be seen by their provider after they checked in 150 (30.5%) waited 1-10 minutes 104 (21.1%) waited 11-20 minutes 80 (16.3%) waited 21-30 minutes 37 (7.5%) waited 31-60 minutes 14 (2.8%) waited for more than an hour

Appendix B—Database Definitions

Patient Treatment File (PTF) and Outpatient Care File (OPC)—Both files collect nationwide data and are housed in the Austin Automation Center (AAC). The PTF collects discharge data about each inpatient episode of care. It contains demographics, ICD-9 discharge diagnoses, up to 32 ICD-9 procedures for each episode of care including dates of the procedure, and up to five surgical procedures. The corresponding outpatient file collects data on each outpatient visit, but diagnoses have been collected only for a few years. Its validity has not been as widely studied as that of the PTF. The companion Beneficiary Identification and Records Locator Subsystem (BIRLS) is an administrative database frequently used to track patient mortality, as it does not require locating veterans through receipt of medical care.

Functional Independence Measure (FIM)—A disability assessment tool considered the industry standard. It is a basic indicator of severity of disability, using an 18-item scale that addresses seven levels of function.

Functional Status and Outcomes Database for Rehabilitation (FSOD)–A database established in 1997 through a cooperative agreement between the Office of Physical Medicine and Rehabilitation, the Uniform Data System for Medical Rehabilitation (UDSmr), and the Austin Automation Center. It tracks outcomes through the full continuum of rehabilitative care.

National Prosthetic Patient Database—A nationwide database that tracks prosthetics-provided equipment and supplies and repairs and can provide summaries of volume and costs.

Veterans SF36 (Short Form Functional Status Assessment for Veterans)—Adapted from the Medical Outcomes Study (MOS) SF-36, this is a primary measure of health-related quality of life (HRQL). It measures eight concepts of health: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health.

Uniform Data System for Medical Rehabilitation (UDSmr)—UDSmr is the largest national registry of standardized information on medical rehabilitation inpatients in the U.S.

Appendix C—Bibliography

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