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Summary of Cost Analysis of Access Complications

It is well understood that prevention of thrombosis is critical for quality of care of dialysis patients, and most people realize that surveillance and monitoring of AV accesses can be effective at identifying patients at risk for clotting. But in this new era of 'the bundle', justifying the cost for surveillance and monitoring remains a challenge.

In order to address this business issue, Vasc-Alert undertook an intense research effort to develop the business case that proactive surveillance can pay for itself while providing a higher quality of care for dialysis patients.

The key 'cost' variables that were thought to be quantifiable were a) missed treatments due to AV access complications and b) the use of a catheter for patients who are AV access capable. (Under the bundle, centers do not receive an additional payment to cover the higher costs of catheter use.) While there are other costs related to clots such as disruptions to normal center operations, these were considered too nebulous to quantify.

Background on Method of Analysis and Basic Findings

Historical records covering both session treatment data and intervention records were obtained from 28 dialysis centers associated with three large provider organizations. The treatment data provided the ability to count the number of treatments a patient received each week as well as the type of access that was in use. The intervention data indicated which patients underwent an intervention such as an angioplasty or thrombectomy. The historical time period analyzed covered either 6 months or 10 months of patient care during a 'baseline' period (prior to using Vasc-Alert).

To arrive at the count of missed treatments, we made the assumption that patients could be expected to have 3 treatments per week. If we only counted 2 treatments in a given week, we assumed the patient missed one treatment. The treatment record also told us when an AV access capable¹ patient used a catheter.

With this information, we were able to segment the patients into 5 categories:

- Patients on permanent catheters (no evidence of AV access use).
- Patients using an AV access who showed no evidence of access issues, i.e. no intervention records.
- Patients using an AV access undergoing at least one angioplasty.
- Patients using an AV access undergoing at least one thrombectomy.
- Patients using both an AV access and a catheter during the study period.

¹ Evidence of prior use of an AV access.

In order to focus the analysis on ‘normal’ patients, we used a number of rules to govern which patients to exclude due to chronic illness, non-compliance or transience. For example, a patient had to be present for at least 2 months during the study period and had to attend at least 60% of the possible treatments during that time, assuming 3 sessions per week. We also eliminated a number of centers from one organization due to the evidence of inaccurate treatment data.

We received records on 2,000 patients who met the attendance rules at the 28 centers. The resulting number of patients in each category from all 3 providers was remarkably similar as seen in the columns showing minimum and maximum from the weighted average mean. (See addendum for full data set.)

	Count	Avg. %	Minumum	Maximum
Patients only on a catheter	323	16%	14%	18%
AV access without any issues	970	48%	42%	56%
AV access with angioplasty	394	20%	8%	26%
AV access with thrombectomy	57	3%	2%	4%
Treatments both on AV access and catheters	256	13%	11%	16%
Total	2,000	100%		

Since the focus of our analysis is determining the cost of access complications for patients using an AV access we can ignore the patients on a permanent catheter with the resulting breakdown by category:

	Count	%
AV access without any issues	970	58%
AV access with angioplasty	394	22%
AV access with thrombectomy	57	3%
Treatments both on AV access and catheter	256	15%
Total	1,677	100%

‘Access complications’ for an AV access site are almost always caused by a clotting incident, requiring a thrombectomy to reopen. Even if the intervention is successful, this procedure damages the cells of the blood vessel walls, which generally causes recurring access issues. Patients that are observed as using both an AV access and a catheter, are almost always using a catheter due to a prior clotting incident, even if there is no evidence of thrombosis during the study period.

So we can identify 313 patients as having access complications either because they suffered a thrombectomy (57 patients) or were observed using both both a catheter and an AV access during the study period (256 patients). The percentages of patients with access complications broken down by provider are as follows:

	Provider A	Provider B	Provider C	Total
# AV access patients	540	315	822	1,677
# with access complications	115	56	142	313
% with access complications	21.3%	17.8%	17.3%	18.7%

The similarity of the percentages across the three providers suggests that our sample of dialysis centers reflects the population as a whole.

Missed Treatments

By using the treatment records and assuming 3 treatments per week, we were able to determine the number of average missed treatments for each patient category during their respective study periods. We then projected this out for the entire year:

	Weighted Yrly. Avg. Across All Providers	Minimum	Maximum
AV – No issues	5.60	3.45	6.24
AV – Angioplasty ²	4.63	2.41	5.42
AV – Thrombectomy	7.11	5.95	8.04
AV and Catheter	8.77	7.03	9.69

Given that every patient misses treatments, it is important to develop a ‘baseline’ of missed treatments for patients without complications. This allows us to determine the costs of missed treatments attributable to access complications in excess of this ‘baseline’.

Clearly, patients that showed no evidence of having an issue with their AV access are included in this baseline group. Given that the purpose of a vascular access management program is the prevention of thrombosis by a preventive angioplasty procedure, patients who undergo only an angioplasty should also be included in the baseline.

The baseline was determined by calculating the weighted average of the patients without issues and those with only angioplasty procedures.

Weighted average baseline of missed treatments: 5.32 treatments / year

² It is interesting to note that patients from each of the three providers who underwent only angioplasty all showed fewer missed treatments by an average of 17%. It is the opinion of Dr. Anatole Besarab of Henry Ford Health Systems that this may be due to patients paying more attention to their dialysis regimen following an intervention.

We then determined the number of missed treatments in excess of this baseline:

	Avg. Missed Tx	Less Baseline	Result	Number of Patients in Category	Missed Treatments per Year
AV access with thrombectomy	7.11	5.32	1.79	57	102.04
Treatments both on AV access and catheters	8.77	5.32	3.45	256	882.8
Excessive missed treatments per year due to access complications					984.9

It stands to reason that patients who thrombosis will miss more treatment days than baseline patients. But it is surprising that patients who are observed as using both a catheter and an AV access will miss even more treatments. This could be due to increased hospitalizations due to infections caused by catheter use, difficulties in scheduling interventional procedures, or regrettably, the use of a 'bridge' catheter following the loss of the AV access site.

Use of Catheters

The primary reason for catheter use by an AV access capable patient is complication of the AV access, almost always caused by thrombosis. The treatment records are a reliable indicator of when a patient uses a catheter and when they use an AV fistula or graft. By counting treatments on a catheter by AV capable patients and extrapolating to a full year, we can determine the number of catheter treatments per year for each of the organizations:

	Provider A	Provider B	Provider C	Total
# treatments using catheters for AV capable patients	5,766	3,055	6,229	15,050
# patients in the AV and catheter category	105	48	103	256
Avg. treatment days on catheter	54.9	63.6	60.5	58.79

The average number of treatments on a catheter is derived by dividing the total number of treatments per year by the number of patients in the 'AV and catheter' category. Again, the results across the three providers are very similar.

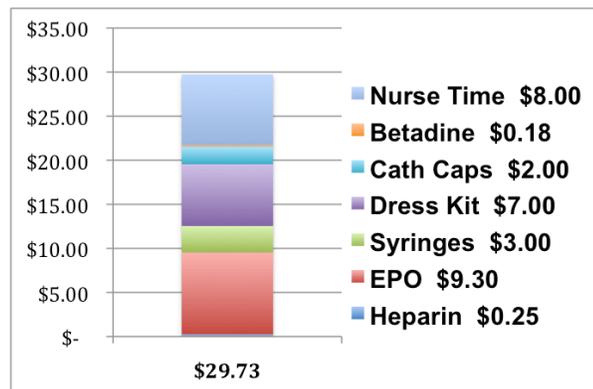
Note: Patients coming into the study on a catheter and who later switch over to an AV access underwent an additional screen to determine if they were new to dialysis. If the patient's 'first day of dialysis' was within 60 days of our first record of the patient, the patient was considered 'new' to dialysis and therefore their time on a catheter up through their first use of an AV access was not included in this tally.

Cost Assumptions

Estimating the cost of missed treatments requires assumptions on the patient mix – some Medicare and some private payment. While every organization knows their own average revenue per patient, for purposes of estimating we took the following approach:

Base payment for Medicare patients:	\$240
Avg. revenue pre treatment for DaVita and Fresenius ³ :	<u>\$340</u>
Average:	\$290
Less variable expenses for consumables not used:	(\$70)
Average Revenue per treatment:	\$220

To estimate the extra cost to the center for a patient on a catheter, we took a ‘bottom up’ approach, estimating the cost of the extra consumables used during treatment plus the extra cost of a nurse compared to a technician for putting the patient on and taking the patient off of the treatment.⁴



Extra cost per catheter treatment: \$30⁵

Note that this figure does not include costs associated with treating infections, more common with patients using catheters.

³ From DaVita's and Fresenius SEC filings

⁴ Because most states require that a nurse put on and take off a dialysis patient (estimate 20 min), this cost represents the difference between the hourly wage of a nurse and a technician.

⁵ Both DaVita and Fresenius consider a catheter patient costs them an extra \$10,000 per year or \$65 per treatment. We suspect that this figure includes missed treatments and other costs.

Calculating Cost of Access Complications

By taking the results of the analysis and combining them with the estimated costs, we can arrive at a total of lost revenue and extra cost due to access complications:

	Missed Tx's Yearly	Revenue Loss per Treatment	Total
Lost Revenue due to Missed Treatments	984.9	\$220	\$216,671

	Treatments on a Catheter	Extra Cost	Total
Extra Cost for Use of Catheter in AV Access Capable Patients	15,050	\$30	\$451,500

Total lost revenue and extra costs due to access complications: \$ 668,171

Dividing this total cost by the number of AV access patients (1,677):

Cost of access complications per AV access patient: \$ 398

Converting this figure into per treatment cost:

Cost per treatment of AV access patients @ 145 Tx's/Yr: \$ 2.75

Money on the 'Table'

Because every AV access will eventually fail, it is unrealistic to expect that any surveillance and intervention program will recoup all of these 'costs' by preventing thrombosis events. There will always be patients who clot and those patients will probably miss more treatments than patients without issues as well as spending time on catheters.

The issue is whether or not a surveillance program can reduce the number of patients who experience access complications, thereby recapturing some of this lost revenue and reducing costs (the opportunity). Even if the surveillance and access site maintenance effort only reduces the incidence of thrombosis by half, over the long term the savings should be sufficient to not only pay for the service but actually provide a positive financial return.

Addendum to Summary Analysis of Cost of Access Complications

Patient Count by Category

	Provider A		Provider B		Provider C		Total	
	Count	%	Count	%	Count	%	Count	%
Catheter Only	119	18%	71	18%	133	14%	323	16.2%
AV – No issues	372	56%	162	42%	436	46%	970	48.5%
AV – Angioplasty	53	8%	97	25%	244	26%	394	19.7%
AV - Thrombectomy	10	2%	8	2%	39	4%	57	2.9%
AV and Catheter	105	16%	48	12%	103	11%	256	12.8%
Total	659	100%	386	100%	955	100%	2,000	100%

Missed Treatments by Category

	Provider A	Provider B	Provider C	Weighted Avg.
Catheter Only	6.19	4.97	8.52	6.88
AV – No issues	6.24	3.45	5.86	5.60
AV – Angioplasty	5.05	2.41	5.42	4.63
AV - Thrombectomy	8.04	5.95	7.11	7.11
AV and Catheter	9.69	7.03	8.64	8.77

Extra Cost of Loss of all AV Access Sites

While some number of the 323 patients who were on a catheter during the entire study period were most likely on a catheter because they had lost all their AV access sites. This is almost always due to access complications due to thrombosis. While we did not have any information to identify this segment, a 2007 CMS study⁶ found that 19% of catheter patients are on a catheter because they had lost all their access points. For the 323 patients presumably on a permanent catheter, this works out to 61 patients.

Looking only at the cost of catheter use, if these patients spent an entire year on a catheter, the extra cost would be \$4,350 per patient per year. This would bring the cost of access complications per treatment for AV access patients to \$3.83, up nearly 40% from the figure of \$2.75 calculated above.

⁶ 2007 Annual Report ESRD Clinical Performance Measures Project – p 27