Reducing Unwarranted Clinical Variability Visit Frequency 2.0

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INTRODUCTION

As part of the People-first, Patient-centered focus, Healogics[®] is dedicated to continuously improving patient outcomes. A process was developed to identify and evaluate critical topics to determine the levers which would result in reducing unwarranted clinical variability across our organization and improve Comprehensive Healing Rates (CHR) amongst our patients. Four levers were identified utilizing the "CLEAR" (or Clinically-Led, Evidence-based, Analytically-driven, Research-informed) Approach, which involved reviewing internal and external research to identify evidence-based recommendations.

Patient visit frequency, along with preventing stalled wounds, increasing patient engagement and utilizing advanced modalities, were identified as four key levers to reduce unwarranted clinical variability and improve CHR. This white paper is a follow-up to "Reducing Unwarranted Clinical Variability through Patient Visit Frequency" published in 2020 and examines new data since the onset of COVID-19.

VISIT FREQUENCY IN CHRONIC DISEASE MANAGEMENT

Visit frequency and patient outcomes is not a topic unique to wound care. Support exists in medical literature for better outcomes treating chronic diseases with more frequent visits, such as in managing hypertension control, diabetes and cholesterol.

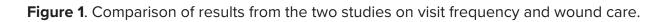
Peer-reviewed research studies have demonstrated both short-term and long-term benefits of higher visit frequency. For instance, one retrospective study of over 5,000 patients with diabetes and chronic hypertension demonstrated a direct relationship between blood pressure control and visit frequency (Turchin, Saveli, Goldberg, Shubina, Einbinder, & Conlin, 2010). The more frequently patients had encounters during a hypertensive period, the faster their blood pressure decreased and was able to normalize.

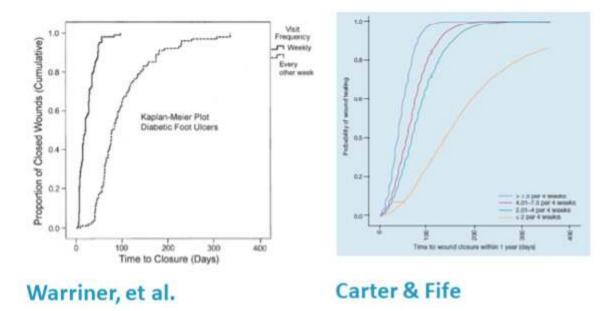
Additional studies of patients with diabetes have yielded comparable results, demonstrating that higher visit frequency led to a higher likelihood of meeting treatment goals, as well as faster achievement of their A1c, blood pressure and cholesterol targets (Asao, McEwen, Crosson, Waitzfelder, & Herman, 2014; Morrison, Shubina, & Turchin, 2011).

The benefits of higher visit frequency are not limited to patients with diabetes. A study of patients with rheumatoid arthritis found that the number of annual visits to rheumatologists was directly correlated with improvements in pain scores and functional disability metrics (Ward, 1997).

VISIT FREQUENCY IN WOUND CARE

In 2012, the first study specific to visit frequency and wound outcomes was published using a subset of data from the Healogics[®] wound database (Warriner, Wilcox, Carter, & Stewart, 2012). This study was limited in a few ways. Only a small number of Centers and wounds were included. The size and depth of wounds studied were restricted and visit frequency was evaluated within the first four weeks of treatment only. Despite limitations in trial design, patients seen weekly during the first four weeks of treatment had significantly higher healing rates and a shorter time to closure than those seen less frequently. Using a larger study sample of almost 40,000 diabetic foot ulcers, researchers found similar results to the Warriner paper, with those seen more frequently having a higher likelihood of healing (Carter & Fife, 2017).

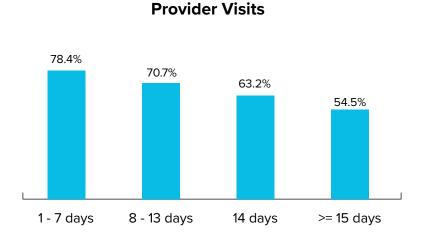




VISIT FREQUENCY IS IMPORTANT THROUGHOUT TREATMENT: HEALOGICS RESEARCH

Of all patients discharged in 2019 and in treatment for at least 30 days but less than six months (n: 236,983), those seen at least weekly throughout their treatment course had the highest wound healing outcomes. Additionally, as average visit frequency increased, healing increased.

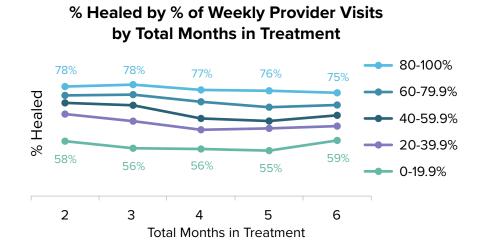
Figure 2. Heal rates by the average days between provider visits for patients discharged in 2019.



% Healed by Average Days between

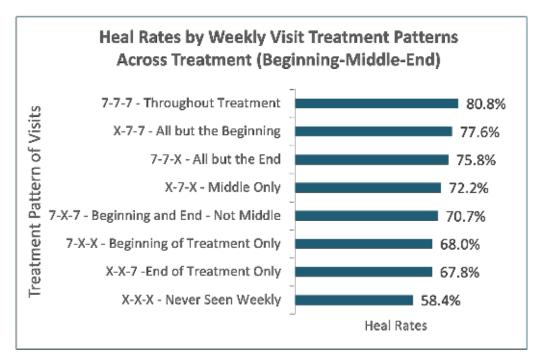
These patterns persisted regardless of the total time in treatment. Those with a higher percent of all their visits weekly demonstrated the highest healing rates, and those with the fewest weekly visits had the lowest healing outcomes.

Figure 3. Heal rates by the percent of visits that were weekly across their episode of care by total months in treatment for patients discharged in 2019.



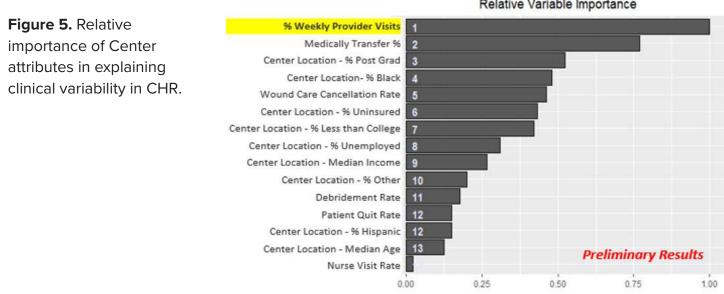
While having weekly visits throughout treatment had the best outcomes, with a healing rate of almost 81%, those having more consistent time periods of weekly visits throughout the treatment episode had better outcomes than those who only had weekly visits at the beginning or end of treatment.

Figure 4. Heal rates by the patterns of weekly visits across the episode of care for patients discharged in 2019 and in treatment for a minimum of three months.



VISIT FREQUENCY IS A TOP DRIVER OF CLINICAL VARIABILITY

To better understand the causes of clinical variability in healing rates, researchers at the University of Southern California proposed and conducted a retrospective study utilizing Healogics data. We analyzed more than one hundred potential variables, including zip code population data, Center characteristics, hospital partner characteristics, and treatment and operational metrics. Interestingly, the percent of patients seen weekly was the top predictor in explaining why Centers do not perform as expected on Comprehensive Healing Rates (CHR). Above all other Center and demographic characteristics of Center locality, the biggest factor in clinical variability was the percent of patients seen on a weekly basis. Centers that saw more patients on a weekly cadence were more likely to have higher CHR than to be expected based on their patient mix. Centers that saw fewer patients weekly were more likely to have lower CHR results.



Relative Variable Importance

OTHER CONSIDERATIONS DRIVING POSITIVE OUTCOMES WITH MORE FREQUENT VISITS

The potential inherent benefit of frequent visits independent of treatment modalities is highlighted in the results of a randomized clinical trial of human cell-based therapy on venous leg ulcers (VLU) that failed to improve healing outcomes over the standard of care (Edwards, Courtney, Finlayson, Shuter, & Lindsay, 2009). Both the treatment and standard of care control groups were required to visit weekly and both attained a higher than average healing rate for VLUs at week 12. With the standard of care group reaching high heal rates and rates like those with advanced treatment, this demonstrates the potential positive impact of close patient follow-up over the potential advantages of advanced treatment modalities.

Further evidence shows that more frequent visits can provide additional pathways for improved healing via increased social interaction and support. A randomized controlled study of patients with leg ulcers found those treated in a model emphasizing socialization and peer support had significantly better healing rates and improved well-being in comparison to patients treated via home visits (Kirsner et al., 2016). The results of this study suggest that the social environment may have advantages other than just the provision of consistent, evidence-based care. As seen in Healogics Wound Care Centers, a bond forms between the patient and care team during their episode of care. As suggested by this study as well as other researchers, social interaction and support may be additional mechanisms by which visit frequency can drive improved wound healing beyond the effects of consistent care.

NEW DATA:

COVID-19 presented an opportunity to confirm the correlation between improved outcomes and visit frequency. With colleagues at the University of Southern California, we analyzed all patients between January and June of 2019, and during the same period for 2020. The data set included 152,225 wounds from 90,629 patients overall (Cho, Mattke, Sheridan, & Ennis, 2022b). The primary outcome

was total healing at 12 weeks, which was identified as a time frame used in many clinical trials and for which we have already produced a predictive algorithm with good predictive capacity (Cho, Mattke, Gordon, Sheridan, & Ennis, 2020). Using year-overyear data, debridement rates, cancellation/loss to follow-up, and weekly visit rates were unchanged during the pandemic compared to 2019.

While overall patient volume decreased secondary to the pandemic, the adjusted healing rate remained stable year-over-year.

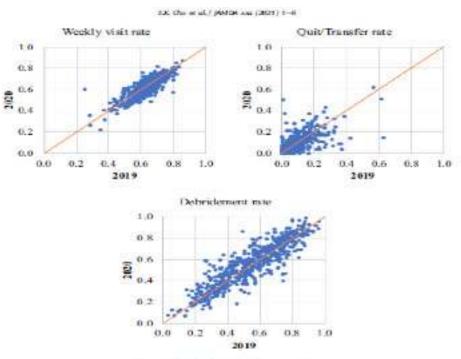


Figure 1. Clinic been measures of care continuity



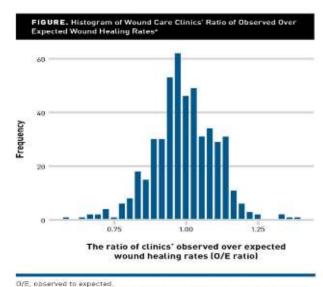
Figure 2. (A) Number of new chronic wounds by the month and year of initial initials assessment (#) Percentage of doos is wounds healed within 12 works by the month and year of initial initials assessment.

These outcomes are secondary to the tremendous effort displayed by our Healogics Centers during the pandemic. Unfortunately, amputation rates increased throughout the world and the US, as many patients chose not to seek care for fear of COVID-19, and when they did go to the emergency department, limb loss was inevitable (Caruso et al., 2020; Lancaster et al., 2020; Schuivens et al., 2020). However, healing rates remained stable even during these challenging times for patients who could access a Healogics Center, where the Big 4 were utilized.

In a second study, we used our predictive algorithm to determine the expected healing rate for a given clinic. We then followed the actual outcome and created what is known as an O/E ratio (observed vs. expected) (Cho, Mattke, Sheridan, & Ennis, 2022a). A major takeaway from this study was that clinical variation is very prevalent with a wide distribution of O/E ratios noted (Fig. below). For clarity, if you observed the same healing rate as predicted, you would have an O/E of 1.0. ratios >1 correlate with high performance, and those <1, with less effective outcomes. This study looked at 180,000 wounds from 488 Wound Care Centers.

CARE CONTINUITY

Regarding care continuity, the differences were significant between the top- and bottom-performing clinics. The overall rate at which patients averaged weekly provider visits was 36%, and the top-performing clinics had significantly higher rates than the bottomperforming clinics, with an absolute difference of 10 percentage points (41% vs. 31%; P<.01). The appointment cancellation rate was 11% overall, with bottomperforming clinics having a rate that was an absolute difference of three percentage points higher than the top-performing clinics (i.e., 13% vs. 10%; P<.01) capacity (Cho, Mattke, Gordon, Sheridan, & Ennis, 2020). Using year-over-year data, debridement rates, cancellation/ loss to follow-up and weekly visit rates were unchanged during the pandemic compared to 2019.



"The C/E ratio is a clinic's observed healing rate divided by expected heating rate

SOCIODEMOGRAPHIC CHARACTERISTICS OF A CLINIC'S CATCHMENT AREA

The sociodemographic characteristics of the populations in the clinics' catchment areas showed notable differences between the top- and bottom-performing clinics. The proportion of African Americans was twice as high in the catchment areas of the bottom-performing clinics compared with the top-performing clinics (20% vs. 9%; P<.01). The populations in the bottom-performing clinics were characterized by statistically significantly higher unemployment rates (8% vs. 6%; P<.01) and lower educational attainment, whereas median age, median household income, and uninsurance rate were comparable.

LINEAR REGRESSION RESULTS

In the multivariable regression model without interaction terms (Table 2), predictors of a higher-thanexpected wound healing rate (i.e., higher O/E ratio) were higher rates of weekly provider visits, nurse visits, and debridement, as well as higher clinic volume and lower appointment cancellation rates: A 10% increase in the weekly provider and nurse visit rates was associated with a 2.5% and 3.0% increase in the O/E ratio, respectively, and a 10% decrease in the cancellation rate with a 2.6% increase in the O/E ratio. A higher debridement rate was also statistically significant and associated with higher O/E ratios, but its effect size was smaller, in that a 10% increase in the debridement rate was associated with a 0.7% increase in the O/E ratio. Additionally, a clinic volume difference of 100 treated wounds was positively associated with a 0.1% change in the O/E ratio. None of the other clinical quality measures were significantly associated with our outcome. The unemployment rate and the proportion of residents in the catchment area with a bachelor's degree or higher were also significantly associated with lower O/E ratios. This model achieved an R2 of 0.30, suggesting that the included variables jointly explain about 30% of the variation in the O/E ratio.

		Original model			With interaction term				
		Coef	SE	t	Р	Coef	SE	t	Р
>	Weekly provider visit	2.5	0.5	4.84	< .01	1.8	0.6	3.14	< .01
Continuity	African American weekly provider visit	Not applicable			4.6	2.3	2.04	.04	
Con	Nurse visit	3.0	1.3	2.36	.02	3.2	1.3	2.52	.01
0	Cancellation	-2.6	1.1	-2.31	.02	-2.4	1.1	-2.16	.03
	Debridement	0.7	0.2	3.04	< .01	0.7	0.2	3.12	< .01
	Compression	0.0	0.2	0.14	.89	0.0	0.2	-0.01	.99
Quality	Skin Substitute	-0.5	0.7	-0.69	.49	-0.5	0.7	-0.67	.50
QU	Hyperbaric oxygen	-0.1	0.2	-0.46	.64	-0.1	0.2	-0.58	.56
	Total contact cast	0.9	0.8	1.02	.31	1.0	0.8	1.23	.22
	Wound count ^c	0.1	0.0	5.51	< .01	0.1	0.0	5.13	< .01
	Median age	0.0	0.0	-1.95	.05	0.0	0.0	-1.82	.07
	Non-hispanic white	Reference			Reference				
	Hispanic	-0.7	0.6	-1.10	.27	-0.5	0.6	-0.93	.35
.Ľ	African American	-0.8	0.3	-2.47	.01	-2.2	0.7	-3.26	< .01
apł	Others	-0.1	0.9	-0.13	.89	-0.1	0.9	-0.13	.90
lbo	Unemployment rate	-4.1	1.9	-2.21	.03	-4.0	1.8	-2.16	.03
lem	Household income ^d	0.0	0.0	1.09	.28	0.0	0.0	1.03	.31
Sociodemographic	Uninsurance rate	-0.8	1.4	-0.60	.55	-1.1	1.4	-0.78	.43
Soc	High school diploma	Reference			Reference				
	Less than high school	-1.8	1.8	-1.00	.32	-2.1	1.8	-1.21	.23
	Some College	-1.1	1.3	-0.84	.40	-1.2	1.3	-0.89	.37
	Bachelors degree or higher	-2.4	0.8	-3.13	< .01	-2.5	0.8	-3.22	.01
	constant	1.0	0.1	12.93	< .01	1.1	0.1	13.37	< .01

Characteristics of a Catchment Area on Clinic's Healing Performance as Measured by the O/E Ratio

Coef, coefficient: O/E, observed to expected; SE, standard error.

*The O/E ratio is a clinic's observed healing rate divided by expected healing rate
*Colefficients show the marginal effects of a 10% change in the independent variables on the clinics healing performance as measured by the O/E ratio. Wound count is in 100s.

NONLINEAR REGRESSION RESULTS

Multiple interaction terms between the sociodemographic characteristics of the catchment area and variables for care continuity and quality were evaluated. Only the interaction between the proportion of African American residents in a clinic's catchment area and the weekly provider visit rate consistently showed a statistically significant association (Table 2). In this model, the weekly provider visit rate was associated with a greater marginal effect on the O/E ratio when the proportion of African Americans in a clinic's catchment area was larger (Table 3). For example, a 10% increase in the weekly provider visit rate was associated with a 2.3% increase in the O/E ratio when 10% of the residents in the catchment area were African American. On the other hand, when 30% of the residents were African American, the same 10% increase in the weekly provider visit rate was associated with a 3.2% increase in the O/E ratio. Other than those two variables interacting, all other variables in this model retained their statistical significance and similar coefficient estimates from the original model.

Clinic's Healing Perform Residents in a Clinic's C	ance Over the Proportion of Africa atchment Area ^a	an American
	Estimated marginal effect	95% CI
Droportion of African	of a 10% increases in the	

TABLE 3. Variable Marginal Effect of Weekly Provider Visit Rate on

	Estimated marginal effect	95% CI		
Proportion of African American residents in clinic's catchment area	of a 10% increase in the weekly provider visit on clinic's healing performance	Upper Cl	Lower Cl	
0.1	2.30	3.27	1.33	
0.2	2.77	3.77	1.76	
0.3	3.23	4.47	1.99	
0.4	3.69	5.27	2.12	
0.5	4.16	6.13	2.18	
0.6	4.62	7.02	2.22	
0.7	5.08	7.92	2.25	
0.8	5.55	8.83	2.27	

•The results show that the estimated effect of weekly provider visit is greater when the proportion of African Americans in a clinic's catchment area is greater. A 10% increase in the weekly provider visit is associated with a 2.30% increase in the clinic's healing performance when the proportion of African American residents in the clinic's catchment area is 10%. When the proportion of African American residents in the clinic's catchment area is 30%, a 10% increase in the weekly provider visit rate is associated with a 3.23% increase in the clinic's healing performance. The weekly provider visit rate represents the proportion of patients at a clinic with at least 1 in-person visit each week.

These results suggest that comparable continuity and quality of care will result in comparable outcomes, even in disadvantaged populations, which is consistent with findings reported by Hicks et al. (Hicks et al., 2018). They analyzed data from a multidisciplinary wound care team and showed that outcomes did not depend on the deprivation index of a patient's residence.

In other words, those groups appear to benefit disproportionately from care continuity. This result is intuitively plausible, because robust support may matter more in vulnerable groups with fewer resources and lower health literacy. Results confirming similar outcomes for disadvantaged groups, when quality of care is comparable, have been reported for diabetes and heart failure (Lanting, Joung, Mackenbach, Lamberts, & Bootsma, 2005; Thomas et al., 2011). Such findings point to a path toward improving equity in health care and might have important implications for policy, clinical and managerial decision-making.

SUMMARY AND CONCLUSIONS

Healogics is focused on improving patient care by reducing unwarranted clinical variability and increasing comprehensive heal rates. One lever to achieve that goal is ensuring that patients are seen frequently. The medical literature across various chronic diseases, including wound care (by both Healogics and independent researchers), demonstrate better outcomes with more frequent visits, particularly in those seen weekly. Frequent visits throughout the course of care allow for the identification of any potential disruptions to healing be identified earlier. Additionally, research suggests visit frequency can also evoke other positive mechanisms on wound healing, including reduced social isolation and increased social support. In addition, our recent results show how improving care continuity might mitigate against social determinants of health and help our patients in the most vulnerable populations.

To heal more patients, reduce time to closure and reduce unwarranted clinical variability, it is important to identify opportunities to maintain and/or improve visit frequency throughout the patient's span of treatment.

REFERENCES:

Asao, K., McEwen, L. N., Crosson, J. C., Waitzfelder, B., & Herman, W. H. (2014). Revisit frequency and its association with quality of care among diabetic patients: Translating Research Into Action for Diabetes (TRIAD). J Diabetes Complications, 28(6), 811-818. doi:10.1016/j.jdiacomp.2014.06.006

Carter, M. J., & Fife, C. E. (2017). Clinic visit frequency in wound care matters: data from the US wound registry. J Wound Care, 26(Sup1), S4-S10. doi:10.12968/jowc.2017.26.Sup1.S4

Caruso, P., Longo, M., Signoriello, S., Gicchino, M., Maiorino, M. I., Bellastella, G., . . . Esposito, K. (2020). Diabetic Foot Problems During the COVID-19 Pandemic in a Tertiary Care Center: The Emergency Among the Emergencies. Diabetes Care, 43(10), e123-e124. doi:10.2337/dc20-1347

Cho, S. K., Mattke, S., Gordon, H., Sheridan, M., & Ennis, W. (2020). Development of a Model to Predict Healing of Chronic Wounds Within 12 Weeks. Adv Wound Care (New Rochelle), 9(9), 516-524. doi:10.1089/ wound.2019.1091

Cho, S. K., Mattke, S., Sheridan, M., & Ennis, W. (2022a). Association of wound healing with quality and continuity of care and sociodemographic characteristics. Am J Manag Care, 28(4), e146-e152. doi:10.37765/ajmc.2022.88868

Cho, S. K., Mattke, S., Sheridan, M., & Ennis, W. (2022b). Outpatient Wound Clinics During COVID-19 Maintained Quality but Served Fewer Patients. J Am Med Dir Assoc, 23(4), 660-665 e665. doi:10.1016/j. jamda.2021.11.001

Edwards, H., Courtney, M., Finlayson, K., Shuter, P., & Lindsay, E. (2009). A randomised controlled trial of a community nursing intervention: improved quality of life and healing for clients with chronic leg ulcers. J Clin Nurs, 18(11), 1541-1549. doi:10.1111/j.1365-2702.2008.02648.x

Hicks, C. W., Canner, J. K., Mathioudakis, N., Sherman, R. L., Hines, K., Lippincott, C., . . . Abularrage, C. J. (2018). Neighborhood socioeconomic disadvantage is not associated with wound healing in diabetic foot ulcer patients treated in a multidisciplinary setting. J Surg Res, 224, 102-111. doi:10.1016/j.jss.2017.11.063

Kirsner, R. S., Vanscheidt, W., Keast, D. H., Lantis, J. C., 2nd, Dove, C. R., Cazzell, S. M., . . . Group, H. P. S. (2016). Phase 3 evaluation of HP802-247 in the treatment of chronic venous leg ulcers. Wound Repair Regen, 24(5), 894-903. doi:10.1111/wrr.12467

Lancaster, E. M., Wu, B., Iannuzzi, J., Oskowitz, A., Gasper, W., Vartanian, S., . . . Conte, M. S. (2020). Impact of the coronavirus disease 2019 pandemic on an academic vascular practice and a multidisciplinary limb preservation program. J Vasc Surg, 72(6), 1850-1855. doi:10.1016/j.jvs.2020.08.132

Lanting, L. C., Joung, I. M., Mackenbach, J. P., Lamberts, S. W., & Bootsma, A. H. (2005). Ethnic differences in mortality, end-stage complications, and quality of care among diabetic patients: a review. Diabetes Care, 28(9), 2280-2288. doi:10.2337/diacare.28.9.2280

Morrison, F., Shubina, M., & Turchin, A. (2011). Encounter frequency and serum glucose level, blood pressure, and cholesterol level control in patients with diabetes mellitus. Arch Intern Med, 171(17), 1542-1550. doi:10.1001/archinternmed.2011.400

Murali, N. S., & Deao, C. E. (2019). Patient Engagement. Prim Care, 46(4), 539-547. doi:10.1016/j. pop.2019.07.007

Schuivens, P. M. E., Buijs, M., Boonman-de Winter, L., Veen, E. J., de Groot, H. G. W., Buimer, T. G., van der Laan, L. (2020). Impact of the COVID-19 Lockdown Strategy on Vascular Surgery Practice: More Major Amputations than Usual. Ann Vasc Surg, 69, 74-79. doi:10.1016/j.avsg.2020.07.025

Thomas, K. L., Hernandez, A. F., Dai, D., Heidenreich, P., Fonarow, G. C., Peterson, E. D., & Yancy, C. W. (2011). Association of race/ethnicity with clinical risk factors, quality of care, and acute outcomes in patients hospitalized with heart failure. Am Heart J, 161(4), 746-754. doi:10.1016/j.ahj.2011.01.012

Turchin, A., Goldberg, S. I., Shubina, M., Einbinder, J. S., & Conlin, P. R. (2010). Encounter frequency and blood pressure in hypertensive patients with diabetes mellitus. Hypertension, 56(1), 68-74. doi:10.1161/HYPERTENSIONAHA.109.148791

Vermeir, P., Vandijck, D., Degroote, S., Peleman, R., Verhaeghe, R., Mortier, E., . . . Vogelaers, D. (2015). Communication in healthcare: a narrative review of the literature and practical recommendations. Int J Clin Pract, 69(11), 1257-1267. doi:10.1111/ijcp.12686

Ward, M. M. (1997). Rheumatology visit frequency and changes in functional disability and pain in patients with rheumatoid arthritis. J Rheumatol, 24(1), 35-42. Retrieved from <u>https://www.ncbi.nlm.nih.gov/pubmed/9002008</u>

Warriner, R. A., 3rd, Wilcox, J. R., Carter, M. J., & Stewart, D. G. (2012). More frequent visits to wound care clinics result in faster times to close diabetic foot and venous leg ulcers. Adv Skin Wound Care, 25(11), 494-501. doi:10.1097/01.ASW.0000422629.03053.06