PHYSICIAN'S WEEKLY
DIABETES & ENDOCRINOLOGY
Vol. VIII • Issue No. 1 • January 2021
WWW.PHYSICIANSWEEKLY.COM

[MEDLAW]

Dealing With Non-Compliant Patients: Avoiding Liability

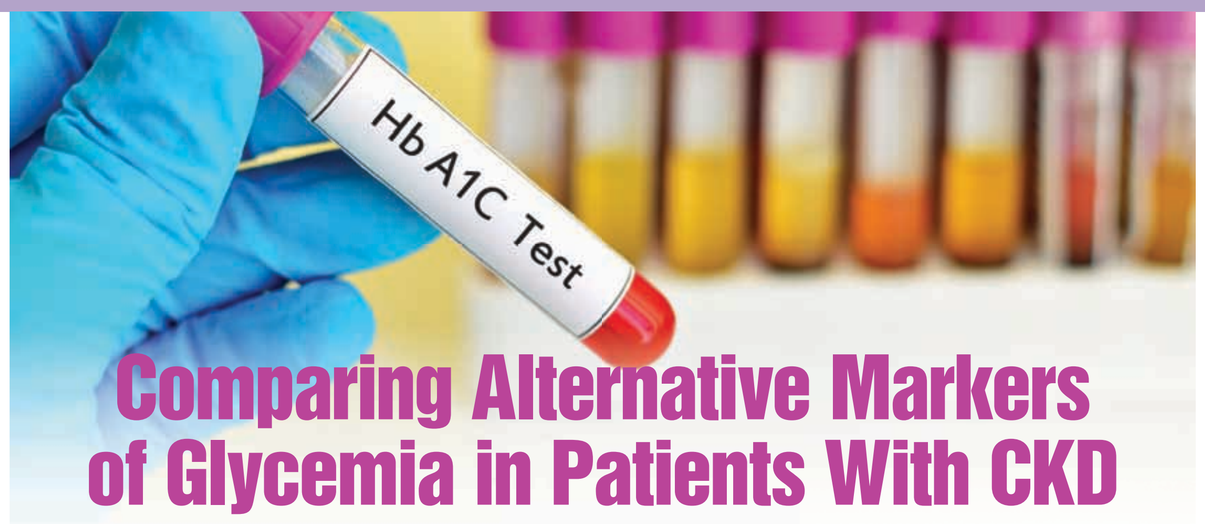
The first step in avoiding liability due to patient non-compliance is identifying that the patient actually is non-compliant. Then, ask about the reason for it and do what you can to counter it. Your record must reflect your attempt to determine what correctable issues underlie the non-compliance and what steps you took to counter it. If non-compliance is not solvable as a single issue and verbal reminders are not fruitful, you can consider a treatment contract, which breaks the compliance into specific acts of patient cooperation that may be easier to follow. Your last option is an "at risk" letter that states the specific non-compliant acts and their clinical consequences. This can include the warning that a failure to correct the non-compliance will result in termination from the practice. You should not create a "decline" note in which the patient signs their refusal to comply. You would be retaining the patient in your practice despite being unable to treat them as you believe is proper.

Your records need to demonstrate that the patient is being non-compliant rather than just being ill-informed. Descriptions of the patient's non-compliant conduct should state the fact of the non-compliance undeniably but without condemnatory or self-serving language. But it should not be so removed as to become meaningless in convincing a reviewer that you are not an appropriate target or in closing off patient claims that you never said something you actually did.

When the therapeutic relationship is irrevocably broken down and it is necessary for you to step away because the patient is actually preventing you from practicing medicine properly, you will have to terminate them from your practice. You will then have to consider abandonment. If you are going to take the maximum step against someone who is already in opposition to you, do so carefully. Non-compliance leading to no option but termination is a gradual process by definition and so an evaluator will want to see that it was handled that way.

You should also consider stating the reason for the termination in a letter. The general rule is to not give a specific reason, but here stating *"As we have discussed, and as outlined in the treatment contract that you agreed to, it was essential that you follow through on prescribed care. Due to your continued refusal to follow treatment guidelines, this practice will no longer be able to retain you as a patient as of (date)"* may stop a retaliatory process before it starts.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney.



Comparing Alternative Markers of Glycemia in Patients With CKD

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Although evidence and experience show that A1C is commonly used to assess diabetes control over time, A1C may not appropriately measure glycemic burden in patients with chronic kidney disease (CKD), with both bias and more variability around the mean possible, according to Leila R. Zelnick, PhD. With red blood cell (RBC) turnover increased in patients with CKD, less opportunity is provided for hemoglobin glycation for a given level of glycemia, such that even small changes in RBC lifespan can affect A1C; consequently, A1C has been shown to underestimate glycemia in those with estimated glomerular filtration rate (eGFR) <30 mL min/1.73 m² and those on dialysis. Also, anemia—common in CKD—and its treatment can affect A1C.

Comparing Biomarkers

With glycated albumin and fructosamine postulated to be better biomarkers of glycemic control than A1C in patients with CKD, Dr. Zelnick and colleagues conducted a study—published in *Diabetes Care*—to evaluate the accuracy, variability, and covariate bias of all three when compared with those of continuous glucose monitoring (CGM)–derived measurement of glycemia across eGFR in patients with type 2 diabetes. "A total of 104 participants with type 2 diabetes (80 with eGFR <60 mL/min/1.73m² and not treated with dialysis, and 24 frequency-matched controls with eGFR ≥60 mL/min/1.73m²) wore a blinded CGM for two 6-day periods separated by 2 weeks," explains Dr. Zelnick. "We collected blood and urine at the end of each CGM period." A1C, glycated albumin, and fructosamine were measured by high-performance liquid chromatographic, enzymatic, and colorimetric nitroblue tetrozolium methods, respectively.

Table I Within-person Repeatability of Glycemia Markers & Mean CGM Glucose Over ~3 Weeks

	Overall		eGFR <60 mL/min/1.73 m²		eGFR ≥60 mL/min/1.73 m²	
	Within-person correlation	Correlation of change in biomarker with change in CGM mean glucose	Within-person correlation	Correlation of change in biomarker with change in CGM mean glucose	Within-person correlation	Correlation of change in biomarker with change in CGM mean glucose
A1C	0.95	0.26	0.96	0.31	0.88	0.05
Glycated albumin	0.93	0.67	0.94	0.73	0.94	0.38
Fructosamine	0.92	0.48	0.93	0.55	0.91	0.25
CGM mean glucose	0.77	--	0.76	--	0.78	--

Analyses exclude one participant with an implausible A1c-to-mean CGM glucose relationship.

Source: Adapted from: Zelnick L, et al. *Diabetes Care.* 2020;43(10):2379-2387.

"Our study found that glycated albumin and fructosamine were not less variable than A1C at a given mean CGM glucose level, with several additional sources of bias," notes Dr. Zelnick. "Compared with mean CGM glucose, glycated albumin and fructosamine were significantly biased by age, BMI, serum iron concentration, transferrin saturation, and albuminuria; A1C was underestimated in those with albuminuria. These results support measuring A1C to monitor long-term trends in glycemia among patients with eGFR <60 mL/min/1.73m² not treated with dialysis."

When assessing within-person repeatability of glycemia markers and mean CGM glucose over about 3 weeks, the study team found all three biomarkers tended to be highly consistent, "which makes sense since these are measures of long-term glycemic exposure," Dr. Zelnick says (Table I). "CGM mean glucose changed more during this period, which could reflect variability as a result of lifestyle, medication use, or in some cases, physician intervention. Knowing about short-term changes in blood glucose can be important clinically; the biomarkers we studied are for long-term glycemic management and cannot capture short-term variability and hypoglycemia in the same way that CGM-derived measurements can." Despite similar correlation with CGM mean glucose for each of the three biomarkers studied, observed values fell within 10% of those predicted by CGM mean glucose more often for A1C than for glycated albumin or fructosamine (Table II). All biomarkers were significantly more variable as a marker of CGM mean glucose for participants with lower eGFR.

A1C No More Variable & Less Biased

"Our results suggest that A1C is no more variable and is less biased than other biomarkers in patients with type 2 diabetes and eGFR <60 mL/min/1.73m² not treated with dialysis, and they support guideline recommendations—including the most recently published—to measure A1C to monitor long-term trends in glycemia in this patient population," says Dr. Zelnick. "Where shorter-term variability is important, these biomarkers are not a substitute for direct measurements of blood glucose, such as those obtained using CGM."

Table II Measure of Correlation, Variability & Accuracy

	Overall			eGFR <60 mL/min/1.73 m²			eGFR ≥60 mL/min/1.73 m²		
	A1C	Glycated albumin	Fructosamine	A1C	Glycated albumin	Fructosamine	A1C	Glycated albumin	Fructosamine
Metric									
Pearson r	0.78	0.77	0.71	0.78	0.78	0.71	0.76	0.72	0.63
Spearman r	0.74	0.69	0.63	0.75	0.66	0.63	0.65	0.79	0.68
Absolute residuals, median (IQR)	-0.0 (-0.4 to 0.5)	-0.1 (-1.7 to 1.4)	-4.7 (-19.4 to 21.9)	0.0 (-0.4 to 0.5)	0.0 (-1.8 to 1.3)	-7.1 (-20.7 to 19.2)	-0.3 (-0.4 to 0.4)	-0.2 (-1.5 to 1.0)	8.7 (-32.6 to 23.2)
p10 (%)	77	56	61	75	55	64	78	52	43
p20 (%)	92	81	83	90	79	84	100	91	83
p30 (%)	99	94	97	99	92	95	100	100	100

Abbreviation: IQR, interquartile range.

Correlations are the correlation of the biomarker with CGM mean glucose. Residuals come from a linear regression of the biomarker on the mean CGM glucose; units for residuals are percent for A1C and glycated albumin and micromoles per liter for fructosamine. p10, p20, and p30 are the proportion of observed biomarkers that fall within 10%, 20%, and 30% of the predicted value of the biomarker from the linear regression, respectively. Analyses exclude one participant with an implausible A1C-to-mean CGM glucose relationship.

Source: Adapted from: Zelnick L, et al. *Diabetes Care.* 2020;43(10):2379-2387.

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Is There Life After Medicine?

By Brian Rifkin, MD

My group of nephrologists is trying to convince our 75-year-old colleague to retire from full-time clinical practice. I think he truly believes that the day he retires, his essence will be forcibly removed from his body, and he will cease to exist. He has told me, more than once, that he will be dead in less than a year if he is forced to stop being a physician. I envisioned this type of machismo was very old-school thinking, but maybe not. Modern doctors strive for a better balance of work and life, but do you ever really stop being a physician?

We all have many titles in life. What happens when the title remains, but the interactions cease? I strive to add quality and not just quantity to the lives of my patients who need to start dialysis. I have type 1 diabetes and realize that their reality may someday be mine. I hope to retire young enough that I can still enjoy all life has to offer.

In nephrology, where we have not been filling fellowship training spots, we are failing to replace ourselves in the workforce. There will likely be a need for me to prolong my work life. When I think about stopping my medical practice, I think about the million ways to not do medicine: volunteering, teaching, reading, writing, relaxing. I love interacting and helping patients. I do not, however, always enjoy the structural, administrative, and financial barriers imposed by day-to-day practice. This has been my point to my senior partner; why not take the best parts of medicine and only do those things that add meaning and pleasure to your life?

But is my partner correct? Do we lose something when we retire? There is some evidence that waiting to retire may have some health benefits. In a 2019 Swedish study, it was suggested that working past age 65 was associated with better overall health, but one can certainly argue cause and effect in this type of observation. Not debatable is that the average age of American physicians is increasing. In a 2017 survey by CompHealth, doctors reported an average retirement age of 68 (vs 63 for all Americans), and only 32% said they looked forward to no longer working in medicine. Losing social interactions at work, feeling a loss of purpose, boredom, loneliness, and depression may provoke an identity crisis at the end of a physician's career.

The ideal retirement means something different for every physician. However, it is clear that the valuable skills we acquire afford the opportunity to contribute long into our golden years. I hope that when I am 75, I have the choice to contribute (or not) as I see fit. There is purpose in being a doctor. The trap is when you assume all that you are is a doctor.

Brian Rifkin, MD, is a nephrologist.

In Case You Missed It

Finerenone Lowers Cardiovascular Events in Patients With CKD & Diabetes

Finerenone treatment lowered the risk of chronic kidney disease (CKD) progression, as well as the risk of cardiovascular (CV) events in patients diagnosed with type 2 diabetes and advanced CKD, according to a study published in the *New England Journal of Medicine*. Dubbed the FIDELIO-DKD trial, the study tested the efficacy of finerenone—a non-steroidal, selective mineralocorticoid receptor antagonist that reduces urinary albumin-to-creatinine ratio in patients with CKD previously treated with a renin-angiotensin system (RAS) inhibitor—in slowing CKD progression and reducing CV events in patients diagnosed with advanced CKD and type 2 diabetes. FIDELIO-DKD randomized 5,734 participants across 48 countries to receive either a once-daily dose of 20 mg oral finerenone or placebo. Adults with type 2 diabetes and CKD who were treated with a RAS inhibitor at the maximum dose were eligible. The primary endpoint was a composite of kidney failure, sustained estimated glomerular filtration rate (eGFR) decrease of at least 40% for at least 4 weeks, or death from renal causes. Kidney failure was defined as end-stage kidney disease with an eGFR less than 15 mL/minute/1.73m². After a median follow-up of 2.6 years, the primary endpoint had occurred in 17.8% of the finerenone group, compared with 21.1% in the control group. The number of participants requiring finerenone treatment to prevent one primary outcome was 29. Additionally, death from CV causes, non-fatal myocardial infarctions, non-fatal stroke, or hospitalization due to heart failure occurred in 13.0% of the finerenone group, compared with 14.8% of the placebo group. The incidence of serious adverse events was similar between both groups: 31.9% in the finerenone group and 34.3% in the placebo group. Specifically, hyperkalemia-related adverse events were twice as frequent in the finerenone group (18.3%) versus the placebo group (9.0%).

Guidelines Developed for Diabetes Management in CKD

In a synopsis of the 2020 Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guideline, in the *Annals of Internal Medicine*, recommendations and practice points are presented for clinicians caring for patients with diabetes and CKD. Sankar D. Navaneethan, MD, from the Baylor College of Medicine in Houston, and colleagues provide a summary of the KDIGO guidelines for diabetes management in CKD. Guidelines include 12 recommendations and 48 practice points for clinicians, and relate to comprehensive care needs, glycemic monitoring and targets, lifestyle interventions, antihyperglycemic therapies, and education and integrated care approaches. For patients with diabetes, hypertension, and albuminuria, treatment with an angiotensin-converting enzyme inhibitor or an angiotensin II receptor blocker should be initiated. Patients with diabetes and CKD who use tobacco products should be advised to quit. Patients' A1C should be used to monitor glycemic control, and individualized targets are recommended, ranging from less than 6.5% to less than 8.0% in patients not treated with dialysis. A protein intake of 0.8 g protein/kg weight/day should be maintained for those with diabetes and CKD not treated with dialysis; sodium intake should be less than 2 g/day. Moderate-intensity activity is recommended for a cumulative duration of at least 150 minutes/week or to a level compatible with cardiovascular and physical tolerance.