Kidney function remote monitoring Role of point of care diagnostics

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In vitro diagnostic industry has been on a roller-coaster ride



The Telemedicine Boom: How the COVID-19 Pandemic is Driving Practices to Go Virtual Apr 20, 2020 | COVID-19



> Prog Transplant. 2021 Dec;31(4):381-384. doi: 10.1177/15269248211046005. Epub 2021 Oct 22.

Home Care Delivery and Remote Patient Monitoring of Kidney Transplant Recipients During COVID-19 Pandemic

Jae-Hyung Chang ¹, Sharlinee Sritharan ¹, Kevin Schmitt ², Shefali Patel ¹, R John Crew ¹, Demetra S Tsapepas ²

EXECUTIVE ORDERS

Executive Order on Advancing American Kidney Health

The purpose of the *Advancing American Kidney Health* initiative was to improve reduce healthcare costs by encouraging preventive modes of care, creating incentives to increase the proportion of home dialysis treatment and making kidney transplants available to more patients.





~70% medical decisions are based on diagnostics (where blood work represent significant proportion)

yet

apart from glucose monitoring and PT/INR there is almost nothing else implemented on significant scale





Kidney function remote monitoring

Suitability of creatinine/eGFR selftesting device

Is it feasible?







> Clin Chem Lab Med. 2021 Mar 15;59(8):1409-1420. doi: 10.1515/cclm-2020-1882. Print 2021 Jul 27.

Evaluating chronic kidney disease in rural South Africa: comparing estimated glomerular filtration rate using point-of-care creatinine to iohexol measured GFR







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> Clin Chem Lab Med. 2015 Sep 1;53(10):1547-56. doi: 10.1515/cclm-2014-0932.

Application of a point of care creatinine device for trend monitoring in kidney transplant patients: fit for purpose?

Céline L van Lint, Paul J M van der Boog, Fred P H T M Romijn, Paul W Schenk, Sandra van Dijk, Ton J M Rövekamp, Anja Kessler, Lothar Siekmann, Ton J Rabelink, Christa M Cobbaert

Results: The StatSensor[®] did not meet total allowable error criterion of 6.9%. Average overall CV_a for the StatSensor[®] was 10.4% and 5.2% for capillary and venous whole blood results, respectively. Overall CV_a for the central laboratory serum creatinine method was <1.5%. For monitoring renal (dys)function, total agreement of the StatSensor[®] with an IDMS-traceable enzymatic test was 68% using a 10% Δ change. No significant differences were found between the changes observed by both methods.

Conclusions: Capillary blood testing with the StatSensor[®] is not advisable for determining current renal function with a single creatinine measurement in kidney transplant patients, mainly due to excessive analytical imprecision. However, our results suggest that capillary blood testing with the StatSensor[®] can be used for daily trend monitoring of kidney function after renal transplantation.











Aims: To explore

- 1. the adequacy and
- 2. the patient's acceptance

of capillary creatinine POCT in different kidney disease patients' groups.

Method:

- 124 patients were recruited at Bern University Hospital: 31 CKD, 69 TPM and 24 HD.
- Creatinine measurement with *Nova Max*[®] *Creatinine* in 3 different capillary measurements (index test) and from venous sampling by the central hospital laboratory (enzymatic reference test).
- In HD patients, analyses performed before and after a hemodialysis session.
- Calculation of intra-essay variation and correlation between index and reference tests.
- Standardized survey explored patients' acceptance and perception of autonomous capillary creatinine measurement at home.

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Intra-assay coefficient variation for creatinine POCT : CKD : 12% (IQR 4-26) TPL : 15% (IQR 7-26) HD, pre-dialysis: 35% (IQR 24-42) Total intra-assay coefficient of variation : 17 % (IQR 7-30)

Correlation between capillary and venous plasma creatinine: CKD patients: R²=0.84, inter-essay CV 10% (IQR 6-23) TPL patients: R²=0.71, inter-essay CV 15% (IQR 6-24) HD patients, pre-dialysis: R²=0.58 CV 33% (IQR 20-41)

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projectcarna.com









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Collect bulk results





Mike Warner mike.warner@mayo_	O Patients			Q Search		∑ : + Add
₩ HCPs	NAME	HCP 💌	CREATININE 0.60 - 1.50 mg/dL	eGFR >59 mL/min/1.73m2	DEVICE	ACTIONS
O Patients	Jerome Bell MRN: 1845611	Kristin Watson	0.72 mg/dL	106 mL/min/1.73m2 7		:
Devices	C Cameron Williamson MRN: 8176465	Eleanor Pena	0.65 mg/dL	98 mL/min/1.73m2 ㅋ		:
E Tests	Leslie Alexander MRN: 6879545	E B Ema Clark	0.49 mg/dL	140 mL/min/1.73m2 अ		:
	Savannah Nguyen MRN: 6879545	Cody Fisher	0.75 mg/dL	105 mL/min/1.73m2 🤊		:
	Jacob Jones MRN: 6879545	Eleanor Pena	0.58 mg/dL	135 mL/min/1.73m2 ≥		:
	Bessie Cooper MRN: 6879545	Kristin Watson	N/A	N/A	N/A	1
	Darlene Robertson MRN: 6879545	Cody Fisher	N/A	N/A	N/A	I
	Arlene McCoy MRN: 6879545	Eleanor Pena	N/A	N/A	N/A	1
	Marvin McKinney MRN: 6879545	Kristin Watson	N/A	N/A	N/A	1
	Darrell Steward MRN: 6879545		N/A	N/A	N/A	1
	R Ralph Edwards MRN: 6879545	E 😗 Ema Clark	N/A	N/A	N/A	:
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What's next?





Electrolyte (Na, K, Ca, Cl) measurement device













Thank you



