



RESOURCE AND PATIENT MANAGEMENT SYSTEM

Health Information Technology Systems and Support

Intervention Risk Management

Plan Summary

Version 1.0
November 2024

Office of Information Technology
Division of Information Technology

1.0 Goals

Goal Map to FAVES Map to ISO 9001	Plan Summary for criterion 170.315(b)(11) Predictive DSI	Validity	Reliability	Robustness	Fairness	Intelligibility	Safety	Security	Privacy
Accountability <i>Fair</i> Appropriate Valid Effective Safe ISO 9001:2015 Requirement: (8) Operations	<ul style="list-style-type: none"> • Impact assessment <ul style="list-style-type: none"> ○ Assess the impacts of any changes in the eGFR calculation on the constituencies that are identified in the interpretation of the test results (i.e., gender and age). If race is added back in to the interpretation of test results, assess the impact of that change as well. ○ Processes and procedures are in place to monitor any changes in the calculations and recommended interpretations of the eGFR value. Healthcare providers who utilize this information in the course of patient care maintain current knowledge of this information. ○ The project team(s) responsible for monitoring any changes receive communication from the NKF and NIDDK and incorporate any changes into the code for those calculations. • Oversight of significant adverse impacts <ul style="list-style-type: none"> ○ The NIDDK routinely evaluates the equation they provide (and which we use) and initiates a task force when it is deemed necessary to reevaluate the equation. ○ The RPMS Health IT makes no change in this calculation. • Fit for purpose <ul style="list-style-type: none"> ○ The result of an eGFR blood test is one point of information used in the diagnosis and treatment of patients. Trend analysis is a big factor in making any treatment decisions based on these test results. 	✓	✓	N/A	✓	N/A	✓	✓	N/A

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	<ul style="list-style-type: none"> • Data governance and management <ul style="list-style-type: none"> ○ As part of a strenuous testing cycle, IHS performs internal alpha/beta testing by entering random creatinine values to test the calculations. We assume that the lab selects the correct eGFR calculation based on the blood creatinine method. RPMS Health IT incorporates multiple eGFR calculations. • Human oversight and control <ul style="list-style-type: none"> ○ IHS provides feedback to NIDDK as to the usefulness of the eGFR calculation. 								
Transparency <i>Fair</i> Appropriate Valid <i>Effective</i> <i>Safe</i> ISO 9001:2015 Requirement: (5) Leadership	<ul style="list-style-type: none"> • System intelligibility for decision making <ul style="list-style-type: none"> ○ In the release documentation for RPMS Health IT, IHS provides the specific calculation used to determine the eGFR value. Here is the text from the user manual for the latest release: <ul style="list-style-type: none"> ▪ The National Kidney Foundation's latest recommended eGFR is the 2021 CKD-EPI eGFR. The algorithm no longer incorporates race as a parameter. ▪ The manual goes on to provide the formula. ○ The user manual also provides the following guidance information: <ul style="list-style-type: none"> ▪ A laboratory that reports eGFR numeric values greater than (>) 60 mL/min/1.73 m² should use the CKD-EPI equation, because the CKD-EPI equation is more accurate for values greater than (>) 60 mL/min/1.73 m² than is the MDRD Study equation. However, the influence of imprecision of creatinine assays on the uncertainty of an eGFR value is greater at higher eGFR values and should be considered when determining the highest eGFR value to report. 	N/A	N/A	N/A	N/A	✓	N/A	N/A	N/A

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	<ul style="list-style-type: none"> ▪ The current GFR delta checks in RPMS Lab use the MDRD Study equation and, as such, do not report any values greater than (>) 60. • Communication to stakeholders <ul style="list-style-type: none"> ○ RPMS Health IT partners receive release notices that communicate any and all changes to the eGFR calculations. • IHS leadership is committed is reflected in the agency’s Mission, which is “to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.” • Providing accurate and reliable tools to healthcare providers enables them to ensure they are providing the best care for their patients. • The Indian Health Manual (IHM) is the reference for IHS employees regarding IHS-specific policy and procedural instructions. Permanent policies, procedures, and operating standards specific and unique to IHS administrative and program operations are maintained in the nine Parts of the IHM. Specifically, Chapter 23 details the Resource and Patient Management System Network, which houses the Predictive DSIs. • RPMS Health IT project teams stay informed of any changes in the calculation of the eGFR value. Healthcare providers remain informed of any changes in interpretation protocols of the calculated eGFR values. 								
Fairness <i>Fair</i> <i>Appropriate</i> <i>Valid</i>	<ul style="list-style-type: none"> • Quality of service & Allocation of resources and opportunities <ul style="list-style-type: none"> ○ Race is not included in the interpretation of test results – only age and gender, which have been shown to have a valid impact on the test results. 	✓	✓	N/A	✓	✓	✓	N/A	✓

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<i>Effective</i> <i>Safe</i>	<ul style="list-style-type: none"> ○ There is a risk in that IHS’s constituency – American Indian/Alaska Native populations – are generally underrepresented in clinical studies upon which many tools are validated. ○ NIDDK’s calculation is a nationally accepted eGFR calculation, deployed in the setting of American Indian/Alaska Native population included and race is not used as a coefficient in the calculation. ○ IHS monitors NIDDK calculations to ensure that IHS continues to apply the correct interpretation to eGFR test results. 								
Reliability & Safety <i>Fair</i> <i>Appropriate</i> Valid Effective Safe ISO 9001:2015 Requirements: (4) Context of the organization (6) Planning (7) Support (9) Performance evaluation (10) Improvement	<ul style="list-style-type: none"> ● Reliability and safety guidance <ul style="list-style-type: none"> ○ NIDDK regularly evaluates and adjusts its eGFR calculation; IHS incorporates any such updates into its calculation and interpretation of eGFR results. ○ The National Kidney Foundation and the National Institute of Health’s National Institute of Diabetes and Digestive and Kidney Diseases have done extensive analysis and recommend the use of this eGFR calculator as a reliable tool to help estimate GFR while acknowledging limitations. ○ Healthcare providers who utilize the IHS RPMS Health IT rely on eGFR to track patients’ health metrics and help them understand the chance of occurrence of future health issues. ○ Those healthcare providers depend on the veracity of the data provided by eGFR and expect that the calculations leading to those metrics are continuously scrutinized to ensure the best possible picture of a patient’s health. 	✓	✓	✓	N/A	N/A	✓	N/A	N/A

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	<ul style="list-style-type: none"> ○ The calculation and interpretation of the eGFR values are documented in the User Manuals provided to the RPMS Health IT partners. • Failures and remediations <ul style="list-style-type: none"> ○ Caution is exercised by providers in their interpretation of eGFR test results as they understand the limitation of a predictive test result based on large data sets of a population that may or may not represent closely a particular patient’s profile. ○ If reliability of eGFR were questionable, the magnitude of harm could be significant in due to misdiagnoses and lack of reliable information on which to base clinical decisions. ○ With any calculation and interpretation of a predictive value, there is a risk of misinterpretation and potential for decisions made that might not, in the end, be in the best interest of the patient. • Ongoing monitoring, feedback, and evaluation <ul style="list-style-type: none"> ○ IHS leverages feedback from practitioners about the efficacy of the eGFR calculations. That feedback is IHS’s trigger to provide that information to the developers of the eGFR calculations. 								
Privacy & Security <i>Fair</i> <i>Appropriate</i> <i>Valid</i> <i>Effective</i> Safe	<ul style="list-style-type: none"> • Privacy Standard compliance <ul style="list-style-type: none"> ○ Feedback data that is shared with NIDDK is de-identified and cannot be associated by anyone working with that data with a specific person or group of persons. ○ Storage, interpretation, and use of calculated eGFR test results are limited to a patient’s record; the IHS Privacy Policy prohibits sharing of such information unless it is de-identified. 	N/A	N/A	N/A	N/A	N/A	N/A	✓	✓

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	<ul style="list-style-type: none"> • Security Policy compliance <ul style="list-style-type: none"> ○ All data stored in IHS systems is secured in accordance with the IHS Security Policy. 								

Acronym List

Acronym	Term Meaning
CKD-EPI	Chronic Kidney Disease Epidemiology Collaboration
DSI	Decision Support Intervention
eGFR	estimated Glomerular Filtration Rate
IHS	Indian Health Service
IHM	Indian Health Manual
IT	Information Technology
MDRD	Modification of Diet in Renal Disease
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NKF	National Kidney Foundation
RPMS	Resource and Patient Management System

Contact Information

If you have any questions or comments regarding this distribution, please contact the IHS IT Service Desk.

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