Territory Kidney Care

Clinical Risk Management Plan

Contents

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Contact details

Paul Kamler
Clinical Nurse Consultant – Health Informatics
Phone: 8946 8514
E: Paul.Kamler@menzies.edu.au

1. Introduction

The use of information and communication technology in health care settings can deliver substantial benefits to patients and professionals in the delivery of clinical care. Health information systems can provide complete and accurate information to professionals to enhance the timeliness, access, accuracy and efficiency of care to individuals. This is particularly relevant in the NT where the provision of optimum care is challenged by remoteness and the highly mobile Aboriginal population, who often access multiple service providers.

However, there are numerous sociotechnical issues associated with the implementation and uptake of clinical health information systems which, if not addressed adequately in the development and deployment phases, can potentially threaten patient safety. Key issues associated with the integration (or lack of effective integration) of systems into the clinical workplace include infrastructure failure, inadequate stakeholder consultation, inaccurate clinical workflow interfaces and lack of policy, training or support. All of these components in isolation or as a whole, can and will contribute to the degradation of Clinical Safety(Bates & Gawande, 2003).

Territory Kidney Care (TKC) is a repository of integrated patient data from disparate clinical information systems utilised by health services in the Northern Territory. TKC is intended to assist with the monitoring and management of people with Chronic Kidney Disease (CKD).

"Monitoring is inherently boring and is not performed well by humans. Moreover, so many data are collected now that it can be hard to sift through them to detect problems. However, if the monitoring of information is computerized, applications can perform this task, looking for relations and trends and highlighting them, which can permit clinicians to intervene before an adverse outcome occurs" (David W. Bates, 2003).

The aim of TKC is to enhance patient care and management through the early identification and targeted clinical decision support of patients with CKD. The system is not intended to replace the source clinical information systems available to health professionals, and from which it receives data. Critically TKC does not change the primary health service user interface, require the adoption of additional technologies by primary health professionals or the completion of paper-based records.

This document (Clinical Risk Management Plan) is a guide to how patient safety compliance of the TKC System was assessed, measured and evaluated. For each clinical hazard logged in TKC, a risk analysis, risk controls and risk evaluation were applied and documented in the Clinical Risk Management Assessment Matrix (Hazard log) (Appendix A).

The Frameworks that have informed the development of the Matrix include the Western Australian Government's Department of Health ICT Patient Safety Risk Assessment – Guide for ICT Projects (Ref) and the NHS Clinical Risk Management Guidelines (NHS Digital, 2016a, 2016b).

2. Clinical Risk Analysis

2.1. Scope and definition

Clinical Scope is the extent of the functionality that is provided within the Health IT System that can be used to support or influence the administration of health care to a patient.

Territory Kidney Care (TKC) is a repository of clinical information from various government and non-government clinical software systems used within the health care sector of the Northern Territory. Clinical data – based on strict selection criteria – is extracted and imported from select electronic health source systems, namely the Primary Care Information System (PCIS) used in the NTG Primary Health Care Services; Communicare System used in the Aboriginal Community Controlled Sector; and Clinical Work Station (Care-Sys) used within the NTG Tertiary Hospitals. The data is consolidated and securely hosted within the Department of Health (DoH) architecture.

"Effective clinical decision-making requires careful assimilation of patient information from multiple fragmented sources, and the integration of vast amounts of new scientific evidence into practice. Reliable and efficient care can often only be achieved with the use of IT" (David W. Bates, 2003)

TKC is in essence a reporting platform. TKC will be an adjunct to clinical systems already available to renal clinicians within the DoH. TKC will enable a small group of tertiary clinicians support the larger primary health workforce with timely and targeted clinical advice. The aim of TKC is to provide a consolidated record of a patients' health care and identify patients who require immediate support and management.

The objectives of TKC are to:

- Improve the patient journey by increasing the identification of undiagnosed CKD, close the information gap between different health services and provide a more complete picture of patient care including results and treatment delivered across health services.
- Improve the timeliness of specialist support and provide risk stratification for disease progression so that patients are prioritised and care is targeted to allow staff to focus on patients who will benefit the most.
- Streamline the specialist referral process and facilitate timely evidence-based advice, reducing the need for face to face appointments and patient travel. This will allow clinicians who have a better rapport and relationship with patients and their families, to discuss management options, and develop a more planned approach to end stage treatment.
- With the high rates of staff turnover in primary health services, TKC can support new staff, directing them to best practice guidelines, providing assistance with education and evidence-based advice to tailor care to individual patients.

- Provide a mechanism for quality improvement using clinical and administrative data for service improvements.
- Promote and facilitate integration, particularly between primary and specialist clinicians, through sharing CQI data and coming together to discuss reports, identify gaps and determine solutions together.
- Provide information for service planning, enabling greater advocacy for resourcing.

*'**Intended use**' is the definition or explanation of who will use the Health IT system and how they will use it, in terms of existing business processes or within new business processes.*

Access to TKC is based on clinical need and is restricted to the clinical support unit (CSU) within the DoH's NT Renal Services. The CSU is made up of CKD nurses and nephrologists who are based in the main centres of Darwin and Alice Springs but travel throughout the NT. They will access TKC via a secure login to the system, hosted on a server within the DoH. Security within the design includes an audit trail where all access to patient information is logged including user identification of the person accessing the record and the record accessed.

The CSU health professionals will use the TKC system to review patient clinical information and provide clinical support to primary health clinicians. TKC outputs include reports across three levels aimed at

1. Providing patient specific recommendations intended to be actioned by the primary health professional in the immediate time frame.
2. Identified lists of patients requiring review and closer monitoring in the near future.
3. De-identified and aggregated reports, identified by the health service to support quality assurance processes, health service planning, projections and advocacy.

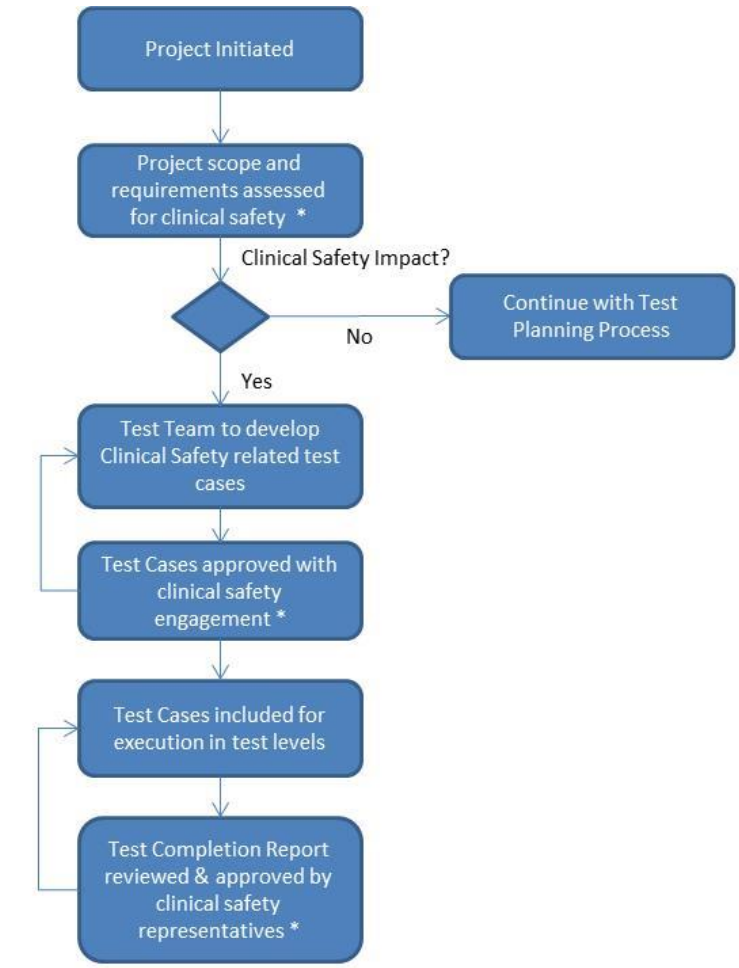
Use of contributed and consolidated information is outlined in the Partnership and Data Sharing Agreement and governed by the Steering Committee, Agreed Use Cases and the DoH's Data Access Protocols.

2.2. Clinical hazard identification

"It is particularly important that testing activities related to clinical safety, clinical functional assurance and clinical usability are clearly identified at the commencement of the project's System Development Life Cycle (SDLC). Comprehensive testing should be planned, designed and executed according to real life business scenario at all test levels as early as possible in order to discover and resolve defects as efficiently as possible" (Department of Health, 2017).

The requirement for the assessment, monitoring and evaluation of patient clinical safety within the NT's eHealth applications is articulated in the NT Health Information Systems Test Frame work (Figure 1). Consideration to clinical safety is factored as an integral element of the system testing throughout the System Development Life Cycle (SDLC).

Figure 1: Clinical Safety Plan for NT Health Information Systems



Pre-development of the system, extensive discussion took place with key stakeholders to identify potential clinical hazards related to the proposed design of TKC. Ongoing advice from the Steering Committee, the Clinical Reference Group and Technical Working Group subsequently informed the build of a prototype which was critical in identifying required controls and risk mitigation strategies. The full system build deployed these controls which were subsequently tested and validated through a series of collaborative forums with key TKC stakeholders, the Clinical Reference Group and Technical Working group. Through this collaboration we have ensured the Clinical Risk Management Plan meets clinician and Industry standards.

The outcome of this engagement is detailed in the Hazard Log (Appendix A).

2.3. Clinical risk estimation

The clinical risk estimation of TKC is based on the NHS Clinical Safety Guidelines in the development and deployment of health information systems (NHS Digital, 2016a, 2016b). The risk estimation uses a matrix that assesses the magnitude of the impact of each identified

Hazard and the likelihood of it occurring. Each Hazard is assessed for severity of the clinical impact on patients if the event was to occur and whether it is likely to affect single or multiple patients. The severity scoring uses a scale of 1 to 5 where 1 is minor and 5 is a catastrophic impact, such as death (Table 1).

Table 1: Severity Scoring for Risk Estimation

Value	Severity Classification	Interpretation	Patients Affected
5	Catastrophic	Death	Multiple
		Permanent life-changing incapacity or severe incapacity where recovery is not expected in the short term	Multiple
4	Major	Death	Single
		Permanent life-changing incapacity or severe incapacity where recovery is not expected in the short term	Single
		Severe injury or incapacity where recovery is expected in the short term	Multiple
		Severe psychological trauma	Multiple
3	Considerable	Severe injury or incapacity where recovery is expected in the short term	Single
		Severe psychological trauma	Single
		Minor injuries where recovery is not expected in the short term.	Multiple
		Significant psychological trauma.	Multiple
2	Significant	Minor injuries where recovery is not expected in the short term.	Single
		Significant psychological trauma	Single
		Minor injury where recovery is expected in the short term	Multiple
		Minor psychological upset; inconvenience	Multiple
1	Minor	Minor injury where recovery is expected in the short term; minor psychological upset; inconvenience; any negligible severity	Single

The severity rating is then calculated against the likelihood of the Hazard occurring (Table 2) with the scoring combination resulting in a Risk Estimation Outcome Score (Table 3).

Table 2: Likelihood Scoring for Risk Estimation

Value	Likelihood Category	Interpretation
5	Very high	Certain or almost certain; highly likely to occur

4	High	Not certain but very possible; reasonably expected to occur in the majority of cases
3	Medium	Possible
2	Low	Could occur but in the great majority of occasions will not
1	Very low	Negligible or nearly negligible possibility of occurring

The Risk Estimation Outcomes Scores are also scaled from 1 to 5 (Table 3).

Table 3: Risk Estimation Outcome Scores

Likelihood						
	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
	Severity					

3. Clinical risk evaluation

The Clinical Risk Evaluation Matrix describes, for each Hazard, the possible causes, controls in place and mitigation strategies required to reduce the estimated risk to a minimum acceptable level. The final risk evaluation score for each Hazard is then considered in light of the Risk Acceptability Criteria. The risk acceptability criteria considers whether the clinical risk of each hazard to a patient has been dealt with satisfactorily and no further action is required, or whether the clinical risk is such that implementation must not proceed. The Risk Acceptability Criteria is scaled from 1 to 5 where 1 is 'Acceptable Risk' and 5 is 'Unacceptable Risk' (Table 4).

Table 4: Risk Evaluation Acceptability Criteria

Risk Evaluation	
Level	**Detail**
5	Unacceptable level of risk
4	Mandatory elimination of hazards or addition of control measures to reduce risk to an acceptable level
3	Undesirable level of risk Attempts should be made to eliminate the hazards or implement control measures to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical
2	Acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical
1	Acceptable, no further action required

4. Clinical Risk Control

4.1. Control option analysis

Each Hazard is described in terms of root cause, controls in place and whether future rehabilitation is planned or deemed necessary. Hazards are then assessed for further risk management requirements including additional controls or mitigation strategies such as the development of implementation business rules.

As Hazards with an Unacceptable Risk Evaluation were identified, modifications within the system were undertaken or external controls were negotiated with stakeholders. The review and modification cycle continued until all Hazards were deemed Acceptable or no further practicable controls were available. In these instances. a Clinical Risk Benefit analysis was completed.

4.2. Risk benefit analysis

A clinical risk benefit analysis is used to justify the residual clinical risk of a Hazard once all possible measures and mitigation strategies have been implemented. If a Hazard is judged unacceptable, a Clinical Risk Benefit Analysis is applied to establish if the IT system is likely to provide more clinical benefits than harm. NHS suggests the concept of ALARP (As low as reasonably practicable) can also be used to measure the residual clinical risk acceptability (NHS Digital, 2016a). ALARP considers two aspects: the technical and economic practicability of achieving further risk reduction. The determination of 'unacceptable clinical risk' should be based on the judgement of expert clinicians and IT officers. Clinical risk benefit should take into account the local context including social, economic, political influences as well as regulatory, clinical and technical impacts.

4.3. Control measure implementation

The assessment and management of the clinical risk during the manufacture and implementation of TKC followed the methodology as described by the NHS Digital (NHS Digital, 2016a, 2016b).

Hazards were identified using root cause analysis methodology and followed the development of the system from data extraction to TKC outputs.

For each hazard, root cause/s were identified, followed by existing controls, controls created during the design and test phase, additional mitigation strategies and business rules required, and the final risk outcome. All control measures were tested and verified to their effectiveness.

The TKC Business Rules and Data Dictionary describe the complete system components and processes of TKC. The Business Rules describe the operations, definitions and constraints applied to achieve the objectives of TKC including the controls and mitigation strategies identified and required to reduce the clinical hazards to acceptable level.

Documentation regarding the Clinical Risk Management of TKC is located in a TKC Risk Management File in both electronic and hard copies.

TKC Risk Management File

The Clinical Risk Management File will be maintained by the TKC Project Team within Menzies during the implementation and evaluation phase. The Project Team includes the DoH Clinical Support Unit's Health Informatics Clinical Nurse Consultant (CNC). The Health Informatics CNC is the Clinical Safety Officer for TKC and the designated officer for reporting of all safety concerns.

The Clinical Safety officer will maintain:

- The Clinical Risk Management Plan (this document)
- All documents and evidence of compliance with required standard
- The clinical decision log for the build and implement phase of the TKC system
- Clinical Hazard log (Attachment A)
- Clinical Safety Report (this document)
- Processes for the review and corrective action of reported incidents.

Once TKC enters the maintenance phase the ongoing management of the TKC Risk Management File will be transferred to the Clinical Support Unit under the authority and management of the DoH.

4.4. Completeness Evaluation

A formal review of the functions and operations of the TKC system was conducted prior to the release and deployment in the 'live' environment. This included clinical risks identified in the hazard log. Testing requirements under the NT Health Information Test Framework included unit and system testing (discrete testing of codes and the application of codes to data components), System Integration Testing (SIT) for whole system compliance, User Acceptance Testing (UAT) to ensure business requirements were met, and Production Verification Testing (PVT) to ensure the system transfers successfully form test to production environments without corruption.

All clinical hazard controls were tested and validated during these processes. The results of the review and the outcomes of the Clinical Risk Evaluation are recorded in Clinical Safety Case Report (Point 6).

5. Deployment

Territory Kidney Care will be deployed in a staged process across the NT. In the first instance, TKC will only receive clinical data from DoH systems, with non-government health services joining region by region. The TKC system will only be accessible to a small number of renal clinicians, which will facilitate the controlled incremental roll-out and the safe management of potential and unforeseen risks.

Health Service Implementation Plans describing TKC deployment processes and identifying health service specific risks have and will continue to be developed for each participating health service. Importantly health services are reminded that TKC is an adjunct to usual processes and is intended to enhance information from current systems, not replace them. The presence and outputs of TKC therefore can not cause decrements to patient care, as access to usual clinical information systems remain unchanged.

The Clinical Safety Officer will implement processes to monitor the impact of the system on users; clinical and management processes; and changes in intended use. This includes the ongoing monitoring of clinical hazards to ensure the clinical risk evaluation base case remains unchanged.

5.1. Post Deployment Monitoring

The Clinical Safety Officer will be responsible for developing the processes for safety incident reporting and management. Requirements include developing the procedure/processes for:

- users to report a potential or actual incident
- assessing the clinical safety hazard and
    - adding the clinical risk to the hazard log
    - referring the incident to the system administrator for resolution
- escalating the incident to the Data/System Owner if necessary
- reporting or issuing safety alerts.

The reporting, management and resolution of all reported incidents should be recorded in the Safety Incident Management Log.

5.2. Modification

TKC deployment is planned in a staged roll-out specifically to facilitate modifications and improvements in subsequent releases. The incremental deployment allows an extended period for validation of clinical outputs with clinicians; and identification of potential system issues as new clinical information systems, not involved in the testing phase, join. Phase two release will include identified modifications, planned design improvements and extension of the functionalities of TKC.

Prior to deployment of Phase two, TKC will undertake the same testing regime as completed for Phase one. This will include a review and update of the Clinical Risk Management Plan, Clinical Risk Assessment Matrix and Clinical Safety Case Report.

6. Clinical Safety Case Report

During the design and development, phase nine clinical safety hazards were identified. The hazards were assessed for existing controls, mitigation strategies and business processes that would moderate the clinical impact of the clinical hazard.

In the first instance, it is imperative to bear in mind that TKC is in essence, a reporting platform and not a critical clinical information and patient management system. The unavailability of the system for hours or days would have no impact on clinical care. TKC is an adjunct to clinical information systems available to the Clinical Support Unit (CSU) within NT Renal Services and is not intended to be used in isolation.

In this regard, many clinical hazards are mitigated by the availability of the source systems and the 'true' source of information. However, they have been retained for the deployment phase and should be reviewed post implementation for their relevance.

Hazard 1. TKC patient record inclusion: relates to the selection criteria for patients to be included in the TKC data base and the clinical hazard is one of incorrect inclusion (and therefore does not require the care of the CSU) or omission (and therefore potentially misses out on the benefit of the additional support provided by the CSU). As usual clinical information systems and business processes will continue, clinical harm is considered negligible. Adjustments and refinement of the script during development improved patient inclusion to clinician satisfaction.

The Likelihood of the hazard occurring is considered **Low** and the Severity is considered **Minor**.

Risk Evaluation Rating = 1

Hazard 2: Clinical Data Accuracy: relates to the data components extracted from source systems and possible loss of data integrity during the extract load and harmonisation processes leading to incomplete data. As usual clinical information systems and business processes will continue, clinical harm is considered negligible. Testing with clinical users and adjustments and validation by the technical working group during the development phase, indicated good concordance of data components. A process of staged roll-out will enable further validation and refinement of the harmonisation script if required.

The Likelihood of the hazard occurring is considered **Very Low** and the Severity is considered **Significant**.

Risk Evaluation Rating = 1

Hazard 3: Poor patient matching and linking: relates to the consolidation of a patient's records from multiple source systems and the potential to incorrectly link different patient records or fail to link the same patient's records. Linking is challenged by the lack of a unique identifier across source systems, arbitrary assignment of dates of birth, patients with multiple names or potential to change names intermittently.

The linking protocol was designed to err on the side of caution and to not link records if a unique identifier was not present. Testing and validation throughout the development phase enabled refinement of the linking protocol. An independent consultant assessed the linking protocol and estimated 1.7% False Negatives (ie possible matches that weren't matched based on same name and DOB) and 0% False Positives (ie linking of different patients). During deployment, TKC will provide health services with audit logs of their source systems, identifying patients not matched due to possible data entry issues or missing details. These logs can be used for checking and updating details, quality assurance purposes and improving data integrity. With the implementation of the national eHealth record and the provision of an identifier unique to all registered patients, linking is expected to improve. Additionally, the DoH is due to complete the Enterprise Master Person Index (EMPI) project in late 2019 which will improve patient matching and linking.

The Likelihood of a False Negative hazard occurring is considered **Low** and the Severity is considered **Minor**.

Risk Evaluation Rating = 1

The Likelihood of a False Positive hazard occurring is considered **Low** and the Severity is considered **Major**.

Risk Evaluation Rating = 3

Hazard 4: TKC Clinical inference engine: relates to errors in the knowledge acquisition and knowledge engineering processes and the subsequent misinterpretation and application of clinical rules, resulting in suboptimal clinical information available to the CSU for clinical advice. Validation and testing of mapped clinical rules undertaken during development and testing phase resulted in refinements. All TKC outputs are reviewed and assessed by clinicians for alignment with medical decisions. Usual clinical systems available to CSU for patient review to confirm decision support. Phase one soft launch will allow further validation and testing of TKC inferences.

The Likelihood of the hazard occurring is considered **Low** and the Severity is considered **Considerable**.

Risk Evaluation Rating = 2

Hazard 5: Data Timeliness: refers to the delay in the extraction or receiving of clinical information from sources systems to the TKC data base with the potential for incomplete information available to the CSU. This is the current situation where the CSU receives adhoc and infrequent patient information. Access to source systems and usual processes remain. Automated secure extraction transfer processes have been built into source systems to counter manual and human error.

The Likelihood of the hazard occurring is considered **Low** and the Severity is considered **Minor**.

Risk Evaluation Rating = 1

Hazard 6: System unavailability: refers to the TKC database being unavailable to the CSU. Access to usual clinical information systems and business processes remain.

The Likelihood of the hazard occurring is considered **Low** and the Severity is considered **Minor**.

Risk Evaluation Rating = 1

Hazard 7: TKC opt-out: refers to the legislative requirement to provide a mechanism for patients to not participate in TKC and the risk of including their data in the TKC data base. Requires source systems to implement appropriate protocols for patient information and system changes to include the Opt-Out functionality. Testing and validation of the two-stage process to ensure the data of patients who are not participating in TKC is not collected from that source system **and all** other source systems has been successful. The clinical risk is related to the legislative requirements and the loss of trust of individuals and health services.

Data already in the system of patients who subsequently Opt-out is required to be deleted and a clinical hazard risk also exists of deleting information of patients who may be incorrectly linked. Processes will be implemented post deployment to ensure that data of patients subsequently choosing to Opt-out is double checked by a clinician, the Clinical Safety Officer and the System Administrator before deletion. However, data is not deleted from source systems and a refresh will replace data.

The Likelihood of the hazard occurring (Failing to opt-out) is considered **Low** and the Severity is considered **Minor, while the hazard for inadvertent deletion of** non-opt-out patient records is considered **Very Low** and the Severity is considered **Significant**.

Risk Evaluation Rating for both = 1

Hazard 8: Data security: refers to the non-compliance or breach of data security and management protocols resulting in identified information becoming publicly available. Functionalities with non-government source systems have been created to facilitate secure transfer of information. Requires health services to upgrade to Communicare 18.3. Additional measures will be available post deployment for sites that have not upgraded to encrypt and password protect files manually transferred to TKC. Data within TKC is managed under the auspices of the NTG and the DoH and abides by their data security, storage, management and access protocols.

The Likelihood of the hazard occurring is considered **Low** and the Severity is considered **Significant.**

Risk Evaluation Rating = 1

Hazard 9: Poor integration of TKC in CSU: refers to uptake and integration of TKC outputs within operational processes of the CSU. TKC has been designed with significant input from clinicians including the mapping of their current operational and clinical processes. Efficiencies in processes are already evident but uptake will be dependent on the individual. Close working relationships with the Project Team and the Health Informatics CNC and a controlled

deployment will ensure that appropriate procedures and training manuals are developed and assistance is readily available throughout the initial implementation phase.

The Likelihood of the hazard occurring is considered **Very Low** and the Severity is considered **Significant**.

Risk Evaluation Rating = 1

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