1 Executive Summary

In July 2002, the Clinical Indemnity Scheme (CIS) was established to rationalise the current medical indemnity arrangements by transferring to the State, via health boards (now the HSE), hospitals and other health agencies, responsibility for managing clinical negligence claims and associated risks. Under the scheme, which is managed by the State Claims Agency (SCA), the State assumed full responsibility for the indemnification and management of all clinical negligence claims. A key feature of the CIS is electronic incident reporting. In 2004 the introduction of the CIS's STARSweb system provided organisations with a central point for the recording of clinical incidents and near misses.

In order to maximise the benefit of the STARSweb system it was necessary to assure the quality and integrity of the data inputted, and thus the resultant information outputted. As a result, the three principal stakeholders involved in the process, the Health Information and Quality Authority (HIQA), the Health Services Executive (HSE) and the Clinical Indemnity Scheme (CIS), instigated a collaborative initiative. Health Care Informed (HCI) were successful in the tender process.

The STARSweb Evaluation Project (Phase 1), in line with the original joint tender document of 2006, aimed to achieve the following objectives:

1.0 *Quantitatively determine the quality of data within the STARSweb system in relation to:*

- **1.1** *Completeness of data*
- **1.2** *Appropriateness of data*
- **1.3** *Variations in the classification of incidents within and between organisations*
- **1.4** *Rate of non-anonymous data (i.e. identifying individuals involved) within free text fields*
- **1.5** *Stratification of data quality per Enterprise*

2.0 *Qualitatively determine, in conjunction with sample Enterprises' STARSweb data entry personnel and risk managers, the following:*

- **2.1** *STARSweb utilisation processes, levels and methods for promotion of use*
- **2.2** *Correlations between data quality levels and Enterprises' risk management activities*
- **2.3** *Validity of STARSweb Data against sample of actual incident occurrences*

The STARSweb Evaluation Project was conducted using best practice project management principles to maximise the effective utilisation of resources and adherence to the defined time lines. The evaluation processes incorporated:

- *Literature Review*
- *Data Quality Audit*
- *Service Users Web Survey*
- *Enterprise Interviews*

The findings from the Literature Review can be summarised as follows:

1. *Effective incident reporting systems require timely feedback*
2. *Staff should have an understanding of the incident reporting process as well as the incident reporting form*
3. *Incident reports should provide for contextual information*
4. *Quality assurance systems should be incorporated into the incident reporting process*
5. *Standardised taxonomies support effective analysis*
6. *There is a legislative duty for state authorities to report incidents in Ireland and other countries*
7. *The House of Commons Committee of Public Accounts, (CPA 2006) identified several weaknesses in the National Patient Safety Agency's (NPSA) National Reporting and Learning System (NRLS), in England and Wales, which may provide a learning experience for the Irish health system*
8. *There exists, in theory, a potential conflict in relation to the need to disclose information relating to clinical incidents and the need to maintain patient confidentiality*

The findings from the Data Quality Audit of the STARSweb system can be summarised as follows:

1. *Data submitted is generally appropriate and predominantly anonymous within free text fields.*
2. *The levels of clarity and comprehensiveness are reasonable.*
3. *A significant number of fields are not being utilised.*
4. *Non-utilised fields may be divided into unnecessary and require removal, optional for more significant events, or necessary and require reinforcing.*

5. *The incidents reported relate predominantly (39.2%) to patient slips, trips, and falls.*
6. *The incidents reported are of a predominantly minor nature (84.6%).*
7. *Very few events are recorded as being near misses (0.08%).*
8. *The nursing profession report the majority of incidents (85.8%).*

The findings from the Service Users Web Survey can be summarised as follows:

1. *Overall the majority of users rated usability of STARSweb as high.*
2. *Within some organisations STARSweb is not perceived, or only partially perceived, as part of their overall clinical incident reporting process.*
3. *Organisations' paper based incident reports were not entirely reflective of the STARSweb system.*
4. *Several fields identified as lacking in importance by service users were also proposed for removal in the Data Quality Audit.*
5. *A significant number of users identified Root Cause Analysis as an unimportant data field (30%).*
6. *The reporting functionality was deemed important but it is not being fully utilised due to a lack of training and perceived difficulty.*
7. *The quality assurance of data inputting, carried out by the Enterprises, requires enhancement.*
8. *Point of occurrence entry of incident data could be considered.*
9. *Data is rarely updated by the Enterprises.*

The findings from the Enterprise interviews can be summarised as:

1. *Administrators are the predominant users of the STARSweb system.*
2. *Administrators have limited, if any, risk management training.*
3. *Organisations were found to have significant differences in their incident reporting processes and related paper based forms.*
4. *Information relating to corrective or preventative actions, contributory factors or root causes was rarely sought by the enterprises.*

5. *Clinical incident data in STARSweb is rarely updated by the enterprises.*
6. *No data quality checks were identified as being carried out by the Enterprises after inputting in STARSweb.*
7. *There is a need for applied training, which incorporates risk management practices.*
8. *There is potential for the use of "point of occurrence" entry of clinical incident data.*
9. *There is user dissatisfaction with the current classifications used by the STARSweb system, including those relating to the general nature of events (43%).*
10. *Difficulties were identified in relation to the use of the reporting function.*
11. *There is a need to have clearly definable aims and objectives communicated, as many users were unclear if the focus of the STARSweb system related to claims management or risk management.*

It is clear from the results of the Data Quality Audit that there is a need to continuously monitor the quality of data being submitted via the STARSweb system. This confirms what was identified by HIQA, the HSE and CIS from the outset of the evaluation process and identified for development in Phase 2. It is proposed that, in the development of a quality assurance tool, consideration be given to continuous monitoring, supplemented by a regular in-depth audit.

In relation to the overall results, it was determined that the information submitted via the STARSweb system is currently not comprehensive. This relates to the fact that, in the majority of incidents, a large number of fields were not completed. In addition, there is bias towards the reporting of patient slips, trips and falls (39%), while 3% of incidents reviewed were classified as major/severe, with none classified as catastrophic.

The data that was submitted was found in general to be appropriate. Exceptions to this included determination of the risk ratings of incidents (52% inappropriate). This related to the mismatch of incident likelihood and/or incident severity being mismatched to the appropriate risk ratings.

No variance in classifications of incidents was identified between organisations. This was predominantly due to the fact that the majority of incidents, across all organisations, were classified as slips, trips and falls. The evaluation identified high levels of anonymity across the free text incident report fields, for example "Details of Event" data field had 87% of submissions deemed anonymous.

It was identified, from the results of the Service Users Web Survey and the enterprise interviews, that the STARSweb utilisation process within the organisations was varied and reflected the variance in the incident reporting processes and forms. No correlations were determined between the quality levels of the data submitted via STARSweb and the Enterprise activities.

In order to validate the data being submitted via STARSweb, samples were examined within the organisations against the actual paper based incident reports. The results found that all incidents had occurred and were clearly documented. The STARSweb data however lacked the comprehensiveness and clarity of the paper based records. This was primarily due to the interpretation, for the purposes of summary, and the lack of a quality check by the Enterprises following data input into STARSweb.

The overall conclusions identified that the STARSweb system is appropriate for the collection of data relating to clinical incidents, however some developments are required. These include a reduction in the number of fields, a refinement of the classification system, and the redevelopment of the reporting system.

It was identified that in order to increase the quality of data received, and the impact of the STARSweb system on patient safety, it is necessary to address incident reporting issues within the Enterprises, as well as the processes relating to the STARSweb system. The report identifies 15 specific recommendations relating to the Clinical Indemnity Scheme (CIS), the Health Services Executive (HSE) and the Health Information and Quality Authority (HIQA).