Digital NEWS-Assessing the Impact of the Syncrophi Digital National Early Warning Score

Report on Syncrophi Pilot
St Luke's Hospital Kilkenny
and
Health Innovation Hub Ireland (HIHI)

Report Prepared by

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Introduction

Extended life expectancy, an increasing older population and spiralling healthcare costs have triggered analysis on potential areas for efficiency while delivering better patient outcomes. There is significant evidence to support the clinical impact of early detection of patient deterioration and timely intervention [1, 2] . Rapid intervention at an early stage of health deterioration enables treatment at the earliest and least complex stage and has been shown to positively impact patient outcomes, for example in the case of early initiation of the Sepsis Six bundle [3]. In response to this, systems have been developed to monitor and detect patient deterioration - namely Early Warning Score Systems (also known as Track and Trigger systems). Early warning score systems have been in use in the UK, Australia and many European countries for the last ten or more years to positive effect [4].In February 2013, the Minister for Health Dr James Reilly issued Ireland's First National Clinical Guideline- the National Early Warning Score for Ireland (NEWS) [5] . Early Warning Scores facilitate the early detection of a patient's deterioration by classifying a patient's severity of illness – through the presentation of a 'score' which is calculated based on a number of clinical observations/measurements. For deteriorating patients, the NEWS 'score' triggers a specific care pathway and prompts nursing staff to request a medical review at specific time points[6]. The current NEWS protocol operational in the Irish public health system relies on the recording of a number of patient measurements (see Appendix 1) by nurses or other

healthcare staff; these are recorded on a standard NEWS chart (paper based) and a calculation of score is completed manually by the nurses by applying weighted scores to each individual vital-sign parameter (see Appendix 1 for paper NEWS chart).
There have been a number of published studies and audits on the NEWS in Ireland including a Health Information Quality Authority (Health Technology Assessment Report[7]) review of health economics [8] and the HSE Healthcare Audit End of Year Report 2017[9] lists QAV005/2017- *An audit on the implemention of selected guidelines on the National Early Warning Score 2014* as a report in progress as of December 2017, with the report due April 2018 (unpublished as of January 1, 2019). However, the assessment of human error in implementing a paper based NEWS system has not been completed in a public hospital in Ireland. A study has been completed in a *private* hospital in Ireland, the 160-bed Galway Clinic and their various audits demonstrated error rates of between 37% and 50% based on the use of standard paper NEWS charts. Similarly, error-rates of up to 40% have been published by a leading UK NHS hospital, the Golden Jubilee National Hospital in Clydebank, Scotland (see Figure 1 and Figure 2). Both of these institutions published their findings and embarked on a program of rapid improvement.

The aim of this study was to compare error rates between NEWS recordings made using the paper version versus a digital capture version of NEWS using the Syncrophi KEWS 300 system.

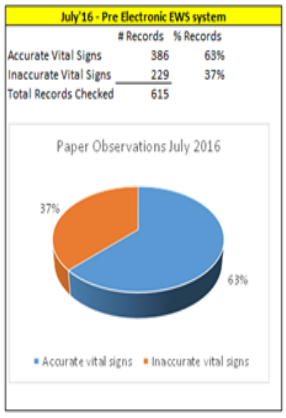
Syncrophi is an Irish company who has developed a digitial system to capture NEWS observations and present them in a manner that allows easy tracking, auditing and monitoring of NEWS scores and subsequent escalation processes for all patients. The information for all patients is presented on a tablet and can be viewed/managed at the bedside and also at the nurses' station to ensure overview of all patients. With the Syncrophi system (KEWS 300), the NEWS observations are recorded automatically on a digital chart (presented at patient bedside on a tablet). Where observations cannot be recorded using a linked vital-sign monitor (for example 'patient alertness' which is a visual assessment), the nurses input the value directly to the digital chart, the NEWS score is calculated automatically and the appropriate escalation/response is displayed.

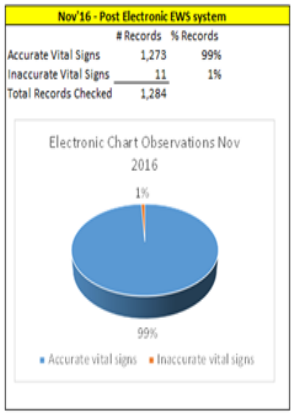
The platform allows the clinical staff at the nurses station to have sight of all patient NEWS scores and vital-signs on a single screen (currently these are only available by manually checking the patient charts). The status of each patient (based on score) is presented in an easy to assess, colour coded format with time remaining until next NEWS recording clearly visible on screen.
In conducting the study we also took the opportunity to assess the degree of staff compliance with the specified time-limits for repeat patient observations. The frequency of observations is governed by the value of the patient's NEWS score, with higher scores demanding more frequent observations. Although KEWS300 provides a definitive 'time-to-next-observation' countdown clock for each patient, which can alert staff to observations falling due, it is clearly a staff management and resourcing matter to optimise compliance. In the AMAU study it was noted that delayed observations were running at over 20% throughout the very busy Winter period regardless of whether staff were using the paper-based system or were using KEWS300. Since timeliness of repeat observations is an important contributor to optimum patient management this is certainly a topic that

deserves further examination by the HSE. (The relevant data is presented in Appendix 8.) For the purposes of this study however we have excluded errors of staff work-scheduling from our analysis. For avoidance of doubt, neither the Galway Clinic nor the Golden Jubilee National Hospital included observation time delays in their published NEWS error reports.

Study Background

When acute hospitals implement the current Clinical Guideline for NEWS they record a number of standard patient measurements on a paper chart (Appendix 1). They then calculate a NEWS score for the patient and this score is an indicator of patient deterioration. Depending on the score, a care escalation process is followed. This clinical guideline was introduced in order to increase patient safety and to identify at-risk patients early in the care pathway. A number of recent studies (Figure 1 and 2) have demonstrated the power of implementing the digital EWS system. In Figure 1 the error rate on the charts in the Galway Clinic dropped from 37% to almost 0% and in Figure 2 the NEWS error-rate in the Golden Jubilee National Hospital in Scotland is shown to be as high as 40% in the year prior to the trial. The result from a one-month trial in a 28-bed ward at Golden Jubilee National Hospital, was that they achieved a 0% error-rate which led to them electing to buy the system for hospital-wide application (which has now been implemented) and showcasing it to the Scottish Health Minister.





Audit 1 - Paper Charts				
Chart	# Records Checked	Correct Records	Record Errors	Anomalies to Audit
1	3	2	1	0
2	3	2	1	0
3	3	2	1	0
4	3	2	1	0
5	3	3		0
6	3	3		0
7	3	3		0
8	3	2	1	0
9	3	1	2	0
10	3	1	2	0
11	3	2	1	1
12	3	2	1	0
13	3	2	1	0
14	3	1	2	0
15	3	1	2	0
16	3	2	1	1
Total	48	31	17	2

% of Anomalies	4.2%
Compliance Rate	95.8%
EWS Error Rate per Validation:	35.4%
EWS Error Rate per Audit:	37.0%

Audit 2 - Electronic Charts				
Chart	# Records Checked	Correct Records	Record Errors	Anomalies to Audit
1	3	3		0
2	3	3		0
3	3	3		0
4	3	3		0
5	3	3		0
6	3	3		0
7	3	3		0
8	3	3		0
9	3	3		0
10	3	3		0
11	3	3		0
12	3	3		0
13	3	3		0
14	3	3		0
15	3	3		0
16	3	3		0
Total	48	48	0	0

% of Anomalies	0.0%
Compliance Rate	100.0%
EWS Error Rate per Validation:	0.0%
EWS Error Rate per Audit:	0.9%

Figure 1 Galway Clinic error rate analysis

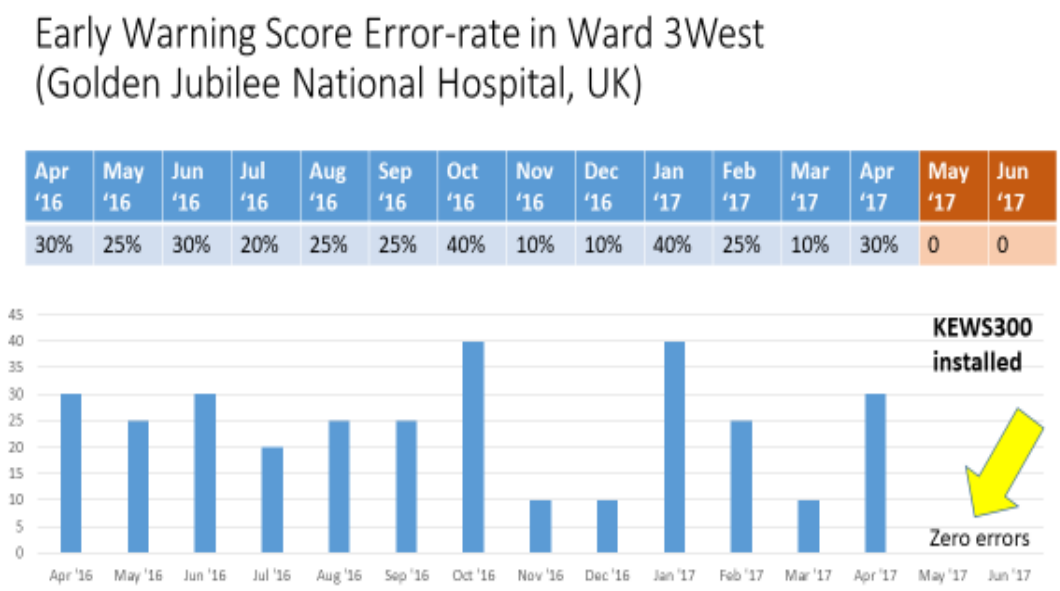


Figure 2 Glasgow Golden Jubilee Study- error-rate before/after KEWS300 implementation

Objectives of Pilot

The objective of this study was to assess whether using the KEWS 300 digital system to record and calculate the NEWS in the AMAU of St Luke's Hospital in Kilkenny reduced error rates compared with the paper version.

The aims of this study were:

(1) to measure the impact on charting and scoring errors compared to the paper version

(2) to measure staff satisfaction and feedback on using the digital version versus the paper version

Structure of Pilot

The pilot was conducted in the Acute Medical Assessment Unit (AMAU) of St Luke's Hospital, Kilkenny.

The clinical Lead for this project was Professor Garry Courtney. Professor Courtney identified the clinical team members from St Luke's who were involved in this project (see below for names and roles). After an initial meeting with the project team, a HIHI Project Plan was agreed (see Appendix 2).

Ethics approval from Waterford CREC was submitted and approval was received in January 2018 (see Appendices 3 and 4 for Ethics Submission and Approval Letter).

Syncrophi installed the necessary equipment in the AMAU of St Luke's Hospital and interfaced them with the existing vital-sign monitors on the ward.

IT integration required that the KEWS300 software be installed on the local HSE server and interfaced with the Patient Administration system.
This work was completed by Alan Busher from the HSE IT staff and the Syncrophi team.

All staff in AMAU were trained by Syncrophi with two super-users trained on the system to assist nursing staff. Amanda Kelly and Maura Hussey Ryan received additional training.
The pilot was conducted over a period of 9 weeks beginning 6th March and ending May 3rd. It was agreed that the digital system would not operate between the hours of 10pm and 7am. This was because of the reduced number of nursing and support staff on duty at those times and the frequent use of agency staff who do not have signing authority and would not have been trained to use the system. In order to ensure continuity of NEWS recordings and to ensure no deviation from standard practice a paper version of the chart was printed daily and included in the patient charts.

Entry Criteria:
All adult AMAU patients that would usually receive a NEWS score were included in the study.

Exclusion Criteria: Pregnant women, children (those under 16 years of age) whose different physiology precluded the use of NEWS. [Note: KEWS300 also supports the Irish Maternity Early Warning Score (IMEWS) and the Paediatric Early Warning Score (PEWS) however these were outside the study scope submitted for Ethics approval]

Procedure: Following notification of the Ethics Committee approval, the Syncrophi units were installed in the AMAU and linked to a dedicated database managed and housed by HSE IT. Nurses continued to manage the care of patients following the standard clinical guideline currently in place for the paper version of NEWS. However this was achieved through recordings which were made digitally using the Syncrophi system and through automated on-screen prompts and guidance regarding the appropriate escalation protocol. At 10pm each night, when some HSE staff were replaced by temporary staff, the Digital NEWS recorded during the day was printed on paper and included in the patient chart. Manual recording on the paper chart continued until the next shift change where HSE nurses were again in the AMAU. If patients were moved from the AMAU to another unit, the digital chart was printed and included in the patient chart/records.

Device: The Digital NEWS was recorded on the KEWS 300 system. This system is CE marked Class II and is already in use in Ireland and in the UK.

Data Storage: Digital NEWS records were stored on a dedicated HSE Server for the purposes on this study. A paper version of the Digital NEWS recording was printed and will remain in the patient's charts as the permanent record. The data will be removed from the server once the study analysis and Project Report has been completed.

Data Analysis: Data Analysis involved the review of 20 paper charts, selected randomly from patients who were admitted to the AMAU in St Luke's Hospital, Kilkenny during the month of November 2017. The de-identified paper charts were reviewed by two CNM2 HSE Nurses working with HIHI. The charts were randomly distributed between both nurses, each chart was reviewed for each required observation and other required information (e.g. date, time etc.) and the scores were recalculated and compared against the score recorded on paper. If any queries arose on a chart, the chart was referred to the other nurse reviewer and results agreed.
All errors were recorded on an error capture/audit tool which records the type of error recorded (see Appendix 6 for error types), the impact on the patient (type 1 or type 2 errors) and provides a final error analysis based on all NEWS observations reviewed.
A similar analysis was performed on the digital charts recorded during the period of the Syncrophi system pilot.

Project Team
HSE:
Clinical Lead- Professor Garry Courtney
Nursing Lead: Amanda Kelly
Specialist Registrar: Dr. Carthage Moran
IT Lead: Alan Busher
Technical Service Manager: Charlie Murphy

Syncrophi:
Dr Colm Connolly- Syncrophi Project Manager
Project lead, IT system installation, staff training, technical support, assistance with ethics preparation and data review
David Toohey- Syncrophi CEO.

HIHI and HSE Staff assigned to HIHI:
Dr Tanya Mulcahy- Project Lead- HIHI
Project oversight, ethics preparation and submission, project management, data review and final report.
Ms Niamh Allen, CNM2, HSE: Data Analysis and review of final report
Ms Noreen Lynch, CNM2, HSE: Data Analysis and review of final report.

Results
Data Analysis:
Error analysis was performed by Ms Niamh Allen CNM 2 and Ms Noreen Lynch, CNM 2, both nurses have been assigned by the HSE to work part-time with HIHI.
20 paper patient charts from November 2017 were selected at random. Patient names and personal information were removed from view. 129 sets of NEWS observations from the 20 charts were reviewed for errors and recorded in an error analysis template/audit tool as described above in Data Analysis (see Appendix 5). Charts were returned to the patient records.

17 digital patient records were selected at random from the HSE server (covering the period of the digital pilot on the Syncrophi system). Patient names and personal information were removed. 105 sets of NEWS observations were reviewed for errors and recorded in an error analysis template/audit tool (Appendix 5).

Definitions:
NEWS Observations (Obs): A set of NEWS observations within a chart. A chart may have a single set of observations (at a single time point) or may have multiple observation sets, at multiple time points- this depends on how long the patient remained in the AMAU. A patient in the AMAU for 24 hours would have at a minimum 3 sets of Obs.
Type 1 error: this error type did not have an impact on the clinical intervention or score. These errors are listed in the Appendix 6. They do impact record managment (missing infomation), and can add time to a process where patient infomation, ward numbers, dates etc. are incomplete or missing.
Type 2 errors are those that relate to a patient's clinical outcome and may impact intervention, such as an incorrect value being recorded, observations omitted, illegible entries or incorrect calculation of the NEWS score. A full list of error types is provided in the Appendix 6.

Incomplete/Partial Observations:
An incomplete observation is where there appears to be some recordings missing so that the set of observations is incomplete. This could have been an error in completing the NEWS process or could have been a nurse wanting to conduct an interim check on a single vital-sign parameter e.g. Blood Pressure. While we found many partial observations, that would be considered an error by most clinical staff, in order to ensure only true errors were assessed, any incomplete observations that did not have a score were removed from the analysis. [Note: this is a conservative interpretation and likely understates the true error-rate in paper charts].

Results:
Paper NEWS Charts:
129 sets of observations were reviewed for accuracy from a selection of 20 paper NEWS charts. 5 partial observations were noted and removed from the analysis, leaving a total of 124 sets of observations. Errors were classified as **Type 1** or **Type 2** errors.

98 of the observation sets had errors from the total of 124 observation sets from paper charts. **This represents an error rate of 79% overall** (98/124).
Most observation sets had more than one error. Eighty-one of the observation sets had one or more Type 1 errors and 61 of the observation sets had one or more Type 2 errors.
This finding is critical: that **49% of observation sets had Type 2 errors** (61/124) – each of which could have an impact on clinical intervention and patient outcome. (See Figure 3)

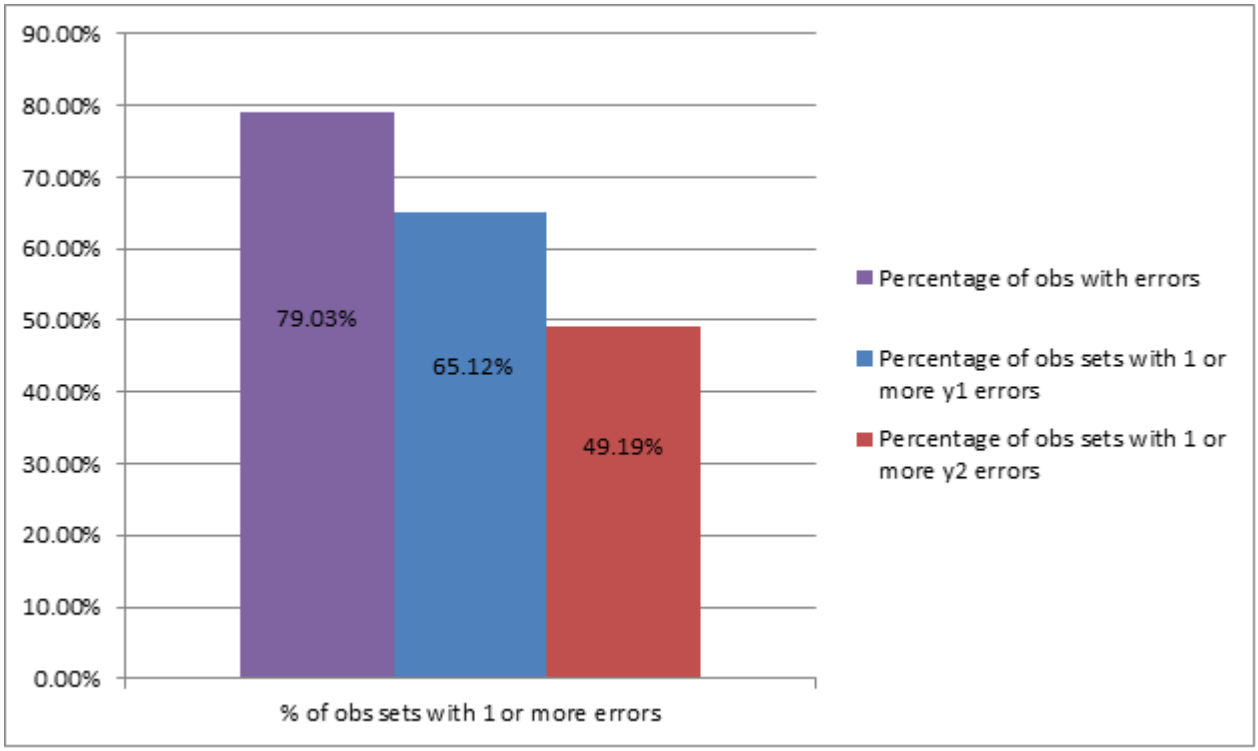


Figure 3 Error-analysis for paper-based NEWS process

A further review of the Type 2 errors highlighted 18.5% where the handwritten observation could not be read and 36% where the observation set was not added up correctly, giving an incorrect NEWS score.

Digital NEWS Charts:
A total of 105 observations were reviewed from a selection of digital NEWS charts. 6 partial observations were noted and removed from the analysis, leaving 99 sets of observations. With regard to the accuracy of vital-sign charting and NEWS score calculation there were no Type I or Type 2 errors found….i.e. **0% error-rate with the KEWS300 system**. (See Figure 4)

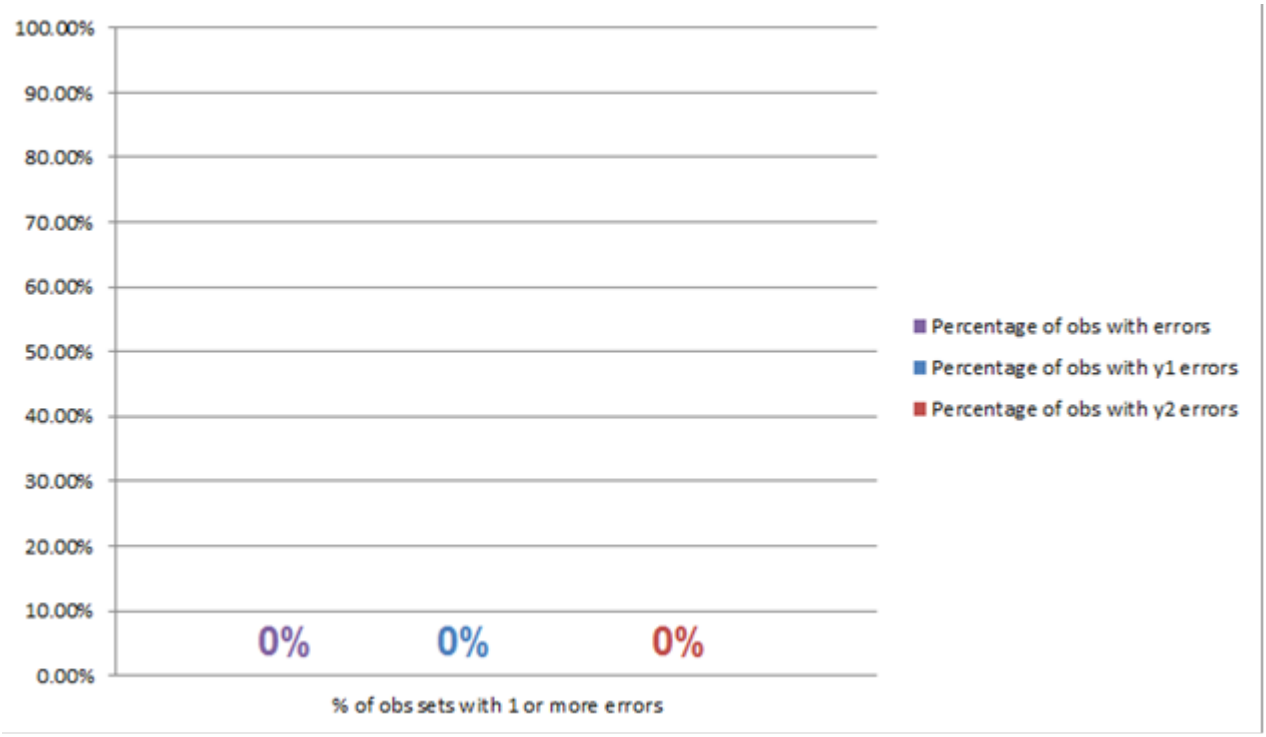


Figure 4 Error analysis for KEWS300-based NEWS process

Survey

As part of the Digital NEWS study, staff who participated in the study were asked to complete a survey. The survey was administered and analysed by Dr Carthage Moran, a Specialist Registrar working within the AMAU.

Survey results

Aim: To measure the ease of use, impact on patient care and personal productivity when using the computerised KEWS300 system, compared to the paper version and to measure the compliance rate for recording NEWS compared to the current rate with the paper version. This was conducted via a survey recording AMAU nursing team feedback on using the digital version versus the paper version.

Methods – The KEWS300 digital system was used in a nine-week trial, at the end of which an anonymous survey was implemented to look at the objective key points. An anonymous 10-question survey (see Appendix 7) was used to measure the degree of acceptance by staff towards using the KEWS300 digital system when compared to the paper version. The survey was also designed to capture the ease of use, impact on patient care and personal productivity when using the digital system. Answers were either on a numerical scale or were binary in nature. Free text space was available for comments on the system. The population sampled for the survey were the 16 staff grade nurses at varying levels of experience who were working in the medical assessment unit. 14 nurses completed the

survey and raw data was inserted into an excel spreadsheet to assess the primary endpoints.

Results – 93% of the AMAU nursing staff involved in the trial reported that they found the KEWS300 system to be much better in terms of its impact on patient care with only 7% reporting that they noted no change. (See Figure 5)

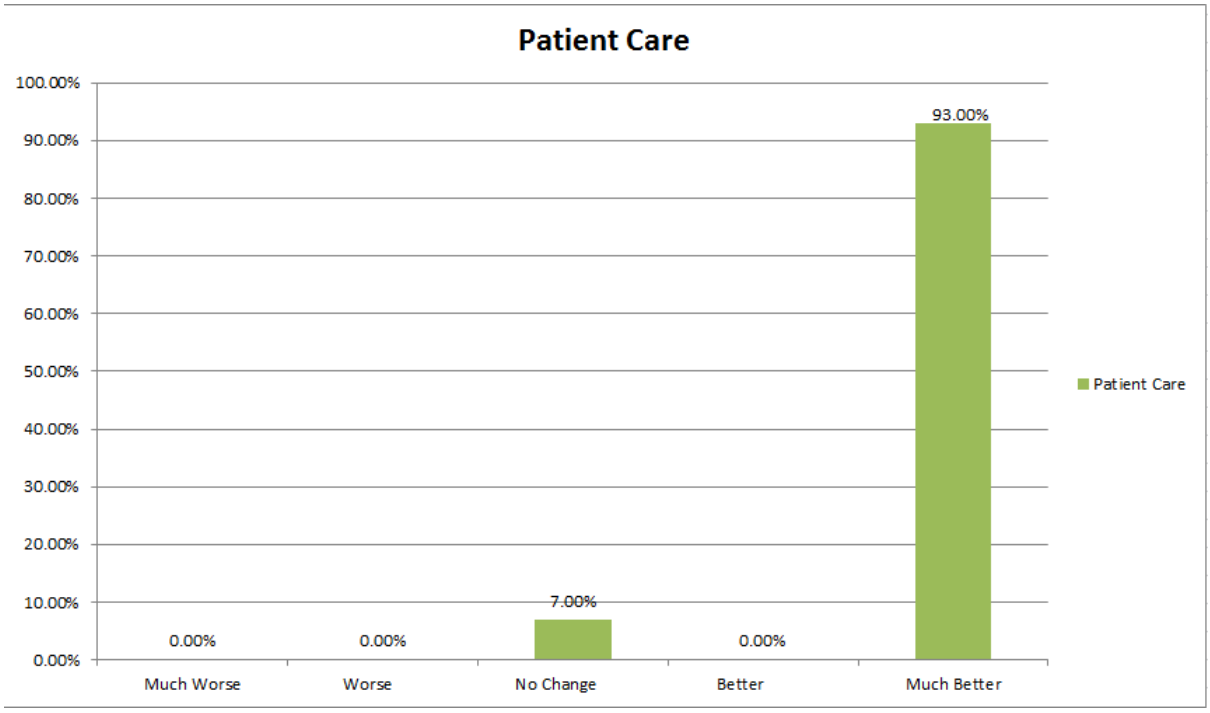


Figure 5 KEWS300 Impact on Patient Care

Seventy-nine per cent of the sample size expressed a much better level of personal productivity using the digital system, while 14% reported a better level, and 7% reported no change. (See Figure 6)

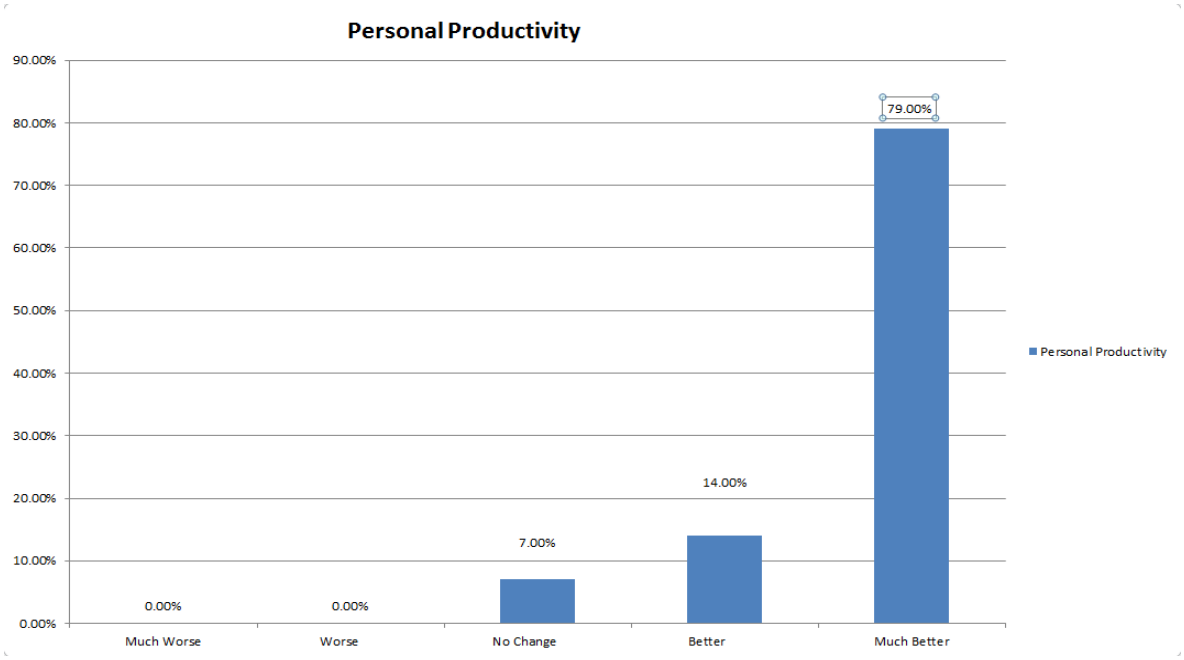


Figure 6 Impact of KEWS300 on Personal Productivity

In terms of the system's ease of use 71% of AMAU nursing staff found the KEWS300 simple to use, 21% rated the ease of use as good, and 7% rated this as poor. (See Figure 7)

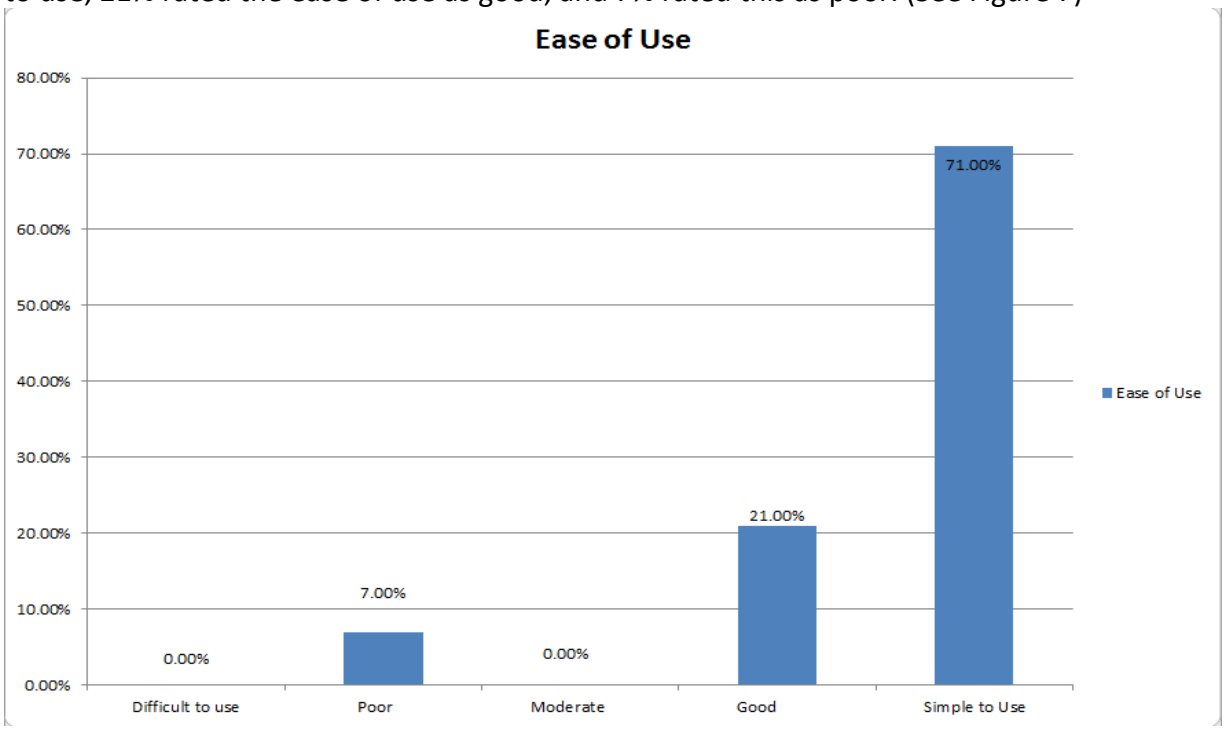


Figure 7 Assessment of KEWS300 regarding Ease-of-Use

There was no difference apparent from the survey in the compliance rate for recording NEWS using the computerised system compared to the current rate with the paper version.

However, in their comments staff reported that what they liked most about the KEWS300 system was that it prompted them to carry out observations when they were due. Other comments noted were that the system was more efficient, more patient-centred and that it was easier to identify when escalation of patient care was required.

Conclusion – Through a survey recording AMAU nursing team feedback on the computerised KEWS300 system, it was found that patient care, personal productivity, and ease of use was significantly enhanced when compared to use of the paper version.

Project Conclusion and Assessment of the Potential Impact to Healthcare.

The results of the HIHI led review of the impact of a digital system in recording and managing NEWS demonstrates unequivocally that replacing a manual paper-based activity with a semi-automated, digital version, **increased productivity,** increased **staff satisfaction** particularly as the 'prompt' system allowed them to record NEWS for all their patients in a more time efficient manner- thus leading to a sense of 'control' and 'completion' amongst the staff. The ability to review the status of all patients on a single screen at the nurses' station provides additional **centralised oversight and management** of all patients, so that in addition to the normal escalation process (where patients have a relevant NEWS score), the status of these patients and follow-up can be monitored centrally so that where follow-up has not occurred, earlier intervention can be triggered.
However, the most important result from the study is that error rates in recording NEWS on the current paper based system are unacceptably high- **with 49% of observation sets having errors that could significantly impact patients** (Type 2 errors). By introducing a semi-automated digital version, the opportunities for human errors (relating to transcription, illegibility, miscalculations, omissions etc) are minimised so that overall error rate (for Type 2 errors) was **reduced from 49% to 0%** . While we did not conduct a review of the impact of errors on the patients, it is well documented that clinical intervention at the earliest stages of deterioration results in better patient outcomes and in the case of sepsis, as an example, may prevent admission to ICU and reduce mortality risk significantly while also avoiding the major cost-escalation associated with high-acuity care settings. It has been shown that non-compliance with the '6-hour sepsis bundle' is associated with a more than two-fold increase in hospital mortality[10].

HIHI recommends that, based on this report, a digital NEWS systems should be considered at a national level, where consideration should be given to patient outcomes, current error rates, potential cost savings (based on early intervention) and staff and patient satisfaction. The implementation of NEWS is a positive action, endorsed by outcomes in other countries. However its impact becomes seriously undermined when unacceptable error-rates compromise its predictive/preventive capabilities.
Ireland should, at the very least consider a digital NEWS system for any new units to be established in hospitals and should consider cost versus impact for a roll-out of a digital system nationally.

References:

1. Downey C.L. et al. Strengths and limitations of early warning scores: A systematic review and narrative synthesis. *International journal of Nursing Studies* 76 2017 106-119
2. Andersen L.W. et al The Prevalence and Significance of Abnormal Vital signs Prior to In-Hospital Cardiac Arrest. *Resuscitation* 2016 January; 98:112-117
3. https://bmjopenquality.bmj.com/content/2/2/u202548.w1443
4. Smith G.B. et al. The ability of the National Early Warning Score (NEWS) to discriminate patients at risk of early cardiac arrest, unanticipated intensive care unit admission, and death. *Resuscitation* 2013 84:465 -470
5. https://www.hse.ie/eng/about/who/cspd/ncps/acute-medicine/national-early-warning-score/national-clinical-guideline/
6. Mitchell I.A. et al. A prospective controlled trial of the effect of a multi-faceted intervention on early recognition and intervention in deteriorating hospital patients. *Resuscitation* 2010 Jun;81(6):658-66
7. (https://www.hiqa.ie/sites/default/files/2017-01/HTA-of-use-of-information-technology-for-early-warning-and-clinical-handover-systems.pdf
8. Murphy, A., Cronin, J., Whelan, R. et al. Economics of Early Warning Scores for identifying clinical deterioration—a systematic review. Ir J Med Sci (2018) 187: 193
9. https://www.hse.ie/eng/about/qavd/audit-service/healthcare-audit-end-of-year-report-2017.pdf
10. Gao F. et al. The impact of compliance with 6-hour and 24-hour sepsis bundles on hospital mortality in patients with severe sepsis: a prospective observational study *Critical Care* 2005 9:R764-R770

Signature Page

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Professor Garry Courtney
Clinical Director
St Luke's Hospital, Kilkenny

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Signature: Date:

Mr David Toohey
Chief Executive Officer
Syncrophi Systems Limited.

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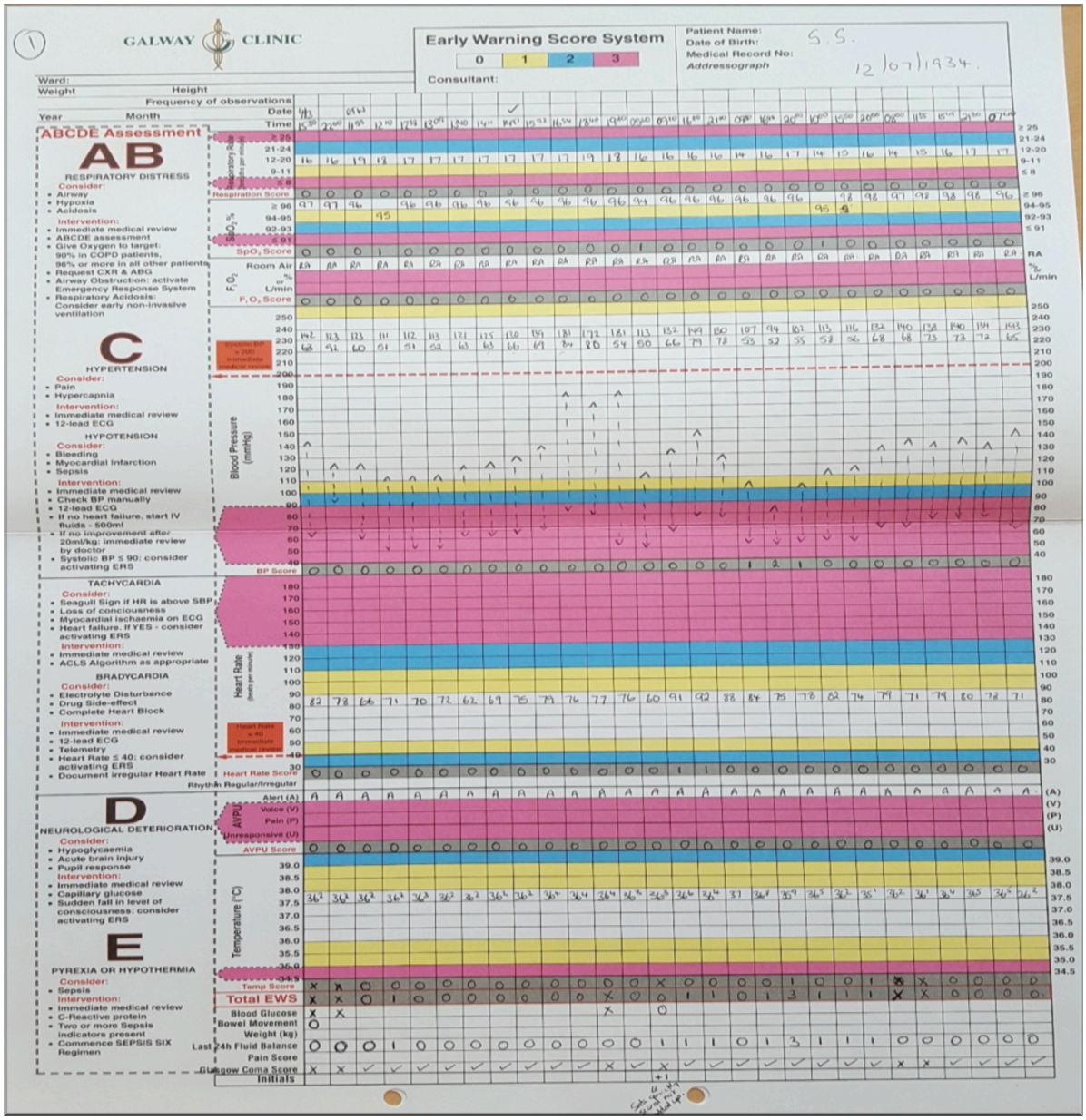
Signature: Date:

Dr Tanya Mulcahy,
National Manager
Health Innovation Hub Ireland

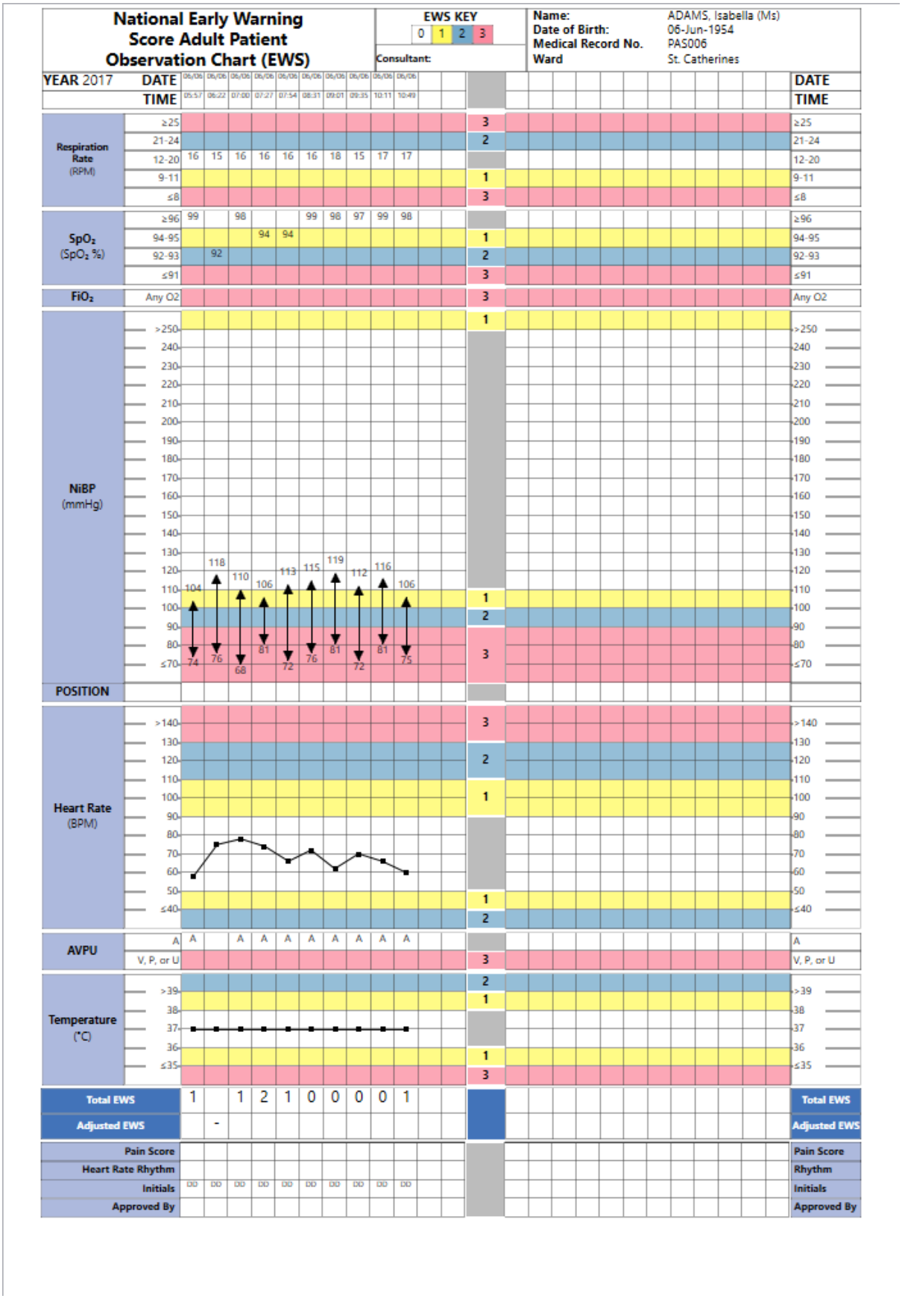
Appendix:

1. Paper NEWS Chart and digital KEWS 300 Chart
2. HIHI Project Plan
3. Ethics Submission
4. Ethics Approval
5. Error Analysis Template.
6. Description of error types
7. Staff Survey.
8. Notes regarding adherence to time schedules

Appendix 1. **Paper NEWS chart**



Digital KEWS300 NEWS chart (printable on demand, or viewable on-screen)



Appendix 2.
HIHI Project Plan

Project Initiation Document and Plan

Project Name:

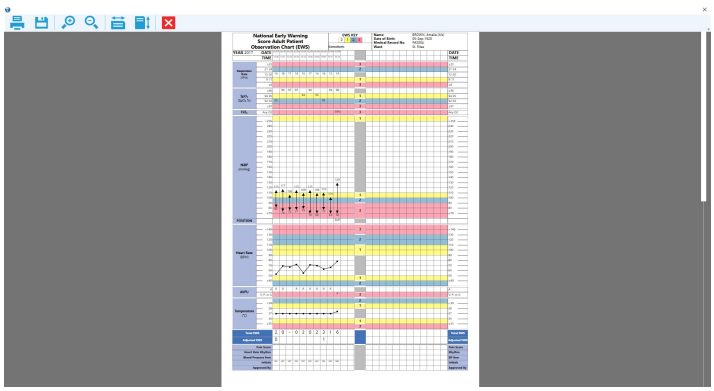
Syncrophi KEWS 300 Pilot in the AMAU St Luke's General Hospital Kilkenny

Parties Involved

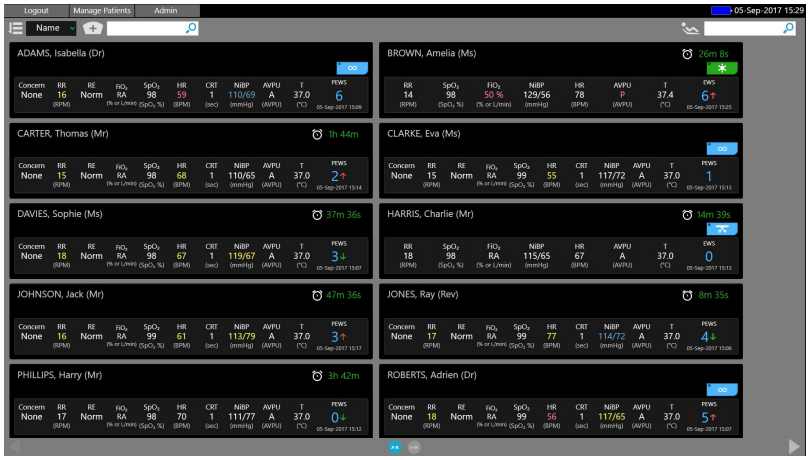
Syncrophi
St Luke's Hospital Staff
Health Innovation Hub Ireland

Project Introduction:

In 2013 the Minister for Health Dr. Reilly launched the first National Clinical Guideline - the National Early Warning Score for Ireland.
The NEWS system currently operates as a paper based system where the caregiver records a series of standard observations on an approved NEWS document. They then calculate the NEWS score and this score gives an indication of risk. An escalation protocol is in place for the management of patients based on the NEWS score.
Recording NEWS is a manual process. A nurse is required to first complete the NEWS form by manually recording a series of patient observations (e.g. blood pressure, temp) The nurse then calculates the NEWS score using the recorded numbers and this provides a final NEWS score. The NEWS score is an indicator of patient risk. An escalation protocol is linked to the scores.
Studies by The Galway Clinic and Golden Jubilee Hospital ,UK indicate an error rate for paper based capture of EWS is close to 40% (Galway Clinic poster and Golden Jubillee Hospital report).
Staff compliance is impacted by the cumbersome nature of the NEWS sheet and the time it takes to complete the process manually.



KEWS 300 is a software product which is deployed in hospital settings at point-of-care. It allows the caregiver, such as a Nurse, to complete Patient observations in a digitally-supported mode through the use of a Tablet touchscreen which is Wi-Fi-linked to the Central Station of the Ward and also to the Server. The System can be linked to whatever patient management process exists within the hospital (example NEWS). In this project the National Early Warning Score (NEWS), which is currently paper based, has been digitized on the system, devices linked to KEWS 300 automatically record a number of the required measurements while the nurse records some others (not currently supported through external devices). The NEWS score is calculated and presented as a dashboard with alerts and escalation steps in line with NEWS.



The objective of this project is to undertake an evaluation of KEWS 300 NEWS system within a single ward (AMAU) within St Luke's. Professor Garry Courtney is the Clinical lead for this project. Prof Courtney is a National Clinical Lead for the Acute Medicine Programme and a sponsor of the National Early Warning Score and associated Education Programme within the HSE

Project Scope:

Adult patients within the AMAU of St Luke's General Hospital will have NEWS observations monitotred using the KEW300 system for a period of 4 weeks (this may be extended at 2 week review stage). Patients will be monitored on KEWS 300 between the hours of 9am and 10pm when the permanent nursing staff are in the unit. After 10pm a paper version of NEWS will be printed for incoming staff (at handover) and this will be used between 10pm and 9am. When patients are released from the AMAU a final paper version of the NEWS recordings will be printed and included in the patient chart.

Out of Scope:

- 24hour monitoring (monitoring will be stopped at 10pm and continued at 9am in the morning)
- Irish Maternity Early Warning System *(*IMEWS*)*
- Paediatric Early Warning Score (PEWS)

- Revert back to paper for any out of scope patients patients
- Temporary night-time staff will not be trained or required to use the KEWS 300 for NEWS.

Objectives

Details of the agreed scope of the evaluation :

- Location will be AMAU
- All patients within the trial area will be monitored using KEWS 300 system for the duration of the evaluation.
- All registered nurses, health care support workers and nurse practitioners will be trained and will use KEWS 300
- NEWS and other additional information to be included e.g. pain score
- Interface with PAS / EMR for demographic data
- Interface with Vital sign monitors Mindray imec 10 and Dinamap V100
- Upload of PDF report on patient discharge to designated networked folder
- Role based access controls to be agreed – specifically for non-registered nursing staff (student nurses)
- Access to remote support to be provided

Responsibilities:

Syncrophi will undertake to:

- develop the required interfaces
- provide equipment and software for monitoring of EWS
- provide details of NEWS trigger protocol and amend where required

o Not deviating from the National guidelines

- provide training for agreed staff
- provide support for the trial

St Lukes will undertake to:

- provide a Location / Ward to run the pilot (AMAU)
- provide “staff” to run the pilot once up and running
- provide vital Sign monitor devices for trial
- provide vital Sign monitor device to Syncrophi to test interface
- provide required server capacity and Wi-Fi capability
- provide specification for interfaces (PAS / EMR / HIS / Vitals monitor / etc..)
- provide IT infrastructure schematic (how everything is interfaced)
- liaise with third party suppliers where required
- develop revised operating procedures for the period of live usage of KEWS 300

HIHI will undertake to

- Project manage the role out of the system
- Develop Evoluation criteria
- Link with Senior HSE staff members to help expedite any issues that might arise

o getting approval for the use of Wi-Fi for the trail

- Mediate any problems that might arise between St Luke’s and Syncrophi

St Luke’s, Syncrophi & HIHI will jointly :

- develop evaluation criteria

- test the system integration prior to sign-off
- test the various system outputs prior to sign-off
- agree and sign-off support agreement to cover pilot

agree and sign-off on configuration documentation

Project Team

HIHI Project Lead	Tanya Mulcahy	t.mulcahy@ucc.ie
St Luke's Clinical Lead	Garry Courtney	Garry.Courtney@hse.ie
Syncrophi Project Manager	Colm Connolly	colm.connolly@gmail.com
Syncrophi Support	Michael Curley and Colm Connolly	michael.curley@syncrophi.com
St Luke's Nursing Team	Carolline Egan Amanda Kelly Emer Tyrrell	Caroline.Egan1@hse.ie emer.tyrrell@hse.ie
Assistant Director of Nursing AMAU	Helen Roche	Helen.Roche2@hse.ie
St Luke's IT Lead	Alan Busher	
St Luke's Bio-engineering Lead	Charles Murphy	Charles.Murphy@hse.ie

Milestone List

- Engagement with clinical team in the AMAU in St Luke's and approval for project to proceed.
- PID approval
- Ethics application – preparation and submission.
- Testing of KEWS300 on in AMAU.
- Development of Project Protocol (including training guide)
- Technical infrastructure, interface and support requirements agreed with eHealth / Supplier and implemented
- Readiness Assessment to be undertaken and signed off by SRO prior to go-live
- Installation of KEWS and test run
- Development of evaluation protocol- baseline, data measurements, surveys etc..
- Staff training at St Luke's
- Go-live (for 4 weeks)
- Mid- stage review (2 weeks)
- Extension or wrap-up?
- Close
- Data collection and report writing.
- St Luke's Publication?
-

Constraints

- Any additional requirements outwith project scope
- Baseline measurements not undertaken
- Staff training and support incomplete
- Business processes not clearly documented
- Communication with stakeholders incomplete or insufficient
- Technical issues related to interfaces or IT

Project Management Process.

The role of the Project Manager is to ensure the project plan is developed and agreed by all parties, to ensure that all stakeholders are aware of their responsibilities and to facilitate and manage all parties in the delivery of project milestones and final project outcome in as close to the agreed timeframe as possible. The Project Manager will facilitate project team meetings, will manage team communications and progress reports and will identify and escalate any problems or issues to the HIHI team if required.

Communications Plan

The Project Manager will manage all team communications and oversee project updates

Scope change and problem management

Any changes in scope should be addressed through the Project Manager to the Project Team. Scope changes should be agreed by all parties. Problems will be managed at a local level initially and escalated to the relevant personell if required.

Project Notes:

Questions from Colm to answered by St Luke's Team.

IT questions:

- IP address
    - We will need a IP per wall mounted device (I believe that is 10 Mindray IMEC 10s). Plus 2 IP's for the mobile vital sign monitors. 1 for the central station.
    - These IPs will need to be on the same network as the KEWS server!

- Backup drive
    - Do we have access to network storage to back up the KEWS300 patient database

- Remote Access to KEWS server
    - We would need remote access to the KEWS300 server to help support the trial

- Active directory connection

- Can we connect within your domain
- Do we need certificates
- Do you use group policies?
  - Can we setup a group policy for the trial with specific attributes for the tablets (I can supply the policy)

- Central Station location
  - We will be suppling a central station to monitor the patients EWS. This needs to be stationed at the main nurse's station.
  - Will there be room available for a 23" touch screen computer?
  - Will there be a spare Ethernet port for the above computer

- Network Storage
  - Is there a network storage where we can save the patients charts to (In PDF format)

- Wi-Fi
  - We will need access to hospital Wi-Fi to run the trial. (the mobile carts / tablets need to communicate with the server over wifi)
  - What type of Wi-Fi is available? 2.4Ghz / 5Ghz.
  - What type of encryption is used?

- PAS interfacing
  - I believe you have iPMs as the Patient administration system we will need to get a ADT feed off it somehow. Who will we need to talk to get the interface working?

- Virtual Machine
  - Can you supply a VM for the trial so we can install our server on it.

    Min Server spec
    - **Windows Server 2012 R2 or windows 2008R2**
    - Quad core
    - 8 Gb ram
    - 100Gb hard drive space
    - **SQL server 2012** (express is ok for the trial)

STANDARD APPLICATION FORM

For the Ethical Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study: _____Digital NEWS.
Assessing the impact of a Digital National Early Warning Score

_____

Application Version No: _____1_____

Application Date: _____

For Official Use Only – Date Stamp of Receipt by REC:

This Application Form is divided into Sections.

*Sections A, B, C, D, E, J and K are **Mandatory.**

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

IMPORTANT NOTE: Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL WHEN COMPLETING THIS APPLICATION FORM.

SECTION A GENERAL INFORMATION

SECTION A IS MANDATORY

A1 Title of the Research Study:

Assessing the impact of a Digital National Early Warning Score

A2 (a) Is this a multi-site study? No

If you chose 'yes' please delete questions A2 (e) and (f), If you chose 'no' please delete Questions A2 (b) (c) and (d)

A2 (e) If no, please name the principal investigator with overall responsibility for the conduct of this single-site study.

Title: Prof. **Name:** Garry Courtney
Qualifications: MB FRCPI
Position: Clinical Director
Dept: Medicine
Organisation: St Luke's Hospital, Kilkenny
Address:
Tel: 0567717110 **E-mail:** garry.courtney@hse.ie

A2 (f) For single-site studies, please name the only site where this study will take place.

St Luke's General Hospital, Kilkenny.

A3. Details of Co-investigators:

Name of site (if applicable):
Title: **Name:**
Qualifications: **Position:** **Dept :**
Organisation:
Address:
Tel: **E-mail:**
Role in Research e.g. statistical / data / laboratory analysis:

A4. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

Name: Dr Tanya Mulcahy
Position: Research Manager
Organisation: Health Innovation Hub Ireland, UCC
Address for Correspondence: Room 2.17 Western Gateway Building, UCC
Tel (work): 021-4205556 **Tel (mob.):** 0867740744 **E-mail:** t.mulcahy@ucc.ie

A5 (a) Is this study being undertaken as part of an academic qualification?
No

SECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

B1. What is the anticipated start date of this study?

January 5th or as soon as a positive response from CREC is received.

B2. What is the anticipated duration of this study?

10 weeks

B3. Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.

In February 2013, the Minister for Health Dr James Reilly Issued Ireland's First National Clinical Guideline- the National Early Warning Score For Ireland (NEWS). Early Warning Scores facilitate the early detection of a patient's deterioration by classifying a patient's severity of illness – through the presentation of a 'score' that triggers a specific care pathway and prompts nursing staff to request a medical review at specific trigger points (Mitchell et al., 2010) The Current NEWS system relies on the recording of a number of patient measurements (see Appendix 1) by nurses; these are recorded on a standard NEWS **paper** document and a calculation of score is made by the nurses.
This study proposes to use a **digital version** of the paper NEWS document- where nurses will input the NEWS measurements onto a tablet containing a digital version of the chart. These measurements can be either manually entered by the nurse typing in the measurement or can be automatically transferred from the vital sign medical device. The NEWS score is calculated automatically and the appropriate escalation/response is displayed. This removes a large percentage of potential errors compared with a paper observation. This has been backed up by an independent Six Sigma investigation and by independent hospitals analysis into the paper system.
The platform allows the clinical staff at the nurses station to have sight of all patient NEWS scores on a single screen (currently these are only available by checking the patient charts). The aims of this study are (1) to measure the impact on transcription errors compared to the paper version (2) to measure compliance rate for recording NEWS compared to the current rate with the paper version (3) through a survey- recording nurse and clinical team feedback on using the digital version versus the paper version. There will be no change in clinical procedure and both a paper and digital record will be available for all patients in this study. A copy of the digital record will be saved in the patient chart.

B4. Provide brief information on the study background.

When acute hospitals implement the current Clinical Guideline for NEWS they record a number of standard patient measurements on a paper chart (see Appendix 1). They then calculate a NEWS score for the patient and this score is an indicator of patient deterioration. Depending on the score, a care escalation process is followed by the nurse. This clinical guideline was introduced in order to increase patient safety and to identify at risk patients early in the care pathway. A number of recent studies (see Figure 1 and 2) have demonstrated the power of implementing the digital EWS system. In figure 1 the error rate on the charts dropped from 40% to almost 0% and In figure 2 the NEWS compliance across the Golden Jubilee National Hospital in Scotland is shown to average 78% in the year prior to the trial. The result from their one-month trial in a 28-bed ward was 100% which led to them electing to buy the system for hospital-wide application and showcasing it to the Scottish Health Minister.

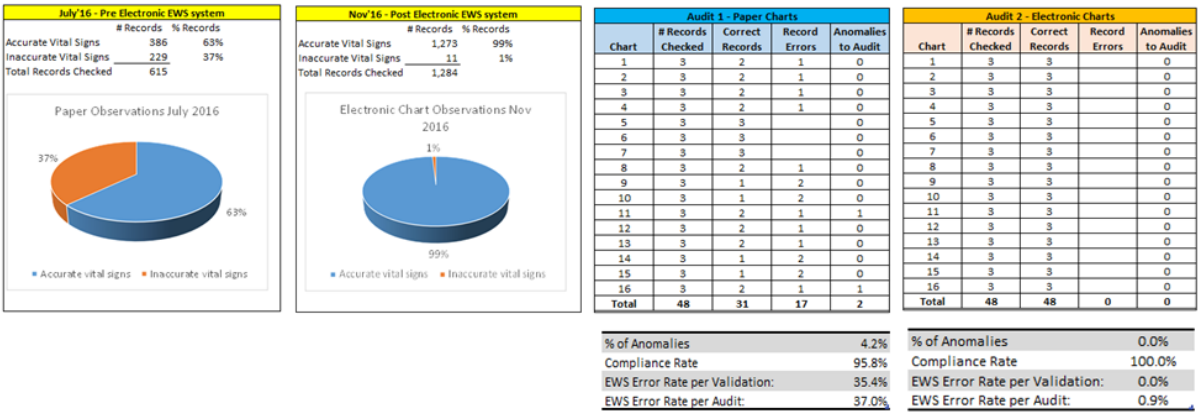


Figure 1 Galway Clinic error rate analysis

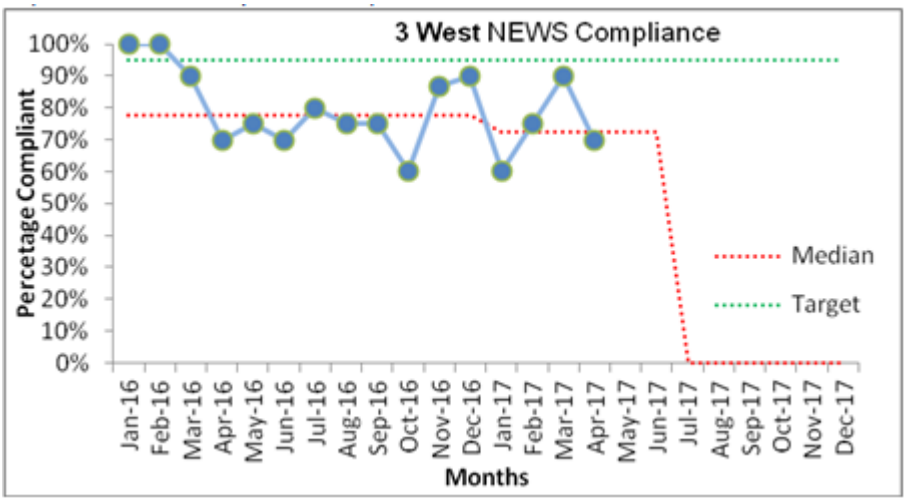


Figure 2 Glasgow Golden Jubilee Study

Note: The studies referred to above were conducted by (1) The Galway Clinic and (2) Golden Jubilee National Hospital, UK.
The findings of the in-house study conducted by the Galway Clinic were presented as a poster at a number of conferences including HISI (Ireland) and the European Medtech user Conference in the UK. The abstract is provided in the Appendix.

The Golden Jubilee Study was an in-house study. The data is taken from their report, which was shared with Syncrophi. The report was based on their experience before and after implementing KEWS300 on a 28-bed Cardio ward. We understand that their normal process is to take 20 charts from each ward every month and analyse them for errors. The chart shown in Section B.4 is their hospital-wide aggregate score for chart accuracy and it can be seen that it shows a typical error-rate per month of 25 to 40%. They assessed the pilot ward in its first month and found zero errors. This was reported to Syncrophi and it drove their immediate decision to implement KEWS300 across the entire hospital, and to showcase it to the Scottish Minister for Health. They will not produce a 'paper' until the system has been fully implemented. Ms. Sally Smith, Director of eHealth, was the study lead.

B5. List the study aims and objectives.

The objective of this study is to assess the impact of using a digital system to record and calculate the NEWS in the AMAU of St Luke's Hospital in Kilkenny with a view to demonstrating that using a digital NEWS platform as a tool to support the implementation of NEWS in acute hospitals results in better compliance (uptake rate by nurses) and lower error rates. The aims of this study are (1) to measure the impact on transcription errors compared to the paper version (2) to measure compliance rate for recording NEWS compared to the current rate with the paper version (3) through a survey- recording nurse and clinical team feedback on using the digital version versus the paper version.

B6. List the study endpoints / measurable outcomes (if applicable).

Measurable Outcomes are	1) Error rate using Digital NEWS vs Paper based NEWS 2) Compliance among staff in implementing NEWS 3) Staff surveys capturing ease of use and functionality.

B7. Provide information on the study design.

All adult and non-pregnant patients admitted to the AMAU of St Luke's Hospital Kilkenny will have NEWS measurements recorded on the KEWS300 Digital System. Digital capture will be conducted by the HSE nurses between the hours of 9am and 9pm over a period of 6 weeks. A paper version of NEWS will be printed from the KEWS300 system each night and maintained in the patient chart. At the end of the 6 week period, the number of patients admitted will be compared against the number of patients where NEWS was recorded- this will provide information on compliance. This will be compared with similar data for a similar time period where only paper based NEWS was recorded. Error rates are currently assessed in the HSE audit process. Error rates for paper NEWS over a six-week period will be compared with Error rates for Digital NEWS over a six-week period.

B8. Provide information on the study methodology.

The study will be an evaluative study- including simple data analysis tracking of error rates (comparison using a digital NEWS recording system vs paper based recording system) and compliance rate- number of patients where NEWS was recorded. Patient information is not being used in this study.

B9. Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.

We will be conducting a simple error rate comparison on a similar number of patients over a similar time period comparing error rates using the paper NEWS form versus the digital NEWS form. We will compare the number of times NEWS was implemented using the paper format vs digital format over a similar time frame on a similar number of patients.

B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

The reduction in error rates measured in previous evaluations has been so dramatic that any direct comparison of more than 50 pairs of charts can be relied on to demonstrate the powerfully beneficial effect. The 50 charts will be randomly selected. We will select 10 charts per week for week 2-6 of the study. 2 charts per day Monday-Friday.

B10 (b) Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

A period of 6 weeks 'live' implementation of the digital NEWS platform was agreed by the clinical team as the optimal time for them to engage in this study. This will provide a statistically significant number of patients (1260) to do a basic comparison of error rates and compliance by nurses in using the NEWS measurement. The number of patients received in the AMAU unit varies but on average there will be approx 30 patients per day where NEWS would be recorded. We will select 2 charts per day (Monday to Friday) to review over weeks 2-6 of the study. This will provide 50 charts for comparison with non-digital recording of NEWS. A comparison of error rates in 50 charts, selected randomly, is comparable to studies completed previously (see section B.4) and will give an indication of error rates and the impact of using digital NEWS recordings.

B11. How many research participants are to be recruited in total?

The study will be recording NEWS on the digital platform for a period of six weeks, every adult patient presenting in the AMAU will have their NEWS measurements recorded using the digital platform- it is expected that there will be approx 1000 patients in the study during that period as all patients may not be suitable for inclusion. All patients will have digital NEWS recorded during this time but a total of 50 charts will be used for the review of error rates.

B12 (a) How many research participants are to be recruited in each study group (where applicable)? Please complete the following table (where applicable). N/A

Name of Study Group:	Name of Study Group:	Name of Study Group:	Name of Study Group:	Name of Study Group:
Answer	Answer	Answer	Answer	Answer
Number of Participants in this Study Group:	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**
Answer	Answer	Answer	Answer	Answer

B12 (b) Please provide details on the method of randomisation (where applicable).

N/A
In this study, we will only be comparing error rates and compliance in recording NEWS for the patients involved. There will be no change to current clinical process and a paper version of NEWS scores will be printed from the digital chart daily and saved in the standard patient chart. We will not be using patient information for the purposes of this study.

B13. How many research participants are to be recruited at each study site (where applicable)? Please complete the following table. N/A

Site:	Number of Research Participants at this site:

SECTION C STUDY PARTICIPANTS

SECTION C IS MANDATORY

C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1.1 How will the participants in the study be selected?

All adult patients presenting to the AMAU in St Luke's Hospital Kilkenny who would normally have their NEWS recorded on a paper chart, will now have their NEWS measurements recorded on a digital chart. This will be printed daily and will stay with the patient chart as a permanent record (as is current practice with the paper version). There is no change to the patients' care pathway. All staff involved in recording NEWS on patients in the AMAU during day shift will be trained to record NEWS values on the KEWS300 system. Training sessions and support is factored into the project plan and the first week of the study is dedicated to installation and training.

C1.2 How will the participants in the study be recruited?

As above.

C1.3 What are the inclusion criteria for research participants? (Please justify, where necessary)

Adult (not maternity) patients presenting to the AMAU.

C1.4 What are the exclusion criteria for research participants? (Please justify, where necessary)

Paediatric patients and maternity patients.

C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project? Not to my knowledge

C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? NO

C2.1 (b) If no, please justify. You must provide a full and detailed explanation as to why informed consent will not be obtained.

Answer: This study will not change the standard patient care process. The current NEWS guideline is compulsory, the Clinical Guideline was recommended in order to improve patient safety and improve patient outcomes in the acute hospital setting. Currently where NEWS is implemented, it is done on paper, in this study we will record NEWS using a digital system as well as paper - this will not negatively impact the patient or change their care process.

C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)

Answer N/A

C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? / No

C2.2 (b) If no, please justify.

Answer: This study will not change the standard patient care process. The current NEWS guideline is compulsory, the Clinical Guideline was recommended in order to improve patient safety and improve patient outcomes in the acute hospital setting. Currently where NEWS is implemented, it is done on paper, in this study we will record NEWS using a digital system- this will not impact the patient or change their care process.

C2.3 (a) Will there be a time interval between giving information and seeking consent? N/A

C2.3 (b) If yes, please elaborate.

Answer: N/A

C2.3 (c) If no, please justify and explain why an instantaneous decision is reasonable having regard to the rights of the prospective research participants and the risks of the study.

Answer- There is no perceived patient risk in this study. Currently the recording of NEWS is a recommended Clinical Guideline - this study is simply, using a digital platform to record NEWS and comparing it to the current practice of recording NEWS on a paper based chart. It is expected that this will improve compliance among staff recording NEWS and improve patient safety by reducing error rates in recordings.

C3 ADULT PARTICIPANTS (AGED 18 OR OVER) - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent? No

If answer is Yes, please delete remaining questions in Section C3

C3.1 (b) If no, please elaborate.

Answer- we will not be seeking informed consent from patients.

C3.2 Is this research of such a nature that it can only be carried out on adults without capacity? Please elaborate.

Answer- N/A

C3.3 Is the research expected to provide direct benefit to the research participants (who lack capacity), or if there is no prospect of direct benefit, are the risks no more than minimal? Please elaborate.

Answer: There is no perceived patient risk in this study. Currently the recording of NEWS is a recommended Clinical Guidelines - this study is simply, using a digital platform to record NEWS and comparing it to the current practice of recording NEWS on a paper based chart. It is expected that this will improve compliance among staff recording NEWS and improve patient safety by reducing error rates in recordings.

C3.4 What arrangements are in place to ascertain the wishes of research participants, who although they lack decision-making capacity, have some ability to understand the significance of the research?

Answer N/A

C3.5 What arrangements are in place for research participants who may regain their capacity?

Answer: N/A

C4 PARTICIPANTS UNDER THE AGE OF 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children? No

If answer is No, please delete remaining questions in Section C4

C5 PARTICIPANTS - CHECKLIST

C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with issues of consent. It is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE's National Consent Policy, particularly Part 3, Section 5.

Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.

(a) Healthy Volunteers No

(b) Patients Yes

- **Unconscious patients** Yes /
- **Current psychiatric in-patients** / No
- **Patients in an emergency medical setting** Yes /

All Patients that are not pediatric and maternity patients that would usually get a NEWS score will be included in the trial including above patients if applicable to the AMAU ward.

(c) Relatives / Carers of patients No

(d) Persons in dependent or unequal relationships Yes

- **Students** Yes possibly
- **Employees / staff members** Yes – clinical staff will be surveyed.
- **Persons in residential care** Yes- possibly, patients may have presented from AMAU having come FROM residential care
- **Persons highly dependent on medical care** Yes –yes possibly

All Patients that are not pediatric and maternity patients that would usually get a NEWS score will be included in the trial including above patients if applicable to the AMAU ward.

(e) Intellectually impaired persons / No
All Patients that are not pediatric and maternity patients that would usually get a NEWS score will be included in the trial if applicable to the AMAU ward.

(f) Persons with a life-limiting condition Yes /
(Please refer to guidance manual for definition)
All Patients that are not pediatric and maternity patients that would usually get a NEWS score will be included in the trial if applicable to the AMAU ward.

(g) Persons with an acquired brain injury / No

All Patients that are not pediatric and maternity patients that would usually get a NEWS score will be included in the trial if applicable to the AMAU ward.

C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).

There is no perceived patient risk in this study. This study is simply using a digital platform to record NEWS and comparing it to the current practice of recording NEWS on a paper based chart. It is expected that this will improve compliance among staff recording NEWS and improve patient safety by reducing error rates in recordings

C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.

Answer: excluded

SECTION D RESEARCH PROCEDURES

SECTION D IS MANDATORY

D1 (a) What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?

Answer:None- the recording of NEWS is currently done on a paper system - nothing will change except that the recordings are entered by the nurse onto a digital system.

D1 (b) What other activities (if any) are taking place for the <u>purposes of this research study</u> e.g. chart review, sample analysis etc?

An objective comparative review of observation recording accuracy and NEWS protocol compliance plus a survey of nursing and clinical staff regarding feedback on usability and other benefits derived from using the KEWS300 system.

Note: The KEWS300 system is technically a Class II medical device within the definition used by the EU Medical Device Directive. It has been fully approved and CE-marked as such. Substantially it is made up of software which users access through touchscreen tablets at the point-of-care and via a large touchscreen PC at the Nurse Central Station.

D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.

Answer: None- the recording of NEWS is currently done on a paper system- nothing will change except that the recordings are entered by the nurse/carer onto a digital system

D3. What is the potential benefit that may occur as a result of this study?

Answer: The aim of this study is to demonstrate that digital recording of NEWS and presentation of patient scores at the nurses station will improve compliance and reduce error rates. This should in turn improve patient outcomes and result in earlier detection of patient deterioration and therefore care escalation.

D4 (a) Will the study involve the withholding of treatment?
Non-applicable

D4 (b) Will there be any harms that could result from withholding treatment? N/A

D4 (c) If yes, please elaborate.

Answer N/A

D5 (a) How will the health of participants be monitored <u>during</u> the study, and who will be responsible for this?

Answer: Standard monitoring of patients as is currently done in the AMAU will continue

D5 (b) How will the health of participants be monitored <u>after</u> the study, and who will be responsible for this?

Answer- N/A

D6 (a) Will the interventions provided during the study be available if needed after the termination of the study? Non-applicable

D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?

Answer N/A

D7. Please comment on how individual results will be managed.

Answer N/A

D8. Please comment on how aggregated study results will be made available.

Answer N/A

D9. Will the research participant's general practitioner be informed that the research participant is taking part in the study (if appropriate)? Non-applicable

D10. Will the research participant's hospital consultant be informed that the research participant is taking part in the study (if appropriate)? Non-applicable

SECTION E DATA PROTECTION

SECTION E IS MANDATORY

E1 DATA PROCESSING - CONSENT

E1.1 (a) Will consent be sought for the processing of data? No

E1.1 (b) If no, please elaborate.

Answer: In this study we will be looking at error rates in recording patient measurements and measuring compliance in the implementation of NEWS. We will not be assessing or processing any patient data.

E2 DATA PROCESSING - GENERAL

E2.1 Who will have access to the data which is collected?

Answer: No patient data will be recorded for the purposes of this study. We will be comparing error rates and compliance rates in the implementation and recording of NEWS.
We will select 50 charts where NEWS was recorded digitally and analyse error rates and then select 50 charts from a time period where NEWS was recorded manually on paper and record the errors on these charts. The patient name and demographics are not required for this study. No charts will leave St Luke's Hospital. The digital charts will be printed and stored as paper versions as per current protocol.
Only error rate data will be used in the final study report.
The KEWS300 system will record measurements and store them on the St Luke's server. We have included Alan Busher, HSE IT in the project and he will manage the server for the purposes of this study. The Study Team will have access to the data, this includes Prof. Garry Courtney (St Luke's), the Nursing Team in the AMAU , St Luke's and two members from the product supplier –Synchrophi.

E2.2 What media of data will be collected?

The patient name, date of birth, gender and vital signs are recorded on a local server on site in the hospital. No patient data leaves the hospital.

E2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?

The interface with the hospital patient database connects the patient details to the systems vital signs. No patient data leaves the hospital.

E2.3 (b) If 'coded', please confirm who will retain the 'key' to re-identify the data?

. N/A

E2.4 Where will data which is collected be stored?

HSE server

E2.5 Please comment on security measures which have been put in place to ensure the security of collected data.

Answer: Standard HSE security measures will be in place. The Office of the Chief Information officer in the HSE is aware of this project and has provided a HSE IT contact to ensure all IT elements are in accordance with HSE policies. All data is encoded while traversing the network.

E2.6 (a) Will data collected be at any stage leaving the site(s) of origin?
Yes

E2.6 (b) If yes, please elaborate.

Answer: Statistical analysis of error rates and compliance may be conducted by a statistician either from UCC or another relevant academic institution. This data will not contain patient information. If any data is to be removed from the site any patient identifying details will be removed

E2.7 Where will data analysis take place and who will perform data analysis (if known)?

Answer: A review of data analysis will be conducted by a statistician from UCC or other relevant academic institution (TBC)

E2.8 (a) After data analysis has taken place, will data be destroyed or retained?

Answer No patient data is being recorded. The patient NEWS Charts will be printed and stored in the Permanent Patient Chart (as is standard practice) and once the study has been completed, the digital chart that is stored on the HSE server will be deleted.

E2.8 (b) Please elaborate.

Answer- see above

E2.8 (c) If destroyed, how, when and by whom will it be destroyed?

Answer: Mr Alan Busher- HSE IT lead for this study.

E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?

Answer: If the system continues after the trial the data will be retained on the HSE server until requested to be deleted. The system can be configured to delete old records

E2.9 Please comment on the confidentiality of collected data.

Answer: There will be no patient sensitive data collected- we will be recording error rates and compliance. The results of this study will not relate to individual patients. Error rates will not be linked to individual staff – the results will be a collective assessment over the period of the study.

E2.10 (a) Will any of the interview data collected consist of audio recordings / video recordings? No

E2.10 (b) If yes, will participants be given the opportunity to review and amend transcripts of the tapes?

Answer

E2.11 (a) Will any of the study data collected consist of photographs/ video recordings? No

E2.11 (b) If yes, please elaborate.

Answer

E3 ACCESS TO HEALTHCARE RECORDS

E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)? No

If answer is No, please delete remaining questions in Section E3

SECTION F HUMAN BIOLOGICAL MATERIAL

F1 BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL

F1 1 (a) Does this study involve human biological material? No

If the answer is No, please delete Section F

SECTION G RADIATION

G1 RADIATION – GENERAL

G1.1 (a) Does this study/trial involve exposure to radiation? No

If answer is No, please delete remaining questions in Section G

SECTION H MEDICAL DEVICES

H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device? Yes

If answer is No, please delete remaining questions in Section H.

H1 (b) If yes, what is the name of the medical device or device nomenclature (system of naming the medical device)?

The name the product from a regulatory stand point is "K2" but from a marketing standpoint it is called "KEWS300"

H1 (c) If yes, please provide a general description of the medical device.

Answer

Intended Use

The KEWS system is intended to be used by clinicians and nurses for vital sign recording and review of adults and paediatrics in sub-acute or step-down care environments. In addition to the recording of patient vital signs, the KEWS software can provide extended recording and reporting of patient data. The clinician is responsible for determining the significance of each detected clinical condition.

The KEWS system allows for a range of data processing options to deliver enhanced functionality to the clinician. The KEWS Server combined with the KEWS Application software provides the recording, reporting and processing functions through a range of user interface screens. Also included is the ability to calculate and display early warning scores based on combining clinician input with the parameters being recorded by the KEWS system.

KEWS is available in multiple product configurations. KEWS systems are custom-configured to meet a customer's unique needs based on healthcare facility size, care protocols, patient demographic and floor layout. In all cases, the user must carefully

review the features and functionality of the KEWS system to ensure that clinical needs are met.

Compliance with Safety Standards
The KEWS system is designed in accordance with the relevant essential requirements of the European Medical Device Directive 93/42/EEC.

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
EN 62304:2006 Medical device software – Software life-cycle processes
EN 980:2008 Symbols for use in the labelling of medical devices
EN 1041:2008 Information supplied by the manufacturer with medical devices
EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 62366:2008 Medical Devices – Application of usability engineering to medical devices

System Description
KEWS tablets transmit observation data wirelessly to the server for further processing. They operate in IEEE 802.11 networks. Industry standard access points provide the server interface in the case of IEEE 802.11 deployments. Wireless coverage within the patient environment is extended by adding additional access points. Data is transferred between the access point and server on a Local Area Network (IEEE 802.11 or wired Ethernet). In turn, the Server communicates with any connected Application software clients on the same network.
Patient observation management is controlled from the user interface where measurement data is also reviewed.

H2 (a) Does the device have a CE mark? Yes	
H2 (b) If the device has a CE mark, is it proposed to use the device within the terms of its CE mark or outside the terms of its CE mark?	**H2 (e) If the device does not have a CE mark, is this study being undertaken for the purposes of obtaining a CE mark?**
Within	No
H2 (c) If outside, please elaborate:	
Answer	
H2 (d) CE MARK NUMBER: 0050	
See Appendix 2 for certification documents.	

H3 (a) Is this an application to conduct a clinical investigation of a medical device? No

H3 (b) If yes, will the Medical Devices section of the Health Products Regulatory Authority (HPRA) be reviewing this study No

SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

I.1 NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

I1.1 (a) Does this study involve a medicinal product? No

I.2 COSMETICS

I2.1 (a) Does this study involve a cosmetic? No

If the answer is No, please delete remaining questions in subsection I2

I.3 FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve food or food supplements? No

SECTION J INDEMNITY AND INSURANCE

SECTION J IS MANDATORY

J1 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study at each site.

All clinical staff are covered by State Clinical Indemnity Scheme

Syncrophi Systems Ltd holds comprehensive insurance policies through Chubb Insurance appropriate for a Medical Products company. This includes Public and Products Liability cover as well as Employers Liability cover.

J2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study for each investigator.

Syncrophi Systems Ltd holds comprehensive insurance policies through Chubb Insurance appropriate for a Medical Products company. This includes Public and Products Liability cover as well as Employers Liability cover.

J3.1 Please give the name and address of the organisation / or individual legally responsible for this research study?

Syncrophi Systems Ltd, Galway Technology Park, Parkmore, Galway

J3.2 Where an organisation is legally responsible, please specify if this organisation is:

A pharmaceutical company No

A medical device company Yes
A university No
A registered charity No
Other No **If yes, please specify:** Answer

J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place, if any, by this organisation / or individual for this research study?

SECTION K COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS

SECTION K IS MANDATORY

K1 COST AND RESOURCE IMPLICATIONS

K1.1 Please provide details of all cost / resource implications related to this study (e.g. staff time, office use, telephone / printing costs etc.)

Answer: This study is being conducted under the Health Innovation Hub Ireland Programme- this initiative is supported by the Dept of Health and the Dept of Business, Enterprise and Jobs. The study must be carried out at no cost to the healthcare system (except for staff time). Staff time during the study will be limited as the study is replacing a paper-based system with a digital system and nurses would normally be recording this data anyway. Staff on the project team have agreed to participate- this includes the nurses, the IT lead and the PI- Dr Garry Courtney. Staff time required will be limited to Project Team Meetings -5 hours. Survey completion- 20 mins and participation in the generation of the final report- 2 hours.

K2 FUNDING

K2.1 (a) Is funding in place to conduct this study?
No

K2.1 (b) If no, has funding been sought to conduct this study? From where? Please elaborate.
Answer NO

K2.1 (c) If yes, please state the source of funding (industry, grant or other), the name of the funder, the amount of funding and duration of funding.

Source of funding (industry, grant or other):
Answer N/A
Name of Funder:
Answer N/A

Amount of Funding:
Answer N/A
Duration of Funding
Answer N/A

K2.1(d) Please provide additional details in relation to management of funds.

Answer N/A

K2.1(e) Is the study funded by a 'for profit' organisation? / No

K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding? No

K2.2 (b) If yes, please elaborate.

Answer

K3 PAYMENTS TO INVESTIGATORS

K3.1 (a) Will any payments (monetary or otherwise) be made to investigators? No

K3.1 (b) If yes, please provide details of payments (including amount).

N/A

K4 PAYMENTS TO PARTICIPANTS

K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants? No

K4.1 (b) If yes, please provide details of payments / reimbursements (including amount).

Answer

SECTION L ADDITIONAL ETHICAL ISSUES

L1 (a) Does this project raise any additional ethical issues? No

Note: If the study outcomes are positive and reflect previous research findings will the KEWS300 continue to be used in the hospital? As with all equipment purchase/service agreement decisions, the team at St Luke's will evaluate the results of the study, assess the benefits to patients and staff versus cost and if positive, will

bring a proposal to the management of St Luke's Hospital Carlow/ Kilkenny and also the EMT in the Ireland East Hospital Group. Prof Courtney believes the findings will be informative for the National Early Warning Score Team (EWS) and will share the results with Ms Avilene Casey, HSE Lead for EWS. The results of this study will be of relevance to the Acute Hospital Directorate and HSE Procurement. The results may inform how NEWS should be recorded nationally to ensure compliance and efficacy.

If answer is No, please delete remaining questions in Section L.

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.

Assessing the impact of a Digital National Early Warning Score

Short Title: Digital NEWS

Sponsor: Syncrophi Systems Limited
Mr David Toohey, CEO Syncrophi Systems Limited

Galway Technology Park
Parkmore, Galway
Ireland

Tel:+353(0)91395578
email:info@syncrophi.com

Prinicpal Investigator:

Prof Garry Courtney MB FRCPI

Clinical Director, St Luke's Hospital KIlkenny

Tel:0567717110
E-mail: garry.courtney@hse.ie

Study Synopsis

Brief Title: Digital NEWS
Title: Assessing the impact of a Digital National Early Warning Score

Sponsor: Syncrophi Systems Limited.

Abstract:

In February 2013, the Minister for Health Dr James Reilly Issued Ireland's First National Clinical Guideline- the National Early Warning Score For Ireland (NEWS). Early Warning Scores facilitate the early detection of a patient's deterioration by classifying a patient's severity of illness – through the presentation of a 'score' that triggers a specific care pathway and prompts nursing staff to request a medical review at specific trigger points (Mitchell et al., 2010) The Current NEWS system relies on the recording of a number of patient measurements (see Appendix 1) by nurses; these are recorded on a standard NEWS paper document and a calculation of score is made by the nurses.
This study proposes to use a digital version (KEWS300) of the paper NEWS document- where nurses will input the NEWS measurements onto a tablet containing a digital version of the chart. These measurements can be either manually entered by the nurse typing in the measurement or can be automatically transferred from the vital sign medical device. The NEWS score is calculated automatically and the appropriate escalation/response is displayed. This removes a large percentage of potential errors compared with a paper observation. This has been backed up by an independent Six Sigma investigation and by independent hospitals analysis into the paper system.
The platform allows the clinical staff at the nurses station to have sight of all patient NEWS scores on a single screen (currently these are only available by checking the patient charts). The aims of this study are (1) to measure the impact on transcription errors compared to the paper version (2) to measure compliance rate for recording NEWS compared to the current rate with the paper version (3) through a survey- recording nurse and clinical team feedback on using the digital version versus the paper version. There will be no change in clinical procedure and both a paper and digital record will be available for all patients in this study. A copy of the digital record will be saved in the patient chart. The Digital NEWS recordings will be compared to manual recordings over a similar number of patients and over a similar time period. Recordings will be assessed for error rates and compliance/completion of NEWS recordings. All data will be stored on a HSE database and patient information will not be used in the study. The KEWS300 device is CE marked and currently in use in The Galway Clinic and in an number of Hospitals in the UK.

Study Design:

Sampling Method and Study Population: All patients who meet the entry criteria over a six week period, will be included in the study. Currently, all patients entering the AMAU in St Luke's Hospital have NEWS recorded on paper charts. It is anticipated that approx. 1000 patients NEWS scores will be included in the study.

Entry Criteria:
All AMAU Patients that are not pediatric and maternity patients that would usually get a NEWS score will be included in the study.

Exclusion Criteria: Pregnant Women, Children (those under 18 years of age).

Procedure: Following notification of the Ethics Committee approval, the Syncrophi units will be installed in the AMAU and linked to a dedicated database managed and housed by HSE IT. Nurses will manage the care of patients following the clinical guideline currently in place for the paper version of NEWS however recordings will be made digitally using the Syncrophi system. At 9pm each night, when HSE staff are replaced by temporary staff, the Digital NEWS recorded during the day will be printed on paper and included in the patient chart. Manual recording on the paper chart will continue until the next shift change where HSE nurses are again in the AMAU. If patients are moved from the AMAU to another unit, the digital chart will be printed and included in the patient chart.

Device: The Digital NEWS will be recoded on the KEWS 300 system. This system is CE marked and already in use in a number of hospitals in Ireland and in the UK.

Study Start Date: Dec 2017 or as soon as possible after ethics approval

Study Duration: 10 weeks total (6 weeks recording of Digital NEWS, 4 weeks analysis).

Statistical Analysis: Digital recording will be compared to manual paper recording for error rates. This is currently performed as part of the HSE audit process and similar methods will be employed in this study. If additional statistical expertise is required, this will be sought from a relevant academic institution.

Data Storage: Digital News records will be stored on a dedicated HSE Server for the purposes on this study. A paper version of the Digital NEWS recording will be printed and will remain in the patient's charts as the permanent record. The data will be removed from the server once the study analysis has been completed.

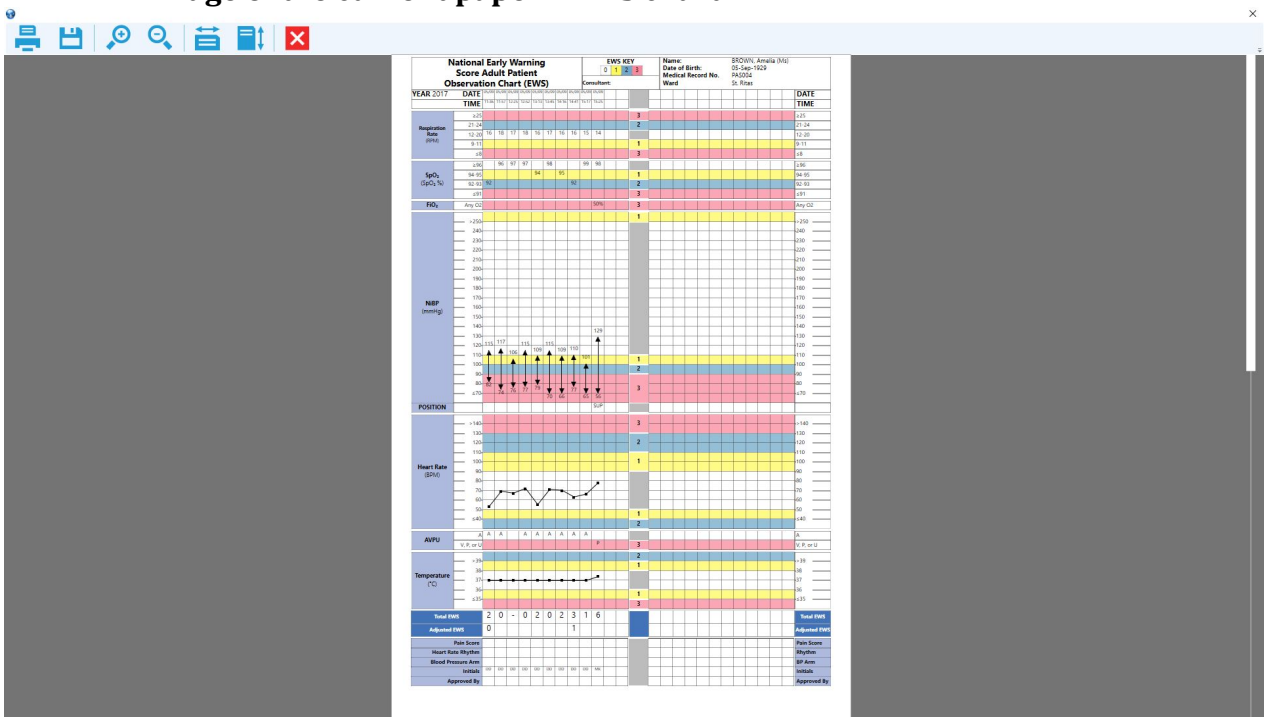
Dissemination: A final report will be generated and if results are significant, a peer- reviewed publication will be prepared and submitted to a relevant journal.

The study is being conducted in St Luke's AMAU, coordinated by Health innovation Hub Ireland. The PI is Professor Garry Courtney, Clinical Director, St Luke's Hospital and the Sponsor is Syncrophi Systems Limited.

Appendix

CREC Application Waterford- St Lukes Hospital Killkenny
PI Prof. Garry Courtney- Synchrophi KEWS

1- Image of the current paper NEWS chart



2- Syncrophi KEWS certification documents.

a. CE Mark
b. ISO13485 Certificate

Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

SyncroPhi Systems Ltd.

Unit 12 Galway Technology Park
Parkmore
Galway
Ireland

to the Product Family

Physiologic Monitoring System, Multi-Patient

GMDN Code: 37595

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.903**
Original Approval:	**18 June 2013**
Last Amended on:	**19 April 2016**
Remains valid until:	**16 June 2019**

Signed:

Approved by:
Kevin D. Mullaney
Chief Executive Officer - NSAI Inc.

Approved by:
Susan Murphy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Cert-114: EC Annex II-NL-A4 (6)

C.

Certificate of Registration
of Quality Management System to I.S. EN ISO 13485:2012

SyncroPhi Systems Ltd

Unit 12
Galway Technology Park
Parkmore
Galway
Ireland

NSAI certifies that the aforementioned company has been assessed and deemed to comply with the provisions of the standard referred to above in respect of:-

The design, manufacture, distribution, installation & service of wireless ambulatory patient monitoring and clinical decision support system.

Approved by:
Kevin D. Mullaney
Chief Executive Officer - NSAI Inc.

Approved by:
Susan Murphy
European Medical Device Operations Manager

MEDICAL DEVICES
- S. EN ISO 13485:2012 -
NSAI Certified

Registration Number: MD19.3981
Certification Granted: 13 May 2010
Effective Date: 13 May 2016
Expiry Date: 12 May 2019

This certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner.

All valid certifications are listed on NSAI's website – www.nsai.ie. The continued validity of this certificate may be verified under "Certified Company Search"

NSAI (National Standards Authority of Ireland), 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800 E: info@nsai.ie www.nsai.ie
NSAI Inc. 20 Trafalgar Square, Suite 603,Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412 E: info@nsaiinc.com www.nsaiinc.com

- 3 Galway Clinic Abstract
-

Introduction of an Electronic Early Warning Score to Aid Patient and Nursing Outcomes with an integrated Escalation Protocol in the Galway Clinic.

Background:

The Galway Clinic is an independent hospital situated in the West of Ireland comprising of 153 beds. It provides a full range of surgical and medical services and facilities to both elective and acute patients. The Galway Clinic is a leader in the use of healthcare technology and is currently in the process of working towards HIMMS (Healthcare Information and Management Systems Society) stage 7. There have been many calls from the patient safety literature (NCEPOD, 2012) to improve the process and management of the deteriorating patient. Early recognition of clinical deterioration followed by a prompt and effective action will help reduce the occurrence of adverse events. National Early Warning Score (NEWS) charts were introduced into Irish Acute Hospitals in 2012, replacing the numerous and widely varied observation charts. However, the potential and success of this tool in identifying the deteriorating patient is dependent on the EWS being documented correctly without error and the escalation protocol being followed. Literature reviews indicate that the use of electronic EWS (e-EWS) contribute to improved response time and ultimately a reduction in mortality rates and reduction of stay in ICU (HIQA 2015).

Aims of the project

Introduce the electronic NEWS as a pilot project in the Galway Clinic, monitor impact on patient outcomes and staff perception of use of the e - EWS and integrated escalation protocol.

Process

A project team was selected which was Nursing Led comprising of Project Manager (Clinical Informatics), Clinical Lead (Nurse), Director of Nursing, Chief Information Officer and Executive Sponsor (Innovation manager). Prior to implementation of the e-EWS an internal sample study of the current EWS chart was carried out. It identified a significant number of inaccuracies ranging from misinterpreting results, calculating an incorrect score, omitting

elements and miscalculating the total EWS. The EWS was built based on the patients' record, the existing IT System and the purchase of equipment from KEWS (Kosmos Early Warning Score). Once the observations are saved, the software automatically calculates the total EWS with the associated escalation protocol on display. The information is integrated with the patient's electronic medical record and is therefore immediately available to all relevant stakeholders involved in the patients care, including the patients Consultant who has secure access to these remotely if they are offsite.

Outcomes

Significant improvements have been recorded in the accuracy and timing of EWS and the response rate to changes in the patient's condition. During the pilot project, the errors relating to misinterpreting or miscalculating the scores were eliminated. This degree of error-elimination was achieved through a blend of automation, elimination of re-keying, optimised user interface and the use of forcing functions. In addition use of the KEWS has assisted and supported clinical nursing supervision of novice nurses and provided the ward manager with an overview of patients in the ward using the status board. As there is less transcribing of data, it allows more time for the nurse to interact and carry out a thorough assessment of the patient, moving away from a task orientated job. An unexpected outcome is the renewed uptake on Compass training for all clinical staff. The project has been evaluated and as an outcome is now being rolled out to all in-patient units in the hospital.

References :

National Confidential Enquiry into Patient Outcome and Death "Time to Intervene" (2012)

Health technology assessment of the use of information technology for early warning and clinical handover systems (2015)

Niamh Laffey
Clinical Nurse Manager 2 (Clinical Lead)
Galway Clinic
Doughiska
Galway
niamhlaffey@galwayclinic.com
091-785275

Prof. Garry Courtney

Born:	Omagh, Co. Tyrone
Education:	Christian Brothers, Omagh, Trinity College, Dublin
Medical Training:	St. James's Hospital, Dublin Beaumont Hospital, Dublin St. Thomas's Hospital, London
Current Position:	Consultant Physician and Gastroenterologist, St. Luke's Hospital, Kilkenny Associate Professor of Medicine, Royal College of Surgeons in Ireland Clinical Director, St. Luke's Hospital, Kilkenny National Lead of the Acute Medicine Programme Fellow/College Tutor, Royal College of Physicians of Ireland Director, Regional Hepatology Unit, HSE/SE Director, Regional ERCP Unit, HSE/SE Member, Executive Medical Board Ireland East Hospital Group
Previous Appointments:	Member, Steering Committee (HSE) A+E Process Mapping Group Board Member, South Eastern Health Board Member, General Hospitals' Committee, SEHB Member, Mount Carmel Medical Board Treasurer, Irish Society of Gastroenterology (ISG) Chairman, Medical Board, St. Luke's Hospital, Kilkenny Secretary, Medical Board, St. Luke's Hospital, Kilkenny Member, National Consultative Council for Hepatitis C Member, Specialized Training Committee, ISG Member, Editorial Board of Modern Medicine of Ireland Member, Oesophageal Cancer Fund Scientific Committee Founder of Trainees in Gastroenterology
Research Interests:	Viral Hepatitis Interventional Endoscopy Inflammatory Bowel Disease Acute Medicine
Publications:	Author/Co-Author on more than 30 peer reviewed articles Book Chapters (2)

2017

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

HSE South,
St. Luke's General Hospital,
Kilkenny,
Ireland.

Telephone 056 7785000
Fax 056 7785170

18th December, 2017

Our Ref: GC/AMA

TO WHOM IT MAY CONCERN

Re: Syncrophi/St. Luke's I.T. Systems NEWS Project in
Acute Medical Assessment Unit, St. Luke's Hopsital, Carlow/Kilkenny

We are delighted that the Syncrophi/St. Luke's I.T. Systems project in NEWS monitoring will be carried out in the Acute Medical Assessment Unit in St. Luke's Hospital, Carlow/Kilkenny with our permission and we will give any support required.

Anne Slattery
General Manager

Helen Butler
Director of Nursing

Garry Courtney
Clinical Director

Any Patient
A Monitored Patient

SyncroPhi

12th December 2017

Re: Pilot evaluation of KEWS300 system in a single-ward setting in St Luke's, Kilkenny

To whom it concerns,

I am writing to confirm that Syncrophi Systems Ltd, who plan to conduct a short pilot evaluation in St Luke's Kilkenny in collaboration with the HIHI and the staff of St Luke's under the sponsorship of Prof. Garry Courtney, is fully covered from an insurance perspective.

Our policy is held with Chubb Insurance and covers Employers Liability and Public/Products Liability.

The policy number is 35974632 and the period of insurance runs to 19th November 2018.

The KEWS300 product is fully approved by the medical regulatory authorities (in the EU and the USA) and is in day-to-day use in hospital settings in Ireland and the UK. The product performance, when used correctly, has been shown to dramatically reduce error rates and to contribute to safer and better patient care.

Full staff training will be carried out by Syncrophi staff to ensure an exceptionally positive outcome for staff and patients.

Yours sincerely

David Toohey

CEO/Director

SyncroPhi Systems Ltd.

Registered Office:
Unit 12, Galway Technology Park
Parkmore, Galway, Ireland

t: +353 (0)91 395578
f: +353 (0)91 444265
e: info@syncrophi.com

www.syncrophi.com

Registered in Ireland Number: 450979 | VAT Number: IE9673125G
Directors: D. Toohey, G. Lyons, D. Chambers

Declaration from Principal Investigator

1. I confirm that the information provided in this application for ethical review is correct to the best of my knowledge and assume full responsibility for it.

2. I agree to abide by the ethical principles governing the Declaration of Helsinki and the European Guidelines of Good Clinical Practice in the proper conduct of research.

3. I agree to submit annual reports on the progress of my research project and submit a copy of the study on its completion to the Research Ethics Office.

4. I will advise the Research Ethics Committee of the details of any sudden unexpected adverse events.

5. I agree to adhere to the study protocol as outlined in this submitted Research Ethics Application form if a favourable ethical opinion is given.

6. I agree to advise the Research Ethics Committee in the event of premature termination of this research project detailing the circumstances relating to the termination.

7. I understand that details pertaining to this research project may be disclosed to Operational Managers, the Health Service Executive and Department of Health and Children if required to monitor research activity and investigate any complaints.

8. I understand that details relating to this research project are subject to the provisions of the Freedom of Information Acts except where statutory exemptions apply.

9. All arrangements will be in place in terms of resources, support and permission from proposed research sites to prior to the deliverance of this research project as detailed in this application.

10. I confirm that I have made the sponsor/Principal Investigator aware of this application and that the sponsor/ Principal Investigator fully accept all associated responsibilities.

Research Title:

Reference Number:

Signed:

Print Name: Professor Garry Courtney

Date: 18.12.17

Declaration from Principal Investigator and/or Academic Supervisor.

I confirm that I have discussed the details of this research project with the Principal Investigator and agree for it to proceed as outlined in this application.

Signed: Title:

Research Ethics Office or hand in at the REC Meeting.

Appendix 5 Error-analysis template

	A	B
1	Chart ID / Number	10
2	Ward	1
3	Year	2017
4	Date	
5	Time	00:00
6	Date / Time of obs	20/01/1904 00:00
7	Manual Vitals Entry	
8	Respiration Rate	13
9	Sp02	98
10	Fi02 (Y or n)	N
11	Heart Rate	69
12	NIBP	101
13	AVPU	A
14	TEMP	35.1
15	Manual paper entry	
16	Paper Respiration Score	0
17	Paper Sp02 Score	0
18	Paper Fi02 Score	0
19	Paper Heart Rate Score	
20	Paper NIBP Score	
21	Paper AVPU Score	0
22	Paper TEMP Score	
23	Paper News Score	0
24	Partial obs	0
25	Counting the number of blank EWS	0
26	Counting the number of blank scores	3
27	Counting the number of blank vitals	0
28	Auto Score calculation	
29	Override Resp score, Enter Y	
30	Override Sp02 score, Enter Y	
31	Override Fi02 score, Enter Y	
32	Respiration Score	0
33	Sp02 Score	0
34	Fi02 Score	0
35	Heart rate Score	0
36	NIBP Score	1
37	AVPU Score	0
38	TEMP Score	1
39	NEWS Score	2
40	Time	
41		
42	Minimum Observation Frequency off manual score	06:00:00
43	Minimum Observation Frequency off Auto score	06:00:00
44	Time obs was completed	
45	Expected Time to next obs	20/01/1904 06:00:00
46	lateness	#VALUE!
47	Lateness in time	
48	% of lateness in relation to NEWS	
49	Lateness in relation to the required Minimum Observation Frequency in %	
50	Lateness grater than 16%	
51	Error count	
52	observation cannot be read (enter y2 or n)	N
53	observation is written in the wrong box (Enter y1 or n)	Y1
54	observation with incorrect date (Enter y1 or n)	Y1
55	Observation not signed off (enter y2 or n)	Y2
56	Chart ID Missing	n
57	Ward Name Missing	n
58	Year missing	n
59	observation set added up incorrectly	y2
60	observation has the date omitted	y1
61	observation has the time omitted	n
62	observation set that has a score but not all observations are filled in	n
63	Any EWS score that is not filled in when a full set of observations is completed	n
64		
65	Resperation entered has incorrect score given	n
66	Sp02 entered has incorrect score given	n
67	Fio2 entered has incorrect score given	n
68	NIBP entered has incorrect score given	y2
69	Heart rate entered has incorrect score given	n
70	AVPUentered has incorrect score given	n
71	Temp entered has incorrect score given	y2
72	Number of y1 Errors	3
73	Number of y2 Errors	4
74	Observation set error	Yes
75	Error rate % per observation in y1	50.00%
76	Error rate % per observation in y2	28.57%
77	Error in set of obs Yes or No	1
78		
79	Number of OBS completed	5
80	Number of Partial OBS (Partial obs not taken into analysis)	0
81	Obs with errors	5
82	Y1 errors	4
83	y2 errors	4
84	Percentage of obs with errors	100%
85	Percentage of obs with y1 errors	80%
86	Percentage of obs with y2 errors	80%

	Error	Number	Percentage
87			
88	observation cannot be read (enter y2 or n)	0	
89	observation is written in the wrong box (Enter y1 or n)	1	
90	observation with incorrect date (Enter y1 or n)	4	
91	Observation not signed off (enter y2 or n)	1	
92	Chart ID Missing	0	0.00%
93	Ward Name Missing	0	0.00%
94	Year missing	0	0.00%
95	observation set added up incorrectly	4	80.00%
96	observation has the date omitted	4	80.00%
97	observation has the time omitted	0	0.00%
98	observation set that has a score but not all observations are filled in	2	40.00%
99	Any EWS score that is not filled in when a full set of observations is completed	0	0.00%
100			
101	Respiration entered was incorrect score given	0	0.00%
102	Sp02 entered has incorrect score given	1	20.00%
103	Fio2 entered has incorrect score given	0	0.00%
104	NIBP entered has incorrect score given	1	20.00%
105	Heart rate entered has incorrect score given	0	0.00%
106	AVPUentered has incorrect score given	0	0.00%
107	Temp entered has incorrect score given	3	60.00%

Appendix 6 Description of Error-types

observation cannot be read (enter y2 or n)	y2
observation is written in the wrong box (Enter y1 or n)	y1
observation with incorrect date (Enter y1 or n)	Y1
Observation not signed off (enter y2 or n)	y2
Chart ID Missing	y1
Ward Name Missing	y1
Year missing	y1
observation set added up incorrectly	y2
observation has the date omitted	y1
observation has the time omitted	y2
observation set that has a score but not all observations are filled in	y2
Any EWS score that is not filled in when a full set of observations is completed	y2
Obs late by over 16% in relation to time	y2
Resperation entered has incorrect score given	y2
Sp02 entered has incorrect score given	y2
Fio2 entered has incorrect score given	y2
NiBP entered has incorrect score given	y2
Heart rate entered has incorrect score given	y2
AVPUentered has incorrect score given	y2
Temp entered has incorrect score given	y2

Appendix 7. St Luke's Questiinaire

One-minute feedback on Syncrophi's KEWS300 system (the paperless Vital-sign/NEWS Observation chart)

This feedback is anonymous. No names required. Syncrophi will collate all the returns and aggregate them.

Q1. Position held by you (circle one):	**Nurse Manager** | **Nurse** | **SHO/RMO** | **Consultant**
Q2. Number of years professional experience (circle one)	**0-5** | **6-10** | **>10**
Q3. During the trial did you use KEWS300, (circle one)	**YES** | **No** | **N/A**
Q4. The original PAPER NEWS observation charts were **paper-based** and stored at the bedside or central station: On average, how many times per day did you review them for a	**stable patient**? ____ **patient-of-concern**? ____
Q5. The KEWS300 system makes the up-to-date vital-signs available: On average, how many times per day do you review them for	**stable patient**? ____ **patient-of-concern**? ____
Q6. In a paper based environment, how often were paper observation charts missing or caused a delay in ward rounds (enter number where applicable)	**Per day** ____ **Per week** ____ **Per month** ____
Q7. Would you find having the ability to view the vital signs and the EWS off Site helpful?	**YES** | **No** | **N/A**
Q7 A. how often would this be helpful for you (circle one):	**Per day** ____ **Per week** ____ **Per month** ____
Q7 B. Would it allow you to direct therapy by phone?	**YES** | **No** | **N/A**
Q7 C. Would it ever save you an out-of-hours return to the hospital?	**YES** | **No** | **N/A**
Q8. Please rate your own experience of **KEWS300** on a scale of 1 to 5 for:	
Q8 A **Ease of Use**	Difficult to Use: **1** | Poor: **2** | Moderate: **3** | Good: **4** | Simple to Use: **5**
Q8 B **Patient Care**	Much Worse: **1** | Worse: **2** | No Change: **3** | Better: **4** | Much Better: **5**
Q8 C **Personal Productivity**	Much Worse: **1** | Worse: **2** | No Change: **3** | Better: **4** | Much Better: **5**
Q9. What did you like most about the KEWS300 system?	
Q10. Any other comment?	

Thank you for taking the time to give us your feedback.

Appendix 8. Notes regarding adherence to time schedules

The purpose of the study was to measure the performance of vital-sign charting and National Early Warning Score, comparing the standard paper-based system with the KEWS300 system.

In conducting the study we also took the opportunity to assess the degree of staff compliance with the specified time-limits for repeat patient observations. The frequency of observations is governed by the value of the patient's NEWS score, with higher scores demanding more frequent observations. Although KEWS300 provides a definitive 'time-to-next-observation' countdown clock for each patient, which can alert staff to observations falling due, it is clearly a staff management and resourcing matter to optimise compliance. In the AMAU study it was noted that delayed observations were running at over 20% throughout the very busy Winter period regardless of whether paper-based or using KEWS300. Since timeliness of repeat observations is an important contributor to optimum patient management this is certainly a topic that deserves further examination by the HSE.

HSE-defined Minimum Observation Frequency is as follows:

NEWS score	Min. Obs Frequency
1	12 hourly
2	6 hourly
3	4 hourly
4-6	Hourly
>=7	Half-hourly

During our analysis a 'grace-period' of 16% was applied before declaring an observation set was 'late'. 16% was chosen as an acceptable time by asking clinical staff members what time they believed was an acceptable time buffer on the various time escalations. Example: 5 minutes late on a 30 min obs schedule. 10 min late on a 1 hour obs schedule. This was to give the staff member the benefit of the doubt when completing obs. Note: the HSE guideline states the required follow-up time as a maximum allowable period between observations, it allows earlier observations but does NOT allow a grace period for being late. Allowing a grace period of 16% in this study therefore understates the degree of non-compliance.

The results were accurately gathered from the sample of KEWS300 charts drawn from the 9-week period of the study, as all the data was clearly available from the time-stamped KEWS300 database. This showed that 24% of follow-on observation sets were conducted 'late'…..i.e. with a delay of more than 16% of the maximum time period.

When the sample of standard paper charts was audited however it was more difficult to accurately assess schedule adherence. This was due to a high incidence of illegible, invalid or missing time entries on the charts. Of the 124 Observation sets sampled the assessment of the usable times indicates a range of 20% to 27% of observations sets were 'late'.

Discussion: Since each nurse is assigned a number of patients. Each of these patients will be on a schedule of observations driven by their personal NEWS score. The paper-based system holds all the NEWS score data on the chart at the bedside. This requires the nurse to remember, not only each patient's score, but also the time they did the last observation set on each patient. This requires a

very high degree of diligence from the nurse, unsupported by any relevant information system. The KEWS300 system however makes all patients' NEWS scores and time-to-next-observation clearly visible on the large screen at the central Nurse Station and also available on-screen on any of the tablets mounted on the vital-sign monitors around the ward. It thus becomes very much easier for a nurse to maintain a close awareness of observation scheduling. The 'time-to-next-observation' countdown clock associated with each patients score is displayed in green until it goes overdue when it changes to red.