The Rotherham NHS Foundation Trust
Electronic Patient Records (EPR)
Serious Incident Review
PRIVATE AND CONFIDENTIAL – FINAL REPORT
Our internal audit work has been performed in accordance with the NHS Internal Auditing Standards. As a result, our work and deliverables are not designed or intended to comply with the International Auditing and Assurance Standards Board (IAASB), International Framework for Assurance Engagements (IFAE) and International Standard on Assurance Engagements (ISAE) 3000.

Internal audit work is conducted on the basis of risk assessment hence resources are directed towards greater areas of risk. However, the Trust should note that all transactions cannot be examined. Thus, whilst implementation of internal audit recommendations may reduce risk and lead to systems being regarded as adequate, recommendations should not be regarded as necessarily comprehensive or completely eliminating risk.

This report has been prepared solely for your use and should not be quoted in whole or in part without our prior written consent. No responsibility to any third party is accepted as the report has not been prepared for, and is not intended for, any other purpose.
1. Executive summary

Background and Scope
In June 2012 The Rotherham NHS Foundation Trust (“the Trust”) went live with Meditech, a business critical electronic patient record system. The implementation has resulted in significant continuing operational difficulty and highlighted a number of weaknesses throughout the project. As the Trust’s internal audit service provider, PwC were asked to undertake a review to seek to understand what went wrong, and to make recommendations to the Trust so that lessons could be learnt to prevent similar potential failures. The detailed Terms of Reference for the scope of this review are included at Appendix 2, however in summary, the scope of our work included the following areas:

- Original objectives compared to accomplished objectives;
- Financial governance and management;
- User engagement;
- Risk management and escalations;
- Key personnel;
- Point of ‘Go Live’; and
- Culture – Tone at the Top.

Due to the nature of this review we have not provided an overall report classification, however, we have made a number of recommendations for improvement against each of the areas. We strongly recommend that the Trust consider how improvements can be made to support the success of implementing projects in the future.

Approach
We held an opening meeting with the Acting Chief of Business Intelligence / Director of Quality & Standards and Julie Hickton -Non Executive Director in February 2013 to agree the scope of the review. A subsequent meeting took place with the Acting Chief of Business Intelligence / Director of Quality & Standards to agree the list of Trust employees’ to be interviewed and identify what documentation should be reviewed. A full list of the individuals interviewed and the documentation reviewed, as part of this review, is provided at Appendix 1.

It is important to note that before and during this review a significant amount of work has been undertaken by the Trust to continue to identify and remedy the issues related to the EPR implementation, this has included some organisational changes and obtaining external support. We also note that KPMG, the Trust’s external auditors, have also undertaken some work in relation to EPR to support their work on the financial statements. The scope of our work has not duplicated the scope and/ or findings from these other pieces of work.

Summary of findings
At the start of the project in 2009, the Trust had identified an urgent requirement to replace the existing PAS and associated systems. The technology in place was considered to be old and it was understood, at the time, that the system would no longer be supported by the supplier beyond 2010. As such, the Trust determined that
a fully integrated Electronic Patient Record (EPR) solution was required, and conducted a market test to select an appropriate product. The system selected by the Trust was Meditech. However, whilst Meditech have an existing UK client base operating a fully anglicised product (version 5.6), the Trust chose to sign a contract that was to support the development of the new version (version 6.0) which did not have a tried and tested client base, and had not been deployed before in the UK.

Consequently, in addition to the local configuration requirements to suit the Trust’s specific needs and the fact that it was a development product, the Trust had to input significant resource to not only support its development but also to anglicise the product to make it suitable for the UK NHS market. This was not reflected in the contract and the contract did not include ‘specific’ key milestone or performance targets and penalties to ensure that the system was developed in line with the Trust’s expectations. In addition the contract also stated that the systems would be developed and Phase 1 fully implemented within 18 months. It is now evident that this timescale was unrealistic and there is now a view that if the Trust had key personnel who had the right level of experience and expertise of implementing these types of projects that it would have alerted the Trust to the fact the timetable was unrealistic.

From our review of the Trust’s business case, whilst this risk was at some point recognised at the selection stage (i.e. prior to formal selection of Meditech in partnership with File Tek UK Ltd as the preferred supplier), the impact of this appears not to have been fully understood or assessed by the Trust. The scale and size of the project and the delivery time required appears to have been grossly underestimated by the Trust. We noted that a very ambitious project timescale was proposed given the level of configuration, customisation and process redevelopment that was identified from the beginning. Although not specifically documented, it appears from our interviews with Trust staff that both Meditech and the Trust had a ‘common incentive’ to accelerate the project: for Meditech to launch its new product in the UK market; and for the Trust, not only to meet its system replacement needs, but also to be at the forefront of clinical solutions technology in the UK.

From the documentation reviewed, at the outset, there appeared to be a plan for robust project management processes to be established. This was clearly described in the Project Initiation Document (PID; and there were clear expectations that project gateway reviews would take place, with achievement of progress against key milestones to be assessed and signed off at each stage before continuing to the next. However, based on the project management documentation we observed during our review, it is unclear how well these processes were executed. From our review of the PID, other evidence provided, and interviews with staff, there were gaps in the governance structure for management of the project from the start. There was also a lack leadership, in particular of internal Information Systems (IS) leadership, a lack of continuity of staff within the project team, and a strong reliance on external consultants. The project governance, systems and processes did not appear to be followed and this may have been as a consequence. This may have been due to the pressure of the implementation timetable, changes in leadership and key personnel throughout the project.

It was also apparent that the process mapping that was carried out during the development stages was based on the patient’s pathway rather than information flows. The information from these activities was also not linked to the ongoing development of the system. There appeared to be a lack of expertise in information flow and mandatory reporting requirements; this was evidenced by the reporting function signed off as ready to go live when it would not deliver the information required to meet the requirements of the PCT contract.

There appeared to be good clinical engagement at the start of the project; but subsequently, due to a number of major issues and concerns being raised by clinical staff, and a high turnover of membership of various project groups, such that the project lost impetus, leadership and clinical engagement. The total time it took to develop the system through to implementation was 4 years and the level of clinical engagement decreased over that timescale. From our interviews criticism has been levelled at executive level management who were involved in the project at the time and that issues and risks were being flagged up repeatedly, but that they were being ignored. Also from the interviews we received comments like, ‘It very much felt like things were pushed through quickly to get things done’ and ‘EPR appeared to be developing like a child on its own’.
The financial governance and controls in relation to the EPR project appear to have been inadequate. The initial costs outlined in the original business case on which the original budget was based is flawed in that the costs were underestimated and in some cases not ‘real’ cash costs i.e. they were opportunity costs. There was also no contingency built into the original budget. The budget was not re-profiled and reforecast throughout the lifetime of the project, and expenditure was not appropriately managed and controlled consistently in all areas. From our interviews we received a comment that ‘Anything relating to EPR basically went and the money was approved regardless’. We identified that external consultants were given authority to approve expenditure, in some cases for their own organisations, which was against the Trust’s SFI’s and we were informed that detailed budget reports of project expenditure to the senior management were not available until post go live.

As previously noted throughout the lifetime of the project there has been significant turnover of staff at the executive level. There has also been a significant number of changes to key project personnel and a high volume of external consultants used to support the delivery of this project. This resulted in fragmented and inconsistent leadership and ‘project drift’ so the original project objectives have not been achieved nor have any of the key financial and non financial benefits that were identified at the outset.

Although a risk register was created at the start of the project, there were gaps in the ownership of those risks to ensure that appropriate mitigating action was considered and addressed, and the risk management process overall appears to have been ineffective in alerting the Trust to the implications of continuing. There were strong views that pressure was applied from the top-down to push for progress, to achieve an eventual ‘go live’ with a radically reduced scope, implementing functionality that was deemed by many of the end-users as not fit for purpose. We noted that there was evidence of numerous concerns being raised, either by email, formal letters to the Chief Executive and verbal challenge to the project team. In particular concerns were raised by clinicians regarding risks to patient safety as a consequence of deploying the system as it was at the point of ‘go live’. In addition several problems had been noted at the point of ‘go live’: from issues with peripheral hardware to support the system, to the inadequate and disorganised training programme. The training programme was also delivered 3 months prior to go live for the majority of staff and included training on a system which was still being developed. As a consequence, a number of ‘workarounds’ had to be developed to get through system processes, which do not meet the requirements for the redesigned business processes, such that the overall integrity of the system may not be reliable.

From our review of the Board papers from January 2012 to the point of go live there is limited evidence to support whether the risks were fully communicated to the Trust Board and whether the EPR project team had fully identified and understood the risks the Trust was exposed to.

Throughout this review there have been some very strong views expressed and criticism regarding the culture and the ‘tone at the top’ from the executive management team in place at the time when EPR was being implemented. It very much felt that EPR had to be implemented at any cost and there was more of a focus on ‘when’ the Trust should go live rather than the risks and outcomes as a result of go live. It was commented on numerous occasions that executive management did not listen or respond well when challenged and in particular the clinical staff interviewed did not feel that they were taken seriously or that their professional opinion was valued.

Whilst it is acknowledged that implementing EPR systems is complex and not without significant risks and challenges, fundamentally there are a number of areas where a breakdown in the Trust’s governance arrangements, culture, stakeholder engagement, project management, processes and controls in relation to the EPR project that failed to operate effectively and this had a significant impact on the project’s overall success.

Our detailed findings against each of the areas of scope can be found in Section 2.

We would like to thank all members of the Trust who have contributed towards this review.
2. Detailed findings

1. Original objectives compared to accomplished objectives

Findings

The original project objective as defined in the PID is stated as:

“First and foremost, the project’s objectives are to deliver an organisational transformation based around the adoption of new working processes to improve patient care and organisational efficiency. The technology deployed as part of the programme provides the means by which the transformation process will be delivered.”

Trust expectations were raised by the founder members of the senior project team from the positive feedback after Meditech’s presentations and demonstrations of the system. However, it is not clear whether the members of the project team were fully aware of the implications and risks they were exposed to given that the version procured had never been deployed in the UK, and that it would not meet NHS requirements without significant development and re-configuration, and what this would mean to the Trust in terms of cost and implementation.

Input from the procurement team in place at the time was limited. Following changes made to the procurement team personnel and a handover in responsibilities for the contract, a review of the File Tek UK Ltd – Meditech contract was undertaken in 2010 which identified a number of observations:

- The contract was based on SYSCON i.e. systems terms and conditions that typically only covers hardware & implementation. Normally, due to the phasing of the systems implementation and the requirement for ongoing support, there should be two contracts in place - one for the hardware and implementation and the other SCON (for software and support).

- The contract used was an ‘Output based specification’ (OBS). There would normally be a contract that would sit alongside the OBS.

- File Tek UK Ltd (are appointed in the United Kingdom representative for the licensing and support of MEDITECH software) had not fully responded to all the questions. For example, responses to some of the questions were ‘we are happy to discuss this requirement’ when it should have said yes or agreed. It is unclear how such responses were considered as part of the evaluation process, or whether this was challenged by the Trust senior management team with File Tek at the time.

- The contract on file states ‘Draft not for Circulation’ signed by Brian James (the then Chief Executive) but is not dated.

- There are penalty clauses within the contract; however they are vague and non specific so difficult to enact. For example a penalty clause states - if the system fails there would be a penalty, however there is no definition of what failure means.

- Despite there being ongoing changes through the project there were no ‘change of control’ notices to make the necessary changes to the contract.
We were informed that these observations were raised at the time by the procurement officer to the then project manager; however it is not known whether the observations were escalated further. No changes were made to the contract at that time. The procurement team were not part of the EPR programme or project board and contract management was the responsibility of the project management team. It is also our understanding that the Trust did seek legal advice when agreeing the contract.

The Meditech system was expected to replace all legacy clinical systems – or at least be fully interoperable with those systems. A number of requirements were stipulated in the Output Based Specification (OBS) for provision of critical functionality, and interfaces to various existing systems. For example, handover plans should be auto-populated for CQUIN information that is already on the system, but to date, this did not happen and is still not in place. We understand from interviews with various members of Trust staff that links have not been adequately developed and that legacy systems cannot be decommissioned. As a result, many of the expected savings identified in the original business case cannot ever be achieved, and operating costs across the whole clinical systems infrastructure may have increased overall.

Work streams involved in system development appeared to be working in silos to a large extent and there was limited co-ordination of activity to ensure that the solutions would be fully integrated. The end product does not reflect all the design work and discussion around each process during the course of the system development stage and Trust users find the functionality is limited and cumbersome, and processes difficult to follow.

To demonstrate to what extent the project failed to deliver against the original PID, many of the modules outlined in Phase 1 of the project which was originally due for completion by July 2010, have still not been delivered in April 2013.

In December 2010 a presentation report named EPR Position Update was presented to the Board of Directors which summarised the outcome of critical review areas, status and key Board recommendations. The presentation did challenge whether the Trust had obtained the right product with the right supplier. It also recognised the problems relating to anglicisation and the complexities with implementation (such as clinical coding and use) along with the timescales for go live. An attempt was made to implement the system in A&E but was quickly withdrawn on day one due to issues with the hardware and access privileges associated with the Registration Authority smartcards.

Other objectives which have not been met include that the system would promote a paperless working environment; however, this is not the case. For example in Theatres, a hard copy of the theatre list still has to be printed for validation purposes. Graphing functionality does not work on screen and so has to be produced separately on paper.

Processes have become more onerous in the new system to the extent that deployment of Meditech is viewed by many users to be a retrograde step. Basic functionality has been criticised, for example:

- There are poor error checking and validation routines.
- Basic ‘sense checks’ that would be expected are not there – a quoted example is that a gynaecology operation could be booked for a male patient.
- Drop-down lists are not presented in a filtered manner relevant to the specific process or clinic, which increases the risk of user error.
- There is no capability to attach scanned documents from physical patient records.

All of these issues should have been identified before go live through testing system processes end to end and through performing testing in a clinical setting. Inadequacies of the system combined with poor training has led to a number of ‘workarounds’ being developed, which in turn may not be consistent across the user base for each process. Some users have found their own ways to get through the end to end process, which in isolation may appear logical, but which
do not meet the requirements of the redesigned business process such that gaps in the system will appear. For example, no enforced follow-up appointment booking for a patient that needs to attend another clinic; whilst this requirement may be registered on the system, a new appointment may not actually be made.

**Recommendations**

We are aware that a significant amount of work has been and continues to be undertaken by the Trust to identify all the issues relating to the operational functionality of EPR and that work is currently being undertaken by the Trust and an external consultant, in consultation with Meditech, to reach a resolution. This work is outside the scope of this review, however will need to be considered when establishing a way forward to meet the desired objective.

Although there was the intention to have the correct governance arrangements, processes and controls in place, what actually happened in practice significantly hindered the success of the project meeting the original objectives. For ongoing and future projects the Trust needs to ensure that:

1.1. Project assurance needs should be mapped over the project lifecycle to ensure that the right assurance is provided at the right time. This should be a continuous exercise, as the focus and timing of assurance may change unexpectedly as the project moves through its lifecycle and responds to change. Assurance activity should be prioritised according to the specific context, content and risk profile of the project.

1.2. Quality management is the development and implementation of an approach and plan used to monitor and evaluate the quality of the work performed within a project. It ensures that individual deliverables are produced and project activities are conducted in line with requirements and expectations, such that when implemented, they collectively deliver the expected project outcomes and benefits. This should be part of a robust testing process.

1.3. A quality plan should be prepared which addresses all aspects of project quality assurance, including quality management requirements, documentation standards, reviews and audits, problem reporting and corrective action.

1.4. Project milestones and checkpoints should be identified and clearly documented in project plans. A critical path analysis should be performed for the project which is clearly identifiable in the plan to allow impact of any changes or delays to be assessed.
**Trust Actions**

The Trust is currently agreeing the ERP recovery programme. Included in this is project management experience from Meditech and the requirement throughout the project is that the learning will be shared with the EPR team. Also included in the recovery plan is training for all EPR team members of project management/assurance. This will ensure that going forward all members of staff have this knowledge and understanding. The key members of staff who will be trained are those within the newly designed Project Management Team who form part of the Health Informative Directorate (HID).

All projects will now go through HID and any project will have: a project plan with project assurance milestones and quality impact assessed. We have also expanded the reporting function with the HID so that all issues for all projects across the directorate will be captured in this function alongside the Datix web risk management process currently aligned to all EPR projects.

The Trust have also developed a change control process – conducted at weekly meetings to ensure that all changes are assessed for risk across the whole EPR system, including reporting and that there is an auditable sign off at each meeting for each change.

Project Assurance and Project management expertise have been allocated as part of the recovery programme to further expand in-house skills and due to the fact that members of the current project team will be leaving the Trust at the end of the year. The agreement for this additional funding will be via the Board meeting in April 2013.
2. Financial governance and management

Findings

The original budget for EPR, which was prepared by the Chief Financial Officer (CFO) at the time, was prepared based on the original business case. This business case was developed in conjunction with company called Ubiquity. The original business case assumed a total budget of £30m over a 10 year period. The original budget was flawed in that it included costs which are not directly linked to EPR or costs without a cash impact, such as opportunity cost of old systems not being used. For the purposes of this review we have not considered the accuracy of the calculations and assumptions made; however we were advised by the current Deputy Director of Finance (DDoF) that miscalculations such as capital charges were inappropriately calculated. Also there were no contingency costs within the budget.

We understand that a finance resource was allocated to the project by the CFO at the time; however this person left the Trust in March 2010. In January 2011 the budget for EPR was reviewed by the DDoF, members of the project team including the project manager and the then Director of Informatics, and the budget was increased from £30m - £40m over the same period. A paper called EPR Financial Position (Interim report) was presented to the Board on 18th March 2011 setting out the financial position with a recommendation to approve the revised baseline subject to a further review in April 2011.

At this point the assumptions in the original budget were not revisited although the budget had significantly increased. Throughout, the focus of the budget monitoring appeared to be the ‘total value’ rather than detailed management of the costs within that. Throughout the project there does not appear to be any detailed financial management i.e. whereby the actual costs are compared against the budget, variance analysis and reforecasting expenditure. We were informed that detailed budget reports on project expenditure to the senior management were not available until post go live. We were also advised that this was the first time that budgets had been calculated realistically for the financial year in question, but this was done independently of the overall resource budget of £40m referred to earlier. Financial information has always been available on the cumulative level of spend against the total resource budget, especially since the DDOF became directly involved, but this was not in a user friendly format for reporting to the senior management team and/or budget holders or to be used as a tool for assisting in budgetary control. This reflects the fundamental flaws in the whole financial governance arrangements surrounding the project.

Although there is evidence that invoices and associated costs relating to EPR went through various authorisation and approval processes that were in place at the time, it is clear that costs relating to specific budget lines were highly underestimated and/ or not well controlled.

There was one particular instance noted where despite the Trust procedures being followed, there clearly was a conflict of interest and this was not addressed at the time by the executive management in post at the Trust. This was in relation to Ubiquity, who were initially appointed through a tender process to help support the preparation of the business case. This appointment was initially for a 6 month contract for an approximate value of about £46k. A director from Ubiquity was then appointed by the Trust as a project manager and was also allowed to approve expenditure for invoices relating to his own company. The total expenditure with the company was £612k. Again, although we are advised that concerns had been raised by staff with members of the executive and senior management team, no action was taken to change the invoice authorisation process.

It was also noted that in addition to the expenditure agreed in the contract a significant amount of expenditure (circa £400k) was incurred outside of the contract for items such as data migration, consultancy and maintenance support. Although these payments were duly authorised by various members of Trust management, and in some cases external consultants, it is unclear whether these costs were expected (budgeted), monitored and, where appropriate, challenged as part of the contract management process.
**Recommendations**

2.1. For major projects such as this, in addition to the Trust SFI's, clear policies, procedures and governance arrangement should be established, in particular where external contractors have delegated responsibility to authorise payments.

2.2. Actual costs incurred should be recorded and effectively monitored against the budget. Cost reporting should be a part of the routine status reporting and escalation processes with a predefined threshold set to indicate where costs are not in line with expectation. Project costs should also be reviewed and re-profiled at key milestones and in particular where they are not within a tolerable variance.

2.3. Where significant / material costs are incurred with suppliers outside of an agreed contract, the nature of any additional expenditure should be fully understood, where appropriate challenged, and authorised at the correct level so there is clearer transparency over the total costs.

2.4. Underlying budget assumptions should be documented and assessed to ensure that they are considered reasonable. A formal process should be in place to identify, document, manage and approve any changes to the budget.

2.5. Project costs and budgets should be managed throughout the project lifecycle to ensure that the expected benefits accrue to the organisation within the specified financial constraints. If costs become out of control or are significantly higher than expected, the project may no longer be viable or cost-effective and the sponsors may consider abandoning it or significantly changing the scope.

2.6. Where external contractors are used or where an external contractor becomes an employee of the Trust for the delivery of a specific project, the Trust must ensure that the appropriate safeguards are put in place. This should include checking for any potential conflicts of interest, secondary authorisation and approval for transactions on behalf of the Trust and/or a regular independent review of the expenditure authorised and approved by the individual concerned.

**Trust actions**

The Trust has assigned the new EPR project costs to the financial plan and have asked for a line by line budget report. This will be provided monthly to the Executive Director in line with the Trust new SFI policy.

Non-recurrent costs associated with the recovery plan for EPR have been budgeted for in both capital and revenue expenditure in 2013/14 based upon information submitted to and approved by the Board of Directors. Monthly budget reports will be produced for both capital and revenue expenditure for EPR in accordance with the Trust’s monthly budgetary control processes and timetable. The Acting Chief of Business Intelligence / Director of Quality & Standards is the sole authorised signatory on all capital expenditure associated with EPR and revenue expenditure signatories are in accordance with the latest version of SFIs, which significantly reduces the number of signatories overall.
3. User engagement

Findings

There appeared to be a good level of clinical engagement at the start of the project. The PID outlines a number of process workshop groups established to gather the development requirements for each clinical/business function, and work on process redesign. However, criticism has been levelled that membership of some groups was inappropriate. The process groups met with varying frequency and had no constructive direct engagement with representatives from the Meditech development team to agree the development strategy. Many of these groups did not have an assigned lead at the outset; as a result the groups became largely ineffective over time.

The total time it took to develop the system through to implementation was 4 years and there was a high turnover of both project management personnel and process group membership, which affected the impetus and direction of the project and user confidence that a fully functional system would be delivered. As a result user engagement diminished over time. There was limited understanding of the impact of business process redesign on user roles and responsibilities in the clinical environment; some of the process changes programmed into the system have affected who does what – for example, responsibility for preparing the patient discharge letters. We also identified from our work undertaken on EPR IT general controls that the user access granted to some users is inappropriate for their roles and responsibilities.

We were informed that a number of requests for system development changes were met with resistance by the Trust project team and Meditech developers, and the time taken to respond to process development requests was considered excessive. This resulted in numerous delays to the project ‘go live’ and another consequence of user members becoming disengaged with the process.

The Trust IT team had expected File Tek UK Ltd to configure the system to an operable level; instead they were provided with what they considered to be “light touch” training which did not reference how the system could be integrated with the Trust’s architecture.

Testing has been described by staff as “abysmal” with no rigour applied. Only limited user acceptance testing was performed. Test scripts used were apparently designed by IT analysts who did not have a full appreciation of real-life scenarios in a clinical environment. Testing was not done ‘end to end’ only vertical, therefore all the clinical aspects and risks within a process were not fully considered. Change management processes were poor; ‘fixes’ were released that caused more problems, and some changes that had been applied in the test system were not rolled forward into the live release.

Similarly, training has been described as “a complete fiasco” and “poor and at times irrelevant”. A generic training package was developed based on software functionality that was also still in development, such that training materials were either re-worked or users did not experience the finished product at the training session. In addition to this the training was not always timely with some staff being trained 3 months prior to the go live date. As the Trust needed to train approximately 3,000 users over the course of 8 weeks additional trainers were engaged (via an agency) who did not fully understand the system or the clinical processes. The Trust used agency staff as part of the go live process and many of these agency staff were trained to be ‘super users’ which made no sense when they were not going to be in the Trust long term. There was no accountability for whether or not staff had been trained, such that some staff members have still not been trained on the system, which has led to improper or ineffective use of the system.
Recommendations

3.1. Major systems implementation projects often fail due to lack of end-user training. A comprehensive training programme should be in place, based on the production version of the software, and which includes realistic operating scenarios. The resources and timescales required for training should not be underestimated with an appropriate budget allocation. Where a high volume of users needs to be trained, a modular or phased implementation plan should be considered, so that training can also be completed in a modular fashion and timed to be delivered as close to the ‘go live’ date as possible. If necessary refresher training sessions should be offered to ensure users are confident that they fully understand the system and the end-to-end process. Most importantly the system should be fully tested in a clinical environment prior to ‘go live’.

3.2. It is essential that all project stakeholders, especially key users i.e. clinical staff, are identified, assessed and managed on an ongoing basis throughout the project. It is important to work with all the project’s key stakeholders as they will be critical in driving success and achieving the agreed benefits.

3.3. Each key project product and deliverable should have defined acceptance criteria which are agreed up front and signed off by the accepting party. There should be a defined test strategy for acceptance testing of project products and deliverables, which addresses the scope of testing, timing, responsibility, approach, pass / fail criteria, corrective action processes and formal sign-off.

3.4. Resource management is the process of ensuring that the project has access to adequate numbers of resources with the correct skill sets and experience, and access to the right assets at the appropriate times. It also addresses the need to provide resources with all the necessary facilities to perform their roles, as well as motivation through performance management processes. Commitment should be obtained from the organisation to provide the necessary representation and resources for the duration of the project (i.e. nominated staff have been released from normal duties; percentage of staff time on the project has been agreed).

Trust actions

Following agreement of the plan the Trust will expand our current work on developing a Trust wide, ongoing training plan for EPR. We have elicited the support of the Learning and Development team and they will be bringing their expertise in developing the programme. In addition we have budgeted £250k for additional trainers and a further £150k to re-establish super users within specialities to ensure that this resource continues throughout the lifespan of the EPR implementation programme.

An additional fund of £250k per year has been requested (April Board) to ensure that we have clinical representation on each programme. The EPR recovery plan sets out a method in which MT, Trust and clinicians will work collaboratively speciality by speciality to ensure that the system and processes are designed to support clinical user and strengthen clinical engagement in the project.

Additional training of the team to ensure we have the correct skills in the teams has been highlighted earlier in the document. Again we have a change control and testing process that does not get implemented until all key stakeholders have agreed via the Change Management Committee with attendance of the Clinical Safety Officer and for major changes (as per 6 month recovery) also via the Clinical User Group.
4. Risk management and escalation

Findings

Initially the Trust’s tried and tested formal risk management process was not adopted by the IT leadership and project team at the time; instead they chose a different method to report risks, which resulted in only reporting the top 6 risks to the EPR programme board. Approximately 6 months before go live and as part of the national requirement a ‘patient safety case’ a hazard log was developed and this was linked to the Trust’s risk management model i.e. the Datix system. From this point going forward the hazard log was reported on a monthly basis to the EPR Patient Safety Committee and formed part of the final national sign off process.

A number of high level risks were identified and documented up front in both the business case and the PID; for example it was identified that the Meditech system needed to be adapted to for the UK market i.e. anglicized. However, there appears to have been inadequate ownership or management of these risks going forwards, and a failure to fully comprehend and assess the impact, such as the implementation timescales, financial and operational implications.

From the documentation we reviewed risks and issues should have been reported to various project groups; however, we have not been provided with any overall project management documentation to support this. From our interviews, we understand that the risk management process was ineffective in many ways:

- There was no formalised process for the management of risks from the outset;
- It was unclear who had overall responsibility for managing risks and at what level;
- From the outset risks were apparently recorded across several different spreadsheets, and may not have been presented in a centralised and consolidated manner; however we understand that risks are now centrally collated on Datix;
- When risks, issues and other concerns were flagged up, these appeared to have been in some instances not appropriately addressed and/or not escalated to the appropriate level; and
- Although a number of gateway checkpoints were indicated in the PID, these did not take place at the appropriate time, such that the overall process was ineffective in alerting the Trust to the implications of continuing.

The hazard log was maintained for risks impacting patient safety where mitigation for any ‘high’ or ‘significant’ risks had to be applied before system ‘go live’. Less than a month before ‘go live’ 23 such risks had been identified, including inaccurate patient data and treatment delays, along with over a hundred lower rated patient safety risks. It is unclear as to whether these risks were fully evaluated by the project board prior to go live and there is no evidence within the Board papers reviewed that these risks were escalated or communicated to the Board for full consideration prior to ‘go live’.

From our review of the minutes for the EPR Patient Safety Committee there is evidence that risks and issues were discussed and, where considered appropriate, were escalated to the CSEC and EPR programme Board; however there is no evidence within the Board minutes that all key risks were then escalated and communicated at Board level.

We reviewed the Board papers from the period January 2012 to July 2012 and it is evident within the minutes there is a clear lack of identification and evaluation of
risks relating to EPR being formally escalated and the impact considered by the Board. This suggests that either:

- the risks were not apparent to the EPR project team;
- there was a lack of understanding of what risks the Trust was exposed to; and
- the risk management framework relating to EPR in place at the time, failed to operate effectively.

**Recommendations**

Effective risk and issue management is based upon ensuring that the process is fit for purpose, i.e. it provides challenge and scrutiny without placing excessive burden on the project team. In practice, risk and issue management is not always practiced effectively. One reason for this is because it can be perceived as onerous, bureaucratic and inflexible by staff and the organisation.

4.1. A formal project risk management process should be established and communicated that is consistent with the organisation's overall approach to risk management. Roles and responsibilities should be clearly defined.

4.2. All project risks should be captured and managed under a single risk management process (i.e. separate processes should not exist for different stakeholders). On-going project risks should remain on the risk register for periodic review, even if the current risk level is acceptable. Contingency plans should be developed for accepted risks. The monitoring mechanism should be used to identify new and evolving project risks (not only those identified during the initial risk assessment).

4.3. The project team and senior management have a good understanding of risk management and the risks impacting the project. The risk management process should address the identification, recording, prioritisation, mitigation, monitoring and reporting of project risks. There should be a process for escalating significant project risks to the Trust Board for consideration, mitigation and resolution.

4.4. Risks and issues should be cross-referenced to project plans to illustrate where they would be expected to impact; this should be used to drive pro-active mitigation.

**Trust actions**

Comments of findings. The patient safety risk were signed off by CfH as part of the EPR patient safety case and agreed by senior CFH staff. The risks were signed off as agreed and with evidence that these were being reviewed and acted upon.

The issue with the risk management process initially was that the directors involved designed their own risk reporting process following the establishment of a risk management process that reflected the Trust and National risk management processes. The 1 page risk report was reported to EPR Board and also my understanding Audit and Assurance. The Chair of the Audit and Assurance committee was a member of the EPR Board. The governance processes were not aligned to the Trust governance processes and therefore risks reported to EPR Board may not have been reported in the same detail at Board meetings. However, Board members were on EPR Programme Board.
The risk management process was reviewed following the change in leadership; all risks relating to EPR have been captured on Datix over the last year. Incidents relating to EPR are also captured via the incident reporting system and highlighted in regular reports and feedback at the Harm meeting to the Executive team and Board and Audit and Assurance.

All 16+ risks are escalated to CMB and have been for some time as per the Trust risk management strategy. The risk will only be escalated to the Board if not resolved or require resources that are not available to resolve the risk – as per all risks in the strategy.

All actions relating to this section are complete.
5. Key Personnel

Finding

Over the lifetime of the project there was a high reliance placed by the Trust on externally engaged project management and IT consultants (for example Ubiquity Health Care Ltd and Dell Consultancy Ltd). It was felt that at times that the Trust used external consultants with limited and/or insufficient knowledge of the Meditech product and/or the NHS and the clinical process. It was felt that there was no real ownership / leadership of the project at the Executive level and IS leadership with the right level of experience was also lacking. There were a number of staff changes at Executive level which led to a lack of consistency and continuity of leadership. Over the lifetime of the project the Trust has had no less than 3 Finance Directors and 3 Human Resources Directors, at least 4 project leads (including the use of external consultants to perform the role) and various external consultants and agency staff.

There was a view from staff that the views of the external consultants appear to have been valued more highly than the input provided by Trust clinicians and consequently a feeling that this is why the system functionality, in many areas, did not meet the requirements of the clinical processes. It was very much viewed that individuals were repeatedly brought in who did not have sufficient experience and who had to learn 'on the job', sometimes attending the same training as Trust staff. There was also a view that some of the staff appointed into key roles, such as the Director of Service Improvement and IT, did not have the right level of knowledge and sufficient technical and informatics experience for such a critical role.

Standard clinical terminology is essential for the interoperability of electronic health records across care settings. As such, integration of the EPR with the SNOMED CT clinical coding solution was a vital component. However, it appears that there was limited understanding of clinical coding requirements within the project team and clinical coders had not been fully engaged in the project.

The Trust’s internal IT resources could have been more effectively used to participate in the project, but mostly their role was to manage the infrastructure installation and oversee development of systems interfaces. There is also criticism that IT were not adequately involved in decision making affecting Trust infrastructure and compatibility with other systems.

Throughout the project there appeared to be clear lack of IS leadership and the relationship between the Trust and the vendor (File TeK UK Ltd) was not well managed and monitored.

Recommendations

For major IT project implementation of business critical systems on the size and scale of EPR, it is critical that IS leadership along with the right level of experience and expertise is present throughout the project. It is strongly believed that the lack of IS leadership, knowledge and expertise had a major impact on the ability to successfully deliver this project.

5.1. The process for appointing consultants to projects of this nature should be formally approved by the project board and where the expected expenditure is deemed to be material or for a prolonged period of time this should also be approved by the Trust Board.

5.2. Most projects involve a number of parties, including suppliers, who work together to play a part in delivering the project. It is therefore important to consider
the nature of each of these parties, their respective roles within the project and their relationships to each other. This includes determining how the various contractual relationships work and understanding what behaviours this drives between the parties.

5.3. The mix of internally sourced and sub-contracted resources should be appropriate for the circumstances of the project, providing a balance between effective project delivery and longer term knowledge capture. A process should be in place to assess skill set requirements and recruit project team members accordingly (both internal resources and sub-contractors). A process should exist to promote knowledge sharing and to transfer skills and knowledge from sub-contracted resources to internal staff.

5.4. There should be a formal structure in place for significant projects which clearly outlines the roles and responsibilities of key personnel. Suitable processes should exist to facilitate project team members joining (induction), transitioning within, and leaving the project (hand over, exit meetings). For large projects, a resource plan should be developed which addresses how and when project resources will be transitioned on and off the project. Suitable succession plans and contingency plans should be in place for key project resources.

Trust actions

We agree with all the above recommendations.

In addition SFIs already cover the financial governance arrangements surrounding such appointments – the Trust need to make sure that these processes are followed in future.
6. Point of ‘go live’

Findings

Several ‘go live’ dates had been planned throughout the project, but were postponed largely due to the inadequacies of the system functionality. Further to press interest in the Trust’s project and increasing disengagement from Trust staff, it was felt that pressure was being applied to make sure that the system would go live in June 2012 (on Queen’s Jubilee bank holiday weekend, as this was considered to be a window of opportunity and it believed at the time that the hospital would be quieter) regardless of the risks and issues still outstanding. From our interviews it was suggested that a designated ‘go live’ date was agreed and that the project implementation plan was derived back from that date, regardless of whether the system was fully functioning at that point. Instead of adopting a parallel running approach the Trust decided to go for the ‘big bang’ and worked on the assumption that it would be business as usual within 2 weeks. In order to achieve ‘go live’, the scope of the implementation had to be radically cut down. Nevertheless, there is a criticism that parts of the delivered system functionality had still not been seen by the main clinicians involved at the point of ‘go live’ – either as part of the project development and testing phase, or in training.

It is not clear if there was ever a formal approval for the system to ‘go live’; there was no evidence available to us to suggest that a robust readiness check was performed prior to ‘go live’ and that any risk exposure was fully reported, assessed and formally accepted by the Board. From our review of the Board minutes relating to EPR for March and April 2012 it states:

*There was no formal update at the meeting in relation to EPR. However presentations had been given to both the Corporate Management Board (CMB) and Audit and Assurance Committee earlier in the week. The Board NOTED that a Go Live of early June continued to be progressed.*

For the minutes relating to May 2012 in relation to EPR it states that EPR was discussed at the May Audit and Assurance Committee.

After ‘go live’ numerous issues were experienced with regard to the existence or operation of peripheral hardware – including access control smartcard readers and availability of printers – to such an extent that A&E had to revert back to their existing system on day one of the rollout. From our review of the minutes these points appear to have been discussed at the June 2012 Board meeting.

Some of the designed process functionality had been developed without taking into consideration links to other systems, such as SNOMED, such that processes are very cumbersome to use, or ‘workarounds’ have emerged. There was feedback that the ‘floor workers’ deployed throughout the Trust were very good and helpful, however it seemed that even though they escalated concerns nothing happened.

There did not appear to be any contingency plans in place for go live and just after go live a number of key people went on leave and or were not available during a critical period.

Development and bug fixing has been ongoing since ‘go live’, but testing and change management processes are not robust.

For a programme of this scale and complexity, the management arrangements were not sufficiently extensive or robust. There were many issues with the software and data migration, the training of users and operational go-live planning. The Trust Board and the EPR Programme Board did not plan to have, and did not receive, sufficient independent assurance that the state of the programme supported a decision to go-live.

Complex IT implementations are never without risks and issues that need to be managed, even at the point of go-live. The scale of the issues in this implementation was
Recommendations

6.1. For future IT / business critical system implementations a full readiness assessment should be carried out for the relevant business or clinical functional teams or departments and acceptance of the technical solution. This ‘go live’ readiness assessment should be based on agreed ‘go live’ criteria and should provide the key input to the Board’s "Go/No Go" decision. The assessment should be completed by both the business or clinical functional area representatives and the project teams.

6.2. The assessment should involve a review of the ‘go live’ criteria checklist to ensure that they have been met or that mitigating actions have been put in place to allow a successful ‘go live’. These criteria should include as a minimum:

- Satisfactory completion of user acceptance testing;
- Agreed workarounds (if required) and their status;
- System access authorisations and set-up complete;
- End user training completed to an acceptable level;
- Acceptance of project products and deliverables should include an overall readiness of staff to adopt new processes, systems and procedures (e.g. staff knowledge and training, documentation, support processes migration approach and resource levels); and
- Support teams in place – e.g. IT helpdesk and post-implementation support.

A formal “Go / No Go” decision should be taken by the Board and evidenced.

Trust actions

The ‘Go/No go’ situation and discussions around this were reported to the Board and A&A and they took the decision to Go Live – this may not have been evidence in the minutes but an extra ordinary meeting was convened specifically for this purpose.

All of the above are in the current developments in relation to EPR Recovery plan as highlighted earlier in the document; however it will not be a Go /No go live scenario – mainly for major changes and update with risk assessment /QIA to the Board at the now monthly update presentations/reports.
7. Culture – ‘tone at the top’

Findings
From our interviews it was very clear that Trust staff felt failure of the EPR implementation was inevitable based on the behaviours of the executive team members and those responsible for the EPR implementation. During the interview the former Chief Executive was described as ‘a good commander but a poor leader’ and other members of the executive team were considered to be ‘out of their depth’, ‘arrogant’ and ‘not willing to listen’ at that time.

We were informed that the key members of the executive team, including the Chief Executive and Chief of Hospital dismissed any concerns raised so as to demonstrate that progress was being made. There was evidence of correspondence and emails to executive members where concerns had been raised, in particular from clinicians. Any significant risks or deficiencies in the system functionality appear not to have been identified or largely ignored, and we were informed that the project team were told in no uncertain terms to “make it work”.

The culture was such that staff became afraid of voicing concerns. There was and still is a belief that the Meditech EPR system will not meet requirements, in particular the clinical requirement, therefore staff have lost confidence in the system.

Recommendations
Having the right culture and setting the right tone from the top is critical to building trust and value with stakeholders, employees, patients and business partners. Following the implementation of EPR the Trust Board will need to rebuild trust and work with staff to gain their confidence that they will ‘do the right thing’. ‘Tone from the Top’ is about creating a culture where everyone has ownership and responsibility for doing the right thing, because it is the right thing to do. The following principles are key to establishing and sustaining the right ‘Tone from the Top’:

7.1. Understand what the prevailing culture is first, before attempting to make any wide-sweeping changes, to inform and drive your Tone from the Top messages;

7.2. Consistent and visible executive sponsorship for ethics and compliance-related issues is not just key, it is mandatory, if change is to occur;

7.3. Leaders must consistently ‘do as they say’, not ‘do as they want to do’, in a way that is aligned and enforces the core values of the Trust;

7.4. Good behaviours must be rewarded and recognised, poor behaviours must be acted upon and necessary action undertaken, openly and transparently; and

7.5. Embedding systems and processes to support the Tone from the Top as ‘business as usual’ will help shape the Trust culture and measure the effectiveness of leadership actions and behaviours over a period of time.
### Trust actions

The culture in the Trust in relation to EPR has now changed to one of inclusivity evidenced by much positive feedback. The clinical engagement and various user groups also support this change.

Allocating PAS to clinicians will provide a structure of accountability along with the newly devised governance processes, change control processes, surrounding this programme of work.
### Appendix 1. List of interviewees and documentation reviewed

<table>
<thead>
<tr>
<th>Documentation reviewed</th>
<th>Staff interviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original Business Case</td>
<td></td>
</tr>
<tr>
<td>PID</td>
<td></td>
</tr>
<tr>
<td>Full Business Case (dated 16/12/2009)</td>
<td></td>
</tr>
<tr>
<td>EPR risk assessment (dated 20/3/2013)</td>
<td></td>
</tr>
<tr>
<td>List of cost outside of contract – with supporting invoices</td>
<td></td>
</tr>
<tr>
<td>Report on EPR financial position to the Board of Directors (dated 18/3/2011)</td>
<td></td>
</tr>
<tr>
<td>Letters of correspondence to the Chief Executive relating to EPR</td>
<td></td>
</tr>
<tr>
<td>Minutes from the EPR Patient Safety Committee (from May – Sept 2012)</td>
<td></td>
</tr>
<tr>
<td>EPR Programme status report (dated 10/11/2011)</td>
<td></td>
</tr>
<tr>
<td>EPR position updated to Board of Directors (dated 16/12/2010)</td>
<td></td>
</tr>
<tr>
<td>Financial spreadsheet relating to EPR project costs</td>
<td></td>
</tr>
<tr>
<td>Contract between the Trust and File Tek UK Ltd</td>
<td></td>
</tr>
<tr>
<td>Board papers from January 2012 to July 2012</td>
<td></td>
</tr>
<tr>
<td>Audit and Assurance papers from March 2012 – May 2012</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2. Terms of Reference

The Rotherham NHS Foundation Trust

Terms of reference – EPR Serious Incident review

This review is being undertaken as part of the 2012/2013 internal audit plan.

Background

The Trust implemented the Meditech Electronic Patient Record system (EPR) during June 2012. However, following implementation there has been a number of significant issues identified whereby the system is not operating as intended.

The Trust has now declared EPR as a serious incident and has requested that Internal Audit undertake a review that will seek to understand that lesson can be learnt in respect of the both the system in both terms of systems implementation, training, project management and overall governance.

Issues known to management

Management have already started to perform their own internal reviews and investigation into what has gone wrong with EPR and the sequence of events. We will consider the work already undertaken by management and form an independent view of those findings.

Scope

The objective of this audit is to undertake a post implementation review of the EPR system in respect of the following:

<table>
<thead>
<tr>
<th>Sub-process</th>
<th>Audit coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original objectives compared to accomplished objectives.</td>
<td>• Review of business case, business requirements, progress reports, timelines, minutes of meetings, cost/benefit reports against accomplished objectives.</td>
</tr>
<tr>
<td>Financial governance and management</td>
<td>• Review the financial governance and management arrangement in place to ensure that all cost were controlled and in line with the agreed and approved budgets. Also has the Trust accurately forecasted for future costs.</td>
</tr>
</tbody>
</table>
### Limitations of scope

The scope of our review will be limited to cover the areas identified in the scope above. Issues relating to data quality are excluded from this review as this area will be covered by a separate review being undertaken by KPMG as part of the quality accounts assurance work.

<table>
<thead>
<tr>
<th>Sub-process</th>
<th>Audit coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>User engagement</td>
<td>• Review the work undertaken by the project team to engage with users identify what actions where and have been taken as a results, including training of users and testing of system.</td>
</tr>
<tr>
<td>Risk management and escalations</td>
<td>• Review of the risk management arrangement and incident reporting throughout the project lifecycle.</td>
</tr>
<tr>
<td>Key Personnel</td>
<td>• Consider the appropriateness of the process for the appointment of key staff and consultants to the project team.</td>
</tr>
<tr>
<td>Point of 'Go Live'</td>
<td>• To understand at the point of 'go –live' did the Trust and project team have a clear understanding of the risks and had plans been developed to mitigate them</td>
</tr>
<tr>
<td>Culture – Tone at the Top</td>
<td>• We will consider how the impact of the culture and behaviours of those charged with responsibility during the period of implementation affected the success of the project.</td>
</tr>
</tbody>
</table>
Appendix 3. Limitations and responsibilities

Limitations inherent to the internal auditor’s work
We have undertaken the review of the EPR Serious Incident, subject to the limitations outlined below.

Internal control
Internal control systems, no matter how well designed and operated, are affected by inherent limitations. These include the possibility of poor judgment in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Future periods
Our assessment of controls relating to the EPR Serious Incident is as at March 2013. Historic evaluation of effectiveness is not relevant to future periods due to the risk that:

- the design of controls may become inadequate because of changes in operating environment, law, regulation or other; or
- the degree of compliance with policies and procedures may deteriorate.

Responsibilities of management and internal auditors
It is management’s responsibility to develop and maintain sound systems of risk management, internal control and governance and for the prevention and detection of irregularities and fraud. Internal audit work should not be seen as a substitute for management’s responsibilities for the design and operation of these systems.

We endeavour to plan our work so that we have a reasonable expectation of detecting significant control weaknesses and, if detected, we shall carry out additional work directed towards identification of consequent fraud or other irregularities. However, internal audit procedures alone, even when carried out with due professional care, do not guarantee that fraud will be detected.

Accordingly, our examinations as internal auditors should not be relied upon solely to disclose fraud, defalcations or other irregularities which may exist.
This document has been prepared only for Rotherham NHS FT and solely for the purpose and on the terms agreed with Rotherham NHS FT. We accept no liability (including for negligence) to anyone else in connection with this document, and it may not be provided to anyone else.

Freedom of Information Act

In the event that, pursuant to a request which The Rotherham NHS Foundation Trust has received under the Freedom of Information Act 2000, it is required to disclose any information contained in this report, it will notify PwC promptly and consult with PwC prior to disclosing such report. The Rotherham NHS Foundation Trust agrees to pay due regard to any representations which PwC may make in connection with such disclosure and The Rotherham NHS Foundation Trust shall apply any relevant exemptions which may exist under the Act to such report. If, following consultation with PwC, The Rotherham NHS Foundation Trust discloses this report or any part thereof, it shall ensure that any disclaimer which PwC has included or may subsequently wish to include in the information is reproduced in full in any copies disclosed.

© 2013 PricewaterhouseCoopers LLP. All rights reserved. In this document, "PwC" refers to PricewaterhouseCoopers LLP (a limited liability partnership in the United Kingdom), which is a member firm of PricewaterhouseCoopers International Limited, each member firm of which is a separate legal entity.