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Shine 2012 final report

Supporting Patients to be Active Participants in Anticoagulant Medication Safety

UCLH NHS Hospitals NHS Foundation Trust

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Part 1. Abstract

Project title: Supporting Patients to be Active Participants in Anticoagulant Medication Safety

Lead organisation: UCLH NHS Hospitals NHS Foundation Trust

Partner organisation: NA

Lead Clinician: Sandra Hallett, Yogini Jani

Abstract

Background
Patients who take blood thinning drugs (i.e. anticoagulant medications) are at risk of developing blood clots or bleeds if too little or too much medication is taken. Their health care treatment is managed jointly by community (pharmacists, general practitioners) and secondary care teams (doctors, ward and anti-coagulant clinic nurses, pharmacists and allied healthcare professionals). Hence, there are many complex interfaces between the health care teams involved.

The local problem
Analysis of medication incident reports identified that patients on anticoagulants are the patient group most likely to be harmed by medication errors. Discharge from hospital was identified as the most high risk time for medication errors.

Failures in discharge processes led to either unnecessary continuation of therapy, delayed, or omitted treatment, and sometimes to preventable readmissions. Inadequate or no transfer of information at discharge and failure to arrange follow up monitoring after discharge were contributory factors.

The findings from the analysis of incident reports were supported by complaints data, feedback from GPs and the annual Trust anticoagulant medication audit.

Patient interviews identified issues with lack of engagement of patients in their anti-coagulation management during their in-patient stay, delays in communicating INR results and dose changes between members of the multi-disciplinary team, and with patients. Patients also reported that ward staff sometimes get distracted onto other tasks leading to omissions or delays in recording patient INR test results. This may partly explain the inaccurate information in discharge summaries identified in the annual audit.

The project aimed to improve the quality of information available to patients during admission and at discharge, about their inpatient anticoagulation treatment.

Description of innovation
We developed two innovations to enhance the quality of discharge summaries and information available to patients to empower them to be partners in their care.

i. Patient-centred run charts that show INR test result, drug dose and target INR level in a pictorial format.

ii. Patient-led discharge summary 'time outs'.

Methods used for testing / implementation so far including ethics, plans, measures, methods for evaluation & analysis
Ethics approval was not required because this was a service improvement project. Patients were given written and verbal information about the project and participation was voluntary.

PDSA tests were used to test prototypes and to spread the innovations across the ward. Process measures were the number of patients admitted to Level 3 Heart Hospital who were provided with a patient-centred run chart and who engaged in a discharge time out (as a proportion of the overall number of patients on anticoagulants on the ward).

Outcome measures were:
1. Number of readmissions directly related to poor anticoagulation management, measured against a baseline established from our ward readmissions audit.
2. Comparative analysis of the frequency, type and severity of incidents pre and post intervention.
3. The percentage of patients with missing information on their discharge summary, (as defined by the Trust's audit standards), compared to the baseline figures from the 2011 Trust anticoagulation medication audit.

Evaluation of the innovations was carried out iteratively using patient feedback via PDSA testing. Patient surveys were used to evaluate improvements in patient perceptions of involvement in their care.

What was achieved – (method, process, context, challenges)
PDSA testing of the patient-centred run charts and discharge time out were successful and provided excellent feedback enabling us to adapt the prototype patient-centred run chart and discharge time out tool. The run chart is now established into routine practice at the Heart Hospital on levels 3 & 4 and is offered to all patients initiated on anticoagulation, as well as those that are established.

Initial testing of the run chart involved six patients and four patients engaged in a discharge time out. None of the patients involved in testing the two innovations were readmitted within 30 days, or involved in reported incidents. Feedback received from the six patients involved in PDSA testing of the run chart was comprehensive. We were confident all necessary adaptations had been carried out to the prototype across the six testing cycles. A decision was therefore taken to adopt the run chart and it has now been implemented and sustained on Heart Hospital level 3. Further testing of the discharge time out is required before the prototype is adopted.

The percentage of patients with missing information relating to 'discharge dose' and 'discharge INR' on their discharge summary improved by 6% and 8% respectively in the 2013 re-audit.

What went well? What have been the challenges and how have these been overcome?
Assimilating baseline data in a scanning template, auditing readmissions and PDSA testing of the patient-centred run charts have been successful. PDSA testing has provided excellent feedback enabling us to adapt the prototype patient-centred run chart (see Appendices B and D). We adapted an FMEA (failure modes and effects analysis) from one carried out by the Institute of Safe Medication Practice in the United States to reflects what could go wrong with anticoagulation management at UCLH (see Appendix F).

The main challenges which led to fewer patient numbers, delays in testing and the inability to carry out FMEA workshops have been:

(i) Nursing engagement at the start of the project. We overcame this by presenting the SHINE project at nursing away days.

(ii) Staff turnover. We resolved this issue by briefing the new Divisional Clinical Director, Head of Nursing and Ward Sister about the project.

(iii) Ward leadership of the project. We addressed this by maintaining a visible presence on the ward working with pioneers who led the testing and implementation of the interventions, using senior nurses to unblock barriers and extending the project to Heart Level 4 to increase the patient cohort.

(iv) Identifying surgeons to lead testing of the discharge summary time out. We overcame this by involving the discharge pharmacist who provided insights into the variation and complexity in the discharge process, and a link to the surgical team.

(v) Fewer in-patients on anticoagulation than anticipated (leading to fewer opportunities to carry out PDSA tests and less survey responses than originally anticipated). We established that although the Heart Hospital site had the highest number of patients on anticoagulation, many of the patients were admitted for short durations of less than 24-48 hours thus making them unsuitable for participation in the project.

Part 2. Quality impact: outcomes

Nature of setting and innovation
Adult cardiac surgery and cardiology patients admitted to the Heart Hospital, Level 3.

The innovations were a patient-centred run chart, (designed to empower patients to be partners in their care), and a patient-led discharge summary 'time-out (to enhance the quality of discharge summaries).

Course of intervention, tests of change, adjustment
The prototypes were tested, adapted and spread across the ward using PDSA cycles (see appendix A and Table 1).

Table 1: Summary PDSA test results

PDSA TESTS ON PATIENT-CENTERED RUN CHART		
PDSA Test number	**What was learnt?**	**What decisions were taken based on what was learnt (i.e. adapt, adopt, abandon)**
1	**Lesson 1:** The patient thought that the run chart was a good idea that could potentially engage patients in developing a better understanding of their anti-coagulant medications. However, he felt that we needed to give patients INR test result and dose information when carrying out the PDSA testing so that we could see how they use the tool and patients could provide feedback based on having practised to use the tool.	Adapt the PDSA testing approach so that future tests gave patients the opportunity to use the run chart, as opposed to simply asking them to comment on it.
2	**Lesson 2:** The patient reported that she was happy with her anticoagulant management and that she did not need a run chart. We learnt that the willingness of the patient to be involved in their anticoagulation management influences how they view and interact with the run chart.	To adapt the testing approach to establish patient interest and willingness to be more in control of their anticoagulation management before exploring views about the run chart.
3	**Lesson 3:** (carried out with the patient and her carer) The patient initially fed back that she would find using the run chart anxiety provoking because she is a naturally anxious person. 'If my INR is heading to the red zone that would worry me.' However, her carer reported that the run chart would be very useful for him because it provides a visual summary of his wife's INR level etc. The carer reported that the prototype run chart needs additional information on it to advise patients what action they should take if their INR level is drifting into the red zone. The patient agreed with this comment and reported that she would like to use it if a revised version contained clearer instructions on what action a patient should take in the event that their INR drifts towards the red zone.	Adapt the prototype run chart to include instructions for patients on what action should be taken if their INR level drifts towards the red zone.
4	**Lesson 4:** The patient immediately pointed out the visual impact of the chart – green is the safe zone; pinks are not. He was able to plot his own data and commented on how, throughout his in-patient treatment his INR levels had changed and were now heading towards the green zone. The patient commented that the run chart would be useful to monitor trends over time.	No changes made but we decided to re-test the revised prototype on another patient
5	**Lesson 5:** The patient "loved" the chart commenting that he likes to keep his own records, and could see the run chart as a way of looking after his interests. He identified that the green was where he needed to be and the pinks were not good. The patient fed back that the chart needed a larger/ darker font for the INR scale. The patient also stated that the chart would be a useful tool to reassure his wife who could not understand why he was still in hospital (awaiting INR in range pre-discharge).	Adapt the INR font size
6	NB: The next test involved a patient continuing to use the run chart following his discharge from hospital **Lesson 6:** A telephone debrief with the patient showed that he had found the run chart simple to	Continue to test the run chart with patients who are willing to keep plotting their data after they have been discharged from hospital. This provides useful feedback about the continuation of care across the acute to community

	use when he continued plotting his data after he had been discharged from hospital. Furthermore, the patient had taken the run chart into the local anticoagulant outpatient clinic and to his GP appointment with him and shown it to staff there. The outpatient clinic staff also found the information on the run chart useful because it provided them with a clear visual summary of the patient's recent dosing and INR levels. In short, it filled the gaps in their understanding of the patient's INR profile and dosing regimen. The patient's GP was also positive about the run chart. The patient reported that the run chart 'makes it a lot simpler to communicate' about the anticoagulation medication.	care boundary.
PDSA TESTS ON PATIENT LED DISCHARGE TIME OUT		
PDSA Test number	**What was learnt?**	**What decisions were taken based on what was learnt (i.e. adapt, adopt, abandon)**
1	**Lesson 1**: The patient found the discharge time out really useful and the like the opportunity it provided to ask questions. The discharge facilitator pharmacist reported the time out tool was better than the current discharge summary to enable the time out, but recommended changes to the content and layout of the tool.	Adapt the prototype to incorporate fluid balance and stool section into the medicines section, and include a section on who to contact if the patient has problems when they get home.
2	**Lesson 2**: The patient reported that he had not realised there were going to be as many changes to his medicines. He reported that the discharge time out was beneficial because it provided an opportunity for these changes to be discussed with a pharmacist. Explanations about medicine changes needed to be repeated a couple of times, which showed that if there was no 'timeout' then patient may not have fully understood details of their stay prior to being discharged home. Patient particularly liked that information about anticoagulation follow up arrangements were discussed and clear.	No changes to the prototype were suggested following this PDSA testing cycle. It was therefore decided to test the discharge summary time out tool with another team. Hence the focus of the next PDSA cycle was on testing the tool's usability with a pharmacist who was not involved in its development.
3	**Lesson 3**: The patient was engaged and reported that the 'one-on-one' time the discharge time out provided was very useful. It provided the opportunity to ask questions and confirm that follow-up arrangements had been made. The clinical pharmacist reported that the tool was useful in guiding the flow of the session, but the information had to be gathered from nurses and patient records before the timeout could be conducted.	Continue to test the timeout prototype with other members of the team.
4	**Lesson 4:** The patient was very already very aware and engaged in his own care, but found the discharge time out provided a good structure and mechanism to check and confirm the details at point of discharge. The surgical senior house officer reported that contrary to initial belief, the discharge time out was a good way to summarise the events during hospitalisation, and in particular to go through follow up arrangements, who to contact in case of problems and the medication. They reported that the time taken would need to be considered as surgical commitments may make it difficult to have a discharge time out with all patients.	No changes to the prototype were suggested following this PDSA testing cycle. Continue testing to identify which member of the team is best placed to conduct the discharge time out.

The PDSA test results showed mixed responses to the run chart: Whereas some patients felt it empowered them to be partners in their anti-coagulant management, other patients did not want to monitor their own INR results. Patients should therefore be given a choice about whether or not they use a run chart. We have ensured patient choice was reflected into the implementation of the run chart on Heart Level 3. Ward pharmacists report that on average, six patients per month are now receiving and using the run chart.

Primary and secondary data sources and accessibility
The data sources were ward level patient frequent feedback, incident reporting, complaints, readmissions data, anticoagulant discharge summary documentation, and the SHINE anticoagulant patient survey (Appendix C). Survey data was difficult to access, because there were fewer patients taking anticoagulants than anticipated. All other types of data were easy to access.

Validity and reliability of the data
The patient survey (Appendix C) was developed based on patient interviews but we cannot claim it has construct or internal validity. Our objective has not been to carry out a research study which proves the reliability and validity of the survey.

Changes made demonstrated by data
Outcome measures:

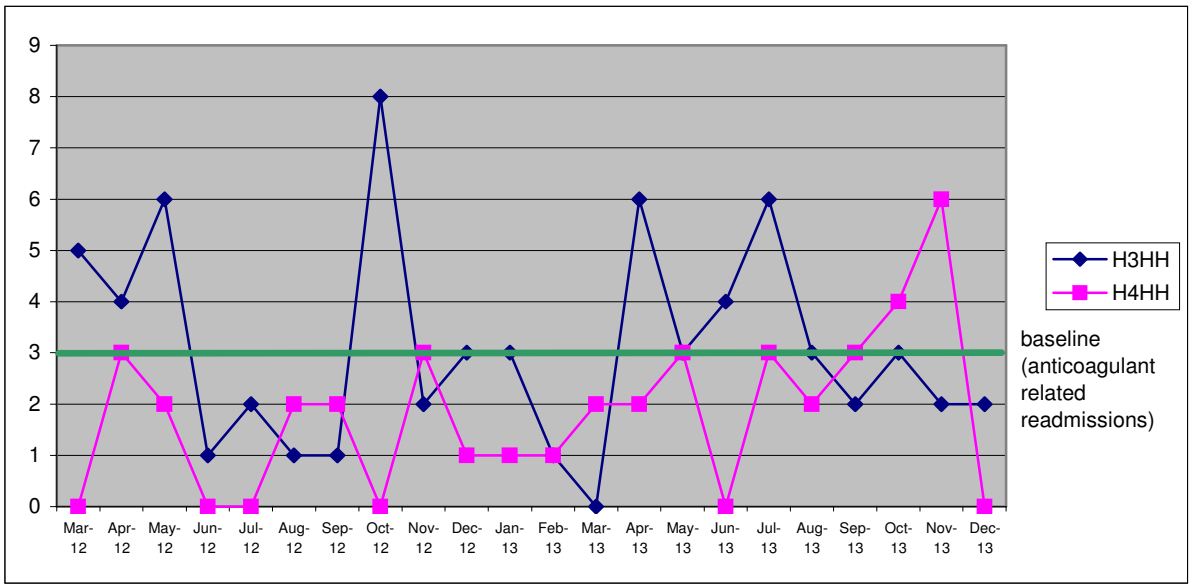
1. **Number of readmissions directly related to poor anticoagulation management**. A baseline audit of readmissions between April 2012 and January 2013 showed that out of 33 readmissions, involving thirteen patients on an anticoagulant, three were directly related to poor anticoagulant management. During the testing period (April 2013 to December 2014), the number of readmissions remained at 33, with 13 patients on anticoagulation but none of the readmissions related to poor anticoagulant management (see figure 1).

Table 2: Patient readmission tracking data

Patient number	Innovation tested	Readmission status (readmitted within 30 days of discharge? Yes/No).
Patient 1	Patient-centred run chart	Not readmitted
Patient 2	Patient-centred run chart	Not readmitted
Patient 3	Patient-centred run chart	Not readmitted
Patient 4	Patient-centred run chart	Not readmitted
Patient 5	Patient-centred run chart	Not readmitted
Patient 6	Patient-centred run chart	Not readmitted
Patient 7	Discharge time out	Not yet readmitted (still within 30 day period)
Patient 8	Discharge time out	Not yet readmitted (still within 30 day period)
Patient 9	Discharge time out	Not yet readmitted (still within 30 day period)
Patient 10	Discharge time out	Not yet readmitted (still within 30 day period)

From the overall readmissions data, we cannot demonstrate that the innovations led to a reduction in readmission rates. However, Table 2 shows that none of the patients involved in testing the two innovations were readmitted within 30 days of discharge. This data provides tentative evidence that the innovations have potential to contribute to reductions in readmission rates (although we accept that the number of patients is small). Further work is needed over a longer time period to be able to evaluate the impact of the innovations on readmission rates, but the initial results shown in Table 2 are promising.

Figure 1: Number of readmissions to Heart Hospital Ward 3 and 4



2. **Comparative analysis of the frequency, type and severity of incidents** pre and post intervention. There were a total of four incidents reported during the project period, two from the Heart level 3 (intervention period but not involving patients with run charts) and two from Heart level 4 (baseline period). None of the patients who had tested the intervention were involved in these incidents.

3. **Information on discharge summary**: The percentage of patients with missing information relating to 'discharge dose' and 'discharge INR' on their discharge summary, (as defined by the Trust's audit standards), improved by 6% and 8% respectively in the 2013 re-audit (see table 3).

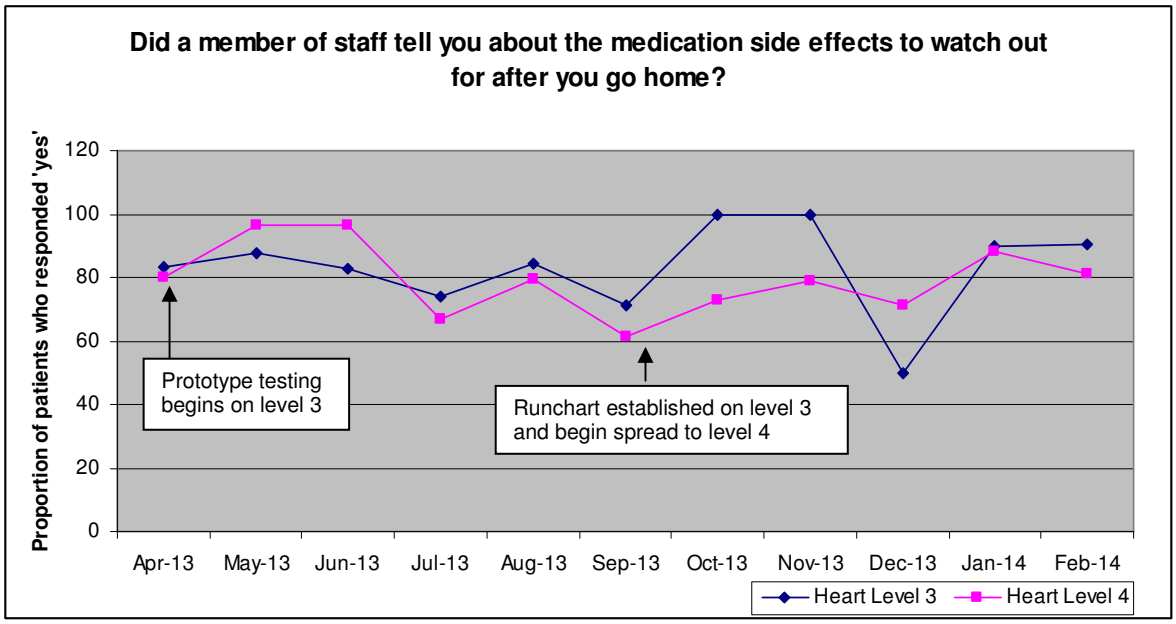
Table 3: Percentage compliance to warfarin discharge standards

Standard (100% documentation)	2011 Audit (%) n= 74 (of which THH n = 26)	2013 Re-audit (%) n=46 (of which THH n = 23)
Anticoagulant (A/C) name	100	100
Indication	100	100
INR range	80	83
Discharge dose	90	96
Discharge INR	70	78
A/C book updated	Not audited	13
Next A/C appointment	90	87
Anticoagulation clinic details	89	91

4. **SHINE Patient Survey results**.

Thirteen patients completed the survey between April 2013 to November 2013 (11 from Level 3 and 2 from Level 4). The response rate was low because fewer suitable patients were admitted to the test wards during the timeframe in which the project was carried out. The SHINE survey response size is too small to measure whether the innovations led to improvement. However, patient frequent feedback survey data (see Figure 2) does show an improvement in the number of patients responding 'yes' to the statement, 'Did a member of staff tell you about the side effects to look out for when you got home.' In April 2013 83% patients on level 3 and 80 % patients on level 4 responded 'yes' to this statement. By February 2014 this had increased to 90% on level 3. There was no improvement observed on ward 4.

Figure 2: Patient frequent feedback survey data



Description of data quality and confidence

Baseline data was collected in accordance with our SHINE proposal. We surveyed fewer patients than originally envisaged.

Adjustments made to outcome measures from the original application

We dropped the measure *'% of patients discharged before 11am (as per the Trust's discharged target).* Ward pharmacists indicated that discharge delays sometimes occur because they are resolving inaccuracies in the discharge summary. Therefore, the measure is inappropriate and may negatively impact patient safety.

We have also dropped plans to collect data from community discharge alerts after identifying the gap in the Heart Hospital's processes for learning from this data. Both of these issues have provided valuable learning for the Trust; showing the limitations with our safety measurement approach and learning processes, respectively.

Assessment of the effect of your project on the quality of the service and the experience of patients

PDSA test results indicate the patient-centred run chart has the potential to bridge the information gaps between acute and community care providers, thus enhancing patient experience and quality of care. There was a definite 'pull' for the run chart from patients involved in the PDSA tests, many of whom requested that they would like to continue using the run-chart after being discharged home. Patient led discharge time outs provide an opportunity for patients to ask questions and clarify changes in medication and follow up arrangements for anticoagulation management. Further PDSA testing of the time outs is planned.

The anticoagulant audit and frequent feedback survey results indicate that patients were better informed about their anticoagulation medicines management during hospitalisation and at discharge.

The project enabled nursing staff to be more involved in discussing anticoagulation medication with patients, an area that was previously perceived to be the responsibility of pharmacists.

The patient led timeouts have the potential to provide a structured tool to ensure all aspects of the patient's care are discussed with the patient prior to discharge. The optimal time, and the responsible professional remains to be established.

Part 3. Cost impact

Measuring cost improvement and cash releasing savings was not a primary objective of the project as outlined in our SHINE application. We discussed this with the external consultant who mentored our project team who agreed that our focus should not be on cost savings. However, we have calculated the cost of the SHINE intervention by developing implementation costs including the development of an app for the run chart (see Table 4) Cash releasing savings have not been demonstrated, but our initial findings suggest the potential for improved efficiency due to a reduction in readmissions and medication incidents. As stated previously, the run chart is now embedded in practice on Heart ward 3. It has been incorporated into the routine work of ward pharmacists who introduce it to patients during conversations to check patients understanding of their medications. Thus, the cost of implementing and sustaining the intervention has been minimised because there is a 'natural fit' between the run chart and already established checks of patients' understanding of their medications. This demonstrates that where new innovations are developed, both sustainability and cost reductions can be achieved when the innovation dovetails with existing practice. This needs to be monitored over a longer period of time and would require an economic analysis. As stated previously, this was not an explicit aim of the project.

Table 4: development implementation costs

Resource	**Estimated cost of developing the intervention**
Head of Quality Improvement	£22,000
Medication Safety Pharmacist	£22,000
Human Factors Consultant	£16,500
Project Assistant (developing SHINE patient survey using the Meridien system)	£ 1,500
Ward pharmacists (testing innovations)	£3,000
Ward nurses (testing innovations)	£3,000
Performance and partnership analyst (for collating data on readmissions)	£1,500
Run-chart 'app' development	£4,500

Further work is needed to demonstrate the potential for the interventions to reduce costs. This work could include a more comprehensive evaluation of the readmission penalty cost savings and opportunity cost savings associated with each intervention (for example, emails and correspondence between GPs and acute providers to check incomplete anticoagulant information on the discharge summary or to clarify the reasons for starting a patient on anti-coagulants etc).

Part 4: Learning from your project

Achievements and learning

We successfully achieved our aim to improve the quality of information available to patients during admission and at discharge, about their inpatient anticoagulation treatment.

The patient-centred run chart was spread to all wards at the Heart Hospital site, and the patient led discharge time out has been shown to be a useful way of providing patients information about their treatment at discharge.

One of the main factors that helped this achievement was local leadership from the clinical pharmacist, ward sister and charge nurse for the wards involved. We presented at nursing away days to promote and explain the project. We also developed a SHINE project briefing for ward nurses and hospital pharmacists. On-going engagement with ward staff was maintained with a visible presence from the project leads on the ward.

We learnt the importance of patient feedback gathered through PDSA testing to shape safety improvements. Patients value being asked their opinion about safety interventions and yet this is not routine practice.

Challenges and changes to plan

We originally hoped to spread the innovations to all patients taking anticoagulant medication at UCLH. This has not been achieved but we plan to use the PDSA findings to persuade other wards to adopt the two innovations. We feel that the SHINE project has provided a strong foundation for spreading the innovation further but we were unable to achieve complete spread in the timescale of the project.

Illness, annual leave and engaging the ward sister at an early stage of the project caused delays in project initiation, but these were subsequently overcome and resolved. We also struggled to identify surgeons to lead testing of the discharge summary time out. Problems with access and willingness of surgeons to lead the testing of this innovation meant it became a pharmacy-led initiative.

There were considerable staff changes involving senior leadership (ward sister, matron, divisional clinical director and divisional manager) at the Heart Hospital site. These changes increased the need to re-communicate information about the project to senior leaders.

An FMEA (failure modes and effects analysis) had been adapted from one carried out by the Institute of Safe Medication Practice in the United States. The adapted version reflects what could go wrong with anticoagulation management at UCLH. However, FMEA workshops have not been carried out due to the issues with engaging ward nurses discussed above in the report.

In terms of what we would do differently next time around: Firstly, we would not select the testing ward solely on where the data tells us the biggest problem is. We have learnt that testing the ward sister's commitment to implement quality improvement is vital at the planning stage of an improvement project.

Part 5. Plans for sustainability and spread

Spread and sustainability

In terms of sustaining the benefits of the project beyond March 2014, we are concerned about sustainability. In the past we have encountered problems with sustaining quality improvement work, especially when staff change roles and after the initial project has been completed. We have therefore begun discussions to develop simple process measures, reportable on ward scorecards that enable us to continue to monitor the number of patients treated on wards who use a run chart to monitor their care or who engage in a discharge time out. We are also seeking support from divisional leads to embed the innovations into standard procedures at admission (runchart) as part of medicines reconciliation and at discharge (timeout).

Most of the outcome measures used during this project i.e. readmissions, medication incidents, complaints and frequent feedback surveys, are collected monitored on an ongoing basis. We will continue to review these at 6 monthly intervals to assess the impact of the two innovations in the longer term.

Following PDSA tests feedback, we have also discussed developing an app of the patient-centred run chart with the Trust's IT department, and an iPad has been procured to enable this. We anticipate that an app version will be a more effective way of enhancing the spread of the intervention in other areas of UCLH. We have also identified a patient who has used the run chart who has agreed to be videoed discussing how useful it has been to him. Once again, this will be a valuable tool to enhance spread.

External interests and key stakeholders

In terms of spreading the intervention beyond UCLH we need further data and evidence to confirm the initial benefits seen, patient acceptance and sustainability. We would then require support from the Health Foundation and the Patient Safety Division in NHS England (notably Dr David Cousins who leads national work on safe medication practice). The aforementioned person is the most notable contact we need to engage with. Professor Nick Barber and stakeholders from the British Society for Haematology, who produce the 'yellow book,' would also be useful to engage with in the future.

Appendix 2: Resources from the project

Please attach any leaflets, posters, presentations, media coverage, blogs etc you feel would be beneficial to share with others

APPENDIX A: SHINE BRIEFING: *SUPPORTING PATIENTS TO BE ACTIVE PARTICIPANTS IN IMPROVING ANTICOAGULANT MEDICATION SAFETY*

Background:
Patients who take anti-coagulation medications are at risk of developing blood clots or bleeds if too little or too much medication is taken, respectively. We know from UCLH incident report data that there have been 348 incidents involving anticoagulants reported since 2010.

When a patient is prescribed anti-coagulation medications their health care treatment is complex because there are many interfaces between the health care teams involved in delivering safe patient care. Supporting patients to be active participants in their own care is therefore particularly important for this patient group.

The UCLH SHINE project
The Director of Quality and Safety at UCLH, Sandra Hallett, has been awarded funding from the Health Foundation to test innovations to improve anti-coagulation medication safety. The two innovations are:

i. **Patient-led discharge summary 'time outs'** (involving patients in reviewing the content of their discharge summary prior to discharge will improve communication between the hospital and General Practitioner).

ii. **Patient-centred run charts,** showing INR test result, drug dosage and target INR level in a pictorial format. This educational tool will engage patients in understanding their anticoagulant management plan.

We believe that innovations which engage patients and carers in checking what is written in the discharge summary could help to improve the quality of information. Similarly, developing patient-centred run charts which show INR results, target INR and dose rates over time will help patients to monitor and communicate potential safety issues across team and organisational boundaries.

The project team comprises Guy Young, Head of Quality Improvement, Yogini Jani, Medication Safety Pharmacist, Beth Ward, Ward Pharmacist and Jane Carthey, Human Factors Specialist. The project duration is 15 months.

The benefits of the project for you and your patients
Throughout the project, the project team will be working with ward nurses, pharmacists, doctors and nursing assistants to develop, test and spread the two innovations described above. Prototype patient-centred run charts and discharge time outs will be tested using Plan Do Study Act (PDSA) cycles and spread using 90 day rapid improvement cycles. The project provides an exciting opportunity for ward staff to:

- Gain experience in leading quality improvement work.
- Be mentored by project team members on carrying out PDSA tests and quality improvement work.
- Work collaboratively with patients and carers to test innovations that will improve patient safety.
- Work on a project that is likely to influence national guidance on the management of patients taking anti-coagulants.

Being involved in the projectis also an opportunity for you to add quality improvement experience and skills onto your curriculum vitae.

What next?
We aim to start the project off by:

- Carrying out a survey of patients treated on Level 3 which aims to collect baseline data on their in-patient experience.
- PDSA test a prototype run chart developed by the Medication Safety Pharmacist.
- Carry out a Failure Modes and Effects Analysis (FMEA).

Project contacts:
If you would like more information on the SHINE project, please email yogini.jani@uclh.nhs.uk, jane.carthey@uclh.nhs.uk or guy.young@uclh.nhs.uk. Alternatively, you can contact Yogini on 07946 381368 or Jane on 07824 535477.

We look forward to working with you on this very exciting project.

Yogini, Beth, Guy & Jane

APPENDIX B: SHINE PDSA TEST EXAMPLES

PDSA Worksheet

Objective of this cycle: To see if using an anticoagulant run chart helps patients feel involved in decision making about their anticoagulant medications

Team Name: Infection control team

Test start date: April 10th Test end date:April 10th

PLAN:

1. **Describe the change or intervention you are testing (include a short summary of who is carrying out the test, when and where the test will be carried out and how it will be carried out):**

JC and Sadeer (ward pharmacist) will test the run chart with one patient on Level 3 at the Heart Hospital. We will seek the patient's feedback on the prototype run chart and opinions on whether it is worthwhile as an intervention to increase patient inclusion and awareness of their INR test results and dose regime.

2. **What do you predict the result of your test of change will be (i.e. what do you expect will happen)?**
   - We predict that the patient will think the run chart is potentially useful

DO:

3. **Whatactually happened when you carried out the test? (Describe your observations, findings and any problems encountered)**

- AS PREDICTED THE PATIENT THOUGHT THE RUN CHART WAS POTENTIALLY USEFUL. HE FELT THAT HAVING A GRAPH WHICH SHOWED HIS TEST RESULTS WOULD BE USEFUL.
- HOWEVER, THE PATIENT FELT THAT THE APPROACH TO TESTING THE PROTOTYPE NEEDED TO BE MODIFIED. AS A PATIENT IT IS DIFFICULT TO GIVE FEEDBACK ON WHETHER THE PROTOTYPE WOULD BE OF BENEFIT TO PATIENTS WITHOUT GIVING THEM THE OPPORUNITY TO USE IT. HE RECOMMENDED THAT WE SHOULD CONSIDER GIVING PATIENTS SOME DATA AND ASKING THEM TO USE THE RUN CHART, THEN ASKING THEM WHETHER THE RUN CHART WAS USEFUL OR NOT.

STUDY:

4. **What did you learn? (Compare your results to your predictions)**

- WE LEARNT THAT, AS PREDICTED THE PATIENT LIKED THE CONCEPT OF HAVING A RUN CHART,
- WE ALSO LEARNT LESSONS ABOUT OUR TESTING APPROACH BASED ON THE PATIENT'S COMMENTS.

ACT:

5. **What will you do next? Adopt, adapt, or abandon the change?**

- CONSIDER ADAPTING OUR APPROACH TO TESTING THE RUN CHART BY GIVING PATIENTS INVOLVED IN FUTURE PDSA TESTS DATA TO PLOT AND THEN SEEKING THEIR FEEDBACK

PDSA Worksheet

Objective of this cycle: To see if using a run chart helps patients feel involved in decision making about their anticoagulant medications and will give them more ownership of their anticoagulant medication information

Team Name: SHINE

Test start date: May 23rd
Test end date:May 23rd

PLAN:

6. Describe the change or intervention you are testing (include a short summary of who is carrying out the test, when and where the test will be carried out and how it will be carried out):

YJ will test the run chart with one patient on Level 3 at the Heart Hospital. We will seek the patient's feedback on the prototype run chart and opinions on whether it is worthwhile as an intervention to increase patient inclusion and awareness of their INR test results and dose regime. The patient (RF) has been on warfarin previously and is managed by her GP.

7. What do you predict the result of your test of change will be (i.e. what do you expect will happen)?

- We predict that the patient will think the run chart is a potentially useful mechanism to increase patient inclusion and awareness of their anticoagulant medication dose and their INR test results.

DO:

8. Whatactually happened when you carried out the test? (Describe your observations, findings and any problems encountered)

The patient could see the benefits of the run chart but liked to "keep things simple which the book does" can take in information and process it e.g. target was 2.5; results came back at 2.3 so was expecting a small dose increase; GP manages at home; clinical team in charge once in hospital - "they know what they need to do in view of op"; also had to deal with spreadsheets and graphs at work and doesn't like them!

STUDY:

9. What did you learn? (Compare your results to your predictions)

Non healthcare experiences can influence patient's views about health information and how it is provided. The patient felt that others may benefit from a visual representation of their results, but was happy to manage her own results in a tabular format which she felt was simpler.

ACT:

10. **What will you do next? Adopt, adapt, or abandon the change?**

ADAPT – revise the run chart to tone down the colours and see if it makes a difference

PDSA Worksheet

Objective of this cycle: To see if using a discharge time out tool helps patients feel involved and have a greater understanding of events which occurred throughout their inpatient stay

Team Name: SHINE

Test start date: Feb 28th 2014 Test end date:Feb 28th 2014

PLAN:

11. Describe the change or intervention you are testing (include a short summary of who is carrying out the test, when and where the test will be carried out and how it will be carried out):

BW and SF (discharge pharmacist) will test the discharge time out with one patient on Level 3 at the Heart Hospital. We will seek the patient's feedback on the prototype and opinions on whether it is worthwhile as an intervention to increase patient inclusion and awareness of the details of their inpatient stay, warfarin and INR test results and dose regime, medications and management once discharged.

12. What do you predict the result of your test of change will be (i.e. what do you expect will happen)?

- We predict that the patient will think the discharge time out is a valuable tool to increase patient inclusion and awareness of their medications (including anticoagulation) and events throughout their stay

DO:

13. Whatactually happened when you carried out the test? (Describe your observations, findings and any problems encountered)

PATIENT WAS ENGAGED THROUGHOUT. PATIENT WAS THANKFUL FOR THE TIME SPENT. THEY WEREN'T AWARE THERE WERE GOING TO BE AS MANY CHANGES TO THEIR MEDICINES.

STUDY:

14. What did you learn? (Compare your results to your predictions)

PATIENT LIKED THE OPPORTUNITY TO ASK QUESTIONS. EXPLANATIONS NEEDED TO BE REPEATED A COUPLE OF TIMES, WHICH SHOWED THAT IF THERE IS NOT A 'TIMEOUT' THEN PATIENT MAY NOT HAVE FULLY UNDERSTOOD DETAILS OF THEIR STAY PRIOR TO BEING DISCHARGED HOME.
PATIENT HAS BEEN ADMITTED TO HOSPITAL ON OTHER OCCASSIONS AND HAS NOT EXPERIENCED A 'TIMEOUT' SUCH AS THIS. HE FELT IT WAS EXTREMELY USEFUL.
PATIENT PARTICULARLY LIKED THAT IT WAS SPECIFIED WHEN HE NEEDED TO SEE GP NEXT, AND LIKED THAT ANTICOAG APPOINTMENT HAD BEEN MADE FOR HIS GP SURGERY RATHER THAN THE HOSPITAL AS THIS WAS MORE CONVENIENT FOR HIM

ACT:

15. **What will you do next? Adopt, adapt, or abandon the change?**
Adopt and trial with another patient

APPENDIX C: SHINE PATIENT SURVEY

INCLUSION							
Num	**Question Text**	**Competencies**	**Responses**	**Weight**	**N/A**	**MR**	**Question Tip**
1	Were decisions about your anticoagulant medication clearly explained to you?		• Yes, always (100) • Yes, sometimes (50) • No (0) • Not sure / Don't know (-)	1	N	N	
TIMELY COMMUNICATION BETWEEN HEALTHCARE TEAM MEMBERS							
Num	**Question Text**	**Competencies**	**Responses**	**Weight**	**N/A**	**MR**	**Question Tip**
2	Was there good communication between doctors, nurses and pharmacists about your anticoagulant medications?		• Yes, always (100) • Yes, sometimes (50) • No (0) • Not sure / Don't know (-)	1	N	N	
COMPLETENESS AND ACCURACY OF HEALTHCARE RECORDS							
Num	**Question Text**	**Competencies**	**Responses**	**Weight**	**N/A**	**MR**	**Question Tip**

3	Did you think that information on your anticoagulants was being recorded in your notes?		• Yes, definitely (100) • Yes, to some extent (50) • No (0) • Not sure/don't know (-)	1	N	N	
UNDERSTANDING HOW TO TAKE MEDICATIONS							
Num	**Question Text**	**Competencies**	**Responses**	**Weight**	**N/A**	**MR**	**Question Tip**
4	Did a member of staff explain how to take your anticoagulant medications?		• Yes, completely (100) • Yes, to some extent (50) • No (0) • I did not need an explanation (-) • Not applicable (-)	1	N	N	
5	Do you understand how and when to take your anticoagulant medications?		• Yes, completely (100) • Yes, to some extent (50) • No (0) • Not sure/don't	1	N	N	

			know (-)				
SHARING INR REST RESULTS							
Num	**Question Text**	**Competencies**	**Responses**	**Weight**	**N/A**	**MR**	**Question Tip**
6	Were your INR test results shared with you when you were in the hospital?		• Yes, always (100) • Yes, sometimes (50) • No (0) • Not sure / Don't know (-)	1	Y **NA Text:** Not applicable	N	
DISCHARGE							
Num	**Question Text**	**Competencies**	**Responses**	**Weight**	**N/A**	**MR**	**Question Tip**
7	Was your anticoagulant follow up appointment booked before you went home?		• Yes (100) • No (0) • Don't know (-)				

APPENDIX D: SHINE PRESENTATION (INCLUDING PATIENT CENTERED RUN CHART)

The Health Foundation
Inspiring improvement
Shine
Supporting patients to be active participants in improving anticoagulant medication safety
Yogini Jani, Medication Safety Pharmacist
Jane Carthey, Human Factors Specialist
Guy Young, Head of Quality Improvement
20th May 2013

Shine

Patient safety issues

- Patient x on warfarin following heart valve prosthesis
- Target INR 2.5 to 3.5 (managed at Whittington clinic)
- Admitted to UCLH. Bridging plan – dalteparin continued until INR back to >2.5
- Final few days of UCLH admission INR dropped below 2
- Dalteparin was re-commenced at a dose of 7,500 units twice daily – INR = 2.06 on discharge to a nursing home
- Conflicting recommendations by pharmacist and doctor on discharge summary
- Both dalteparin and warfarin continued in the nursing home
- GP visit ~ 1 week post discharge: patient breathless and pale.
- Large haematoma around his hip prosthesis

Shine

The patient's perspective

Person-centredness:

Community providers empower patients with information on INR results, rationale for dose changes etc..

- Once admitted to hospital information is not shared with patients so readily. Hence, patients are not supported to be partners in their own care.

'I only found out I had been prescribed warfarin when the nurse administering medications gave me the tablets and I asked what they were.'

Communication: Information about INR test results, dose changes and their rationale, and how the anticoagulant medication decision making fits within a broader patient management plan, is not communicated in a timely way between members of the multi-disciplinary team, and the patients and their carers.

Safety: Ward nurses, doctors and pharmacists sometimes get distracted onto other tasks leading to omissions or delays in recording patient INR test results. These data omissions could have a negative impact on the accuracy of information in discharge summaries.

Shine

Why Heart Level 3?

Anti-coagulant medication audit

- **Seventy-four patients in total were discharged from UCLH on anti-coagulants over the 10 day audit period {warfarin (46), LMWH (13), warfarin and LMWH (15)}.**
- **Twenty-six patients were treated at the Heart Hospital and forty-eight at UCH.**
- **Approximately 14.8% of all discharges from the Heart Hospital were taking an anticoagulant medication, compared to 3.7% of all discharges from University College Hospital.**

The Health Foundation

Shine

Method

- **Quality improvement methodology (scanning, focus, testing & reporting)**
- **Test prototype interventions using Plan Do Study Act tests of change**
- **Measurement for improvement**

The Health Foundation

The project's objectives

To test two innovations

1. Patient-centred run charts which show INR test result, drug dose and target INR level in a pictorial format.

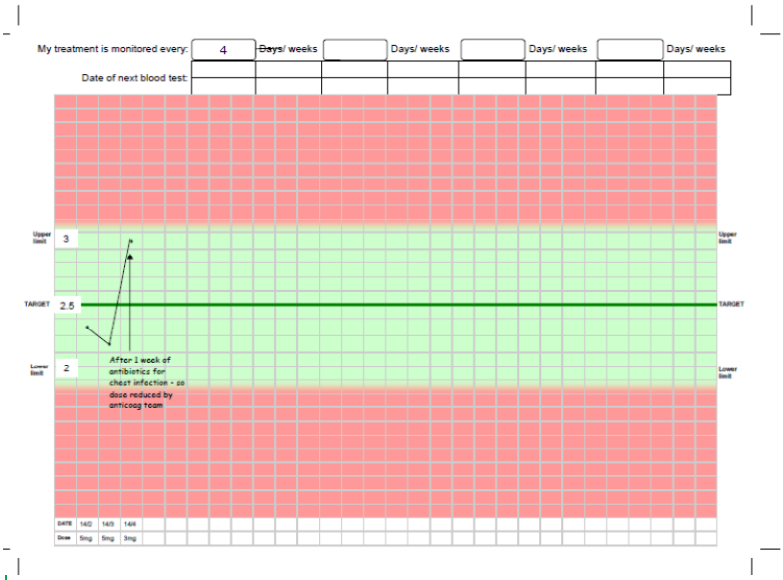
Aim- This educational tool will engage patients in understanding their anticoagulant management plan.

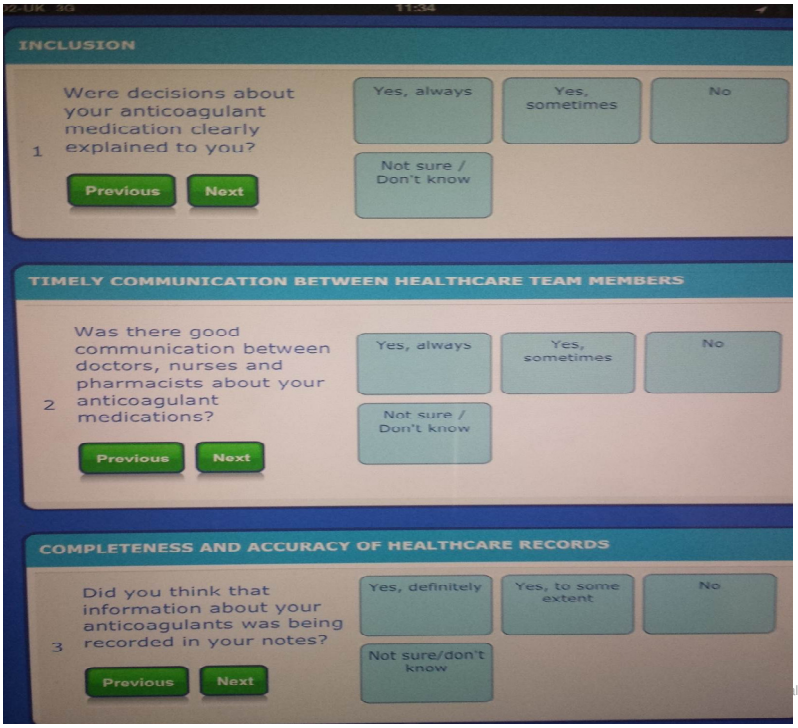
2. Patient-led discharge summary 'time outs.

Aim- by involving patients in reviewing the content of their discharge summary prior to discharge we will improve communication between the hospital and General Practitioner.

Prototype patient centred run chart

Shine




INCLUSION
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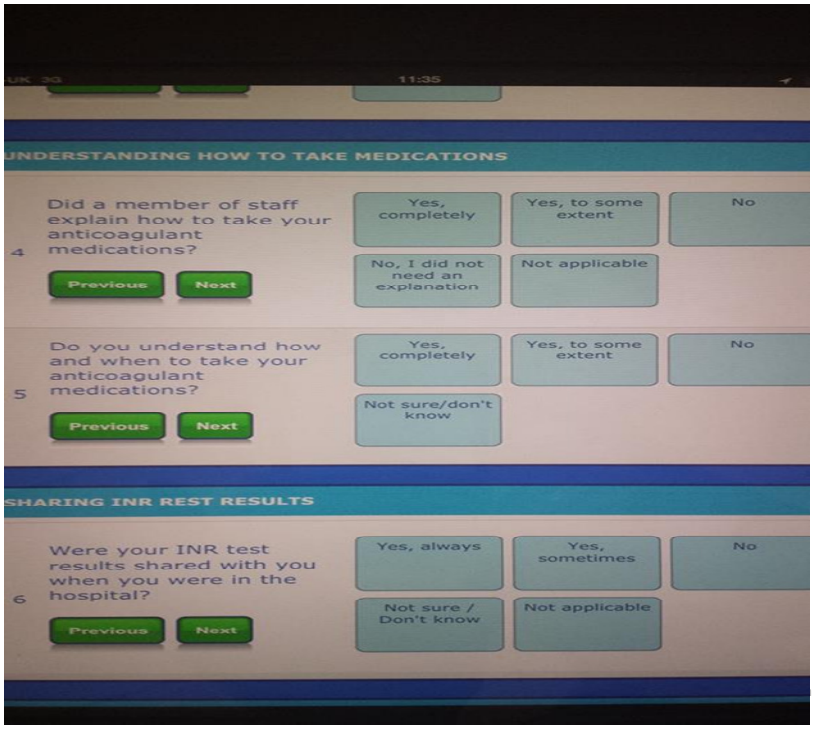
1
Yes, always
Yes, sometimes
No
Not sure / Don't know
Previous
Next
TIMELY COMMUNICATION BETWEEN HEALTHCARE TEAM MEMBERS
Was there good communication between doctors, nurses and pharmacists about your anticoagulant medications?
2
Yes, always
Yes, sometimes
No
Not sure / Don't know
Previous
Next
COMPLETENESS AND ACCURACY OF HEALTHCARE RECORDS
Did you think that information about your anticoagulants was being recorded in your notes?
3
Yes, definitely
Yes, to some extent
No
Not sure/don't know
Previous
Next

Shine


UNDERSTANDING HOW TO TAKE MEDICATIONS
Did a member of staff explain how to take your anticoagulant medications?
4
Yes, completely
Yes, to some extent
No
No, I did not need an explanation
Not applicable
Previous
Next
Do you understand how and when to take your anticoagulant medications?
5
Yes, completely
Yes, to some extent
No
Not sure/don't know
Previous
Next
SHARING INR REST RESULTS
Were your INR test results shared with you when you were in the hospital?
6
Yes, always
Yes, sometimes
No
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Not applicable
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Shine

Initial PDSA findings

Patient 1:

- Run chart would be useful for patients.
- Positive about the way staff on the ward had communicated with him.
- - Need to give patients data on dose, INR levels etc.. and ask patients to plot them.
- Would empower me to 'keep an eye on things myself.'

Patient 2:

- Newly started on warfarin.
- More useful for healthcare staff
- Useful way of communicating but could not see what role he, as a patient, could have if the data was coming from the healthcare team.

The Health Foundation

Presentation title set in header

Patient safety issues

- Patient x on warfarin following heart valve prosthesis
- Target INR 2.5 to 3.5 (managed at Whittington clinic)
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Shine

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The Health Foundation

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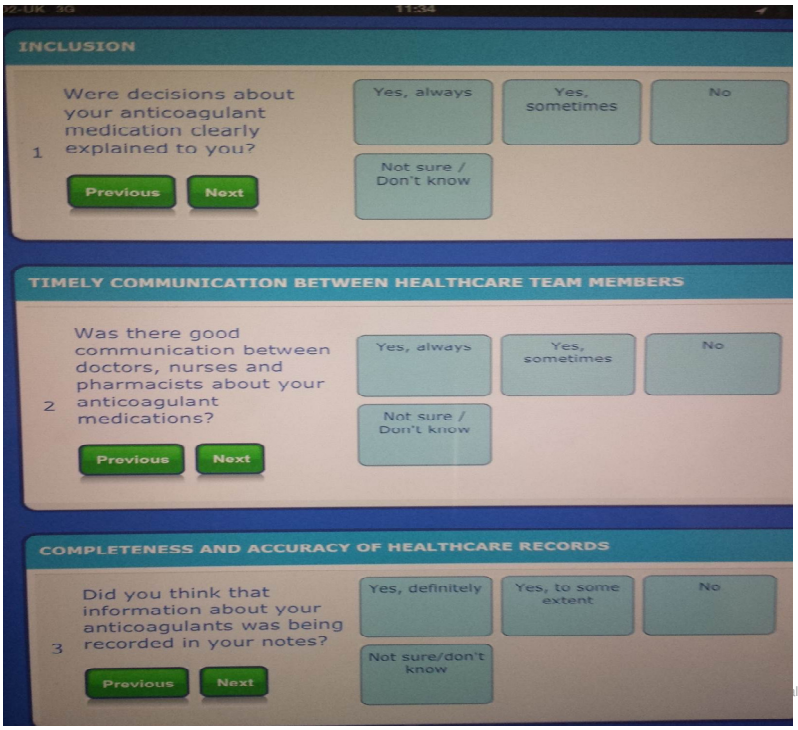
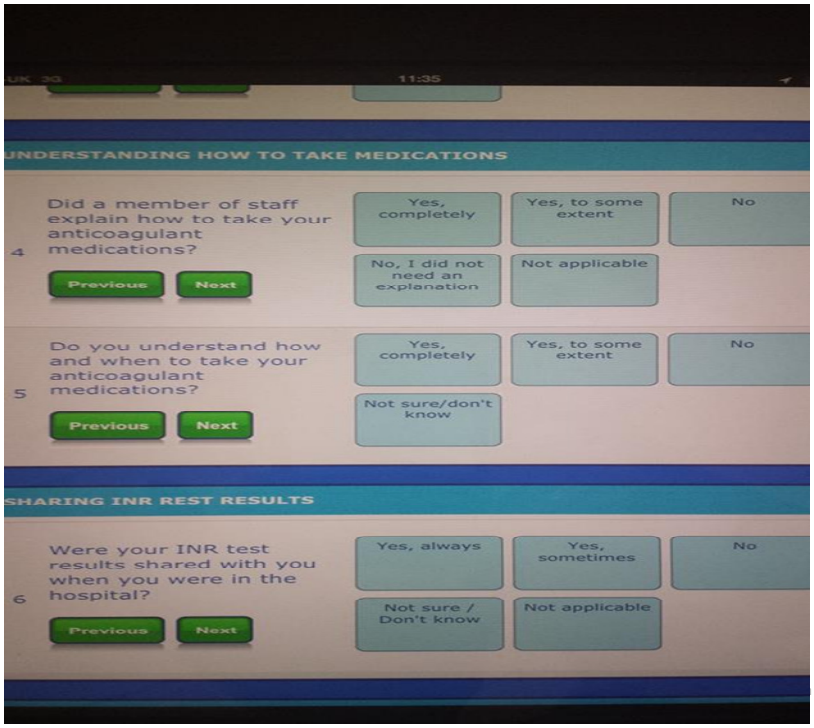
Prototype patient centred run chart

The Health Foundation



lth Foundation 8



Shine

Foundation 9

Shine

Initial PDSA findings

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- More useful for healthcare staff
- Useful way of communicating but could not see what role he, as a patient, could have if the data was coming from the healthcare team.

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Appendix E - Surgical Discharge Time-Out Proforma: SHINE Project Version 2

<table>
<tr><td>Name</td><td colspan="4"></td></tr>
<tr><td>Hospital Number</td><td colspan="4"></td></tr>
<tr><td>Ward & Bed No.</td><td colspan="4"></td></tr>
<tr><td>Discharge Diagnosis</td><td colspan="4"></td></tr>
<tr><td>Post op / discharge comments</td><td colspan="4"></td></tr>
<tr><td>Discharge Destination</td><td colspan="4"></td></tr>
<tr><td>Social Services Needs</td><td colspan="4"></td></tr>
<tr><td>Wound Care</td><td colspan="4"></td></tr>
<tr><td>Stitches</td><td colspan="4"></td></tr>
<tr><td rowspan="4">Discharge Medications

Fluid management / diuretic needs & r/v date

Bowels open

Other meds:</td><td>Continued</td><td>Changed</td><td>New</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td rowspan="8">Anticoagulation</td><td rowspan="4">Warfarin</td><td colspan="3">Indication:</td></tr>
<tr><td colspan="3">D/C dose:</td></tr>
<tr><td colspan="3">Appointment:</td></tr>
<tr><td colspan="3">Counselled: Y / N</td></tr>
<tr><td rowspan="3">LMWH</td><td colspan="3">D/C dose:</td></tr>
<tr><td colspan="3">Duration:</td></tr>
<tr><td colspan="3">Administered by:</td></tr>
<tr><td rowspan="2">NOAC</td><td colspan="3">Indication:</td></tr>
<tr><td colspan="3">Followed up by: a/c clinic GP</td></tr>
<tr><td>Antiplatelets on discharge? (please name and specify duration)</td><td colspan="4"></td></tr>
<tr><td>Acid Suppression required on discharge?</td><td colspan="4">If yes: Indication: Duration:</td></tr>
<tr><td>Antibiotics on discharge?</td><td colspan="4">If yes: Indication: Duration:</td></tr>
<tr><td>Activity Goals
(eg what should and shouldn’t be doing walking / lifting wise)</td><td colspan="4"></td></tr>
</table>

Medicines Management problems?	
Outpatient follow up date	
Outpatient tests required	
Are there any major NEW lab abnormalities to be followed up by GP	If yes, what are they? When does patient need to see GP?
If patient has problems /questions, who do they contact?	
Any other questions?	

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
Formulating a plan of care							
1) Assess patient	b) Anticoagulant contraindicated	- Didn't know about current/prior treatment - Didn't know about disease interactions, drug interactions, other contraindications and incompatibilities - Unreliable patient history	Patient receives anticoagulant when contraindicated B, ADR, D	10			
	c) Unnecessary use of anticoagulants, particularly heparin	- Knowledge deficit - Outdated policies/ procedures	Unnecessary risk of error B, ADR	5			
2) Choose the anticoagulant	a) Wrong anticoagulant selected for specific patient	- Clinical diagnosis not - known/considered - Patient-specific parameters not known/considered (e.g., renal and hepatic function, - allergies, platelet count) - Knowledge deficit about drug indication - Drug specific contraindications not known - Mental slip - Standard protocols/ - prescribing guidelines not followed or do not exist - Didn't know about prior treatment with anticoagulants	Allergic response Patient receives the wrong anticoagulant B, T, ADR, D	10			
Prescribing (Process step 3)							
3) Prescribe the anticoagulant	a) Failure to initiate standard order set/pre-printed orders	- Don't exist - Don't know they exist - Not followed/don't agree with protocols - Outdated/inaccurate - Numerous individual modifications	Therapy may not meet standard of care B, T, ADR, D	10			
	b) Sections of pre-printed orders are incomplete *[target INR, indication etc on in-patient chart]*	- No standard process for making selections on forms/screens (e.g., cross outs, check marks, initials, fill in blanks) - Unfamiliarity with process - Human factors	Therapy may not meet standard of care Wrong drug/ dose/ frequency B, T, ADR, D	10			
	c) Wrong drug/form of drug/route of administration	- Knowledge deficit - Mental slip - Information about drug not readily available - Inadequate medication reconciliation process	B, T, ADR, D	10			
	d) Wrong dose (e.g. daily	- Clinical situation not known or considered (e.g.,	B, T, ADR, D	10			

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
	dose, loading dose, maintenance infusion, titration)	weight, age, renal function, platelelet count) - Dose based on unverified weight - No distinction between treatment and prophylaxis - Knowledge deficit - Mental slip - Wrong selection from list - Calculation error - Lab error (e.g., equipment calibration, overfilling, blood collection tubes) - Inadequate medication reconciliation process					
	e) Wrong frequency	- Knowledge deficit - Information about drug readily available - Inadequate medication reconciliation process	Overdose B Subtherapeutic dose T	8			
	f) Unsafe concomitant therapy with other anticoagulants Failure to adjust the dose when receiving concomitant therapy	- Prior anticoagulant therapy not known/documented - Prior anticoagulants not considered/not discontinued - Knowledge deficit about safe timing of first dose of new anticoagulant after prior anticoagulant discontinued - Human factors (e.g., forget) - Inadequate medication reconciliation process	Overdose B, D	10			
	g) Prescribed on wrong patient	- Similar patient name - Patient identifier not checked/not clear - Name does not appear on order form or immediate screen when prescribing - Mistakenly pick up/ select the wrong chart/ file - Environmental factors (e.g. distractions, poor lighting	Patient receives anticoagulant when not indicated B, ADR, D Patient does not receive anticoagulant when indicated T, D	5 10			
	h) Orders for patient monitoring omitted, incomplete, or inaccurate (e.g., wrong lab test, frequency too often or not frequently enough)	- Knowledge deficit - Human factors - Environmental factors (e.g. distractions) - No standard protocol for monitoring	Failure to adjust the dose properly Failure to detect problems early to minimise harm B, T, ADR, D	10			

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
	i) Accidental discontinuation of anticoagulant	- Forget to restart after holding orders temporarily - Automatic stop orders (especially for patients taking an anticoagulant for an alternative purpose such as atrial fibrillation)	Omitted therapy T	8			
10) Prescribe onto chart	a) order not processed	- written in wrong place on order form - Electronic order entry system not functioning	Omitted therapy T, D	10			
	d) order not reconciled	- Unverified patient history - Time constraints - Inadequate medication - reconciliation process	Wrong drug therapy B, T, D	10			
	e) Order entered onto chart incorrectly	- Knowledge deficit - Too many sections/pages of chart - Lack of support staff training - Environmental factors (e.g., distractions, noise, poor lighting) - Human factors - Failure/absence check	Delay in therapy Subtherapeutic dose T, D Overdose B, D	10			
	g) Order onto wrong patient's chart	- Unclear presentation of patient demographics on chart (e.g., light imprint) - Look-alike patient names - Environmental factors (e.g. Interruption during transcription, noise, poor lighting, cluttered space) - Order transcribed before patient identifier added to form	Patient receives anticoagulant when not indicated B Patient does not receive anticoagulant when indicated T, D	5 10			
Dispensing (Process steps 4-9)							
6) Evaluate safety/ appropriateness of order (pharmacy screening)	a) Order not evaluated by a pharmacist/ not evaluated in a timely manner	- Time constraints - Environmental factors (e.g., interruptions) - Didn't receive the order - Didn't know there was an - order	Floor stock drug administered: possible error Delayed therapy B, T, ADR, D	10			
	b) Indication/ appropriateness not verified	- Did not know information about the patient (e.g., weight, age, renal function, communicate patient information to the lab monitoring values, diagnosis) - Inadequate medication reconciliation process	Unsafe/inappropriate Medications/ doses reach the patient B, T, ADR	5			
	c) Contraindications,	- Knowledge deficit	Unsafe/inappropriate	10			

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
	interactions, unsafe doses and routes of administration not detected	- Use of non-formulary drug - Inadequate medication reconciliation process (patient taking unknown medications) - Patient diagnoses unknown	medications/ doses reach the patient B, T, ADR, D				
7) Prepare medication	a) Wrong product or dose/ concentration	- Look-alike products stored near each other (e.g., different strengths of heparin vials and solutions) - Look-alike products mistakenly sent by wholesaler and/or misplaced in pharmacy stock - Failure to use a standard concentration - Label ambiguity - Calculation error - Unsafe admixture technique - Admixing when premixed solutions are available - Knowledge deficit	Allergic reaction Overdose B, ADR, D Subtherapeutic dose T, D	10			
8) Check medication before distribution	b) Check failed to detect an error	- Human factors - Environmental factors (e.g., - distractions, space, lighting - noise) - Inefficient workflow - Check does not include comparison to original order	Potential error not detected B, T, ADR, D	10			
9) Deliver medication to patient care unit	a) Delay in distribution of medications	- Inefficient drug delivery system - Inadequate staffing patterns/equipment (e.g., tubes) used for delivery of drugs - Delivery equipment mechanical failure	Delayed therapy Omitted therapy Use of floor stock: possible error B, T, ADR	5 (Routine) 10 (Urgent)			
	b) Delivered to wrong unit, or “lost” in system	- Inadequate, untimely communication or interface with admission/ transfer information - Human factors - Drug mislabelled as to location of patient	Delayed therapy Omitted therapy T Use of floor stock: possible error B, T, ADR, D Unneeded drug on wrong unit (possible administration to the wrong patient) B	8			

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
Administration (Process steps 10-19)							
10) Receive order	a) order not processed	- Written in wrong place on order form	Omitted therapy T, D	10			
	b) Written order misunderstood	- Illegible order - Use of abbreviation (e.g. U) - Use of trailing zeroes - Misread decimal doses - Knowledge deficit	Delay in therapy Subtherapeutic dose T, D Allergic response Overdose B, D	10			
	g) Order onto wrong patient's chart	- Unclear presentation patient demographics on chart (e.g., light imprint) - Look-alike patient names - Environmental factors (e.g. Interruptions, noise, poor lighting, cluttered space)	Patient receives anticoagulant when not indicated B Patient does not receive anticoagulant when indicated T, D	5 10			
11) Nurse receives signal to administer medication	a) Signal not received (nurse does not know to administer the medication at a particular time)	- Nonstandard time for administration - Transcription error - Missing chart - Thought someone else was administering the drug - Failure to communicate that dose is due during change in shift or level of care	Dose omitted/delay in therapy T, D	10			
12) Evaluate appropriateness of the anticoagulant	a) Current lab values not checked	- Lab values not available - Low perceived value - Time constraints - Wrong lab values checked (e.g., wrong patient, wrong day/time)	Dose not adjusted appropriately B, T, ADR	8			
	b) Diagnosis does not support administration of anticoagulant	- Diagnosis not available - Evaluating wrong patient - Knowledge deficit about indication for drug therapy	Patient receives anticoagulant when not indicated B, ADR	5			
13) Obtain medication	a) Cannot find medication/ not available on unit	- Pharmacy delivery problem - The medication was not yet dispensed due to a problem (e.g., allergy, unsafe dose, interaction) - Medication time/frequency was scheduled incorrectly	Delay in therapy T, D				

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
		- Order was not sent to - pharmacy - No communication to nurse that medication was delivered - Par levels of floor stock inadequate - Non-formulary drug - Medication was given but not documented - Medication was given, but documentation of administration not seen - Drug was discontinued but remains on chart					
	b) Select the drug/ concentration /dose or the wrong product for indication and route of administration	- Drug available as floor stock and obtained without pharmacy review - Look-alike product near each other in cabinets, floor stock, refrigerator - Drug strength not clear on vial - Wrong drug stored in usual area/bin/shelf - Unnecessary multiple concentrations available - Knowledge deficit - Calculation error (e.g., with loading dose, infusion rate)	Overdose B, D Allergic reaction ADR Subtherapeutic dose Omitted drug Wrong drug T	10			
18) Administer anticoagulant	a) Wrong patient	- Look-alike names - Failure of double check at bedside using two identifiers - Anticoagulant ordered on wrong patient - Anticoagulant transcribed on wrong MAR - Failure to match drug with an indication for use	Patient receives anticoagulant when not indicated B, ADR Patient does not receive anticoagulant when indicated T, D	5 10			
	b) Wrong drug, dose, or flow rate	- Failure to review/consider current lab values - Failure to review/consider prior doses - Unlabeled syringe or infusion bag - Start/restart the wrong solution if multiple infusions are running - Failed or absent double check - Pump malfunction - Loss of power to pump - Pump not protected from free flow - Inaccurate pump calibration	Overdose B, D Subtherapeutic dose T, D	10			

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
	c) Wrong route	- Line attachment confusion - Failure or absence of double check at bedside - Knowledge deficit	Toxicity Hematoma B, D	10			
	d) Duplicate dose/ dose administered too soon	- The medication was already given but not documented - The medication was already given but documentation of administration was not seen - Documentation of drug therapy on various forms (e.g., ED notes, OR record, PACU record, MAR) - Failed hand-off communication upon transfer of the patient - Transcription error - Failure to discontinue another form of anticoagulant - Knowledge deficit - Start time of new anticoagulant not clear (especially in relation to a previously discontinued anticoagulant)	Overdose B, D	10			
	e) Interruption of therapy	- Stopping heparin infusion for administration of another drug - Failure to restart the anticoagulant after placed on hold temporarily - Infiltration	Subtherapeutic dose T, D	10			
19) Document anticoagulant	a) Drug administration not documented/ misdocumented	- Human factors - Environmental factors (e.g., distractions) - Time constraints - Inefficient documentation process - Multiple MAR pages - Documentation required in multiple locations - Documentation before actual administration	Duplicate therapy Overdose B, D Drug omission T	10			
Monitoring (Process steps 20-21)							
20) Monitor the effects of the anticoagulant	a) Lab tests not performed, incomplete, or inaccurate	- Failure to request prescribed lab tests - Blood collection on the wrong patient - Wrong test performed on blood specimen - Lab error (e.g., human error, using the wrong reagent with testing equipment, mechanical failure) - Variations in INR readings based on different equipment	Failure to detect and treat thrombocytopenia B, T, ADR	8			

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
		- Knowledge deficit - Environmental factors (e.g., - distractions) - No standard protocol for monitoring, leading to variability - Ineffective communication between practitioners					
	b) Lab tests ordered at the incorrect times and intervals	- Knowledge deficit - Failed or absent standard protocol for testing - Mental slip - Ineffective communication between practitioners	Failure to detect and treat thrombocytopenia Infrequent or inaccurate dose adjustments B, T, ADR	8			
	c) Current lab values not checked	- Lab values not available - Low perceived value of tests - Assume someone else is checking lab tests - Time constraints - Wrong lab values checked (e.g., wrong patient or wrong time/day)	Failure to detect and treat thrombocytopenia B, T, ADR	8			
	d) Failure to monitor for signs of bleeding and/or thrombosis/ communicate changes to the physician/treat condition	- Lack of standard evaluation process - Knowledge deficit - Time constraints - Difficult to detect occult bleeding - Reluctance to call prescriber with assessment information (intimidation) - Practitioner not informed to alert practitioners to signs and symptoms	B, D, T, D	10			
	e) Failure to diagnose/treat thrombocytopenia	- Knowledge deficit - Inadequate lab monitoring - Forget to discontinue all sources of heparin	Thrombocytopenia T, D	10			
21) Adjust doses according to monitoring results	a) Failure to adjust the dose properly in a timely manner Failure to treat patient/ treat patient incorrectly when therapeutic levels are dangerously elevated	- Lab studies not performed or communicated - Failure to monitor patient lab values frequently enough - Critical lab values not flagged for reporting - Critical lab values/ assessment findings not communicated in a timely manner - Unable to reach physician with critical lab results/ assessment information - No protocols for dose adjustments	Labile anticoagulant levels B, T, D	10			

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
		- No protocols for treatment of dangerously elevated - INR/aPTT - Forgot to restart medication after holding - Interpreter biases - Patient-specific parameters not known/considered (e.g., renal and hepatic function, allergies, platelet count) - Making dose changes more or less frequently than necessary for the desired clinical outcomes - Failing to consider the residual blocking effects of phytomenadione if this drug has been administered before a procedure (to reverse the effects of an anticoagulant)					
Patient Self-Administration (Process step 22)							
22) Patient complies with prescribed therapy after discharge	a) Patient is not educated about his/her illness, medication, error/injury and prevention	- Language barrier - Literacy barrier - Time constraints - Caregiver not available for education and/or translation - No written educational material available to give patient (in the correct language/reading level) - Healthcare provider knowledge deficit - Accountability for educating patients is not clear	Possible readmission B, T, ADR, D	10			
	b) Patient does not fill his/her prescription after discharge	- Duration of therapy is not clear to patient - Financial/ insurance reimbursement concerns - Local pharmacy does not carry the prescribed medication - Lack of transportation to pharmacy	Possible readmission T, D	10			
	c) Patient does not take the medication as prescribed/ follow consistent dietary guidelines	- Understanding is not assessed before discharge - Failure to provide written materials in primary language and reading level - Changes in dose are not clearly provided to the patient when dose adjustments are required - Verbal instructions are misheard or misunderstood when doses are changed - Actual dose may not match the directions on the current supply of medication	Possible readmission B, T, ADR, D	10			

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number
		- Confusion regarding brand and generic names (thus may be taking duplicate therapy) - Confusion regarding doses to be taken on alternate days - Patient unaware of who to call for clarification of instructions after discharge - Instructions conflict with instructions from other healthcare providers - Financial incentives lead to taking less than the prescribed dose or taking the medication on alternate days					
	d) Patient does not have outpatient blood tests completed or attend the follow-up visit with the primary care physician or specialist	- Appointment not made for first outpatient lab test, if indicated, before discharge - Appointment not made for first outpatient visit with physician - Appointment dates and locations not communicated to the patient - Patient misunderstands directions for follow-up care - Patients are not called if they miss an appointment to find out why and to reschedule the appointment - Patient may have no form of transportation after discharge - Primary care physician is unaware that the patient was hospitalized and the medications prescribed for the patient upon discharge	Possible readmission B, T, ADR, D	10			

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