Formative Evaluation of Martha's Rule – FAQs

The purpose of this document is to outline some of the background to the formative evaluation of the implementation of Martha's Rule and answer some FAQs we have been asked throughout the planning cycle of this project.

Why is this research important for safety?

Poor clinical monitoring on hospital wards has been identified as a cause of preventable death in 31% of cases (Hogan et al, 2012). Despite UK wide implementation of a National Early Warning Score system that monitors vital signs and escalates issues if the scores reach a pre-defined threshold, undetected deterioration continues to contribute to patient harm in hospitals. Evidence suggests that patients and families are in a unique position to provide important insight into the detection of deterioration (Albutt et al, 2017) but they do not always speak up and when they do, may be ignored.

In 2021, we heard of the tragic story of 13 year old Martha Mills, who died after developing sepsis in hospital, where she had been admitted with a pancreatic injury after falling off her bike. Martha's familes' concerns about her deteriorating condition were not responded to, and in 2023 a coroner ruled that Martha would probably have survived had she been moved to intensive care earlier. It is cases of this kind that led to Martha's Rule being developed for implementation in the UK.

What is Martha's Rule?

Martha's Rule is a new patient safety initiative being piloted by NHS England. Martha's Rule gives all NHS inpatients, their carers and NHS ward staff the right to an independent clinical review of a patient's condition whenever they feel that themselves or a loved one/patient is deteriorating, but they don't feel that their concerns are being taken seriously by the immediate ward staff looking after them. It also requires ward staff to obtain information relating to a patient's condition directly from patients and their families at least daily.

In June 2024, the implementation of Martha's rule commenced in 143 NHS Trusts where 24/7 critical care outreach was in place. In the first instance, this will cover all inpatients in acute hospital trusts with the exception of maternity, neonatal and emergency department services. The first rollout of Martha's Rule will also not include mental health or community services.

Why are we doing this evaluation?

There is a strong moral imperative for Martha's Rule and its potential to make significant improvements in patient care and outcomes. However, the evidence base for this initiative is limited and its implementation is likely to be challenging. Rapid implementation of such an initiative before it has been adequately tested could lead to unintended consequences such as diverting critical care resources and potentially increasing inequalities (Rae et al., 2018). Therefore, there are unanswered questions about the potential and actual impact of the implementation of Martha's Rule for services, healthcare staff and patients/families.

What are we evaluating?

Our formative evaluation will be evaluating the *implementation phase* of Martha's Rule, understanding how the sites have operationalised Martha's Rule and the factors that have helped or hindered how successful that process of implementation was. The research aims to address a number of research questions about the potential impact of the first phase of implementation/rollout of Martha's Rule for services, healthcare staff and patients/families as well as factors that contribute to successful implementation.

We aim to use the outcomes of this evaluation to inform a full-scale summative evaluation of the implementation of Martha's Rule which will be focussed on effectiveness.

What is the principal research question?

What are the facilitators and barriers that have affected the implementation of Martha's Rule at a personal, relational, organisational and wider policy and societal level?

What are the secondary research questions/objectives?

1. Where an intervention that includes components of Martha's rule already exists (in the UK and elsewhere) how well is it working? Is there a one size fits all approach or is there a requirement for flexibility. What are the challenges and implications of intervening in this way?
2. To what extent has Martha's rule been implemented in three pilot sites in England and how has this been done over the course of the first phase of implementation?
3. What are the anticipated benefits and costs of implementing Martha's rule for various stakeholders including staff, patients and family for the organisation?
4. What are the potential challenges and facilitators of delivering Martha's Rule?
5. What are the (potential or) realised unintended consequences?
6. Do members of the public, patients and their families know about and understand Martha's Rule?
7. Who activates critical care service outreach teams and how frequently is it used?
8. What do patients and family members report to critical care outreach teams?
9. How do patients experience escalating for critical care outreach team review and being asked about their condition on a daily basis and does this latter intervention trigger escalation by staff?

Who is carrying out this evaluation?

The evaluation is being carried out by the patient safety arm of the National Institute for Health and Care Research (NIHR) Policy Research Unit in Quality, Safety and Outcomes for Health and Social Care (NIHR QSO PRU) at the Yorkshire Quality and Safety Research Group (YQSR). It is led by Professors Rebecca Lawton and Beth Fylan. The delivery team includes Sally Prus (Policy Research Programme Manager), Dr Lavanya Thana (Senior Policy Research Fellow), Sinenhlanhla Zondo (Research Fellow) and is supported by five Research nurses/allied health professionals.

Who is providing advice or input to the project?

Extensive stakeholder engagement was conducted to support the planning and design of this evaluation including from clinical and patient safety experts, leaders in patient safety research, senior leaders, NHS England teams, the Department of Health and Social Care and patient advocate and community groups.

The project is supported by an advisory group of leading experts, NHS England representatives, improvement and evaluation leads, a patient and public advisor and leads from each of the six Patient Safety Research Collaboratives. This group will meet throughout the lifespan of this project to provide advice on the design, development, translation and dissemination of findings from the evaluation.

How have we involved patients in the design and conduct of this research?

A lay 'clinical research advisor' and central QSO PRU patent and public involvement and engagement lead are supporting this work. We have also set up a group of patients and the public with relevant lived experience who will advise and help us in the design, delivery and dissemination of this programme of work.

What are the timeframes for this study?

It started in June 2024 and is due to conclude in November 2025.

What are the intended outputs and outcomes?

With input from stakeholder groups, we will collate and triangulate this evidence to produce a set of recommendations including for future summative research, any changes to policy and guidance for other trusts who are planning to implement Martha's rule in the future.

We will share our findings with the Department of Health and Social Care, NHS England including NHS policy makers and particularly patient safety specialists and managers to help them in setting up Martha's Rule in ways in which it might be most successful.

What does the formative evaluation of Martha's Rule involve?

The primary focus of the evaluation will involve an in depth case study across three of the 143 pilot sites. This will include carrying out a set of research observations in selected wards and of critical care outreach (CCO) teams, and a small number of interviews with frontline, operational and strategic staff and patients/family members on wards at each site. We will also review relevant strategy documents and communication materials.

This will be accompanied by a survey of the general population about their awareness of Martha's Rule conducted in collaboration with PickerEurope and YouGov.

This project will update an existing systematic review (Albutt et al, 2017) on the evidence around patient and family led systems for identifying deterioration and escalating concerns.

Who are our chosen sites?

We will be evaluating two large teaching hospitals and one district general hospital with varied and diverse populations. We have agreed to keep the sites we are evaluating anonymous. This is because the evaluation of Martha's Rule is a high-profile, national initiative and we want to ensure sites feel able to be fully open and transparent when engaging with the research without judgement or bias.

Which wards do we plan to evaluate in each of these sites?

We will conduct in-depth evaluation of two wards on each of the three participating sites. We plan to include a diverse range of wards across the sites including both adult and paediatric wards. We are working with our local collaborators at each site to select wards based on where the sites are implementing Martha's Rule first and, where possible, the clinical areas that our advisory group and team of experts have advised us to focus on.

Are we evaluating Martha's Rule in paediatric wards?

We recognise the great importance of evaluating Martha's Rule in paediatrics, but it is important to note that we are evaluating wards at sites at the *implementation phase* of Martha's Rule and that most sites are rolling out Martha's Rule in a phased way. This means that we are limited by the wards that they choose to implement Martha's Rule in first with many pilot sites not rolling out Martha's Rule on paediatric wards until much later in the process. However, we are in the fortunate position that at least one of our sites does plan to implement Martha's Rule across their paediatric services in the early phase of their rollout and therefore we are able to do an in-depth evaluation of at least one paediatric ward as part of our study.

How transferrable will the data be to other hospital contexts?

This evaluation is a small scale formative evaluation of which we are operating under a number of constraints including available resources, the short timeframe in which the evaluation needs to be completed (by November 2025) and the phased rollouts that most pilot sites are employing. This means that we are limited in the number and type of wards we can select and evaluate. However, in order to balance the need to generate an in-depth understanding of implementation with the need to cover a diverse range of patient populations, clinical specialties and types of Trusts, we have therefore opted for an in-depth, single case study evaluating six wards across the three sites. This will give us the depth of data needed to highlight some of the relative barriers, facilitators and perceived unintended consequences of the implementation of Martha's Rule, which in turn will be used to inform a larger summative evaluation across a more diverse cohort of settings.

Are we measuring effectiveness and cost-effectiveness?

No. The research will focus on evaluating the barriers, facilitators and unintended consequences of sites applying Martha's Rule during *implementation.* It will try to understand the staff, patients and families experiences when using (or choosing not to use) Martha's Rule, whilst paying attention to potential culturally relevant factors and biases. It will also explore the influence of leadership, implementation teams and communications/culture on wards on the success of the implementation process.

As part of this work, we aim to explore some of the *perceived* or *anticipated* benefits and consequences of the use of Martha's Rule for patients, family and staff, but it will not be the main focus. However, this evaluation will inform the proposal for a much wider summative evaluation focused on outcomes and cost effectiveness at a much broader scale across sites.

Further Questions / Queries:

Any further questions on this evaluation, please contact marthasrule.study@bthft.nhs.uk

References

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