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Developing and implementing a digital formulation informed risk management framework in mental health and learning disability services

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Conflict of interest

There are no conflicts of interest to report.

Ethics

The project did not require ethical approval as it was a service development using improvement methodology

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ABSTRACT

Purpose

Risk assessment is a fundamental part of clinical practice in mental health and learning disability services in the UK. Most services use a tool or framework to structure their clinical judgments but there doesn't appear to be a consensus on which risk assessment tool should be used. The aim of this paper is to describe the development, implementation and evaluation of an evidence-based *Formulation Informed Risk Management (FIRM)* framework in mental health and LD services.

Design and methodology

Development of FIRM and evaluation was based on the *Model for Improvement*, with an emphasis on co-production broken down into three distinct yet interdependent phases of co-production: *Co-design, Co-create and Co-deliver*. Following implementation of the FIRM framework, a post-implementation survey was distributed to a sample of clinical staff to capture experiences in first three months post-implementation.

Findings

The three co-production stages were pivotal for successful implementation in clinical practice. The key ingredients for success seemed to be acknowledging human factors and varied responses to change, communication, engagement and involvement of stakeholders. Early evaluation post-implementation demonstrated the benefits in terms of confidence in use, formulation of risk, risk management and communication. Further quality improvement initiatives are underway to evaluate impact up to 12 months post-implementation and to improve quality of FIRM in practice. Future research is planned to look at enhancing personalised risk assessment and management.

Originality

This paper describes and demonstrates the value of co-production with clinicians and stakeholders in service development. The FIRM has improved the clinical practice of risk assessment, formulation and management, and use of digital technology.

INTRODUCTION

Risk assessment is a fundamental part of clinical practice in mental health and learning disability services in the UK. Decisions on risk will always be based on clinical judgements, although unstructured risk assessments have been criticised for being ambiguous, subjective, impressionistic and inaccurate (Doyle and Dolan, 2007). In response, most services adopt some form of tool or framework to structure their clinical judgments, and the use of evidence-based tools has been recommended at a national level in the UK for over a decade (Department of Health, 2007).

However, concerns have been raised about the reliability, validity and practical utility of risk assessment tools, especially if they are bespoke to a service and based on questionable evidence and/or are used to predict rather than inform judgements about risk of self-harm (Quinlivan et al, 2017) and for risk to others (Doyle et al., 2012). Despite concerns, structured risk assessment guidelines or tools are used extensively across the world (Ayun and Ustan, 2021) and although the evidence to support effectiveness of risk assessments is limited, the perception of clinical staff in mental health services is that risk assessment and management frameworks are effective in reducing risk in mental health care (Wand et al., 2015). They can be beneficial if used to prevent rather than predict risk outcomes and if they inform judgements and formulate (explain) risks, communicate risks between staff and services, consider strengths and protective factors and when service user and carers are involved in the assessment (Doyle and Logan, 2012; Department of Health, 2007). NICE quality standards in the UK for self-harm (NICE, 2013) and violence and aggression (NICE, 2015) support the judicious use of tools in this way if in addition to a comprehensive assessment of physical and mental health needs.

Currently, there doesn't appear to be a consensus on which risk assessment tool or framework should be used (Ayun and Ustan, 2021; Graney et al., 2020). A recent large-scale review of risk assessment tools used in the UK supported this view, concluding that assessment processes need to be consistent across services with adequate training provided on how to assess, formulate, and manage risk with an emphasis on patient and carer involvement (Graney et al., 2020). Furthermore, the authors recommended that risk assessments should not be used to predict future behaviour, and management plans should be personalised and collaboratively developed with patients and their families and carers, although patients are often not directly involved or are unaware that an assessment has taken place and those

assessing the risk need to be more aware of the need for shared decision-making (Ahmed et al., 2021).

Formulation-based approaches to risk management have been recommended previously (Doyle and Dolan, 2002, 2007; Lewis and Doyle, 2009) and recently in Wales, a formulation-based approach to clinical risk management, the WARRN (Wales Applied Risk Research Network), was found to enhance the clinical skills of practitioners in formulation, safety-planning and communication while increasing confidence in their skills and abilities in these areas (Snowden et al., 2019). From a legal perspective and in support of the risk-formulation approach, a recent review of over 100 suspected suicides by *NHS Resolution* (2018) concluded that risk assessments should always occur as part of a wider needs assessment of individual wellbeing and more personalised formulations of risk should be used rather than crude 'cut offs' of risk (e.g. high, low).

In summary, risk tools remain an important part of clinical practice to support decision making if used to develop personalised risk formulations that inform risk management interventions aimed at preventing harm (Doyle and Logan, 2012). The aim of this paper is to describe the development, training, implementation and evaluation of an evidence-based *Formulation Informed Risk Management (FIRM)* framework in mental health and LD services in England.

CONTEXT AND BACKGROUND

South West Yorkshire Partnership NHS Trust (SWYPT) provides inpatient and community mental health and learning disability services to a population of 1.22m people who live in four local authorities; Barnsley, Calderdale, Kirklees, and Wakefield, and specialist forensic services across the Yorkshire region. At any one time there are about 1400 registered clinical staff (e.g. Doctors, Nurses, Psychologists, Occupational Therapists) in post. In 2017, having used one electronic clinical records system for a number of years, SWYPT decided to adopt a new electronic health record known as *SystemOne*.

The *Sainsbury Risk Assessment* (Morgan, 200) was the principal risk assessment tool used across the Trust at this time and this is used widely across the UK (Stein, 2005). The format requires the user to review service user history for the presence of particular risk factors and then to write a brief summary to inform immediate care and risk management. One perceived and observed limitation of this assessment was that it relied very much on a "tick box" approach, and users tended to focus on this element of the tool, rather than articulating their understanding of risk. Whilst the tool has a section on formulation and risk

management, users in SWYPT tended not to record and communicate this effectively, taking into account the historical context. The risk assessments were subject to regular review following serious incidents such as suicide, and issues were regularly highlighted in terms of the quality of individual risk assessments and a risk formulation was rarely present to guide the understanding of risk.

METHOD

This was a service development to transition to a new improved evidence-based risk framework with practical utility. Our approach to the development and evaluation of the new FIRM framework was based on the *Model for Improvement*, which is widely used in healthcare service developments and has been endorsed by the *Institute for Healthcare Improvement* (Langley et al., 2009). This is an integrated approach with an emphasis on co-production, drawing on clinical, operational, and technical knowledge and expertise, supported by those who are experts through lived experience. The development programme was broken down into three distinct yet interdependent phases of co-production: *Co-design, Co-create and Co-deliver*. These stages of co-production were followed to implement new FIRM framework on *SystemOne* and findings from each stage were reviewed before moving iteratively onto the next stage towards implementation in practice.

Following implementation of the FIRM framework, a post-implementation electronic survey questionnaire was designed based on feedback from clinical staff during FIRM training. This was distributed to a sample of clinical staff to capture experiences in first three months post-implementation. The survey was designed to evaluate if the FIRM improved on the previous Sainsburys risk assessment in terms of formulation, risk management, communication, confidence and understanding. A Likert scale was used offering five responses, Strongly disagree, Disagree, Neutral, Agree, Strongly Agree, against the following statements:

1. I felt confident using the FIRM framework
2. The FIRM framework allowed me the opportunity to explain/formulate risks adequately
3. The risk management section allowed me to clarify interventions to reduce risk adequately
4. It is easy to view identified risks from the FIRM Risk View
5. I feel more confident in making decisions about risk management using the FIRM assessment
6. The FIRM framework improves understanding of risk

7. The FIRM framework is relevant to my clinical practice
8. I prefer using the FIRM risk assessment tool to Sainsburys

The data from the survey were analysed and findings presented.

RESULTS

Co-design

An expert reference group was formed, with membership from all clinical disciplines and service managers including representatives from service users and clinical services provided across the Trust. The expert reference group considered the strengths of the Sainsbury Risk Assessment together with the characteristics of an ideal risk management framework based on clinical experience and review of the literature. The focus of risks being addressed by the new system would be i) risks to service user, including suicide, self-injury, self-neglect, exploitation, safeguarding children and vulnerable adults and physical health, and ii) risks from the service users, including violence and safeguarding others. The group concluded that any new system should be based on the following criteria:

1. Focused on the synthesis of relevant clinical information to arrive at a formulation of risk.
2. Suitable for use across the whole scope of disorders seen in mental health and learning disability services.
3. Sensitive to the complexity of the person being assessed so with less complex cases it would be a relatively short document to complete.
4. Box ticking kept to a minimum, with more emphasis on explaining the risk concisely.
5. Conditional logic would be used so that the tool was responsive for recording of information about a particular risk only if there were historical or current concerns about that risk.
6. Focused on understanding and preventing risk rather than categorical predictions about the likelihood of a particular outcome being low, moderate or high.
7. Facilitated service user's views and ensured these informed risk management plans
8. Readily accessible, user-friendly with practical utility within the electronic records system.

A prototype risk framework was developed underpinned by a commonly used *Five-step structured professional judgement approach* that reflects clinical risk management as a dynamic and continuous process mediated by changing conditions (Doyle and Dolan, 2007; Table 1).

Table 1 about here

This framework logically guides the assessor by collating relevant sources of clinical information, identifying historical and current risk factors and protective factors before synthesising this information to arrive at a formulation of risk that leads to a service user-informed and accessible risk management plan. Throughout the process service user involvement is encouraged and the assessment cannot be finalised without their input and the risk management plan is articulated in the first-person voice, for example using the phrase *"when my health is getting worse, these are the things that I experience or that other people might start to notice"*, to describe early warning signs.

Co-creation

The new framework underwent extensive evaluation, testing and redesign as part of co-creation. Over a three-month period between September and December 2019, over 350 experienced clinicians attended a training session on Formulation Informed Risk Management (FIRM based on an evidence-based training module developed at the University of Manchester by lead author (MD: See Table 2).

Table 2 about here

All attendees were provided with access to the electronic 'test' version of the risk framework and encouraged to critically evaluate the tool and share with service users for feedback where appropriate. The main message from service users was clear; they should always be consulted on and involved in their own risk management. Overall, the responses were positive from staff and service users, although there were a number of concerns raised and improvements suggested. Based on feedback, the FIRM framework was re-constructed to ensure:

1. A simpler interface for staff and service users
2. Quicker completion of the assessment
3. Risk information was aligned so that relevant risk information that might be captured in other forms in the clinical record system (e.g. Comprehensive Assessment) could be pulled through and duplication avoided
4. Risk Management / Staying Safe Plan reflected service-specific needs

A final series of consultation events then took place, with attendance over a two-month period at clinical improvement groups, academic meetings and with drop-in demonstration sessions in all localities. The feedback from these sessions was universally positive. Final changes and improvements were made, and the design of the FIRM framework was presented and signed off at Trust Board Level.

Co-deliver

As part of co-delivery, to manage anxieties about changing practice, a consensus was reached acknowledging that the FIRM framework was designed to enhance current clinical practice as the fundamental principles of risk assessment and management remain unchanged. Rather, the FIRM framework provides a more robust framework for staff to explain/formulate risk, to inform clinical judgements that inform management and care plans. Nonetheless, changing the risk assessment tool was a source of anxiety both for clinicians and the organisation as a whole. Therefore, the implementation of FIRM was closely monitored by a Steering Group which was representative of stakeholders and chaired by a Trust Director.

Communication about the changes commenced early in the project to raise awareness and ensure maximum clinical engagement in the development and testing phase. A Learning Needs Assessment (LNA) sent out to all clinical staff in February 2020 suggested a blended learning approach to training would be preferred to support roll-out of the FIRM framework with over 400 (40%) of staff responding. This included a combination of face to face seminars, technical support and local clinical support and supervision. Based on feedback, the approach for training and support to co-deliver the FIRM included:

- a. FIRM Champions identified across all teams and localities. These individuals were not expected to be 'experts'. Rather they would act as a 'point of contact' for any questions/issues and were able to offer guidance to others within their teams to support roll out and best practice, directing people to existing resources such as user guides, training slides and the intranet pages.
- b. Face to face clinical risk assessment training available for staff responsible for carrying out risk assessment focusing on:
 - Core principles of risk assessment
 - Formulation and the FIRM framework

- c. 'How to' User Guide and e-Learning videos, online learning resources around Formulation and Sample Formulations.
- d. Updated Clinical Risk Assessment and Management Policy and Clinical Record Keeping Policy

Face-to-face training commenced in February 2020 with extremely positive feedback. However, in light of the rapidly changing situation with regard to Covid-19 face to face training was suspended and implementation of the FIRM was delayed from April 2020 to October 2020.

Early Adopter Implementation Pilot

Despite the competing demands of the pandemic, services were still keen to make the transition to the FIRM framework, and this was supported by the success of virtual face to face training using Microsoft teams. As part of co-delivery, and due in part to the delays arising from the pandemic, an early adopter pilot was agreed across SWYPT Child and Adolescent Mental Health Services (CAMHS). The rationale for CAMHS services being an early adopter was:

- Most CAMHS clinicians were already familiar with the principles of formulation, attendance at training was high at over 90% and readiness to take forward was very high amongst clinicians with committed management and clinical leadership.
- The numbers of service users likely to 'transition' from CAMHS to adult services during pilot period could be mitigated to avoid confusion of using different risk management systems.
- The focus on a smaller number of staff in CAMHS meant communication was more likely to be successful within the timeframes, and support – both pre and post implementation was more likely to be available.
- Ahead of go-live, resources including training guides, Q&A sessions, Frequently Asked Questions and training were provided to the FIRM champions. The Clinical Record Keeping procedures and Clinical Risk Assessment and Management Policy were updated to include reference to the FIRM framework.

The CAMHS pilot proved to be a very useful stage in development, transition and implementation of the FIRM framework. Following the pilot of the FIRM framework in

CAMHS, events and online webinars were held to share the learning across all staff, and the framework was revised slightly to enhance practical utility and address IT issues. The implementation across all mental health and LD services followed based on the implementation plan for CAMHS.

As of 28th October 2019 go-live date, 969 front-line registered clinical staff had been trained at least once face-to-face in classroom or online and all registered clinicians had been trained and/or instructed in the use of the FIRM framework before use. Of the 969 front-line staff who attended training, 63% (N=610) were nursing staff, 6% (59) were medical staff and the remaining 31% (300) were allied health professionals or similar.

Post implementation evaluation

An electronic survey was sent out to a sample of FIRM users across the Trust, at the end of January 2021, three months post implementation date. Of the 282 responses received, 227 (81%) had opportunity to complete a FIRM assessment on SystmOne. Most of those who had not completed a FIRM indicated that this was because none had yet been required in the timeframe or others had completed on their behalf. Only four (1.4%) suggested it was because they lacked confidence in completing the FIRM.

In terms of the eight key statements used to guide the evaluation, there was a significant minority of staff who responded neutral 'neither agree nor disagree' in each of the questions, ranging from 14.3% for *'The FIRM framework is relevant to my clinical practice'* to 47.42% for *'I feel more confident in making decisions about risk management using the FIRM framework'*. The neutral responses were recorded and then the percentage of staff who strongly disagreed or disagreed with those who strongly agreed or agreed with each of the eight statements were compared (Figure 1). In all statements but one, the responses were in favour of the FIRM. In five of the eight statements, most staff who responded agreed that the FIRM was positive. For confidence in using the FIRM 106 staff agreed or strongly agreed v 46 disagreed/strongly disagreed; for formulation of risk it was 119 v 34; to inform clinical interventions 122 v 29; ease of use, 83 v 39; improves understanding of risk, 66 v 34; relevant to practice, 143 v 28, and prefer FIRM to Sainsbury's risk assessment, 85 v 62. The only area where disagree/strongly disagree responses were higher was for the feeling more confident in making decisions where 51 staff disagreed/strongly disagreed and 44 agreed/strongly agreed, although nearly half of all staff, 70 (42%) neither agreed or disagreed (See Figure 1 for percentage responses)

Figure 1 about here

Qualitative feedback

As part of the post-implementation survey, respondents were invited to make comments and offer suggestions (Table 3). The responses were mixed but generally in favour of the new FIRM framework. Where specific team issues were identified then these were managed as potential areas for development and revisions made to the process to enhance acceptability and practical utility. For example, revisions made to align with LD-specific issues, and the risk triage following comprehensive assessment was enhanced so that FIRM only completed where indicated as part of conditional logic afforded by digital format.

DISCUSSION

The service development and evaluation of the FIRM framework described in this paper, highlights the importance and value of a systematic programme management approach. As far as we are aware this is the first time a bespoke evidence-based risk framework has been developed digitally using systematic co-production. The importance of the three co-production stages focusing on co-design, co-creation and co-delivery, were pivotal for successful implementation in clinical practice.

The key ingredients for success seemed to be acknowledging human factors and varied responses to change, communication, ownership by staff, engagement and clinical leadership. The involvement of stakeholders and the collaborative iterative process adopted until a consensus was achieved, ensured clinical ownership and an enthusiasm and readiness for the framework to be implemented. The pilot of the FIRM framework in CAMHS was useful in validating the FIRM for use in the wider mental health and LD services. Although the CAMHS pilot proved to be a very useful stage in development, transition and implementation of the FIRM framework, and paved the way for a smoother transition and adoption by other services, it is recognised that CAMHS implementation needs a more specific, detailed review and evaluation, and this is currently underway.

. The covid-19 pandemic delayed implementation but also led to development and improvements in virtual face-to-face training and supervision, and e-learning generally. Early evaluation post-implementation demonstrated the benefits of the new FIRM framework in terms of confidence in use, formulation and understanding of risk, risk management and communication, while most found it relevant to their practice and most staff preferred FIRM compared to the previous risk assessment. These findings are similar to those found by

Snowden and colleagues (2019) and consistent with best practice recommended in recent literature (Graney et al., 2020; Ayun and Ustan, 2021). Unlike the WARRN (Snowden et al., 2019), the FIRM framework was digitally designed so benefitted from contemporary software, a networked system and conditional logic. The framework could be easily adopted for similar clinical record systems to SystmOne and be used on a range of digital devices.

The evaluation also highlighted areas for further review and development to ensure optimal benefits of the new system. The FIRM framework did not give greater confidence in making risk decisions, but further discussion revealed that wider determinants and not just the choice of risk framework would impact on this rating by staff, including workload, perceived control over decisions and response of management if things go wrong. It is not clear if confidence was higher or lower than before implementation of the FIRM and adapting to a new system will require time to build confidence. Future training will have more of a focus on defensible and shared decision-making, supervision and need for a just culture in accordance with best practice (Ahmed et al. 2021; NHS Resolution, 2018; Slade, 2017).

Other areas for development included better alignment to local priorities (e.g. CAMHS, LD), quality assurance of risk formulations, use of staying safe plan and integration into routine care pathway. These are currently targets being addressed through quality improvement projects using the principles of co-production (Langley et al., 2009). The service development and evaluation undertaken highlights several critical issues in educating and developing a skilled and committed mental health workforce. Implementation of the FIRM framework was hampered and delayed due to implications of the Covid-19 pandemic. Despite this, alternative ways of training staff were found to be successful, and the delay prompted a useful pilot stage in CAMHS to inform wider roll out across the Trust and maintain the momentum for change. The iterative test and re-test approach of co-creation was high maintenance in terms of project management and monitoring evolution of the framework, but the steering group and local champions proved vital for maintaining momentum and achieving milestones. Clinical knowledge, skills and experience in clinical risk management were key to the successful implementation in practice but IT coaching and practice were also important for navigating the FIRM framework. In conclusion, the development and implementation of the FIRM framework was a qualified success and related QI projects ongoing.

This project was a service development using a model for improvement to transition to a new improved evidence-based risk framework with practical utility. Further more rigorous validation and reliability projects are underway. The qualitative findings were

additional comments taken from the survey monkey questionnaire and not via interview or focus group. Therefore, the data are limited and make it difficult to conduct any meaningful analyses. Further evaluations will use a mixed methodology with a range of data collection techniques.

Service users were involved in the production of the FIRM framework with clinical staff and champions, but a more formal-structured engagement of service users may have enhanced the quality of the framework and implementation (Graney et al., 2020). Further quality improvement initiatives are underway using similar areas for review and will engage and involve service users to evaluate impact of FIRM up to 12 months post-implementation and to improve quality of FIRM in practice. To support new initiatives, the survey will be reviewed and further tested for reliability and face validity. For the next stage development, research is being planned to evaluate the validity and reliability of the FIRM framework to include self-assessment and self-management, support relapse prevention approaches and enhance personalised risk formulations. A new university module based on the FIRM training has been developed at post-graduate level to equip mental health and LD staff to apply in practice, and offers additional focus on defensible decision making, the impact of health inequalities and importance of an open honest and transparent learning culture.

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TABLES AND FIGURES

Table 1 5-Step Approach to Clinical Risk Management (after Doyle and Dolan, 2007)

• Step 1:	Case Information
	History, Mental State, Substance Use
• Step 2:	Presence/relevance of Risk Factors
	Historical, Current, Contextual
• Step 3:	Presence/relevance of Protective Factors
	Historical, Current, Contextual
• Step 4:	Risk Formulation
	5 x Ps: Problem, Predisposing, Precipitating, Perpetuating, Protective
• Step 5:	Management Plan
	Treatment, Management, Monitoring, Supervision, Victim Safety Planning

Table 2 Training summary specification

Aim

Prepare staff to assess, formulate and manage risk to self and others using the FIRM framework on SystmOne electronic clinical record system.

Learning Outcomes

By the end of training, participants will be able to:

- Recap on the complexities of risk assessment and management across different services
- Highlight importance of risk formulation
- Be familiar with how to complete the FIRM framework on SystmOne

Delivery

- Blended learning delivered face to face and virtually by senior clinician and technical staff
 - Interactive style with participant engagement throughout
 - Asynchronous presentation made available for use by FIRM champions
 - Live demonstration of FIRM framework on SystmOne
-

Table 3 Survey responses post-implementation

- | |
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| <ul style="list-style-type: none">• Very useful both to ensure I haven't missed any areas and to work through risk assessment with clients.• There are occasions when it is difficult to complete as we offer short interventions which is 3 sessions only and therefore all the information required in the FIRM is difficult to obtain making it difficult to complete• It really is not relevant to cases where there are no identified risks, yet we have to complete it,• This is a much more comprehensive way to look at managing risk and formulating for complexity. It also encourages contribution from other agencies and allows both multiagency and multidisciplinary input.• Very useful way to be able to go beyond previous risk tool in explaining the balance within risks and protective factors that mitigate the risks, alongside allowing to provide further context.• It is better than the Sainsburys but could still be more child/adolescent focused.• It is a much better more relevant tool. I do feel there is duplication, and I am repeating myself. I am not sure if this will reduce as I get used to the tool or if the tool itself asks for this duplication / repetition.• My only comment is in relation to the staying safe plan. I do not think it has taken into consideration the differences in risk within the LD population. I think the risk in LD can be very different to MH and this is where the crisis/contingency plan about becoming unwell doesn't fit as LD is a long-term condition. |
|---|

- A lot of the information is unknown, and some of the questions do not have a not known box, and the essential bits get lost in the midst of it all.
- Confidence in decision making depends on the response of management if things go wrong and not the risk tool
- Some of the sections seem repetitive, and difficult to make clear if the client is very young
- Much improved on previous tool.
- Yes it fits better to CAMHS better than the previous tool.

Figure 1 Post-implementation evaluation of percentage of staff who strongly disagreed or disagreed compared to strongly agreed or agreed with eight evaluation statements

