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RESEARCH PROTOCOL: A FITNESS FOR PURPOSE STUDY OF THE FIELD ASSESSMENT CONDITIONING TOOL (FACT)

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Keywords: Medical Education, Paediatric, Trauma, Change Management

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ABSTRACT

Introduction

We aim to explore whether a framework approach can assess the complex and interactive competency domains of team function and interaction with healthcare systems and provides the requisite vocabulary to effect change, in the clinical arena of paediatric trauma. The framework approach was chosen based upon on understanding that there is a complex relationship between an ever-changing team of multi-professional healthcare individuals within the context of their own working environment. This framework, termed the Field Assessment Conditioning Tool (FACT), has been designed to be used by team members to describe, evaluate and provide the insight to act as a healthcare advocate to improve care provision within their organization. The FACT draws upon quantitative data including clinical care points in addition to self-reflective qualitative data. The FACT has been designed to feedback this assessment data both horizontally across fellow potential team members and vertically to the hospital/organization governance structure, enabling process gaps identification and an agenda of improvements to be realized. The aim of the project is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy according to the FACT objectives.

Methods and Analysis

The FACT tool will be implemented and studied in three district hospitals around a major trauma centre in the United Kingdom, United States and New Zealand. Using a qualitative approach with standardized semi-structure interviews and thematic analysis we will explore the following question: Is the FACT fit for purpose in terms of providing a framework to evaluate, reflect and act upon the individual hospital's own performance (trauma team – hospital interactions) in terms readiness to receive traumatically injured children?

Ethics and Dissemination

Ethics approval has been approved at all participating centres. The study results will be disseminated to participating sites, respective networks and via publication in high impact journals.

STENGTHS & LIMITATIONS

Strengths:

- Depth of understanding of complex relationships
- Flexibility of approach to answering research question

Weakness:

- Subjectivity of qualitative approach

BACKGROUND

Trauma is the leading cause of death in children less than nineteen years of age in the UK & worldwide, [1]. One of the components to improve health outcomes for these injured children is a health system trained and ready to care for these children. As part of a program of research aiming to improve the outcomes of traumatically injured children, a multisource tool has been developed to allow trauma team members and hospital governance administrators, both to reflect on and act upon, complex trauma team-hospital systems interactions. We have termed this tool a Field Assessment Conditioning Tool (FACT). The FACT has been designed to enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of traumatically injured children in the respective hospital, providing the opportunity to reflect and learn on the rare but high stakes complex clinical events associated with managing such children. The FACT tool is furthermore designed to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure, systems and patient care. In this paper we describe the methodology of evaluating the fitness for purpose of the FACT.

The clinical need for FACT

Children presenting with traumatic injuries to hospitals require optimal care to decrease mortality and morbidity. Optimal care provision is a complex interaction between an inter-professional team of health care providers, each with individual knowledge, skills and attitudes and the health care system in which the team work. There are a number of challenges to overcome to ensure optimal care provision. One challenge is to maintain the experience and confidence of the clinicians, who may not treat children requiring major trauma care on a regular basis. Another challenge is to provide the opportunity for team members to reflect on the care provided in their hospital and empower them to act as advocates of change to improve care provision. In addition, the composition of hospital trauma teams is highly variable, with team membership changing on a daily basis and some members only staying six months in one hospital.

There is a clear need for the development of an effective and systematic paediatric trauma training program aiming to optimize the interactions between provider teams and healthcare systems, in both major trauma centres and rural/district hospitals. To meet those challenges the research team has developed a multisource tool for all potential members of trauma teams and decision makers in the hospital governance structure. The goal is to provide reflection on their own trauma team hospital interactions and the vocabulary and opportunity to describe gaps in care and invoke positive changes. In essence, we have developed a healthcare advocacy/quality improvement tool.

The objectives of the FACT are as follows:

1. To enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of injured children in the respective hospital, enhancing the opportunity to reflect and learn on the rare but high stakes complex clinical events associated with managing such children.

2. To provide the opportunity to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure, systems and patient care, in the face of constantly changing team compositions.

AN OVERVIEW OF THE METHODS USED TO GATHER DATA FOR THE FACT

There is significant evidence [2-5] that the clinical care provided to children can be enhanced by targeted simulation training with child-like human patient simulators. The simulators are, computerized and programmed to respond in real time to interventions or lack of and can be programmed to behave in terms of physiological responses (including vocal, pupillary responses, breathing, cardiovascular and neurological status) as a real human. Cutting edge simulation technology and techniques provide the appropriate environment to encourage self-reflection, to identify deficits in knowledge, skills and attitudes, the opportunities to develop performance and self-confidence, and to improve the patient care provided by an individual or a clinical team, directly where they work. The process of participating in simulated trauma training is reflective and designed to promote learning with debriefing strategies highlighting good practice and areas for improvement in care. Mobile mannequin technology allows simulation-based critical pediatric trauma

exercises to be conducted onsite rather than be conducted in a learning laboratory or classroom the simulations of major paediatric trauma care occur where staff members work routinely to deliver trauma care. This adds further advantages. This allows staff to "train together when they work, with whom they work and where they work". In situ simulations are therefore the core of the data collection for FACT. This approach also allows reflection on the complex healthcare processes involved in trauma care and the opportunity to invoke healthcare changes to improve care at all levels. In developing such an approach it is integral to consider that trauma teams are made up of ever changing staff members each day and the hospital trauma care systems are different in different hospitals. Within the elements of the FACT framework are documented measurable outcomes for patient care that can be organizationally managed and improved. The tool also measures both the technical (for example procedural skills) and non-technical skills (for example communication, situation awareness and decision making), using both quantitative and qualitative elements.

Aligned to principles of assessment,[6] the FACT construction has embraced the concept that the assessment program must maximally facilitate learning (assessment for learning); must maximize the robustness of high- stake decisions (reaching targets/readiness to receive) and provide information for improving education and patient care, both horizontally to staff & vertically to hospital governance boards. It is known that no single assessment instrument can effectively describe and measure complex interactions relating to performance (individual, team & hospital). However it is recognized that assessment systems require triangulation of data sets to build up a picture of performance & interactions,[7,8]. Moreover an effective assessment instrument should be transparent, justifiable, evidence based and recognize the restraints of the 'real world',[9].

Data collection to create the FACT

The FACT data elements include both qualitative and quantitative domains. These domains include the mental modelling of the team members in response to a pre-constructed case-based knowledge test conducted after the simulation. Caring for children represents many facility and equipment related challenges to health care. Various sizes of equipment to care for the very young to the adult must be available.

To address this concern each facility is examined in advance to see if they comply with the necessary equipment needs,[10]. In addition care performance metrics such as time to key patient evaluations, team assembly, and interventions related to outcome measures are also collected. Teams are asked to reflect about their performance through the use of structured surveys. Further informing the evaluation process are insights gained from facilitated debriefing conducted post exercise. These insights are gained by exploring the gaps/errors/or lack equipment.

How the FACT combines with simulation

High reality human patient simulators of traumatically injured children are brought into the emergency bay at the pilot hospital by researchers acting as paramedics. Prior to this, the hospital is notified using the same standard Major Trauma Alert procedure for all traumatically injured children, as used by the paramedic ambulance service. A hospital wide trauma alert code is activated, team members arrive, and work together on the severely injured simulated child in the emergency bay. Each team member then completes a questionnaire (as described in Table 1). All team members record their role in the team, for example Trauma Team Leader or trauma nurse, but not their names to ensure anonymity. A team-debrief then follows, conducted by an experienced facilitator from the research team. The process takes approximately 45 minutes in total, for each of the two scenarios. The time line for collection of the FACT data is shown in Table 1. Details on the principles behind the development of the FACT can be found elsewhere,[11]. The components of the FACT are depicted below (Figure1).

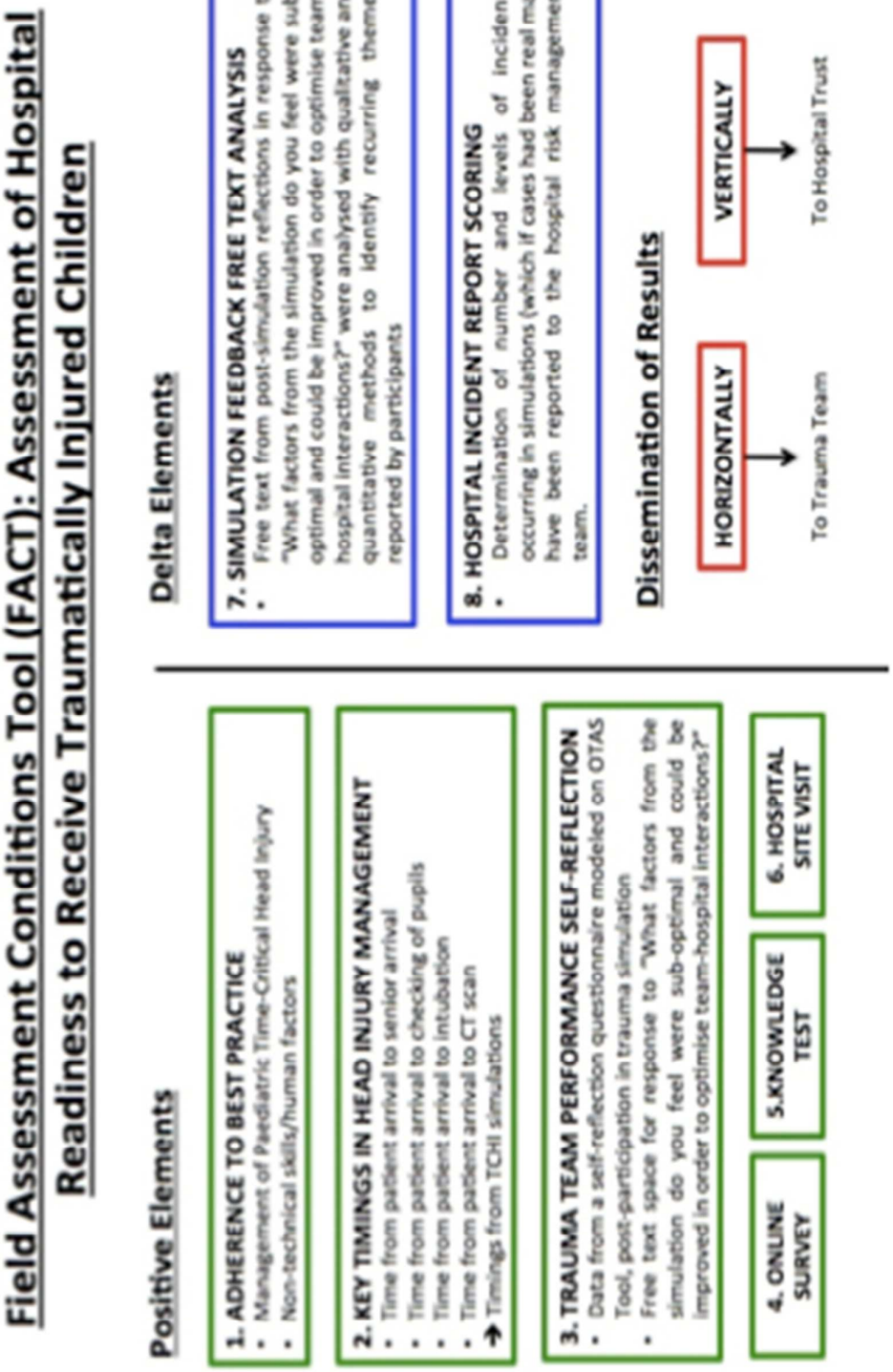
Table 1. The timeline of FACT data collection.

Time points	FACT Elements
1. First visit by research team	The trauma care facility, equipment and standard operating procedures are reviewed using the World Health Organization (WHO) trauma essentials checklist,[10]. **Hospital Site Visit** section in FACT

2. Trauma team members participate in two In-situ simulations of traumatically injured children in their hospital trauma bay (second visit of research team).	The team performance in providing advanced trauma care is assessed against latest trauma care guidelines (including the Advanced Trauma Life Support program objectives), [12]. **Adherence to Best Practice** section in FACT The process of care is measured against key timing points recorded in the Trauma Audit Research Network database network. **Key Timings section** in FACT
3. Trauma team members complete the on-line Knowledge Test & Online (Mental Model) Survey	A random sample of the potential medical & nursing trauma team members undertake a twenty question multi-choice, standard questionnaire on the management of traumatically injured children. **Knowledge Test** section in FACT All potential members of the trauma team (nursing, medical and allied health professionals) are invited to participate in an online survey of practice. They are shown a video of a standard case with differing vital signs and questioned on their clinical priorities and the factors delaying the passage of such traumatically injured child from the emergency bay, to CT scanner to operating theatre. **Online Survey** sections in FACT
4. Trauma team members anonymously complete a modified OTAS questionnaire	Team Performance in Communication, Co-operation, Co-ordination, Leadership, Monitoring & Global Assessment Factors requiring improvement to enhance Team-Hospital interactions.

	Team participants are invited to complete a standard Observational Teamwork Assessment for Surgery (OTAS),[13] checklist of the team performance. In addition the members are asked to complete a free text box, by answering the following standard question, "How could we improve the care provision of the traumatically injured child that you have just managed, in terms of the trauma team and hospital systems interactions?" **Trauma Team Performance Self-Reflection** and **Simulation Feedback Free Text Analysis** sections in FACT.
5. Trauma team members participate in a standard team debrief	Critical (sudden untoward) Incidents Participants allowed to add to their previous comments Any free text answers to the above standard question ("How do you feel the trauma team – hospital interaction could be optimized to improve the care of the traumatically injured child you have just managed?") that would trigger a critical incident/sudden untoward incident report in real-life are captured. These comments are graded against a standard Hospital Risk Management Matrix (from the research pilot site) **Hospital Incident Report Scoring** section in FACT

Figure 1. The components of the FACT.



Distribution of the FACT within hospitals

The FACT for each hospital will be constructed based on the above findings. There will be an electronic copy and a hard copy of the FACT made available. The hard copy consists of a four-page document. The FACT will be distributed horizontally across all the potential members of the trauma team in each hospital. This will be completed by the clinical leads, for each discipline/role within the team. Vertical transmission of the FACT will be achieved through direct contact of each member of the hospital trauma governance infrastructure by the research team.

THE PRE PILOT EVALUATION OF THE FACT

In order to examine the use usability, configuration and acceptability of the FACT, a small pre-pilot assessment was conducted in a major UK paediatric trauma centre. The purpose of this brief study was to investigate the initial design of the reporting structure prior to a subsequent fitness for purpose study and to investigate whether the reporting structure filled a perceived gap/need for those that will receive the results and whether the format is understandable and useful to identify areas of excellence and those in need of improvement for clinical, managerial, and administrative staff of the hospital undergoing a pediatric trauma practice assessment.

Figure 2. Outline of methods for pre-pilot FACT study

The pre-pilot study methods:

1. Two onsite high-fidelity pediatric trauma scenarios conducted at a major pediatric trauma center in the UK.
2. A purposive sample of representative stakeholders/providers was selected for semi-structured interviews (not involved in the scenario):
    a. 3 Clinicians- a senior nurse, a consultant/attending physician from the emergency department, and a neurosurgical consultant/attending.
    b. 3 Managers/administrative staff- a senior trauma operations managers (including a quality manager).
3. A sample FACT report was prepared based on the results from the two scenarios and presented 48 hours prior to the interview process.
4. Pre-scripted semi-structured interviews were conducted by one of the investigators (RM), the interviews were recorded and transcribed verbatim.
5. The scripts were analyzed for common themes related to whether the format was usable, understandable, and potential uses.
6. Brief summary of findings was prepared.

The interviews initially focused on the respondents understanding of quality outcomes in the trauma setting, and their own role in improvement work. The second part of the interviews focused on the configuration, reliability, validity, educational impact and acceptability of the FACT, to provide an opportunity for healthcare advocacy.

Preliminary analysis of the first part of the interviews has revealed a common difficulty in measuring quality of care. No tool at present was identified to facilitate reflection and learning on high quality care provision occurring at the pre-pilot centre. There is an audit process focusing on reaching target times and high-risk poor clinical management is reviewed by a root cause analysis mechanism. This system currently invokes any changes to improve care, there is no individual / team based advocacy opportunity. A need for a balanced input in terms of external and internal expertise to assess performance was identified and moreover there is no tool currently available. This pre pilot thereby supports the underlying concepts of developing a tool such as FACT. The second part of the interviews revealed a uniform sense that the FACT does provide a common language to provide the opportunity to invoke health care advocacy changes, is acceptable in the current configuration and format but evolution to an on-line version could be desirable.

EVALUATION OF THE FACT: ASSESSMENT OF THE FITNESS FOR PURPOSE OF THE FACT

The aim of the project is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy according to the FACT objectives.

In order to reach this goal, we aim to explore one core research question:

Is the FACT fit for purpose in terms of providing a framework to evaluate, reflect and act upon the individual hospital's own performance (trauma team – hospital interactions) in terms readiness to receive traumatically injured children?

As the aim at this stage of our research is to explore the perceived fitness for purpose of FACT a qualitative approach was deemed most suitable. To answer our research question, we have considered the work of Van der Vleuten (14) who previously described a 'utility index' as a framework for tool design & evaluation. The utility index has five components, reliability, validity, educational impact, cost-efficiency and acceptability. At this pilot stage we are not in the position to assess the cost-efficiency of the introduction of the FACT, however we aim to explore the other components to gain information that will highlight areas of an improvement for the FACT to meet our aims. An exploration of perceived reliability, validity, educational impact and acceptability of FACT is an integral step in development of the FACT. This will also provide a valuable insight into the optimal configuration and dissemination of the FACT to achieve the goals of improved patient care and safety.

Planned Research

The FACT tool will be implemented according to Table 1 within three district / non-paediatric hospitals around each participating major trauma centre in the study. The study is being conducted in the United Kingdom, United States and New Zealand at three major paediatric trauma centres.

Pilot Data collection

Semi-structured interviews will be conducted at each of the participating hospitals. We aim to sample potential clinical interprofessional members of trauma teams and also hospital administrators / managers. A minimum of twelve interviews will be

conducted at each hospital with representative variation in the respondents' profession, years in practice, gender and age. The interviews will be conducted within two weeks of the FACT result from the second pilot test being made available to the hospital. The semi-structured interviews will be conducted by an external researcher to avoid bias. All interviews will be recorded and transcribed. The findings of pre-pilot interviews were used to formulate the interview guide with all participants encouraged to freely express their views, with the expectation of no correct or incorrect answers and all viewpoints accepted.

Parents or carers almost always accompany traumatically injured children in the emergency department. The parents or carers are also integral to the care provided. The parents can be directly next to or very close to the acute care provision, their perspective and thoughts as to the design and process of a tool to improve the complex trauma team – hospital interactions is invaluable. Patient, parent or carer input will be sought to provide a child and family centred lens on the FACT composition. This will be achieved by inviting parents to attend and participate in a forum at the base major trauma centre, facilitated by an external (to the trauma centre) member of the research team. The perspective of both parents and carers will be sought on current trauma team care training in addition to the FACT methodology.

All interviews will be analysed using an inductive thematic approach within the broad framework of the utility index. Two researchers will analyse the data from each centre independently before they meet and review the coding until consensus is reached. Once data from all three centres is analysed, the findings will be compared and contrasted.

Publications will be subject to the scrutiny of the Trauma project Manuscript Oversight Committee of the INSPIRE network (www.inspiresim.com).

DISCUSSION

The objective of this study is to explore the fitness for purpose of the FACT as a health care advocacy tool, to provide the opportunity for all potential members of the trauma team and trauma governance infrastructure, to evaluate and impact positively upon the trauma care provision within different hospitals. The performance of a qualitative analysis of the fitness for purpose of the FACT, in terms of configuration,

reliability, validity, educational impact and acceptability, will provide an invaluable insight in to the development of a tool to promote patient safety and improved quality of care for high risk complex children that present infrequently to hospitals. This study will also shed further light on our understanding of the measurement of quality in the paediatric trauma setting, how we collect, represent and display key learning opportunities across an ever changing mix of staff. The development of a tool that provides a common language, horizontally across team-members and vertically through the governance tree, to empower individuals throughout an organization to invoke positive changes to patient care will be a positive step forward. The input from a parental perspective will constitute a different but equally vital addition to this process. In this pilot stage we will only be exploring the perception of staff throughout the hospital organizations as to whether they have been provided with the opportunity to change staff behavior, impact positively on trauma education, change hospital systems, reduce adverse events and improve patient care. The next step will be to optimize the FACT as a healthcare advocacy tool as per our findings from this study. With an optimal FACT in operation in hospitals, we aim as a research group to introduce trauma care interventions that we have developed, to directly impact positively on care provision.

While the primary focus on this project will be the provider, and provider/team capability improvement the unit of analysis, we also intend to explore whether simulation training has the potential to effect "system change". This is a novel application of onsite simulation, and this method of assessment may be cutting edge. Traditional methods that are typically used to change systems include policy, regulatory, and political interventions. We must be cognizant that effecting system change may not occur as a result of this approach, but local health care systems will benefit from this operationalized approach and the summary recommendations that will result.

CONTRIBUTORSHIP STATEMENT

All authors have provided
substantial contributions to the conception or design of the work, given approval for publishing and are accountable for all aspects of the work.

Professor MacKinnon & Dr Kennedy provided the initial concept, Dr Stenfors-Hayes added qualitative analysis concepts. Drs Shepherd, Doherty and Cole working with Professor MacKinnon, Dr Kennedy and Dr Stenfors-Hayes developed the design of the protocol together, adding elements relating to country specific healthcare systems and wider design points. All team members have communicated closely on this protocol, commenting in turn on iterations prior to this submission.

COMPETING INTERESTS: nONE

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APPENDIX 1 INTERVIEW GUIDE

Quality Improvement work (in paediatric trauma care)

Whose role is it to assess & invoke improvements at present?

What is your personal role in the improvement work in the trauma setting?

Can you describe a situation where you 'were an advocate' for an improvement process in the trauma setting?

What improvement processes have you worked with before?

Where is the expert judgment in the process?

FACT

The process

What are your thoughts or concerns on participating in the different steps of creating the FACT?

The results

Who did you receive the results from? What were your thoughts when you looked at it?

What in particular does the FACT provide **you** with?

Was there something in the results that surprised you?

Was there anything in the results that you think should be discussed or acted upon?

The follow up

Did you discuss the results with anyone?

Where any initiatives taken by anyone for any follow up or actions based on the outcome?

Who should act upon these results?

What is your role in acting upon these results?

How do you see yourself using this tool to invoke changes?

So the aim of FACT is to enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of traumatically injured children in the respective hospital, and to thereby enhancing the opportunity to reflect and learn on the rare but high stakes complex clinical events associated with managing such children. The FACT tool is furthermore designed to provide the opportunity to effect positive changes in staff knowledge, skills, behavior,

attitudes, team-hospital infrastructure and systems and patient care. What are your reflections on that?

Further development and use

Is there anything else that you feel should be present in the FACT that is not currently there?

Do you feel the tool has any usage outside of the trauma setting?

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Keywords: Medical Education, Paediatric, Simulation, Trauma, Quality Improvement

Word Count: 300

ABSTRACT

Introduction

As part of a program of research aiming to improve the outcomes of traumatically injured children, a multisource health care advocacy tool has been developed to allow trauma team members and hospital governance administrators, both to reflect on and act upon, complex trauma team-hospital systems interactions. We have termed this tool a Field Assessment Conditioning Tool (FACT). The FACT draws upon quantitative data including clinical care points in addition to self-reflective qualitative data. The FACT is designed to feedback this assessment data both horizontally across fellow potential team members and vertically to the hospital/organization governance structure, enabling process gaps identification and an agenda of improvements to be realized. The aim of the study described in this paper is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children.

Methods and Analysis

The FACT will be implemented and studied in three district hospitals around a major trauma centre in the United Kingdom, United States and New Zealand. Using a qualitative approach with standardized semi-structure interviews and thematic analysis we will explore the following question: Is the FACT fit for purpose in terms of providing a framework to evaluate, reflect and act upon the individual hospital's own performance (trauma team – hospital interactions) in terms readiness to receive traumatically injured children?

Ethics and Dissemination

Ethics opinion was sought and deemed not required from each research host organization.

The results will be disseminated to participating sites, networks and published in high impact journals.

STENGTHS & LIMITATIONS

Strengths:

- Depth of understanding of complex relationships

- Flexibility of approach to answering research question

Weakness:

- The main disadvantage of the method of data collection is that the information provided is filtered through the respondent's memory and the social context of the interview.

BACKGROUND

The rationale for this study

The aim of the study described in this paper is to explore the perceived fitness for purpose of a tool to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children.

Trauma is the leading cause of death in children less than nineteen years of age in the UK & worldwide, [1]. One of the components to improve health outcomes for these injured children is a health system trained and ready to care for these children. To improve the outcomes of traumatically injured children, we have developed a multisource tool to allow trauma team members and hospital governance administrators, both to reflect on and act upon, complex trauma team-hospital systems interactions. We have termed this tool a Field Assessment Conditioning Tool (FACT). The FACT has been designed to enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of traumatically injured children. We propose that the FACT provides the opportunity to reflect and learn on the rare but high stakes complex clinical events associated with managing such children. The FACT tool has been developed to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure, systems and patient care. In essence, the FACT has been designed to allow all potential members of the clinical trauma team and associated governance team to act as advocates within their own working environment to improve the care provided to traumatically injured children.

The clinical need for FACT

Children presenting with traumatic injuries to hospitals require optimal care to decrease mortality and morbidity. [2,3] Optimal care provision is a complex interaction between an inter-professional team of health care providers, each with individual knowledge, skills and attitudes and the health care system in which the team work. [4] There are a number of challenges to overcome to ensure optimal care provision. One challenge is to maintain the experience of the clinicians, who may not treat children requiring major trauma care on a regular basis.[5] Another challenge is to provide the opportunity for team members to reflect on the care provided in their

hospital and empower them to act as advocates of change to improve care provision. [6] In addition, the composition of hospital trauma teams is highly variable, with team membership changing on a daily basis and some members only staying six months in one hospital. [5]

There is a clear need for the development of an effective and systematic paediatric trauma training program aiming to optimize the interactions between provider teams and healthcare systems, in both major trauma centres and rural/district hospitals. [3,5] A recent study across Norway demonstrated an improvement in participant self-confidence, knowledge and perceived trauma team performance in live trauma resuscitations after initiation of an in-hospital simulation based training program. [7] This eight year study highlighted the potential for continued improvement in trauma care in those team members who had not participated in the one day trauma training course [7].

The objective of the study presented in this research protocol is to evaluate the FACT in terms of the ability of the tool to:

1. To enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of injured children.

2. To provide the opportunity for all potential trauma team and governance team members to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure, systems and patient care.

Recent evidence [8-11] suggests that one can enhance the clinical care provided to children with targeted simulation training, using child-like human patient simulators. Highly realistic human patient simulators have been used as surrogates for real life patients in both the development of the FACT and in this study to evaluate the tool.

THE PRE PILOT EVALUATION OF THE FACT

In order to examine the usability, configuration and acceptability of the FACT, we conducted a small pre-pilot assessment in a major UK paediatric trauma centre. The purpose of this brief study was to evaluate whether the FACT filled a perceived gap/need for those that will receive the results and whether the format is understandable and useful to identify areas of excellence and those in need of

improvement for clinical, managerial, and administrative staff of the hospital undergoing a pediatric trauma practice assessment.

Figure 1. Outline of methods for pre-pilot FACT study

The pre-pilot study methods:

1. Two onsite high-fidelity pediatric trauma scenarios were conducted at a major pediatric trauma center in the UK.
2. A purposive sample of representative stakeholders/providers was selected for semi-structured interviews (not involved in the scenario):
    a. 3 Clinicians- a senior nurse, a consultant/attending physician from the emergency department, and a neurosurgical consultant/attending.
    b. 3 Managers/administrative staff- a senior trauma operations managers (including a quality manager).
3. A sample FACT report was prepared based on the results from the two scenarios and presented 48 hours prior to the interview process.
4. Semi-structured interviews were conducted by one of the investigators (RM), the interviews were recorded and transcribed verbatim.
5. The transcripts were analysed for common themes related to whether the format was usable, understandable, and their potential uses.
6. Brief summary of findings was prepared.

The interviews initially focused on the respondent's understanding of quality outcomes in the trauma setting, and their own role in improvement work. The second part of the interviews focused on the configuration, reliability, validity, educational impact and acceptability of the FACT, to provide an opportunity for healthcare advocacy.

Analysis of the first part of the interviews revealed a common difficulty in measuring quality of care. No tool at present was identified to facilitate reflection and learning on high quality care provision occurring at the pre-pilot centre. An audit process focusing on reaching target times was identified and high-risk poor clinical management is reviewed by a root cause analysis mechanism. However, no individual / team based advocacy opportunities were identified. Respondents felt a need for a balanced input in terms of external and internal expertise to assess performance, but lacked a tool for this process. This pre pilot thereby supports the underlying concepts of developing a tool such as FACT.

The second part of the interviews revealed a uniform sense that the FACT does provide a common language to provide the opportunity to invoke health care

advocacy changes that it is acceptable in the current configuration and format but that evolution to an on-line version could be desirable.

THIS STUDY: THE EVALUATION OF THE FACT

The aim of the project is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children. We use the term 'fitness for purpose' here as a criteria for establishing whether or not a tool meets quality, measured against what is seen to be the goal of the tool.

To achieve this aim a qualitative approach was deemed most suitable. We have also considered the work of Van der Vleuten [12] who previously described a 'utility index' as a framework for tool design & evaluation. The utility index has five components, reliability, validity, educational impact, cost-efficiency and acceptability. At this stage we are not in the position to assess the cost-efficiency of the introduction of the FACT, however the other components will be explored to gain information that will highlight areas in need of development in the FACT. By conducting interviews we get access to the respondent's personal perspectives and experiences of the FACT process and results. The main disadvantage of this method of data collection is that the information provided is filtered through the respondent's memory and the social context of the interview. [13]

Planned Research

Ethics opinion was sought from research host organization. In the UK, in accordance with current governance guidelines for health research, studies on NHS staff and service provision and the engagement of the general public to seek opinion of this service provision, this research project does not require NHS Research Ethics Approval.

The FACT tool will be implemented according to Table 1 in Appendix 2, within three district / non-paediatric hospitals around each participating major trauma centre in the study. The study is being conducted in the United Kingdom, United States and New Zealand at three major paediatric trauma centres.

At time of publication, the both UK & NZ major trauma centres had recruited three district / non-paediatric hospitals.

Data collection

Semi-structured interviews will be conducted at each of the participating hospitals, using a purposeful sample to achieve maximum variation. The interview is guided by a predetermined set of open ended questions. However the researcher and respondents are free to pursue additional topics that are deemed relevant.[14] We aim to sample potential clinical interprofessional members of trauma teams and also hospital administrators / managers. A minimum of twelve interviews will be conducted at each hospital with representative variation in the respondents' profession, years in practice, gender and age. Variation in the sample will enable a broad range of perspectives and experiences to be captured and thereby leading to a deepened understanding. Previous research has shown that saturation of findings occurs within the first twelve interviews, even when the variation in the sample is high (such as different national contexts).[15] Due to the high variation within each national context in our study, we have chosen a minimum of twelve respondents at each site. Participants will be recruited via an email that provides information about the study and invites participation. The interviews will be conducted within two weeks of the FACT result from the second pilot test being made available to the hospital. The semi-structured interviews will be conducted by an external research team member not known by the respondent and which has not been part of developing the FACT tool to avoid bias and power dynamics in the interview situation. The interviews will be conducted at a time and place convenient for the participant. All interviews will be audio or video recorded and transcribed. The findings of pre-pilot interviews were used to formulate the interview guide with all participants encouraged to freely express their views, with the expectation of no correct or incorrect answers and all viewpoints accepted.

All interviews will be analysed using an inductive thematic approach within the broad framework of the utility index. A thematic approach has the advantage that it can be applied across a range of theoretical and epistemological approaches. Through its theoretical freedom, thematic analysis provides a flexible and useful research tool, which can potentially provide a rich and detailed, yet complex account of data. [16] An inductive approach means the themes identified are strongly linked to the data

themselves. [17] Inductive analysis is therefore a process of coding the data *without* trying to fit it into a pre-existing coding frame, or the researcher's analytic preconceptions. The analytic process will include interpretation at the latent level which goes beyond the semantic content of the data, and starts to identify or examine the underlying ideas, assumptions, and conceptualisations. However, as we have chosen to relate our findings to the utility index, our analysis will include some deductive aspects as well as the inductive.

The interviewer (an external PhD trained qualitative researcher) and one local research team member will analyse the data from each centre independently before they meet and review the coding until consensus is reached. The local team member will be able to add to the analysis by their fuller contextual understanding and medical knowledge, whilst the external researcher will reduce bias as they have not been involved in the development of the tool, nor having been present when the FACT was tested. When reading the transcripts, ideas expressed by the interviewees will be condensed, compared and grouped into themes that represent similar ways of understanding the phenomena under scrutiny. This process will occur iteratively, that is, as new perspectives arise they will be examined in the context of the entire data set. The analytic process used is similar to what is commonly referred to as constant comparison. [18] The themes are not dependent on quantifiable measures – but in terms of whether it captures something important in relation to the overall research question. Once data from all three centres is analysed, the findings will be compared and contrasted. Dependability of the data will be ensured by maintaining an audit trail of interview transcripts, analytical memos and the developing themes and their relations. [19] The trustworthiness of the findings will be strengthened because the analysis being conducted by a team of researchers who will discuss and debate their interpretations until consensus is achieved.[20]

DISCUSSION

The aim of the study described in this paper is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children. The performance of a qualitative analysis of the fitness for purpose of the FACT, in terms of configuration, reliability, validity, educational impact and acceptability, will provide an

invaluable insight in to the development of a tool to promote patient safety and improved quality of care for high risk complex children that present infrequently to hospitals. This study will also shed further light on our understanding of the measurement of quality in the paediatric trauma setting, how we collect, represent and display key learning opportunities across an ever changing mix of staff.

Recent discussion on the epistemology of patient safety (defined as the science of the method of finding about patient safety) from the perspective of a risk management framework developed key issues in this domain of including identifying, analysing, evaluating and managing risk [21]. The authors also emphasise the importance of a deep understanding of the context where healthcare delivery occurs, the need for communication, monitoring and review [21]. With the goal of patient safety at the forefront, the authors highlight the strength of combining a mixed qualitative and quantitative framework approach to achieve this. We propose that the FACT uses this mixed approach and builds upon these patient safety principles, particular with reference to the delta elements of the tool. We aim to also highlight excellent care provision by paediatric trauma teams (the positive elements of the FACT) and disseminate this horizontally and vertically, as discussed above, to all potential team members and advocates to improve care.

The development of a tool that provides a common language, horizontally across team-members and vertically through the governance tree, to empower individuals throughout an organization to invoke positive changes to patient care will be a positive step forward. The input from a parental perspective will constitute a different but equally vital addition to this process. At this stage we will only be exploring the perception of staff throughout the hospital organizations as to whether they have been provided with the opportunity to change staff behavior, impact positively on trauma education, change hospital systems, reduce adverse events and improve patient care. The next step will be to optimize the FACT as a healthcare advocacy tool as per our findings from this study. With an optimal FACT in operation in hospitals, we aim as a research group to introduce trauma care interventions that we have developed, to directly impact positively on care provision.

While the primary focus on this project is to evaluate a healthcare advocacy tool to empower potential trauma team members to make changes to improve their own team and hospital system interactions, in forthcoming research we also intend to

explore whether other educational interventions have the potential to positively effect "system change" and directly impact patient care. This is a novel application of in-situ simulation, the use of simulation-based education directly at the place of work where healthcare professionals provide care. This method of assessment may be cutting edge as traditional methods that are typically used to change systems include policy, regulatory, and political interventions. We must be cognizant that effecting system change may not occur as a result of this approach, however one can visualize that local health care systems will benefit from this operationalized approach and the summary recommendations that will result.

A. CONTRIBUTORSHIP STATEMENT

All authors have provided substantial contributions to the conception or design of the work, given approval for publishing and are accountable for all aspects of the work.

Professor MacKinnon & Dr Kennedy provided the initial concept, Dr Stenfors-Hayes added qualitative analysis concepts. Drs Shepherd, Doherty and Cole working with Professor MacKinnon, Dr Kennedy and Dr Stenfors-Hayes developed the design of the protocol together, adding elements relating to country specific healthcare systems and wider design points. All team members have communicated closely on this protocol, commenting in turn on iterations prior to this submission.

B. COMPETING INTERESTS

There are no competing interests

C. FUNDING

This project has been awarded small grant funding from Health Education – North West (Greater Manchester) UK and the Auckland District Health Board Charitable Trust, New Zealand.

D. DATA SHARING

Authors are content with data sharing. There is no unpublished data from this protocol available.

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APPENDIX 1 INTERVIEW GUIDE

Quality Improvement work (in paediatric trauma care)

What is your personal role in the improvement work in the trauma setting?
Whose role is it to assess & invoke improvements at present?
Can you describe a situation where you 'were an advocate' for an improvement process in the trauma setting?
What improvement processes have you worked with before?
Where is the expert judgment in the process?

FACT

The process

How would you describe the aim of the FACT process in your won words?
What are your thoughts or concerns on participating in the different steps of creating the FACT?
Who did you receive the FACT results from?

The results

What were your thoughts when you looked at the FACT results?
Did you feel the FACT results paint a fair picture of your team –hospital interaction?
What in particular does the FACT results provide **you** with?
Was there something in the FACT results that surprised you?
Was there anything in the FACT results that you think should be discussed or acted upon?
Do you feel there is anything else that should be looked at in the context of the hospital team interaction that is not on the FACT at present?
Do you feel the FACT adds anything to your understanding of trauma management in your hospital?

The follow up

Did you discuss the FACT results with anyone?
Where any initiatives taken by anyone for any follow up or actions based on the outcome of the FACT?
What is your role in acting upon these results?
Who should act upon these results?
How do you see yourself using FACT to invoke changes?

So the aim of FACT is to enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of traumatically injured children in the respective hospital, and to thereby enhancing the opportunity to reflect and learn on the rare but high stakes complex clinical events associated with managing such children. What are your reflections on that?

The FACT tool is furthermore designed to provide the opportunity to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure and systems and patient care. What are your reflections on that?

Further development and use

Is there anything else that you feel should be present in the FACT that is not currently there?

Do you feel the FACT has any usage outside of the trauma setting?

APPENDIX 2 DESIGN OF THE FACT

Based upon our understanding of the complex relationship between an ever-changing team of multi-professional healthcare individuals in the emergency bays of hospitals that receive traumatically injured children on an infrequent basis, we chose a framework approach to the FACT tool. In situ simulations are the core of the data collection for FACT as there is significant evidence [8-11] that the clinical care provided to children can be enhanced by targeted simulation training with child-like human patient simulators. The simulators are, computerized and programmed to respond in real time to interventions or lack of and can be programmed to behave in terms of physiological responses (including vocal, pupillary responses, breathing, cardiovascular and neurological status) as a real human. Cutting edge simulation technology and techniques can provide the appropriate environment to encourage self-reflection, and to furthermore identify deficits in knowledge, skills and attitudes, the opportunities to develop performance and self-confidence, and to improve the patient care provided by an individual or a clinical team, directly where they work.[22] The process of participating in simulated trauma training as designed in FACT, is reflective and designed to promote learning with debriefing strategies highlighting good practice and areas for improvement in care. Mobile mannequin technology allows simulation-based critical pediatric trauma exercises to be conducted onsite this allows staff to “train together when they work, with whom they work and where they work”. The FACT approach also allows reflection on the complex healthcare processes involved in trauma care and the opportunity to invoke healthcare changes to improve care at all levels.

An assessment systems require triangulation of data sets to build up a picture of performance & interactions.[23,24] Moreover an effective assessment instrument should be transparent, justifiable, evidence based and recognize the restraints of the ‘real world’.[25,26] To achieve this, FACT is designed based on a number of different data sources, both qualitative and quantitative, as described elsewhere.[6]

Keeping a family centered lens

Parents or carers almost always accompany traumatically injured children in the emergency department. The parents or carers are also integral to the care provided. The parents can be directly next to or very close to the acute care provision, their

perspective and thoughts as to the design and process of a tool to improve the complex trauma team – hospital interactions is invaluable. Patient, parent or carer input will be sought to provide a child and family centred lens on the FACT composition. This will be achieved by inviting parents to attend and participate in a forum at the base major trauma centre, facilitated by an external (to the trauma centre) member of the research team. The perspective of both parents and carers will be sought on current trauma team care training in addition to the FACT methodology. The forum will be set up as a focus group, with 4-8 family members and carers present for each group. Focus groups provide opportunity for a dynamic and interactive exchange and reflection. By hosting regular forums the family centered perspective will remain central in the FACT development and use.

How the FACT combines with simulation

High reality human patient simulators of traumatically injured children are brought into the emergency bay at the pilot hospital by researchers acting as paramedics. Prior to this, the hospital is notified using the same standard Major Trauma Alert procedure for all traumatically injured children, as used by the paramedic ambulance service. A hospital wide trauma alert code is activated, team members arrive, and work together on the severely injured simulated child in the emergency bay. Each team member then completes a questionnaire (as described in Table 1). All team members record their role in the team, for example Trauma Team Leader or trauma nurse, but not their names to ensure anonymity. A team-debrief then follows, conducted by an experienced facilitator from the research team. The process takes approximately 45 minutes in total, for each of the two scenarios. The time line for collection of the FACT data is shown in Table 1. Details on the principles behind the development of the FACT can be found elsewhere [6]. The components of the FACT are depicted below (Figure 2).

Distribution of the FACT within hospitals

The FACT for each hospital will be constructed based on the findings of the FACT data collection. There will be an electronic copy and a hard copy of the FACT made available. The hard copy consists of a four-page document. The FACT will be distributed horizontally across all the potential members of the trauma team in each hospital. The distribution will be achieved via the clinical leads within the teams.

Vertical transmission of the FACT will be achieved through direct contact of each member of the hospital trauma governance infrastructure by the research team.

Table 1. The timeline of FACT data collection.

Time points	FACT Elements
1. First visit by research team	The trauma care facility, equipment and standard operating procedures are reviewed using the World Health Organization (WHO) trauma essentials checklist.[27] **Hospital Site Visit** section in FACT
2. Trauma team members participate in two In-situ simulations of traumatically injured children in their hospital trauma bay (second visit of research team).	The team performance in providing advanced trauma care is assessed against latest trauma care guidelines (including the Advanced Trauma Life Support program objectives).[28] **Adherence to Best Practice** section in FACT The process of care is measured against key timing points recorded in the Trauma Audit Research Network database network. **Key Timings in Clinical Management section** in FACT
3. Trauma team members complete the on-line Knowledge Test & on-line Mental Model Survey	A random sample of the potential medical & nursing trauma team members undertake a twenty question multi-choice, standard questionnaire on the management of traumatically injured children. **Knowledge Test** section in FACT All potential members of the trauma team (nursing, medical and allied health professionals) are invited to participate in an online survey of practice. They are shown a video of a standard case with differing vital signs and questioned on their clinical priorities and the factors delaying the passage of such traumatically injured child from the emergency bay, to CT scanner to operating theatre. **On-line Mental Model Survey** sections in FACT

4. Trauma team members anonymously complete a modified OTAS questionnaire	Team Performance in Communication, Co-operation, Co-ordination, Leadership, Monitoring & Global Assessment Factors requiring improvement to enhance Team-Hospital interactions. Team participants are invited to complete a standard Observational Teamwork Assessment for Surgery (OTAS),[29] checklist of the team performance. In addition the members are asked to complete a free text box, by answering the following standard question, "How could we improve the care provision of the traumatically injured child that you have just managed, in terms of the trauma team and hospital systems interactions?" **Trauma Team Performance Self-Reflection** and **Simulation Feedback Free Text Analysis** sections in FACT.
5. Trauma team members participate in a standard team debrief	Critical (sudden untoward) Incidents Participants allowed to add to their previous comments Any free text answers to the above standard question ("How do you feel the trauma team – hospital interaction could be optimized to improve the care of the traumatically injured child you have just managed?") that would trigger a critical incident/sudden untoward incident report in real-life are captured. These comments are graded against a standard Hospital Risk Management Matrix (from the research pilot site) **Hospital Incident Report Scoring** section in FACT

Figure 2. The components of the FACT.

FIELD ASSESSMENT CONDITIONING TOOL (FACT)

Assessment of the Hospital Readiness to Receive Traumatically Injured Children

POSITIVE ELEMENTS

These elements aim to highlight the high quality care already being provided by each hospital.

1. ADHERENCE TO BEST PRACTICE

2. KEY TIMINGS IN CLINICAL MANAGEMENT

3. TRAUMA TEAM PERFORMANCE SELF-REFLECTION

4. ON-LINE MENTAL MODEL SURVEY

5. KNOWLEDGE TEST

6. HOSPITAL VISIT

DELTA ELEMENTS

These elements aim to highlight area for improvement of care provision at each hospital, based upon the thoughts and reflections of the team members within each hospital.

7. SIMULATION FEEDBACK FREE TEXT ANALYSIS

8. HOSPITAL INCIDENT REPORT SCORING

DISSEMINATION

HORIZONTALLY – TO ALL POSSIBLE TEAM MEMBERS

VERTICALLY - TO HOSPITAL GOVERNANCE BOARD

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RESEARCH PROTOCOL: A FITNESS FOR PURPOSE STUDY OF THE FIELD ASSESSMENT CONDITIONING TOOL (FACT)

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RESEARCH PROTOCOL: A FITNESS FOR PURPOSE STUDY OF THE FIELD ASSESSMENT CONDITIONING TOOL (FACT)

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ABSTRACT

Introduction

As part of a program of research aiming to improve the outcomes of traumatically injured children, a multisource health care advocacy tool has been developed to allow trauma team members and hospital governance administrators, both to reflect on and act upon, complex trauma team-hospital systems interactions. We have termed this tool a Field Assessment Conditioning Tool (FACT). The FACT draws upon quantitative data including clinical care points in addition to self-reflective qualitative data. The FACT is designed to feedback this assessment data both horizontally across fellow potential team members and vertically to the hospital/organization governance structure, enabling process gaps identification and an agenda of improvements to be realized. The aim of the study described in this paper is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children.

Methods and Analysis

The FACT will be implemented and studied in three district hospitals around a major trauma centre in the United Kingdom, United States and New Zealand. Using a qualitative approach with standardized semi-structure interviews and thematic analysis we will explore the following question: Is the FACT fit for purpose in terms of providing a framework to evaluate, reflect and act upon the individual hospital's own performance (trauma team – hospital interactions) in terms readiness to receive traumatically injured children?

Ethics and Dissemination

Ethics opinion was sought and deemed not required from each research host organization.

The results will be disseminated to participating sites, networks and published in high impact journals.

STENGTHS & LIMITATIONS

Strengths:

- Depth of understanding of complex relationships

- Flexibility of approach to answering research question

Weakness:

- The main disadvantage of the method of data collection is that the information provided is filtered through the respondent's memory and the social context of the interview.

RESEARCH PROTOCOL: A FITNESS FOR PURPOSE STUDY OF THE FIELD ASSESSMENT CONDITIONING TOOL (FACT)

BACKGROUND

The rationale for this study

The aim of the study described in this paper is to explore the perceived fitness for purpose of a tool to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children.

Trauma is the leading cause of death in children less than nineteen years of age in the UK & worldwide.[1] One of the components to improve health outcomes for these injured children is a health system trained and ready to care for these children. To improve the outcomes of traumatically injured children, we have developed a multisource tool to allow trauma team members and hospital governance administrators, both to reflect on and act upon, complex trauma team-hospital systems interactions. We have termed this tool a Field Assessment Conditioning Tool (FACT), (Appendix 1).[2] The FACT has been designed to enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of traumatically injured children. We propose that the FACT provides the opportunity to reflect on and learn from events associated with managing such children. The FACT tool has been developed to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure, systems and patient care. In essence, the FACT has been designed to allow all potential members of the clinical trauma team and associated governance team to act as advocates within their own working environment to improve the care provided to traumatically injured children.

The clinical need for FACT

Children presenting with traumatic injuries to hospitals require optimal care to decrease mortality and morbidity.[3,4] Optimal care provision is a complex interaction between an inter-professional team of health care providers, each with individual knowledge, skills and attitudes and the health care system in which the team work.[5] There are a number of challenges to overcome to ensure optimal care

provision. One challenge is to maintain the experience of the clinicians, who may not treat children requiring major trauma care on a regular basis.[6] Another challenge is to provide the opportunity for team members to reflect on the care provided in their hospital and empower them to act as advocates of change to improve care provision.[2] In addition, the composition of hospital trauma teams is highly variable, with team membership changing on a daily basis and some members only staying six months in one hospital.[6]

There is a clear need for the development of an effective and systematic paediatric trauma training program aiming to optimize the interactions between provider teams and healthcare systems, in both major trauma centres and rural/district hospitals.[3,6] A recent study across Norway demonstrated an improvement in participant self-confidence, knowledge and perceived trauma team performance in live trauma resuscitations after initiation of an in-hospital simulation based training program.[7] This eight -year study highlighted the potential for continued improvement in adult trauma care in those team members who had not participated in the one-day trauma training course.[7]

The objective of the study presented in this research protocol is to evaluate the FACT in terms of the ability of the tool to:

1. To enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of injured children.

2. To provide the opportunity for all potential trauma team and governance team members to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure, systems and patient care.

Recent evidence [8-11] suggests that one can enhance the clinical care provided to children with targeted simulation training, using child-like human patient simulators. Highly realistic human patient simulators have been used as surrogates for real life patients in both the development of the FACT and in this study to evaluate the tool.

THE PRE PILOT EVALUATION OF THE FACT

In order to examine the usability, configuration and acceptability of the FACT, we conducted a small pre-pilot assessment in a major UK paediatric trauma centre. The purpose of this brief study was to evaluate whether the FACT filled a perceived

gap/need for those that will receive the results. Also whether the format is understandable and useful to identify areas of excellence and those in need of improvement for clinical, managerial, and administrative staff of the hospital undergoing a pediatric trauma practice assessment.

An outline of methods for pre-pilot FACT study:

1. Two onsite high-fidelity pediatric trauma scenarios were conducted at a major pediatric trauma center in the UK.
2. A purposive sample of representative stakeholders/providers was selected for semi-structured interviews (not involved in the scenario):
    a. 3 Clinicians- a senior nurse, a consultant/attending physician from the emergency department, and a neurosurgical consultant/attending.
    b. 3 Managers/administrative staff- a senior trauma operations managers (including a quality manager).
3. A sample FACT report was prepared based on the results from the two scenarios and presented 48 hours prior to the interview process.
4. Semi-structured interviews were conducted by one of the investigators (RM), the interviews were recorded and transcribed verbatim.
5. The transcripts were analysed for common themes related to whether the format was usable, understandable, and their potential uses.
6. Brief summary of findings was prepared.

The interviews initially focused on the respondent's understanding of quality outcomes in the trauma setting, and their own role in improvement work. The second part of the interviews focused on the configuration, reliability, validity, educational impact and acceptability of the FACT, to provide an opportunity for healthcare advocacy.

Analysis of the first part of the interviews revealed a common difficulty in measuring quality of care. No tool at present was identified to facilitate reflection and learning on high quality care provision occurring at the pre-pilot centre. An audit process focusing on reaching target times was identified and high-risk poor clinical management is reviewed by a root cause analysis mechanism. However, no individual / team based advocacy opportunities were identified. Respondents felt a need for a balanced input in terms of external and internal expertise to assess

performance, but lacked a tool for this process. This pre pilot thereby supports the underlying concepts of developing a tool such as FACT.

The second part of the interviews revealed a uniform sense that the FACT does provide a common language to provide the opportunity to invoke health care advocacy changes that it is acceptable in the current configuration and format but that evolution to an on-line version could be desirable.

THIS STUDY: A FITNESS FOR PURPOSE STUDY OF THE FIELD ASSESSMENT CONDITIONING TOOL (FACT)

Study Aim

The aim of the project is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children. We use the term 'fitness for purpose' here as a criterion for establishing whether or not a tool meets quality, measured against what is seen to be the goal of the tool. In this context, we define healthcare advocacy as the empowerment of all potential trauma team members to make changes to improve their own team and hospital system interactions during the management of traumatically injured children.

To achieve this aim a qualitative approach was deemed most suitable. To explore the fitness for purpose of the FACT, we have considered the work of Van der Vleuten [12] who previously described a 'utility index' as a framework for tool design & evaluation. The utility index has five components, reliability, validity, educational impact, cost-efficiency and acceptability. At this stage we are not in the position to assess the cost-efficiency of the introduction of the FACT, however the other components will be explored to gain information that will highlight areas in need of development in the FACT. By conducting interviews we get access to the respondent's personal perspectives and experiences of the FACT process and results. The main disadvantage of this method of data collection is that the information provided is filtered through the respondent's memory and the social context of the interview. [13]

METHODOLOGY

Ethical Issues

Ethics opinion was sought from research host organization. In the UK, in accordance with current governance guidelines for health research, studies on NHS staff and service provision and the engagement of the general public to seek opinion of this service provision, this research project does not require NHS Research Ethics Approval. All participating individuals consent to do so and are provided with a participant information document.

Study Design

Using a qualitative approach with standardized semi-structure interviews and thematic analysis we will explore the following question: Is the FACT fit for purpose in terms of providing a framework to evaluate, reflect and act upon the individual hospital's own performance (trauma team – hospital interactions) in terms of the readiness to receive traumatically injured children?

Study Timeline

The study is being conducted in the United Kingdom, United States and New Zealand at three major paediatric trauma centres. The study will be conducted over a one-year period, as depicted in Table 1. A FACT report will be constructed at each participating hospital, as detailed in Appendix 1. The FACT will be disseminated to all potential trauma team members. This process will be repeated at six months and then semi-structured interviews will be conducted at each of the participating hospitals, to assess the fitness for purpose of the FACT.

Table 1. Timeline for study

	Months 1-4	Months 5-8	Months 9-12

Activity		Recruitment &Consenting	FACT Implementation	FACT Report Construction	FACT Report Dissemination	Repeat FACT Report & Dissemination	Semi-structured Interviews	Data Transcription	Data Analysis	Project Write up	Dissemination of Findings
a	UK	→									
b	NZ	→									
c	US	→									

Sample & Recruitment

The FACT tool will be implemented according to Table 2 in Appendix 1, within three district / non-paediatric hospitals around each participating major trauma centre in the study. The principle investigator at each major trauma centre will recruit the district / non-paediatric hospitals and consent participating individuals at each hospital. At time of publication, the both UK & NZ major trauma centres had recruited three district / non-paediatric hospitals.

Data collection

Semi-structured interviews will be conducted at each of the participating hospitals, using a purposeful sample to achieve maximum variation. The interview is guided by a predetermined set of open-ended questions (Appendix 2). However the researcher and respondents are free to pursue additional topics that are deemed relevant.[14] We aim to sample potential clinical interprofessional members of trauma teams and also hospital administrators / managers. A minimum of twelve interviews will be conducted at each hospital with representative variation in the respondents' profession, years in practice, gender and age. Variation in the sample will enable a broad range of perspectives and experiences to be captured and thereby leading to a deepened understanding. Previous research has shown that saturation of findings occurs within the first twelve interviews, even when the variation in the sample is high (such as different national contexts).[15] Due to the high variation within each national context in our study, we have chosen a minimum of twelve respondents at each site. Participants will be recruited via an email that provides information about the study and invites participation. The interviews will be conducted within two weeks of the FACT result from the second pilot test being made available to the hospital. The semi-structured interviews will be conducted by an external research team member not known by the respondent and which has not been part of developing the FACT tool to avoid bias and power dynamics in the interview situation. The interviews will be conducted at a time and place convenient for the participant. All interviews will be audio or video recorded and transcribed. The findings of pre-pilot interviews were used to formulate the interview guide with all participants encouraged to freely express their views, with the expectation of no correct or incorrect answers and all viewpoints accepted.

Data analysis

All interviews will be analysed using an inductive thematic approach within the broad framework of the utility index. A thematic approach has the advantage that it can be applied across a range of theoretical and epistemological approaches. Through its theoretical freedom, thematic analysis provides a flexible and useful research tool, which can potentially provide a rich and detailed, yet complex account of data. [16] An inductive approach means the themes identified are strongly linked to the data themselves. [17] Inductive analysis is therefore a process of coding the data *without* trying to fit it into a pre-existing coding frame, or the researcher's analytic preconceptions. The analytic process will include interpretation at the latent level, which goes beyond the semantic content of the data, and starts to identify or examine the underlying ideas, assumptions, and conceptualisations. However, as we have chosen to relate our findings to the utility index, our analysis will include some deductive aspects as well as the inductive.

The interviewer (an external PhD trained qualitative researcher) and one local research team member will analyse the data from each centre independently before they meet and review the coding until consensus is reached. The local team member will be able to add to the analysis by their fuller contextual understanding and medical knowledge, whilst the external researcher will reduce bias as they have not been involved in the development of the tool, nor having been present when the FACT was tested. When reading the transcripts, ideas expressed by the interviewees will be condensed, compared and grouped into themes that represent similar ways of understanding the phenomena under scrutiny. This process will occur iteratively, that is, as new perspectives arise they will be examined in the context of the entire data set. The analytic process used is similar to what is commonly referred to as constant comparison.[18] The themes are not dependent on quantifiable measures – but in terms of whether it captures something important in relation to the overall research question. Once data from all three centres is analysed, the findings will be compared and contrasted. Maintaining an audit trail of the interview transcripts, analytical memos and the developing themes and their relations will ensure dependability of the data.[19] The trustworthiness of the findings will be strengthened because the analysis being conducted by a team of researchers who will discuss and debate their interpretations until consensus is achieved.[20]

Strengths & limitations

The strengths of this study include the depth of understanding of complex relationships that will be explored and the flexibility of the methodological approach to facilitate answering of the research question. The main disadvantage of the method of data collection is that the information provided is filtered through the respondent's memory and the social context of the interview.

Dissemination Of Findings

The results of this study will be disseminated to participating sites, regional and international trauma networks and published in high impact journals.

DISCUSSION

The aim of the study described in this paper is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children. The performance of a qualitative analysis of the fitness for purpose of the FACT, in terms of configuration, reliability, validity, educational impact and acceptability, will provide an invaluable insight in to the development of a tool to promote patient safety and improved quality of care for high risk complex children that present infrequently to hospitals. This study will also shed further light on our understanding of the measurement of quality in the paediatric trauma setting, how we collect, represent and display key learning opportunities across an ever changing mix of staff.

Recent discussion on the epistemology of patient safety (defined as the science of the method of finding about patient safety) from the perspective of a risk management framework developed key issues in this domain of including identifying, analysing, evaluating and managing risk.[21] The authors also emphasise the importance of a deep understanding of the context where healthcare delivery occurs, the need for communication, monitoring and review.[21] With the goal of patient safety at the forefront, the authors highlight the strength of combining a mixed qualitative and quantitative framework approach to achieve this. We propose that the FACT uses this mixed approach and builds upon these patient safety principles, particular with reference to the delta elements of the tool. We aim to also highlight excellent care provision by paediatric trauma teams (the positive elements of the

FACT) and disseminate this horizontally and vertically, as discussed above, to all potential team members and advocates to improve care.

The development of a tool that provides a common language, horizontally across team-members and vertically through the governance tree, to empower individuals throughout an organization to invoke positive changes to patient care will be a positive step forward. The input from a parental perspective will constitute a different but equally vital addition to this process. At this stage we will only be exploring the perception of staff throughout the hospital organizations as to whether they have been provided with the opportunity to change staff behavior, impact positively on trauma education, change hospital systems, reduce adverse events and improve patient care. The next step will be to optimize the FACT as a healthcare advocacy tool as per our findings from this study. With an optimal FACT in operation in hospitals, we aim as a research group to introduce trauma care interventions that we have developed, to directly impact positively on care provision.

While the primary focus on this project is to evaluate a healthcare advocacy tool to empower potential trauma team members to make changes to improve their own team and hospital system interactions, in forthcoming research we also intend to explore whether other educational interventions have the potential to positively effect "system change" and directly impact patient care. This is a novel application of in-situ simulation, the use of simulation-based education directly at the place of work where healthcare professionals provide care. This method of assessment may be cutting edge as traditional methods that are typically used to change systems include policy, regulatory, and political interventions. We must be cognizant that effecting system change may not occur as a result of this approach, however one can visualize that local health care systems will benefit from this operationalized approach and the summary recommendations that will result.

CONTRIBUTION STATEMENT

All authors have provided substantial contributions to the conception or design of the work, given approval for publishing and are accountable for all aspects of the work.

Professor MacKinnon & Dr Kennedy provided the initial concept. Dr Stenfors-Hayes added qualitative analysis concepts. Drs Shepherd, Doherty and Cole working with Professor MacKinnon, Dr Kennedy and Dr Stenfors-Hayes developed the design of the protocol together, adding elements relating to country specific healthcare systems and wider design points. All team members have communicated closely on this protocol, prior to this submission.

COMPETING INTERESTS

There are no competing interests.

FUNDING

This project has been awarded small grant funding from Health Education – North West (Greater Manchester) UK and the Auckland District Health Board Charitable Trust, New Zealand.

DATA SHARING

Authors are content with data sharing. There is no unpublished data from this protocol available.

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APPENDIX 1 DESIGN OF THE FACT

Based upon our understanding of the complex relationship between an ever-changing team of multi-professional healthcare individuals in the emergency bays of hospitals that receive traumatically injured children on an infrequent basis, we chose a framework approach to the FACT tool. In situ simulations are the core of the data collection for FACT as there is significant evidence [1-4] that the clinical care provided to children can be enhanced by targeted simulation training with child-like human patient simulators. The simulators are, computerized and programmed to respond in real time to interventions or lack of and can be programmed to behave in terms of physiological responses (including vocal, pupillary responses, breathing, cardiovascular and neurological status) as a real human. Cutting edge simulation technology and techniques can provide the appropriate environment to encourage self-reflection, and to furthermore identify deficits in knowledge, skills and attitudes, the opportunities to develop performance and self-confidence, and to improve the patient care provided by an individual or a clinical team, directly where they work.[5] The process of participating in simulated trauma training as designed in FACT, is reflective and designed to promote learning with debriefing strategies highlighting good practice and areas for improvement in care. Mobile mannequin technology allows simulation-based critical pediatric trauma exercises to be conducted onsite this allows staff to "train together when they work, with whom they work and where they work". The FACT approach also allows reflection on the complex healthcare processes involved in trauma care and the opportunity to invoke healthcare changes to improve care at all levels.

An assessment system requires triangulation of data sets to build up a picture of performance and interactions.[6,7] Moreover an effective assessment instrument should be transparent, justifiable, evidence based and recognize the restraints of the 'real world'.[8,9] To achieve this, FACT is designed based on a number of different data sources, both qualitative and quantitative, as described elsewhere.[10]

Keeping a family centered lens

Parents or carers almost always accompany traumatically injured children in the emergency department. The parents or carers are also integral to the care provided. The parents can be directly next to or very close to the acute care provision, their perspective and thoughts as to the design and process of a tool to improve the complex trauma team – hospital interactions is invaluable. Patient, parent or carer input will be sought to provide a child and family centred lens on the FACT composition. This will be achieved by inviting parents to attend and participate in a forum at the base major trauma centre, facilitated by an external (to the trauma centre) member of the research team. The perspective of both parents and carers will be sought on current trauma team care training in addition to the FACT methodology. The forum will be set up as a focus group, with 4-8 family members and carers present for each group. Focus groups provide opportunity for a dynamic and interactive exchange and reflection. By hosting regular forums the family centered perspective will remain central in the FACT development and use.

How the FACT combines with simulation

High reality human patient simulators of traumatically injured children are brought into the emergency bay at the pilot hospital by researchers acting as paramedics. Prior to this, the hospital is notified using the same standard Major Trauma Alert procedure for all traumatically injured children, as used by the paramedic ambulance service. A hospital wide trauma alert code is activated, team members arrive and work together on the severely injured simulated child in the emergency bay. Each team member then completes a questionnaire (as described in Table 2). All team members record their role in the team, for example Trauma Team Leader or trauma nurse, but not their names to ensure anonymity. A team-debrief then follows, conducted by an experienced facilitator from the research team. The process takes approximately 45 minutes in total, for each of the two scenarios. The time line for collection of the FACT data is shown in Table 2. Details on the principles behind the development of the FACT can be found elsewhere [10]. The components of the FACT are depicted below (Table 3).

Distribution of the FACT within hospitals

The FACT for each hospital will be constructed based on the findings of the FACT data collection. There will be an electronic copy and a hard copy of the FACT made available. The hard copy consists of a four-page document. The FACT will be distributed horizontally across all the potential members of the trauma team in each hospital. The distribution will be achieved via the clinical leads within the teams. Vertical transmission of the FACT will be achieved through direct contact of each member of the hospital trauma governance infrastructure by the research team.

Table 2. FACT data collection timeline for each participating hospital

Time points	FACT Elements
1. First visit by research team	The trauma care facility, equipment and standard operating procedures are reviewed using the World Health Organization (WHO) trauma essentials checklist.[11] **Hospital Site Visit** section in FACT
2. Trauma team members participate in two In-situ simulations of traumatically injured children in their hospital trauma bay (second visit of research team).	The team performance in providing advanced trauma care is assessed against latest trauma care guidelines (including the Advanced Trauma Life Support program objectives).[12] **Adherence to Best Practice** section in FACT The process of care is measured against key timing points recorded in the Trauma Audit Research Network database network. **Key Timings in Clinical Management section** in FACT
3. Trauma team members complete the on-line Knowledge Test & on-line Mental Model Survey	A random sample of the potential medical & nursing trauma team members undertake a twenty question multi-choice, standard questionnaire on the management of traumatically injured children. **Knowledge Test** section in FACT All potential members of the trauma team (nursing, medical and allied health professionals) are invited to participate in an online survey of practice. They are shown a video of a standard case with differing vital signs and questioned on their clinical priorities and the factors delaying the passage of such traumatically injured child from the emergency bay, to CT scanner to operating theatre. **On-line Mental Model Survey** sections in FACT

4. Trauma team members anonymously complete a modified OTAS questionnaire	Team Performance in Communication, Co-operation, Co-ordination, Leadership, Monitoring & Global Assessment Factors requiring improvement to enhance Team-Hospital interactions. Team participants are invited to complete a standard Observational Teamwork Assessment for Surgery (OTAS),[13] checklist of the team performance. In addition the members are asked to complete a free text box, by answering the following standard question, "How could we improve the care provision of the traumatically injured child that you have just managed, in terms of the trauma team and hospital systems interactions?" **Trauma Team Performance Self-Reflection** and **Simulation Feedback Free Text Analysis** sections in FACT.
5. Trauma team members participate in a standard team debrief	Critical (sudden untoward) Incidents Participants allowed to add to their previous comments Any free text answers to the above standard question ("How do you feel the trauma team – hospital interaction could be optimized to improve the care of the traumatically injured child you have just managed?") that would trigger a critical incident/sudden untoward incident report in real-life are captured. These comments are graded against a standard Hospital Risk Management Matrix (from the research pilot site) **Hospital Incident Report Scoring** section in

	FACT

Table 3. The FACT components

FIELD ASSESSMENT CONDITIONING TOOL (FACT)

Assessment of the Hospital Readiness to Receive Traumatically Injured Children

POSITIVE ELEMENTS

These elements aim to highlight the high quality care already being provided by each hospital.

1. ADHERENCE TO BEST PRACTICE

2. KEY TIMINGS IN CLINICAL MANAGEMENT

3. TRAUMA TEAM PERFORMANCE SELF-REFLECTION

4. ON-LINE MENTAL MODEL SURVEY

5. KNOWLEDGE TEST

6. HOSPITAL VISIT

DELTA ELEMENTS

These elements aim to highlight area for improvement of care provision at each hospital, based upon the thoughts and reflections of the team members within each hospital.

7. SIMULATION FEEDBACK FREE TEXT ANALYSIS

8. HOSPITAL INCIDENT REPORT SCORING

DISSEMINATION

HORIZONTALLY – TO ALL POSSIBLE TEAM MEMBERS

VERTICALLY - TO HOSPITAL GOVERNANCE BOARD

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APPENDIX 2 INTERVIEW GUIDE

Quality Improvement work (in paediatric trauma care)

What is your personal role in the improvement work in the trauma setting?
Whose role is it to assess & invoke improvements at present?
Can you describe a situation where you 'were an advocate' for an improvement process in the trauma setting?
What improvement processes have you worked with before?
Where is the expert judgment in the process?

FACT

The process

How would you describe the aim of the FACT process in your own words?
What are your thoughts or concerns on participating in the different steps of creating the FACT?
Who did you receive the FACT results from?

The results

What were your thoughts when you looked at the FACT results?
Did you feel the FACT results paint a fair picture of your team –hospital interaction?
What in particular does the FACT results provide **you** with?
Was there something in the FACT results that surprised you?
Was there anything in the FACT results that you think should be discussed or acted upon?
Do you feel there is anything else that should be looked at in the context of the hospital team interaction that is not on the FACT at present?
Do you feel the FACT adds anything to your understanding of trauma management in your hospital?

The follow up

Did you discuss the FACT results with anyone?
Where any initiatives taken by anyone for any follow up or actions based on the outcome of the FACT?
What is your role in acting upon these results?

Who should act upon these results?

How do you see yourself using FACT to invoke changes?

So the aim of FACT is to enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of traumatically injured children in the respective hospital, and to thereby enhancing the opportunity to reflect and learn on the rare but high stakes complex clinical events associated with managing such children. What are your reflections on that?

The FACT tool is furthermore designed to provide the opportunity to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure and systems and patient care. What are your reflections on that?

Further development and use

Is there anything else that you feel should be present in the FACT that is not currently there?

Do you feel the FACT has any usage outside of the trauma setting?

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RESEARCH PROTOCOL: A FITNESS FOR PURPOSE STUDY OF THE FIELD ASSESSMENT CONDITIONING TOOL (FACT)

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RESEARCH PROTOCOL: A FITNESS FOR PURPOSE STUDY OF THE FIELD ASSESSMENT CONDITIONING TOOL (FACT)

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ABSTRACT

Introduction

As part of a program of research aiming to improve the outcomes of traumatically injured children, a multisource health care advocacy tool has been developed to allow trauma team members and hospital governance administrators, both to reflect on and act upon, complex trauma team-hospital systems interactions. We have termed this tool a Field Assessment Conditioning Tool (FACT). The FACT draws upon quantitative data including clinical care points in addition to self-reflective qualitative data. The FACT is designed to feedback this assessment data both horizontally across fellow potential team members and vertically to the hospital/organization governance structure, enabling process gap identification and an agenda of improvements to be realised. The aim of the study described in this paper is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children.

Methods and Analysis

The FACT will be implemented and studied in three district hospitals around a major trauma centre in each of the United Kingdom, United States and New Zealand. Using a qualitative approach with standardized semi-structure interviews and thematic analysis we will explore the following question: Is the FACT fit for purpose in terms of providing a framework to evaluate, reflect and act upon the individual hospital's own performance (trauma team – hospital interactions) in terms of readiness to receive traumatically injured children?

Ethics and Dissemination

Ethics opinion was sought and deemed not required for each research host organization participating.

The results will be disseminated to participating sites, networks and published in high impact journals.

STENGTHS & LIMITATIONS

Strengths:

- Depth of understanding of complex relationships

- Flexibility of approach to answering research question

Weakness:

- The main disadvantage of the method of data collection is that the information provided is filtered through the respondent's memory and the social context of the interview.

RESEARCH PROTOCOL: A FITNESS FOR PURPOSE STUDY OF THE FIELD ASSESSMENT CONDITIONING TOOL (FACT)

BACKGROUND

The rationale for this study

The aim of the study described in this paper is to explore the perceived fitness for purpose of a tool to provide an opportunity for healthcare advocacy by professionals caring for traumatically injured children.

Trauma is the leading cause of death in children less than nineteen years of age in the UK & worldwide.[1] One of the components to improve health outcomes for these injured children is a health system trained and ready to care for these children. To improve the outcomes of traumatically injured children, we have developed a multisource tool to allow trauma team members and hospital governance administrators, both to reflect on and act upon, complex trauma team-hospital systems interactions. We have termed this tool a Field Assessment Conditioning Tool (FACT), (Appendix 1).[2] The FACT has been designed to enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of traumatically injured children. We propose that the FACT provides the opportunity to reflect on and learn from events associated with managing such children. The FACT tool has been developed to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure, systems and patient care. In essence, the FACT has been designed to allow all potential members of the clinical trauma team and associated governance team to act as advocates within their own working environment to improve the care provided to traumatically injured children.

The clinical need for the FACT

Children presenting with traumatic injuries to hospitals require optimal care to decrease mortality and morbidity.[3,4] Optimal care provision is a complex interaction between an inter-professional team of health care providers, each with individual knowledge, skills and attitudes and the health care system in which the team work.[5] There are a number of challenges to overcome to ensure optimal care

provision. One challenge is to maintain the experience of the clinicians, who may not treat children requiring major trauma care on a regular basis.[6] Another challenge is to provide the opportunity for team members to reflect on the care provided in their hospital and empower them to act as advocates of change to improve care provision.[2] In addition, the composition of hospital trauma teams is highly variable, with team membership changing on a daily basis and some members only staying six months in one hospital.[6]

There is a clear need for the development of an effective and systematic paediatric trauma training program aiming to optimise the interactions between provider teams and healthcare systems, in both major trauma centres and rural/district hospitals.[3,6] A recent study across Norway demonstrated an improvement in participant self-confidence, knowledge and perceived trauma team performance in live trauma resuscitations after initiation of an in-hospital simulation based training program.[7] This eight -year study highlighted the potential for continued improvement in adult trauma care in those team members who had not participated in the one-day trauma training course.[7]

The objective of the study presented in this research protocol is to evaluate the FACT in terms of the ability of the tool to:

1. To enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of injured children.

2. To provide the opportunity for all potential trauma team and governance team members to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure, systems and patient care.

Recent evidence [8-11] suggests that one can enhance the clinical care provided to children with targeted simulation training, using child-like human patient simulators. Highly realistic human patient simulators have been used as surrogates for real life patients in both the development of the FACT and in this study to evaluate the tool.

THE PRE PILOT EVALUATION OF THE FACT

In order to examine the usability, configuration and acceptability of the FACT, we conducted a small pre-pilot assessment in a major UK paediatric trauma centre. The purpose of this brief study was to evaluate whether the FACT filled a perceived

gap/need for those that will receive the results. In addition, we explored whether the format is understandable and useful to identify areas of excellence and those in need of improvement for clinical, managerial, and administrative staff of the hospital.

An outline of methods for pre-pilot FACT study:

1. Two onsite high-fidelity pediatric trauma scenarios were conducted at a major pediatric trauma centre in the UK.
2. A purposive sample of representative stakeholders/providers was selected for semi-structured interviews (not involved in the scenario):
    a. 3 Clinicians - a senior nurse, a consultant/attending physician from the emergency department, and a neurosurgical consultant/attending.
    b. 3 Managers/administrative staff - senior trauma operations managers (including a quality manager).
3. A sample FACT report was prepared based on the results from the two scenarios and presented 48 hours prior to the interview process.
4. Semi-structured interviews were conducted by one of the investigators (RM), the interviews were recorded and transcribed verbatim.
5. The transcripts were analysed for common themes related to whether the format was usable, understandable, and their potential uses.
6. Brief summary of findings was prepared.

The interviews initially focused on the respondent's understanding of quality outcomes in the trauma setting, and their own role in improvement work. The second part of the interviews focused on the configuration, reliability, validity, educational impact and acceptability of the FACT, to provide an opportunity for healthcare advocacy.

Analysis of the first part of the interviews revealed a common difficulty in measuring quality of care. No tool at present was identified to facilitate reflection and learning on high quality care provision occurring at the pre-pilot centre. An audit process focusing on reaching target times was identified and high-risk poor clinical management is reviewed by a root cause analysis mechanism. However, no individual / team based advocacy opportunities were identified. Respondents felt a need for a balanced input in terms of external and internal expertise to assess

performance, but lacked a tool for this process. This pre pilot thereby supports the underlying concepts of developing a tool such as FACT.

The second part of the interviews revealed a uniform sense that the FACT does provide a common language to provide the opportunity to invoke health care advocacy changes that it is acceptable in the current configuration and format. It was also stated that evolution to an on-line version could be desirable.

THIS STUDY: A FITNESS FOR PURPOSE STUDY OF THE FIELD ASSESSMENT CONDITIONING TOOL (FACT)

Study Aim

The aim of the project is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy by healthcare professionals caring for traumatically injured children. We use the term 'fitness for purpose' here as a criterion for establishing whether or not a tool provides quality, measured against what is seen to be the goal of the tool. In this context, we define healthcare advocacy as the empowerment of all potential trauma team members to make changes to improve their own team and hospital system interactions during the management of traumatically injured children.

To achieve this aim a qualitative approach was deemed most suitable. To explore the fitness for purpose of the FACT, we have considered the work of Van der Vleuten [12] who previously described a 'utility index' as a framework for tool design & evaluation. The utility index has five components, reliability, validity, educational impact, cost-efficiency and acceptability. At this stage we are not in the position to assess the cost-efficiency of the introduction of the FACT, however the other components will be explored to gain information that will highlight areas in need of development in the FACT. By conducting interviews we gain access to the respondent's personal perspectives and experiences of the FACT process and results. The main disadvantage of this method of data collection is that the information provided is filtered through the respondent's memory and the social context of the interview. [13]

METHODOLOGY

Ethical Issues

Ethics opinion has been sought from research host organisations. In the UK, in accordance with current governance guidelines for health research, studies on NHS staff and service provision and the engagement of the general public to seek opinion of this service provision, this research project does not require NHS Research Ethics Approval. All participating individuals consent for audiovisual recording as part of this study and are provided with a participant information document. In New Zealand, the research team has received approval through the regional research committee and ethics waiver through the national Health and Disability Ethics committee. Consent will be sought and provided by all participants for audiovisual recording. In the United States ethics approval has been provided by Children's Mercy Hospital Pediatric Institutional Review Board, Kansas City. All participants will be consented for audiovisual recording of their participation in the study.

Study Design

Using a qualitative approach with standardized semi-structure interviews and thematic analysis we will explore the following question: Is the FACT fit for purpose in terms of providing a framework to evaluate, reflect and act upon the individual hospital's own performance (trauma team – hospital interactions) in terms of the readiness to receive traumatically injured children?

Study Timeline

The study is being conducted in the United Kingdom, United States and New Zealand at three major paediatric trauma centres. The study will be conducted over a one-year period, as depicted in Table 1. A FACT report will be constructed at each participating hospital, as detailed in Appendix 1. The FACT will be disseminated to all potential trauma team members. This process will be repeated at six months and then semi-structured interviews will be conducted at each of the participating hospitals, to assess the fitness for purpose of the FACT.

Table 1. Timeline for study

		Months 1-4				Months 5-8			Months 9-12		
Activity		Recruitment &Consenting	FACT Implementation	FACT Report Construction	FACT Report Dissemination	Repeat FACT Report & Dissemination	Semi-structured Interviews	Data Transcription	Data Analysis	Project Write up	Dissemination of Findings
a	UK	→									
b	NZ	→									
c	US	→									

Sample & Recruitment

The FACT tool will be implemented according to Table 2 in Appendix 1, within three district / non-paediatric hospitals around each participating major trauma centre in the study. The principle investigator at each major trauma centre will recruit the district / non-paediatric hospitals and consent participating individuals at each hospital. At time of manuscript submission, both UK & NZ major trauma centres had recruited three district / non-paediatric hospitals.

Data collection

Semi-structured interviews will be conducted at each of the participating hospitals, using a purposeful sample to achieve maximum variation. The interview is guided by a predetermined set of open-ended questions (Appendix 2). However the researcher and respondents are free to pursue additional topics that are deemed relevant.[14] We aim to sample potential clinical interprofessional members of trauma teams and also hospital administrators / managers. A minimum of twelve interviews will be conducted at each hospital with representative variation in the respondents' profession, years in practice, gender and age. Variation in the sample will enable a broad range of perspectives and experiences to be captured and thereby lead to a deepened understanding. Previous research has shown that saturation of findings occurs within the first twelve interviews, even when the variation in the sample is high (such as different national contexts).[15] Due to the high variation within each national context in our study, we have chosen a minimum of twelve respondents at each site. Participants will be recruited via an email that provides information about the study and invites participation. The interviews will be conducted within two weeks of the FACT result from the second pilot test being made available to the hospital. The semi-structured interviews will be conducted by an external research team member not known by the respondent and who has not been part of developing the FACT tool to avoid bias and power dynamics in the interview situation. The interviews will be conducted at a time and place convenient for the participant. All interviews will be audio or video recorded and transcribed. The findings of pre-pilot interviews were used to formulate the interview guide with all participants encouraged to freely express their views, with the expectation of no correct or incorrect answers and all viewpoints accepted.

Data analysis

All interviews will be analysed using an inductive thematic approach within the broad framework of the utility index. A thematic approach has the advantage that it can be applied across a range of theoretical and epistemological approaches. Through its theoretical freedom, thematic analysis provides a flexible and useful research tool, which can potentially provide a rich and detailed, yet complex account of data.[16] An inductive approach means the themes identified are strongly linked to the data themselves.[17] Inductive analysis is therefore a process of coding the data *without* trying to fit it into a pre-existing coding frame, or the researcher's analytic preconceptions. The analytic process will include interpretation at the latent level, which goes beyond the semantic content of the data, and starts to identify or examine the underlying ideas, assumptions, and conceptualisations. However, as we have chosen to relate our findings to the utility index, our analysis will include some deductive aspects as well as the inductive.

The interviewer (an external PhD trained qualitative researcher) and one local research team member will analyse the data from each centre independently before they meet and review the coding until consensus is reached. The local team member will be able to add to the analysis by their fuller contextual understanding and medical knowledge, whilst the external researcher will reduce bias as they have not been involved in the development of the tool, nor having been present when the FACT was tested. When reading the transcripts, ideas expressed by the informants will be condensed, compared and grouped into themes that represent similar ways of understanding the phenomena under scrutiny. This process will occur iteratively, that is, as new perspectives arise they will be examined in the context of the entire data set. The analytic process used is similar to what is commonly referred to as constant comparison.[18] The themes are not dependent on quantifiable measures – but in terms of whether it captures something important in relation to the overall research question. Once data from all three centres is analysed, the findings will be compared and contrasted. Maintaining an audit trail of the interview transcripts, analytical memos and the developing themes and their relations will ensure dependability of the data.[19] The trustworthiness of the findings will be strengthened because the analysis being conducted by a team of researchers who will discuss and debate their interpretations until consensus is achieved.[20]

Strengths & limitations

The strengths of this study include the depth of understanding of complex relationships that will be explored and the flexibility of the methodological approach to facilitate answering of the research question. The main disadvantage of the method of data collection is that the information provided is filtered through the respondent's memory and the social context of the interview.[13]

Dissemination Of Findings

The results of this study will be disseminated to participating sites, regional and international trauma networks and submitted to high impact journals.

DISCUSSION

The aim of the study described in this paper is to explore the perceived fitness for purpose of the FACT to provide an opportunity for healthcare advocacy by professionals caring for traumatically injured children. The fitness for purpose of the FACT, in terms of configuration, reliability, validity, educational impact and acceptability will be qualitatively analysed. This analysis will provide an invaluable insight in to the development of a tool to promote patient safety and improved quality of care for high-risk complex children that present infrequently to hospitals. This study will also shed further light on our understanding of the measurement of quality in the paediatric trauma setting, how we collect, represent and display key learning opportunities across an ever changing mix of staff.

Recent discussion on the epistemology of patient safety (defined as the science of the method of finding about patient safety) from the perspective of a risk management framework, has developed key issues in this domain.[21] These include identifying, analysing, evaluating and managing risk.[21] The authors also emphasise the importance of a deep understanding of the context where healthcare delivery occurs, the need for communication, monitoring and review.[21] With the goal of patient safety at the forefront, the authors highlight the strength of combining a mixed qualitative and quantitative framework approach to achieve this. We propose that the FACT uses this mixed approach and builds upon these patient safety principles, particularly with reference to the delta elements of the tool. We aim to also highlight excellent care provision by paediatric trauma teams (the positive

elements of the FACT) and disseminate this horizontally and vertically, as discussed above, to all potential team members and advocates to improve care.

The development of a tool that provides a common language, horizontally across team-members and vertically through the governance tree and also empowers individuals throughout an organization to invoke positive changes has the potential to improve patient care. The input from a parental perspective will constitute a different but equally vital addition to this process. At this stage we will only be exploring the perception of staff throughout the hospital organisations as to whether they have been provided with the opportunity to change staff behavior, impact positively on trauma education, change hospital systems, reduce adverse events and improve patient care. The next step will be to optimize the FACT as a healthcare advocacy tool as per our findings from this study. With an optimal FACT in operation in hospitals, we aim as a research group to introduce trauma care interventions that we have developed, to directly impact positively on care provision.

While the primary focus on this project is to evaluate a healthcare advocacy tool to empower potential trauma team members to make changes to improve their own team and hospital system interactions, in forthcoming research we also intend to explore whether other educational interventions have the potential to positively effect "system change" and directly impact patient care. This is a novel application of in-situ simulation, the use of simulation-based education directly at the place of work where healthcare professionals provide care. This method of assessment may be cutting edge as traditional methods that are typically used to change systems include policy, regulatory, and political interventions. We must be cognisant that effecting system change may not occur as a result of this approach, however one can visualise that local health care systems will benefit from this operationalized approach and the summary recommendations that will result.

CONTRIBUTION STATEMENT

All authors have provided substantial contributions to the conception or design of the work, given approval for publishing and are accountable for all aspects of the work.

Professor MacKinnon & Dr Kennedy provided the initial concept. Dr Stenfors-Hayes added qualitative analysis concepts. Drs Shepherd, Doherty and Cole working with Professor MacKinnon, Dr Kennedy and Dr Stenfors-Hayes developed the design of the protocol together, adding elements relating to country specific healthcare systems and wider design points. All team members have communicated closely on this protocol, prior to this submission.

COMPETING INTERESTS

There are no competing interests.

FUNDING

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DATA SHARING

Authors are content with data sharing. There is no unpublished data from this protocol available.

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APPENDIX 1 DESIGN OF THE FACT

Based upon our understanding of the complex relationship between an ever-changing team of multi-professional healthcare individuals in the emergency bays of hospitals that receive traumatically injured children on an infrequent basis, we chose a framework approach to the FACT. In situ simulations are at the core of the data collection for FACT as there is significant evidence [1-4] that the clinical care provided to children can be enhanced by targeted simulation training with child-like human patient simulators. The simulators are, computerised and programmed to respond in real time to interventions or lack of and can be programmed to behave in terms of physiological responses (including vocal, pupillary responses, breathing, cardiovascular and neurological status) as a real human. Cutting edge simulation technology and techniques can provide the appropriate environment to encourage self-reflection, and to furthermore identify deficits in knowledge, skills and attitudes. Such simulation based education techniques provide the opportunities to develop performance and self-confidence, and to improve the patient care provided by an individual or a clinical team, directly where they work.[5] The process of participating in simulated trauma training as designed in FACT, is reflective and designed to promote learning with debriefing strategies highlighting good practice and areas for improvement in care. Mobile mannequin technology allows simulation-based critical pediatric trauma exercises to be conducted onsite this allows staff to “train together when they work, with whom they work and where they work”. The FACT approach also allows reflection on the complex healthcare processes involved in trauma care and the opportunity to invoke healthcare changes to improve care at all levels.

An assessment system requires triangulation of data sets to build up a picture of performance and interactions.[6,7] Moreover an effective assessment instrument should be transparent, justifiable, evidence based and recognise the restraints of the ‘real world’.[8,9] To achieve this, FACT is designed based on a number of different data sources, both qualitative and quantitative, as described elsewhere.[10]

Keeping a family centered lens

Parents or carers almost always accompany traumatically injured children in the emergency department. The parents or carers are also integral to the care provided. The parents can be directly next to or very close to the acute care provision, their perspective and thoughts as to the design and process of a tool to improve the complex trauma team – hospital interactions is invaluable. Patient, parent or carer input will be sought to provide a child and family centred lens on the FACT composition. This will be achieved by inviting parents to attend and participate in a forum at the base major trauma centre, facilitated by an external (to the trauma centre) member of the research team. The perspective of both parents and carers will be sought on current trauma team care training in addition to the FACT methodology. The forum will be set up as a focus group, with 4-8 family members and carers present for each group. Focus groups provide opportunity for a dynamic and interactive exchange and reflection. By hosting regular forums the family centered perspective will remain central in the FACT development and use.

How the FACT combines with simulation

High reality human patient simulators of traumatically injured children are brought into the emergency bay at the pilot hospital by researchers acting as paramedics. Prior to this, the hospital is notified using the same standard Major Trauma Alert procedure for all traumatically injured children, as used by the paramedic ambulance service. A hospital wide trauma alert code is activated, team members arrive and work together on the severely injured simulated child in the emergency bay. Each team member then completes a questionnaire (as described in Table 2). All team members record their role in the team, for example Trauma Team Leader or trauma nurse, but not their names to ensure anonymity. A team-debrief then follows, conducted by an experienced facilitator from the research team. The process takes approximately 45 minutes in total, for each of the two scenarios. The time line for collection of the FACT data is shown in Table 2. Details on the principles behind the development of the FACT can be found elsewhere [10]. The components of the FACT are depicted below (Table 3).

Distribution of the FACT within hospitals

The FACT for each hospital will be constructed based on the findings of the FACT data collection. There will be an electronic copy and a hard copy of the FACT made available. The hard copy consists of a four-page document. The FACT will be distributed horizontally across all the potential members of the trauma team in each hospital. The distribution will be achieved via the clinical leads within the teams. Vertical transmission of the FACT will be achieved through direct contact of each member of the hospital trauma governance infrastructure by the research team.

Table 2. FACT data collection timeline for each participating hospital

Time points	FACT Elements
1. First visit by research team	The trauma care facility, equipment and standard operating procedures are reviewed using the World Health Organization (WHO) trauma essentials checklist.[11] **Hospital Site Visit** section in FACT
2. Trauma team members participate in two In-situ simulations of traumatically injured children in their hospital trauma bay (second visit of research team).	The team performance in providing advanced trauma care is assessed against latest trauma care guidelines (including the Advanced Trauma Life Support program objectives).[12] **Adherence to Best Practice** section in FACT The process of care is measured against key timing points recorded in the Trauma Audit Research Network database network. **Key Timings in Clinical Management section** in FACT
3. Trauma team members complete the on-line Knowledge Test & on-line Mental Model Survey	A random sample of the potential medical & nursing trauma team members undertake a twenty question multi-choice, standard questionnaire on the management of traumatically injured children. **Knowledge Test** section in FACT All potential members of the trauma team (nursing, medical and allied health professionals) are invited to participate in an online survey of practice. They are shown a video of a standard case with differing vital signs and questioned on their clinical priorities and the factors delaying the passage of such traumatically injured child from the emergency bay, to CT scanner to operating theatre. **On-line Mental Model Survey** sections in FACT

4. Trauma team members anonymously complete a modified OTAS questionnaire	Team Performance in Communication, Co-operation, Co-ordination, Leadership, Monitoring & Global Assessment Factors requiring improvement to enhance Team-Hospital interactions. Team participants are invited to complete a standard Observational Teamwork Assessment for Surgery (OTAS),[13] checklist of the team performance. In addition the members are asked to complete a free text box, by answering the following standard question, “How could we improve the care provision of the traumatically injured child that you have just managed, in terms of the trauma team and hospital systems interactions?” **Trauma Team Performance Self-Reflection** and **Simulation Feedback Free Text Analysis** sections in FACT.
5. Trauma team members participate in a standard team debrief	Critical (sudden untoward) Incidents Participants allowed to add to their previous comments Any free text answers to the above standard question (“How do you feel the trauma team – hospital interaction could be optimized to improve the care of the traumatically injured child you have just managed?”) that would trigger a critical incident/sudden untoward incident report in real-life are captured. These comments are graded against a standard Hospital Risk Management Matrix (from the research pilot site) **Hospital Incident Report Scoring** section in

	FACT

Table 3. The FACT components

FIELD ASSESSMENT CONDITIONING TOOL (FACT)

Assessment of the Hospital Readiness to Receive Traumatically Injured Children

POSITIVE ELEMENTS

These elements aim to highlight the high quality care already being provided by each hospital.

1. ADHERENCE TO BEST PRACTICE

2. KEY TIMINGS IN CLINICAL MANAGEMENT

3. TRAUMA TEAM PERFORMANCE SELF-REFLECTION

4. ON-LINE MENTAL MODEL SURVEY

5. KNOWLEDGE TEST

6. HOSPITAL VISIT

DELTA ELEMENTS

These elements aim to highlight area for improvement of care provision at each hospital, based upon the thoughts and reflections of the team members within each hospital.

7. SIMULATION FEEDBACK FREE TEXT ANALYSIS

8. HOSPITAL INCIDENT REPORT SCORING

DISSEMINATION

HORIZONTALLY – TO ALL POSSIBLE TEAM MEMBERS

VERTICALLY - TO HOSPITAL GOVERNANCE BOARD

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APPENDIX 2 INTERVIEW GUIDE

Quality Improvement work (in paediatric trauma care)

What is your personal role in the improvement work in the trauma setting?

Whose role is it to assess & invoke improvements at present?

Can you describe a situation where you 'were an advocate' for an improvement process in the trauma setting?

What improvement processes have you worked with before?

Where is the expert judgment in the process?

The FACT process

How would you describe the aim of the FACT process in your own words?

What are your thoughts or concerns on participating in the different steps of creating the FACT?

Who did you receive the FACT results from?

The FACT results

What were your thoughts when you looked at the FACT results?

Did you feel the FACT results paint a fair picture of your team –hospital interaction?

What in particular does the FACT results provide **you** with?

Was there something in the FACT results that surprised you?

Was there anything in the FACT results that you think should be discussed or acted upon?

Do you feel there is anything else that should be looked at in the context of the hospital team interaction that is not on the FACT at present?

Do you feel the FACT adds anything to your understanding of trauma management in your hospital?

The follow up

Did you discuss the FACT results with anyone?

Where any initiatives taken by anyone for any follow up or actions based on the outcome of the FACT?

What is your role in acting upon these results?

Who should act upon these results?

How do you see yourself using FACT to invoke changes?

So the aim of FACT is to enhance the horizontal and vertical transmission of the performance of trauma team-hospital interactions in the management of traumatically injured children in the respective hospital, and to thereby enhancing the opportunity to reflect and learn on the rare but high stakes complex clinical events associated with managing such children. What are your reflections on that?

The FACT tool is furthermore designed to provide the opportunity to effect positive changes in staff knowledge, skills, behavior, attitudes, team-hospital infrastructure and systems and patient care. What are your reflections on that?

Further development and use

Is there anything else that you feel should be present in the FACT that is not currently there?

Do you feel the FACT has any usage outside of the trauma setting?