

Scottish Trauma Audit Group Patient Reported Outcome Measures Protocol

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1. DOCUMENT CONTROL

1.1 Key Personnel

Title:	Scottish Trauma Audit Group – Patient Reported Outcome Measures Protocol
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Owner:	Stuart Baird

1.2 Version History

Version	Date	Summary of changes	Changes/ comments by
V0.1		Document created	Angela Khan
V0.2	04/05/16	Tracked changes/ comments from Jan Jansen	Jan Jansen
V0.3	25/10/16	Updated/ tracked changes accepted and revised version created with some of the comments addressed and some outstanding.	Hazel Dodds
V0.4	12/07/17	Document revised and updated. No tracked changes.	Hazel Dodds
V0.4	28/07/17	Document reviewed/ changes/ comments added (tracked)	Angela Khan/ Alasdair Corfield/ Emma McNair
V0.5	02/08/17	Document revised and updated. No tracked changes (comments to be resolved remain)	Hazel Dodds
V0.6	01/12/17	Document revised and updated. No tracked changes.	Hazel Dodds
V0.7	01/03/18	Document revised with minor changes. No tracked changes.	Hazel Dodds
V1.0	06/06/18	Finalised following PBPP approval and saved as PDF for uploading to STAG website.	Hazel Dodds
V1.1	04/09/18	Minor updates before adding to STAG website	Hazel Dodds
V1.2	07/02/19	Minor update requested by STAG Steering Group	Hazel Dodds
V1.3	02/06/2020	Updated to reflect move from NHS NSS to PHS	Hazel Dodds

1.3 Distribution

Name/Division/Organisation	Date of Issue	Version

1.4 References

Document title	Document file path
STAG PROMS Protocol	STAG PROMS Protocol Final V1.3.doc

2. Introduction & Background

Injuries due to trauma remain a major cause of morbidity and mortality in the UK and throughout the world¹. It is the leading cause of death in the 15-44 age group² worldwide and a major cause of disability and loss of economic ability³.

Within the spectrum of injury, major trauma describes serious and/ or multiple injuries where there is a high likelihood of death or permanent disability. The internationally accepted definition of major trauma is based on the Injury Severity Score⁴ (ISS) where an ISS>15 defines major trauma. Within Scotland, there are approximately 800 patients with an ISS>15 each year with a further 2300 (ISS 1-15) requiring hospitalisation for more than 72 hours, for critical care or who die from their injury⁵.

The optimal method for providing care for patients with major trauma is the subject of ongoing debate. Recent evidence from the review of trauma care and implementation of a Major Trauma Network in NHS England suggests that in a UK context there may be significant benefits from the implementation of a Major Trauma Network⁶.

Within Scotland, the National Planning Forum (NPF) recommended a reconfiguration of trauma systems to provide a Scottish Trauma Network (STN) and planning for this new system is well under way with implementation commencing in October 2018.

The STAG already report on case-mix adjusted mortality using the Trauma Audit & Research Network (TARN) Ps12⁷ methodology (recalibrated using Scottish data from 2011-2018). The STAG have been asked to assist in the evaluation of the potential effects of the introduction of a new trauma network by collecting and reporting functional outcome and quality of life data using PROMs methodology⁸.

2.1 Aims

- To improve understanding of functional and quality of life outcomes for patients with major and moderate trauma;
- To assess the impact on mortality and functional outcome/ quality of life following the change of provision of trauma care in Scotland to a major trauma system; and
- To use these data as part of an ongoing quality improvement process; which will include reviewing individual cases and hospital/ regional network level trends to help guide where improvements to processes may be required.

3. Methodology

3.1 Current methodology used by STAG

The STAG are part of Public Health Scotland. As part of a national ongoing audit, all adult/paediatric trauma patients admitted to contributing hospitals (N=30) in Scotland are eligible for inclusion in the data collection, subject to meeting the [STAG Inclusion/ Exclusion criteria](#):

- Length of hospital stay >72 hours or
- Requiring critical care or
- Death within hospital.

During their admission, patients are tracked by dedicated staff (STAG Local Audit Coordinators (LAC)) collecting detailed information about the patients' injuries, treatment and hospital stay.

Patients' injuries are objectively assessed using the Abbreviated Injury Score (AIS) 2005 descriptors⁹ and ISS are calculated for all patients. Initial neurological observations, age and gender are recorded and used along with the ISS to calculate the probability of survival using the Ps¹² method⁷.

Patient demographics, predicted and actual survival and compliance with Key Performance Indicators (KPIs) are some of the information reported back to local clinicians as part of a monthly report. Data can also be accessed routinely via the electronic data collection system (eSTAG) and reports within the data visualisation tool (Tableau) to allow timely monitoring of performance, exception reporting and implementation of change processes to drive improvement in care delivery.

3.2 New methodology to enable the collection of PROMs data

At this stage, STAG are carrying out a three-stage survey of patients (aged 16 and over), with initial contact being made whilst the person is still in hospital. This allows for initial face to face contact and an explanation of STAG data collection and the PROMs questionnaires and process by a STAG LAC or appropriately trained member of the trauma team, e.g. trauma or rehabilitation coordinators.

STAG has commissioned the administration process for survey fieldwork to an external survey provider (Quality Health Ltd.), who are experienced in working with TARN in NHS England. They are one of the approved survey providers for NHS Scotland and are used routinely by PHS Consultancy Services, for other large national surveys. A procurement process was completed and Quality Health Ltd. were appointed to this role at the end of December 2017. Initial meetings to confirm the process and required resources were held in January and continue on a regular basis. Appropriate data processing agreements etc. have been agreed with Quality Health Ltd. prior to the launch of the PROMs survey.

Phase 1: Point of care survey of trauma patients in hospital:

Printed Questionnaire 1 (Q1) to be given to patients, before discharge home, transfer to a non-STAG hospital or around 30 days following admission when discharge is not yet planned, by a STAG LAC or other appropriately trained member of the trauma team, e.g. trauma/ rehabilitation coordinator, with a verbal and written explanation of the process given at this time. The patient will also be provided with a covering letter and Privacy Notice at this time as well as a copy of the STAG Patient Information Leaflet (<https://www.stag.scot.nhs.uk/Patient-Information/main.html>).

- a. The STAG LAC will add the unique STAG identification number allocated to the person to the front of Q1 so that the questionnaire remains pseudonymised but the outcome data can

be linked with existing STAG data to review the patient pathway and related outcomes, allowing clinical teams to identify areas for improvement.

- b. Completed paper questionnaires will be collected from participants by health professionals in hospital and securely stored in the Emergency Department or other agreed secure area for up to 5 weeks prior to collection and transportation to Quality Health Ltd. by a specified courier.
- c. Completion of Q1 will provide consent to allow the person to be contacted about participation in Phases 2 & 3 of the PROMs survey.
- d. Questionnaire 1 will also provide the person with the opportunity to document their mobile telephone number. This will be completed only if the patient wishes to receive an alert for the completion of Q2 & 3 online by SMS text messaging.
- e. The STAG LAC will enter information relating to PROMs in eSTAG, i.e. patient/ carer approached about PROMs programme (Yes/No), agreement to participate in PROMs programme (e.g. patient, parent, carer or next of kin), date of agreement, person involved in permission (e.g. STAG LAC)

Phase 2: Issuing, completion and returning of Phase 2 questionnaires:

- a. Questionnaire 2 (Q2) will be distributed to participants at 6 months from the date of injury.
- b. The STAG information analyst will check and confirm appropriate participants from the eSTAG database on a monthly basis. A list of participants (who agreed to participate in PROMs) will be sent to PHS Consultancy Services who will carry out status and address checks prior to forwarding information to Quality Health Ltd. for circulation of Q2.
- c. Quality Health Ltd. will send Q2 to identified participants by post or an alert via SMS text messaging after receiving confirmed mailing list from PHS Consultancy Services (this will be participants who have been checked, as above, and for whom completed Q1 were received by them; PHS Consultancy Services will also carry out timely death checks to confirm that participants have not died since they were last surveyed). The unique STAG identification number will be assigned by PHS Consultancy Services to the mailing list files. Quality Health Ltd. will add bar coding for tracking purposes to Q2.
- d. Recipients will be given the option of completing Q2 on paper and returning to Quality Health Ltd. in a pre-paid addressed envelope or will be given the option to complete the questionnaire online by accessing an electronic survey.
- e. Up to two reminders will be issued to try to improve the receipt of completed questionnaires. PHS Consultancy Services will also carry out death checks for each reminder mail-out.

Phase 3: Issuing, completion and returning of Phase 3 questionnaires:

- a. Questionnaire 3 (Q3) will be distributed to participants at 12 months from the date of injury.
- b. The STAG information analyst will check and confirm appropriate participants from the eSTAG database on a monthly basis. A list of participants (who agreed to participate in PROMs) will be sent to PHS Consultancy Services who will carry out status and address checks prior to forwarding information to Quality Health Ltd. for circulation of Q3.

- c. Quality Health Ltd. will send Q3 to identified participants (who have been checked, as above, and for whom completed Q1 were received. Q3 should still be sent (even if Q2 was not returned) by post or via SMS text messaging after receiving confirmed list from PHS Consultancy Services. Quality Health Ltd. will add bar coding to Q3 for tracking purposes to link with Q1 and 2.
- d. Recipients will be given the option of completing Q3 on paper and returning to Quality Health Ltd. in a pre-paid addressed envelope or will be given the option to complete the questionnaire online by accessing an electronic survey.
- e. Up to two reminders will be issued to try to improve the receipt of completed questionnaires. PHS Consultancy Services will also carry out death checks for each reminder mail-out.

It is proposed that participants will be recruited continuously June 2018 to May 2021 with the survey being completed in December 2022. The aim is to recruit around 800 participants per year.

Questionnaires used to survey English trauma patients have been adapted for the STAG PROMs survey. All questionnaires will contain the EQ-5D-5L¹⁰ and Glasgow Outcome Scale¹¹ standard measures.

3.3 Roles and responsibilities

3.3.1 STAG Central team

In summary, the STAG central team will be responsible for:

- Developing and securing the necessary approvals for the overall survey;
- Confirming list of participants to be checked on a monthly basis and forwarding to PHS Consultancy Services;
- Monitoring of reports received from PHS Consultancy Services and distributing at agreed timescales to relevant hospitals/ Regional Networks included in the STAG audit; and
- Providing reports/ updates at quarterly STAG and STN Steering Group meetings and others as required.

3.3.2 STAG Local Audit Coordinator

In summary, the STAG LAC will be responsible for:

- Receiving batches of blank questionnaires from Quality Health Ltd.;
- Adding unique STAG identification number to Q1 before distributing to the appropriate participants;
- Identification of appropriate participants (following agreed guidelines, i.e. adult patients, aged 16 or over identified as major trauma);
- Distribution of phase 1 survey pack as described above to the identified participants and providing explanation of STAG data collection and the PROMs process, including provision of the STAG Patient Information leaflet (<https://www.stag.scot.nhs.uk/Patient-Information/main.html>) and relevant information about the PROMs survey;

- Providing support for completion of Q1 when needed;
- Adding to eSTAG information relating to PROMs, i.e. patient/ carer approached about PROMs programme (Yes/No), agreement to participate in PROMs programme (e.g. patient, parent, carer or next of kin), date of agreement, person involved in permission (e.g. STAG LAC)
- Collection of completed questionnaires ensuring consent section has been completed, mobile telephone number recorded (as appropriate), secure storage (in envelopes provided by Quality Health Ltd.) and liaison with them for collection and secure onward transportation.

Note: the above responsibilities of the STAG LAC will be joint responsibilities with appropriately trained member(s) of the trauma team.

3.3.3 PHS Consultancy Services

In summary, PHS Consultancy Services will be responsible for:

- Supporting the process of development and securing the necessary approvals for the overall survey;
- Co-ordination of name and address checks for Phases 2 & 3 including any reminders required;
- Co-ordination of status checks for Phases 2 & 3 including any reminders required (to reduce the risk of sending survey packs to deceased participants);
- Analysis and reporting of the data provided by Quality Health Ltd.;
- The analysed dataset will be shared with the STAG team by PHS Consultancy Services; and
- Provision of analysed amalgamated data in an agreed reporting format to the STAG central team.

3.3.4 Quality Health Ltd.

In summary, Quality Health Ltd. will be responsible for:

- Formatting and finalising the agreed questionnaires;
- Administration of fieldwork (printing questionnaires, information sheets, patient letters; preparing an online survey; distribution of blank questionnaires and associated information to hospitals for Phase 1; issuing of Phase 2 & 3 questionnaires, reminders and associated information to identified and checked participants; receipt and scanning of responses); and
- Provision of clean datasets to PHS Consultancy Services (collation of responses including quality assurance and cleaning of data).

If participants cannot answer questions directly (due to the nature of their injuries, or pre-existing pathology), a carer/ family member or representative will be asked if they wish to participate. They will provide proxy information or support the patient in completion of the questionnaire. This will be captured within the questionnaire.

Quality Health Ltd. will also provide a free telephone helpline where participants can ask for advice, complete the form by phone or request translation services if needed.

4. Approvals process

4.1 Public Benefit and Privacy Panel (PBPP)

An application was submitted to the PBPP for approval of the STAG PROMs survey. This process can take 2-6 months from the point at which an application has been submitted.

Further information about the PBPP can be found at <http://www.informationgovernance.scot.nhs.uk/pbpphsc/>

Final approval was received from the PBPP panel on 31st May 2018.

4.2 Research Ethics (REC)

Audits and service evaluations do not usually require REC approval, but it may be required if a PROMs survey attached to an audit is considered to be research.

It has been confirmed that research ethics approval is not required for the STAG PROMs survey.

4.3 NHS Research & Development (R&D) approval

Audits and service evaluations do not usually require NHS R&D approval, it may be required if a PROMs survey attached to an audit is considered to be research. See above.

5. Resources required

A **business case** was successfully submitted to the STN for the cost of the work to be completed by Quality Health Ltd. and PHS Consultancy Services. Funding has been agreed for the initial set up and year one costs with 4 years recurring funding outlined and agreed in principle but for review annually.

All other work will be funded via the core STAG budget.

6. List of abbreviations

AIS	Abbreviated Injury Score
ED	Emergency Department
eSTAG	electronic Scottish Trauma Audit Group
ISS	Injury Severity Score
KPI	Key Performance Indicator
LAC	Local Audit Coordinator
NPF	National Planning Forum
PBPP	Public Benefit and Privacy Panel
PHS	Public Health Scotland
ISD	Information Services Division
PROMS	Patient Reported Outcome Measures
Ps12	Probability of Survival (2012)
Q1, 2, 3	Questionnaires 1, 2 and 3
REC	Research Ethics Committee
STAG	Scottish Trauma Audit Group
STN	Scottish Trauma Network
TARN	Trauma Audit and Research Network

7. References

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