Improving the Scaphoid Pathway with Extremity CT in the ED: The InSPECTED study.

Study Protocol

Version 1.2

24th February 2020

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Contents

Abbreviations and acronyms

CBCT	Cone Beam Computed Tomography
CRF	Case Report Form
ED	Emergency Department
ENP	Emergency Nurse Practitioner
GP	General Practitioner
InSPECTED	Improving the Scaphoid Pathway using Extremity CT in the ED
MRI	Magnetic Resonance Imaging
NICE	National Institute for Health and Care Excellence
NM	Nuclear Medicine
PIS	Participant Information Sheet
PROM	Patient Related Outcome Measure
US	Ultrasound
UTC	Urgent Treatment Centre

1. Contact details

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2. Synopsis

Study Title	Improving the Scaphoid Pathway with Extremity CT in the ED
Short title	InSPECTED
Protocol version and date	1.2 24 February 2020
Study design	Single-centre observational study
Study participants	Participants of 18 years and older who have sustained an injury to the wrist and are suspected of having a scaphoid fracture
Planned study sample	A prospective convenience sample of patients attending the emergency departments (ED) or urgent treatment centre (UTC) across a multi-site NHS Trust in who a scaphoid fracture is suspected. This cohort will be compared to a retrospective sample utilising the same criteria and timeframe during the preceding year. The target number of recruits is 130 per cohort.
Planned study period	20/02/2020-27/02/2020 (retrospective data collection and set-up) 24/02/2020- 31/03/2020 (recruitment) 24/02/2020- 28/08/2020 (including FU)
Primary objective	To evaluate the feasibility of using extremity Cone beam CT (CBCT) to improve the scaphoid pathway
Secondary objectives	1. To quantify issues around delivery of service 2. Evaluate the screening tool 3. To quantify and draw inferences in health-related Quality of Life in the study sample 4. To measure outcomes in a single-centre cohort of patients 5. To investigate, using appropriate statistical and economic analysis methods, the healthcare resource use of the CBCT pathway 6. To confirm robust recruitment rates and feasibility of a multicentre trial. 7. To establish the radiation dose associated with CBCT scaphoid
Underlying hypothesis	That early access to cross-sectional imaging through the utilisation of CBCT could streamline the imaging and management pathway for patients with suspected scaphoid fractures. This may impact patient reported outcome measures, the costs associated with repeated imaging examinations, and other hospital appointments i.e. fracture clinic appointments.

3. Summary

The scaphoid is one of the bones in the wrist, which may be broken during a fall and is particularly common in young adults. Due to the small size of the bone, many fractures are not visible on initial x-rays and patients face a delay of over a month before the fracture is identified. This extended period prior to definitive diagnosis also means that patients may require multiple hospital visits and are immobilised unnecessarily resulting in restrictions to their socioeconomic activities.

There is potential to use other imaging investigations to facilitate earlier diagnosis, including magnetic resonance imaging (MRI) and computed tomography (CT), however these are expensive and capacity issues inhibit their utilisation. The National Institute for Health and Care Excellence (NICE) issued guidance in 2015, advising that organisations consider MRI as the first line imaging tool. Unfortunately, this has been poorly adopted due to capacity constraints in imaging departments. Although MRI remains the most common complex imaging modality there are inherent delays across the country and some centres use computed tomography (CT) which is quicker and easier to access. New extremity CT technology has now been launched which has the potential to reduce costs and enable earlier access to complex imaging with a lower radiation dose.

We will undertake a prospective single-centre observational study exploring the feasibility of utilising extremity cone beam computed tomography (CBCT) early in the pathway for suspected scaphoid fracture. Comparison with a retrospective cohort of patients will evidence whether the pathway changes have resulted in earlier diagnosis, reduced patient hospital visits and healthcare resource utilisation. The outcomes will also help us design a multicentre research study to compare the economic and clinical outcomes of a number of different pathways in the diagnosis of suspected scaphoid fractures.

4. Background

The scaphoid is the most commonly fractured carpal bone, the group of bones, which together with the radius and ulna form the wrist. Accounting for 60-79% of carpal fractures, [1,2] these occur most frequently in young men as a result of a fall on outstretched hand.[3] Scaphoid fractures are seen in approximately 12.4 patients per 100,000 population in UK, although this reaches 18.57 per 100,000 in those with the lowest socio-economic status.[3]

Because of the poor predictive value of x-rays, patients suspected of a scaphoid fracture are managed proactively with immobilisation and repeated hospital visits.[4] This overtreatment is to avoid long term morbidity as a result of non-union,[5] osteoarthritis and avascular necrosis. Importantly, this is not only exacerbated by fracture location and displacement but also delays in diagnosis (beyond 4 weeks).[6] This traditional pathway, where the patient is considered to have a fracture until proven otherwise, represent a significant utilisation of NHS resources particularly in relation to the overstretched emergency departments.[7-10] Despite the strategy for overtreatment, the frequent missed or delayed diagnosis represent an ongoing area for litigation against the NHS.[11]

Clinical examination of the scaphoid has a poor specificity for fracture[12] and diagnosis relies on imaging, commonly with initial and repeat x-rays. The benefits of other imaging modalities has been widely researched and has confirmed high sensitivity and specificity values for both magnetic resonance imaging (MRI) and computed tomography (CT).[13-17] In 2016 NICE published guidance on the imaging of suspected scaphoid fractures[4], which concluded that organisations should consider MRI as the first-line imaging investigation. It has the advantage of not using ionising radiation, and also provides excellent visualisation of other bony or soft tissue injuries. On the other hand, CT is a more rapid examination with fine bony detail. New equipment for extremity imaging, cone beam CT (CBCT), is designed specifically for examination of the limbs and appears to represent a disruptive technology with low radiation dose, reduced cost and easier access.[18-20] Ultrasound has been suggested as an alternative imaging technique[21,22] but is operator dependent.

Despite the acknowledged benefits of using advanced imaging, UK and international surveys[23-25] confirm that serial x-rays continued to be the standard diagnostic protocol for imaging. Other modalities are often only available late in the diagnostic pathway, acknowledged within the 2013 Royal College of Emergency Medicine guidance.[26]
Access to complex imaging is consistently identified as the key constraining factor within the scaphoid (fracture confirmation or exclusion) pathway. This was even acknowledged as a challenge to the implementation of the NICE guidance on the basis of limited NHS capacity.[4] As a result strategies for the management of this patient group vary, with many requiring patients to attend multiple follow up clinics, with subsequent pressures on resources, particularly for EDs.[25,27] Centres are now exploring different strategies to manage patients, including the use of virtual clinics,[28] although these have not been universally adopted and still require imaging departments to be innovative to improve the overall patient pathway.

The Mid Yorkshire Hospitals NHS Trust has recently revised the scaphoid fracture pathway to incorporate extremity CBCT for early diagnosis. The CBCT scanner evaluation is supported by Carestream Health and represents the first NHS installation of such technology.
There remain unanswered questions related to the use of the technology within the pathway; specifically what is the impact to the patient and the organisation of performing a CBCT scan earlier? This includes the potential to reduce the need for ED follow up through the use of virtual clinics and the elimination of MRI scans in patients who have a negative CBCT scan. We therefore propose to undertake a prospective single-centre observational study looking at the feasibility of utilising CBCT for the assessment of patients with suspected scaphoid fracture.

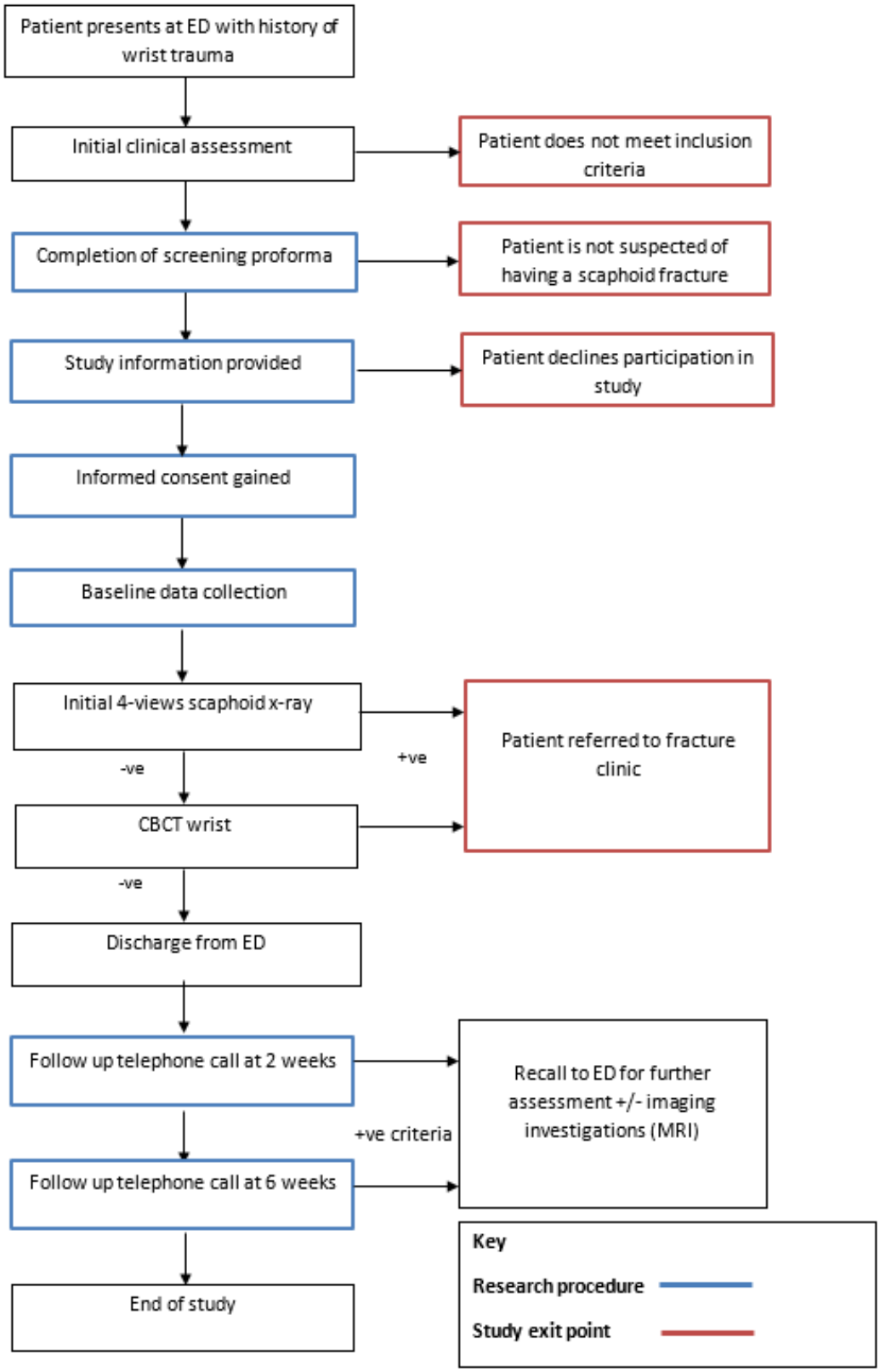
5. Study design

5.1. Study description

The proposed project is a single-centre observational study evaluating the implementation of a clinical pathway incorporating CBCT on the same, or next, day following presentation at any of the emergency departments across the Mid Yorkshire NHS Hospitals Trust. Implemented in September 2019, this is now the standard of care within the study organisation. To estimate the impact of the CBCT enabled pathway a comparison will be made between a prospective cohort of patients presenting with a suspected scaphoid fracture and a retrospective review of the data from the same time period in the preceding year. There has been limited research internationally examining the effectiveness of such a technology on patient diagnostic outcomes and health resource utilisation.[14] Therefore, this research serves as a feasibility study for a multicentre evaluation to compare different clinical pathways for the investigation and management of patients suspected of scaphoid fracture.

In line with local protocol, all participants with a suspected scaphoid fracture will have a four-view x-ray series performed as per standard care. Those patients with a confirmed fracture will be referred for ongoing management and data collection will cease (Figure 1). Patients who have a normal x-ray will have CBCT as per local pathway. Where the scan confirms a fracture the patient will have on-going management with the orthopaedic and trauma service and data collection will cease. Patients with a negative CBCT will be discharged with a removable wrist splint and appropriate advice. They will be followed up at 2 weeks and 6 weeks with telephone interviews, similar to current virtual clinics. Where patients do not respond to the telephone call, 2 further attempts will be made to contact and then a final letter advising how to seek advice if symptoms persist. At these data collection time points, patients who meet specific criteria regarding ongoing symptoms (increased PROMs score or analgesia use) will be reviewed in a (physical) specialist musculoskeletal ED clinic with appropriate further imaging investigations or alternatively may be referred for physiotherapy if the symptoms persist.

Figure 1. Study flowchart



5.2. Objectives

The primary objective of the InSPECTED study is to evaluate the feasibility of using extremity CBCT to improve the scaphoid pathway.
The secondary objectives of the InSPECTED study are:

1. To quantify issues around delivery of service
2. Evaluate the clinical screening tool for scaphoid fractures
3. To quantify and draw inferences in health-related Quality of Life in the study sample
4. To measure outcomes in a single-centre cohort of patients
5. To investigate, using appropriate statistical and economic analysis methods, the healthcare resource use of the CBCT pathway
6. To confirm robust recruitment rates and feasibility of a multicentre trial.
7. Evaluate a trial case report form (CRF) for this patient group

5.3. Outcomes measures

The primary outcome measure for this study is the number of hospital attendances related to the suspected scaphoid fracture*.

The secondary outcome measures in this study are:

- Number of patients presenting at ED with suspected scaphoid fracture*
- Number of patients diagnosed with scaphoid fracture on imaging (prevalence)*
- Number and type of imaging investigations (x-rays, CBCT, CT and MRI scans)*
- Pathway timings*
- Unplanned returns to the ED*
- Planned recalls to the ED*
- ED discharge and referral rates*
- CBCT failure rates/delays (patient, technical, staff)
- Patient demographics*
- Injury demographics including time of presentation, clinical symptoms, injury mechanism and fracture type (if appropriate)*
- Patient reported outcome measures (from CRF)
    - Patient-Rated Wrist Evaluation (PRWE)
    - Health Economics/Quality of Life outcomes (EQ-5D-5L)
- Healthcare resource use
- Radiation dose associated with scaphoid fracture diagnosis / exclusion*
- Recruitment rate (assumed consent)
- Patient baseline CRF (EQ5D-5L and PRWE) completion rates

The data marked with * will also be collected for the retrospective cohort.

Table 1. Data collection time points for the prospective cohort

Time point	Data collection	See
Baseline^	Patient attendance data, clinical screening tool, pathway timings, imaging examinations of the wrist, CBCT failure rates/delays, CRFs, discharge data	Appendix 1 & 2
2 weeks	CRF, record of planned and unplanned returns to the ED or other health care provider, other imaging interventions and healthcare resource use data	Appendix 3
6 weeks	CRF, record of planned and unplanned returns to the ED or other health care provider, other imaging interventions and healthcare resource use data	Appendix 4

^ If not collected at ED attendance will be completed at earliest opportunity, including the patient-completed CRF by telephone if necessary.

Primary endpoint: Confirmation of scaphoid fracture on imaging examination.

Secondary endpoint: Definitive exclusion of scaphoid fracture on imaging examinations and clinical review.

5.4. Study site

The Mid Yorkshire Hospitals NHS Trust is a multi-site organisation based in West Yorkshire with a catchment population of 530,000. Acute services are provided from three locations, Dewsbury and District Hospital (DDH), Wakefield Pinderfields Hospital (WPH) and Pontefract Hospital (PGI). Following service reconfiguration, consultant-led emergency services are provided from WPH and DDH with the PGI site being supported with an urgent treatment centre (UTC). For ease, the term ED has been used throughout this protocol but refers to the appropriate service specification (ED or UTC).

Service pathways are consistent across all sites in both the ED and radiology. Emergency nurse practitioners (ENPs) who work closely with the wider multidisciplinary team provide the majority of the minor injury assessment and treatment. The ENPs work across all hospital sites and will be key to the successful delivery of this project.

The Trust has a single CBCT scanner in place on the WPH site, as is usual practice patient's travel to this site if they require a scan as part of their clinical care. The scan is arranged for the same or next day to fit with patient choice and clinical capacity.

5.5. Study sample

The InSPECTED study will evaluate a prospective convenience sample of patients attending the EDs in whom a scaphoid fracture is suspected. This cohort will be compared to a retrospective sample utilising the same criteria and timeframe during the preceding year.

The target number of recruits is 130 for each cohort, this is based on average attendances for this patient group at the study site of 100 per month and expected attrition rate of 35% as reported in other similar studies.[28]

5.5.1. Eligibility

Patients will be eligible for inclusion in the prospective study if:

- They present at any of the EDs across the Trust with a mechanism of injury consistent with scaphoid trauma and a positive clinical examination.
- They are over the age of 18 and able to provide informed consent

Participants will be excluded from the prospective study if:

- They do not present via the ED
- They have an additional injury, which may affect the primary outcome measure
- There is any evidence that the patient would be unable to adhere to study or procedures or complete questionnaires, for example has cognitive impairment.

5.5.2. Recruitment and consent

Information regarding the prospective study will be prominently displayed around the ED (Appendix 5). When the patient presents at the ED with a suspected scaphoid fracture, an ED clinician (Dr or ENP) will initially identify them as potentially eligible for inclusion in the InSPECTED study. Then, in line with standard practice at the host site, an initial clinical assessment of the affected limb will be made and a screening tool (Appendix 6) completed by the ED clinician. Although the research team has designed this screening tool, which incorporates elements of clinical history and examination of the wrist and scaphoid, it is in standard use locally. Following confirmation of the need for scaphoid x-rays, and hence study eligibility, potential participants will be approached by the ED clinician or alternatively, a member of the research team, who will explain why they are approaching the patient for inclusion in the prospective study. At this point, the potential participant will be provided with a full study information pack, which includes a participant information sheet (Appendix 7) and a consent form (Appendix 8). The participant information sheet (PIS) clearly explains what the research is looking at, what the research would involve and the risks and benefits of taking part. Following a full explanation of the research and the implications of participation, the patient will be offered time to read the information again, discuss any points further for clarification and ask any questions.

If patients choose to participate in the study, they will be recruited and formally consented in a private room for their agreement to share routinely collected hospital data about their ED attendance and to be followed up by telephone by the research team at 2 and 6 weeks after the injury. GCP trained members of ED or research staff will receive this written informed consent prior to the recording of any attendance data, scaphoid x-rays or completion of the baseline questionnaire by the participant (or through a proxy in the event that they are unable to complete it themselves). Only those participants who have positive

clinical signs of scaphoid fracture on examination but a normal four-view x-ray will have CBCT for further assessment.

Of note, there may be a small number of participants in who eligibility for inclusion in the study is not identified prior to 4-veiw scaphoid x-ray or the clinical assessment was undertaken by a clinician who was not able to seek consent. In this case, radiology staff who have received study specific training will initially approach the patients and provide both a short explanation of the study and an information pack. An appropriate ED clinician upon return to the ED will provide more detailed study information, answer questions and receive written consent from the participant where they wish to proceed as a participant of the study.

Following written informed consent, the patient will be allocated a unique study ID number, which will be used on all non-public facing study documentation. Sufficient non-identifiable details will be logged by the research team using the EDGE research management system (University of Southampton, UK). This includes the patient's initials, date of birth, and eligibility checks. The retrospective cohort will be an anonymised dataset extracted from the hospital computer systems (Appendix 8). This information is routinely collected as part of ED and imaging department attendances. Primary search criteria to interrogate these systems will be suspected scaphoid fracture, i.e. scaphoid x-ray. The additional data being collected as part of the prospective study (such as the follow up telephone calls) will not be sought from this cohort. As a result, we will not be seeking individual patient consent to access this data.

5.5.3. Withdrawals/ exclusions and declining to participate

Participants may decline to participate at baseline or withdraw from the prospective study at any time without providing an explanation and without any detriment to their care. A decision to decline to consent or to withdraw will not affect the standard of care that the patient receives, as all patients will follow the diagnosis and management pathway appropriate to their clinical and radiological findings regardless of inclusion. Where patients decline to participate, no routinely collected information will be sought from NHS hospital systems about the initial ED attendance and they will not be contacted by the research team post discharge for purposes other than clinical follow up (virtual fracture clinic). Upon withdrawal of the patient, any data collected up to that point will be retained by the research team and included in analysis.

With the permission of the patient, reasons for declining to participate in the prospective study will be recorded to inform the design of a future multicentre study.

5.6. Imaging technologies being utilised

All patients attending any of the three Trust sites will follow the same clinical care pathway. In line with the current diagnostic procedures, all patients will have an x-ray, some will have

a CBCT scan of the wrist (including scaphoid) and a small number may potentially have an MRI scan of the wrist performed. Further details of the technologies are provided below.

5.6.1. X-ray

The traditional approach to diagnosis of scaphoid fracture following an acute wrist injury has been to perform four radiographic views of the scaphoid. However, fractures are difficult to diagnose early and they can take up to six weeks to manifest radiologically.[29] In spite of the limitations of x-rays, this imaging examination remains the first line imaging tool across the UK. The x-ray images will be reported by a specialist radiographer or a radiologist.

5.6.2. CBCT

In contrast to classical multi-detector CT, CBCT is designed for extremity use and utilises a single flat panel detector to image one volume of the patient in a single rotation in high detail. The radiation dose associated with this technology is significantly less than standard CT and approaches the exposures used for a 4-view X-ray. Whilst the principle of CBCT is well established in areas such as dental; ear, nose and throat; and radiation oncology, there is limited evaluation of systems that are specifically designed for 3D imaging of the extremities. As a new technology, these scans are performed at a single site within the host Trust and are reported by a consultant musculoskeletal radiologist on the same or next day.

5.6.3. MRI

MRI is relatively low risk, as unlike x-ray and CBCT it does not involve the use of ionising radiation. It has superior accuracy in relation to x-ray[12] however; there may be local cost and capacity issues within the acute setting. The host research Trust has MRI capabilities at each of its three sites and a consultant musculoskeletal radiologist reports MRI images usually within a week of referral. A small number of contraindications to the high magnetic field exist, including some pacemakers, recent implants and claustrophobia.

5.7. Adverse event management

This study will be conducted in accordance with International Conference on Harmonisation Good Clinical Practice (ICH-GCP) principles and guidelines, the Declaration of Helsinki, Mid Yorkshire Hospitals Standard Operating Procedures (SOPs), relevant UK legislation and this protocol. ICH-GCP trained personnel will conduct the study.

ICH- GCP definitions of Adverse Events (AE) and Serious Adverse Events (SAE) will be used. All imaging technologies being utilised and imaging protocols are used in everyday practice and their safety profile is well established. A medically qualified investigator at the first appropriate opportunity will consider the relatedness of any AE. Serious adverse events will be documented in the study site file with a copy of the SAE sent to the head of research or R&D. All SAE/AE information will be emailed to midyorks.my.research@nhs.net and the lead member of staff at the study site at the start of each calendar month as per local processes.

5.8. End of study

The end of the study will be defined as the collection of the last follow up questionnaire from the last participant (collected via telephone).

6. Data management

To achieve study objectives, prospective and retrospective data will be drawn from ED notes (including the clinical screening tool for scaphoid fracture), ED electronic systems and the radiology information system, in addition to the study screening log, and the PROMs for the prospective cohort. For each participant, prospective data will be initially collected on the case report form (CRF) relevant to that episode (i.e. baseline or follow up) and transcribed timely into the EDGE research management system. If the baseline patient-completed CRF (PROMs) was not completed by the patient at the time of ED attendance and the patient was not available to complete this on the telephone within 72hours this will be marked as missing data.

6.1. Data security

The original versions of the screening logs, consent form, CRFs and PROMs will be stored in a locked filing cabinet within a locked research office. Only the research team will have access to this data. The electronic version of any data will password protected and stored on a secure Trust drive only accessible to the direct research team. Where data transfer to the statistician/ Health economist at the University of Leeds is undertaken, this will be limited to that required for economic evaluation purposes. All patient identifiable information will be removed and transfer will be through encrypted Trust devices or secure nhs.net email. All reports and dissemination of findings will only include anonymised data.

6.2. Quality control

The research team will incorporate a rigorous programme of quality control. At regular intervals, study data will be exported from EDGE into an Excel spreadsheet and validated by a member of the research team with any data queries checked against source data. The Trust has an established monitoring audit programme for research studies with locally sponsored studies guaranteed to be appraised as part of this process.

6.3. Statistical analysis

Data for all of the outcome measure will be summarised using appropriate summary statistics. Continuous quantitative outcomes will be summarised as means and standard deviations (or medians and inter-quartile ranges in the case of skewed data). Binary and categorical data will be described as proportions. 95% confidence intervals will also be reported.

A logistic regression analysis will be conducted to identify predictors of scaphoid fracture. This analysis will be used to validate the existing questions in the screening questionnaire and, importantly, identify any additional items that may need to be added.

6.4. Economic evaluation

The decision to implement a novel health technology requires rigorous assessment of the relative costs and potential consequences (benefits and harms) of the options under consideration. Economic evaluation provides a systematic framework to trading off the costs and consequences of different intervention options. We will employ these methods to evaluate the potential cost-effectiveness of using a modified care pathway using extremity Cone beam CT (CBCT) for those with suspected scaphoid fractures compared to current practice. The economic evaluation will be conducted in three stages:

1. Care pathway modelling: Prior to commencing the feasibility study, we will map the current care pathway for individuals with suspected scaphoid fractures and the proposed modified pathway, which incorporates the use of CBCT. These respective pathways will be modelled in collaboration with the clinical team involved in the project. In addition to mapping the pathways, we will identify the associated costs with each pathway. Specifically, we will obtain information on NHS resource use across all stages of the pathways.
The pathway map for the modified pathway will be shared with the research team prior to the start of the feasibility trial to provide opportunity to familiarise themselves. We will then ask them to record any deviations from this pathway identified during the study. The research team will then be asked to share any differences they noted and, after refinement, confirm that the mapped modified care pathway is accurate.

2. Analysis of data collected within the feasibility trial: The data collected during the feasibility study will be analysed to provide initial estimate for model parameters. The data from the EQ-5D-5L questionnaire will be analysed to estimate health-related quality of life. This data will have been collected at baseline and at 6 weeks follow-up.

Costs will be estimated at the time of the analysis using cost data obtained directly from the hospital and from published NHS reference costs.

3. A decision analytic model will be constructed to compare the relative difference in costs and consequences between the modified pathway using CBCT and current practice. The evaluation will adopt an NHS perspective. The structure of the model will be based on the care pathways mapped previously. Providing sufficient EQ-5D-5L data, the primary evaluation will be a cost-utility analysis, using the results of the EQ-5D-5L questionnaires to estimate health-related quality of life. Results will be presented as incremental cost-effectiveness ratios (ICERs), representing the cost per additional QALY gained of one care pathway compared to the other. Cost-effectiveness will be explored by comparing the

results to the NICE recommended willingness-to-pay threshold of £20,000 – 30,000. Sensitivity analyses will also be performed to explore alternative scenarios and assumptions to test the robustness of the results. Deterministic and probabilistic (using Monte Carlo simulations) sensitivity analyses will be conducted to explore the impact of parameter value changes on estimates of cost-effectiveness and to determine the level of uncertainty around the results of the analysis.

6.5 Dose evaluation

The data collected will allow the comparison of the radiation dose (entrance surface dose and effective dose) will be calculated using a commercially available computer software system, which utilises Monte Carlo code dose simulation **(**PCMXC**).** Calculations will use the acquisition parameters (exposure factors) for each exposure and imaging investigation which utilises ionising radiation.

7. Study management

7.1. Supervision

This research is a collaboration between the ED and radiology (imaging) department. Professor Bev Snaith, Clinical Professor of Radiography, an experienced researcher and clinical radiographer at the study site, is leading the research. The principal investigator (PI) is Dr Sarah Robertshaw, an established emergency medicine consultant and Head of Clinical Service for the ED. She will provide oversight of the research within the ED, ensuring staff training and study processes have been embedded. The day-to-day management of the study will be the responsibility of the direct research team, comprising registered research radiographers and research nurse. They will support clinical staff within emergency and radiology departments and be responsible for the management of data and trial records. The research team will meet regularly with the PI and CI to inform them on study progress, recruitment and problems arising. The study statistician and health economist, Dr Bethany Shinkins, will be closely involved in the setup of clinical reporting forms (CRFs) and data coding systems. She will lead on the health economics and regression analysis; the local research team will provide analysis support particularly in relation to qualitative and descriptive data.

A member of the research team will perform follow up telephone calls and completion of the 2-week and 6-week CRFs. Clinical decision making regarding patient recall for further evaluation on the basis of the 2-week and 6-week follow up telephone calls and CRF completion will be undertaken in conjunction with the PI. This is specifically if the PRWE and/or analgesia is higher than at baseline. If no baseline patient-completed CRF is available for comparison the information provided on the follow up CRF will guide the decision to invite the patient for physical assessment or to continue recovery as planned.

7.2. Patient and public involvement

Patient and public involvement will be focused and strategic to ensure effective study planning, delivery and dissemination of outcomes. Primarily, patient and public involvement will be organised in collaboration with the Mid Yorkshire Hospitals NHS Trust ED. A PPI representative has been co-opted onto the study team, has reviewed, and contributed the study protocol, with a particular focus on patient-facing study documentation. Where appropriate, at key time points in the process, wider engagement with patient and public representatives will be facilitated through the Yorkshire and Humber Clinical Research Network (CRN) injuries and emergencies group.

7.3. Project timetable and milestones

We are proposing a 7-month study opening January 2020. The planned study timetable is shown below with key milestones and responsible parties:

Month	Specific dates	Activity	Milestone	Responsibility
0		Research planning	Draft protocol and organise 1st research meeting	CI/ RR
		PPI engagement	Participant information sheet	CI/PI/RR
		Final study protocol and supplementary documents	Protocol final version	CI/ PI/RR/ RT/ Stat/HE
		Complete CRFs	CRFs final version	CI/ PI/ RR/ RT/Stat/ HE
		Ethics submission	REC/ HRA approval	CI/ PI/RR/ SP
1	February 2020	Study open at site	Start study recruitment	CI/ PI/RT/ SP
	February 2020	Commence retrospective data review	Data for Retrospective cohort	CI/PI/ RR
2	March 2020	Monitor recruitment	Interim feedback to funder (CareStream Health) and sponsor (MYT) via email	CI/PI/RR
		Data review of first patients	Data validation	CI/PI/RR
3	March 2020	End recruitment	Last patient recruited	CI/RT/SP
4	April 2020	Complete follow up	Completed data sets for target sample in both cohorts	CI/PI/ RT
5	May 2020	Statistical analysis	Regression analysis and other inferential statistics	Stat
	May 2020	Health economics analysis	Economic analysis	HE
	May 2020	Supplementary analysis	Descriptive and qualitative data analysis	CI/PI/RR
6	June 2020	Data review all patients	All data queries completed	CI/PI/RR
	July 2020	Final study report and commence Research dissemination	Final report and Conference presentation	CI/PI/ RT/ stat/ HE
7+	August 2020	Study close and Peer review publication	Journal manuscript submission	CI/PI/RR/RT/ Stat/ HE

CI Chief Investigator, PI Principal investigator, RR Research Radiographer, RT research team, stat statistician HE Health economist, SP Sponsor

7.4. Study support

Carestream Health is supplying the equipment and consumables required to undertake this study however, they will have no intellectual property (IP) rights to the data or outcomes arising from this study.

7.5. Dissemination

The findings from this evaluation study will be disseminated to the academic and clinical community through international conference presentation and peer-review publication. Open access is not being considered within the dissemination of this small-scale feasibility study but will be for prospective multi-centre studies exploring the wider impact of CBCT within the scaphoid pathway. With support from the local communications team, the results of the study will be displayed in the local NHS Trust intranet and newsletter with posters presented within the clinical departments for patients and staff. A formal dissemination strategy will be developed with PPI and stakeholder input as the project develops, including dissemination of research outcomes and impact to study recruits.

7.6. Protocol amendments

Following IRAS submission, the following amendments have been made:

Amendment No.	Date of Amendment	Date of approval
None to date		

8. References

1. Green DP, Hotchkiss RN, Pederson WC, Wolfe SW. *Green's Operative Hand Surgery*. 2005. Philadelphia: Churchill Livingstone.
2. Kozin SH. Incidence, mechanism and natural history of scaphoid fractures. *Hand Clin*. 2001; 17: 515-24.
3. Garala K, Taub NA, Dias JJ. The epidemiology of fractures of the scaphoid: Impact of age, gender, deprivation and seasonality. *Bone Joint J* 2016; 98-B: 654–9.
4. National Institute for Health and Care Excellence. *Fractures (non-complex): assessment and management NG38.* NICE. 2016.
5. Adey L, Souer JS, Lozano-Calderon S, Palmer W, Lee SG, Ring D. Computed tomography of suspected scaphoid fractures. *J Hand Surg Am.* 2007; 32: 61-6.
6. Jenkins PJ, Slade K, Huntley JS, Robinson CM. A comparative analysis of the accuracy, diagnostic uncertainty and cost of imaging modalities in suspected scaphoid fractures. *Injury*. 2008; 39: 768-74.
7. Dorsay TA, Major NM, Helms CA. Cost effectiveness of immediate MR imaging versus traditional follow-up for revealing radiographically occult scaphoid fractures. *AJR*. 2001; 177: 1257-63.
8. Shetty S, Sidharthan S, Jacob J, Ramesh B. 'Clinical scaphoid fracture': is it time to abolish this phrase? *Ann Roy Coll Surg* 2011; 93: 146-8.
9. Bond CD, Shin AY, McBride MT, Dao KD. Percutaneous screw fixation or cast immobilisation for non-displaced scaphoid fractures. *J Bone Joint Surgery Am*. 2001; 83: 483-8.
10. Haisman JM, Rohde RS, Weiland AJ. Acute fractures of the scaphoid. *J Bone Joint Surgery Am.* 2006; 88: 2750-8.
11. Ring J, Talbot C, Price J, Dunkow P. Wrist and scaphoid fractures: A 17-year review of NHSLA litigation data. *Injury* 2015; 46: 682-86.
12. Gemme S, Tubbs R. What physical examination findings and diagnostic imaging modalities are most useful in the diagnosis of scaphoid fractures? *Ann Emerg Med* 2015; 65: 308-9.
13. Yin ZG, Zhang JB, Kan SL, Wang XG. Diagnosing suspected scaphoid fractures: a systematic review and meta-analysis. *Clin Orthop* 2010; 468:723-34.
14. Karl JW, Swart E, Strauch RJ. Diagnosis of occult scaphoid fractures. *J Bone Joint Surg Am* 2015; 97: 1860-8.
15. Rua T, Parkin D, Goh V, McCrone O, Gidwani S. The economic evidence for advanced imaging in the diagnosis of suspected scaphoid fractures: systematic review of evidence. *J Hand Surg Eur* 2018; 43: 642-51.
16. Mallee WH, Wang J, Poolman RW, et al. Computed tomography versus magnetic resonance imaging versus bone scintigraphy for clinically suspected scaphoid fractures in patients with negative plain radiographs. *Cochrane Database of Systematic Reviews* 2015, Issue 6. Art. No.: CD010023. DOI: 10.1002/14651858.CD010023.pub2.

17. Wijetunga AR, Tsang VH, Giuffre B. The utility of cross-sectional imaging in the management of suspected scaphoid fractures. *J Med Radiat Sci* 2019; 66: 30-7.
18. Borel C, Larbi A, Declaux S, et al. Diagnostic value of cone beam computed tomography (CBCT) in occult scaphoid and wrist fractures. *Eur J Radiol* 2017; 97: 59-64.
19. Neubauer J, Bennoff M, Ehritt-Braun C, et al. Comparison of the diagnostic accuracy of cone beam computed tomography and radiography for scaphoid fractures. *Scientific Reports* 2018; 8: 3906. DOI:10.1038/s41598-018-22331-8
20. Edlund R, Skorpil M, Lapidus G, Bäcklund J. Cone-beam CT in diagnosis of scaphoid fractures. *Skeletal Radiol* 2016; 45: 197-204.
21. Kwee RM, Kwee TC. Ultrasound for diagnosing radiographically occult scaphoid fracture. *Skeletal Radiol* 2018; 47: 1205-12.
22. Jain R, Jain N, Sheik T, Yadav C. Early scaphoid fractures are better diagnosed with ultrasonography than X-rays: A prospective study over 114 patients. *Chin J Traumatol* 2018; 21: 206-10.
23. Brookes-Fazakerley SD, Kumar AJS, Oakley J. Survey of the initial management and imaging protocols for occult scaphoid fractures in UK hospitals. *Skeletal Radiol* 2009;38:1045-8.
24. Kelly A-M. Initial management of potential occult scaphoid fracture in Australasia*. Int J Emerg Med* 2010;3:45-7.
25. Smith J, House RH, Gallagher J, Phillips A. The management of suspected scaphoid fractures in English hospitals: a national survey. *Eur J Emerg Med* 2016; 23: 190-3.
26. College of Emergency Medicine. *Guideline for the Management of Suspected Scaphoid Fractures in the Emergency Department*. RCEM. 2013.
27. Chunara MH, McLeavy CM, Kesavanarayanan V, et al. Current imaging practice for suspected scaphoid fracture in patients with normal initial radiographs: UK-wide national audit. *Clinical Radiology* 2019; 74 (6): 450-455.
28. Jenkins PJ, Boyce S, Garvey P, et al. A virtual pathway reduced the need for physical review in patients with suspected scaphoid fracture. *European Research Journal* 2019; 5: 8-13.
29. Rua T, Vijayanathan S, Parkin D, Goh V, McCrone O, Gidwani S. Rationale and design of the SMaRT trial: A randomised, prospective, parallel, non-blinded, one-centre trial to evaluate the use of magnetic resonance imaging in acute setting patients presenting with suspected scaphoid fracture. *Clinical Trials* 2017; 15 (2): 120-129.
30. Singh O, Sen A, Charak SS, Ahmad S. Role of early CT in diagnosis of occult scaphoid fractures- a prospective study. *International Journal of research in medical sciences* 2017;5 (9): 4072-4076.

Appendices

Appendix 1 – Baseline CRF - For Participant Completion

Baseline Questionnaire – For Participant Completion

The following pages have questions to see how your wrist injury is affecting you. If your imaging tests are normal we will need to ask some more questions in a few weeks time to see if things are getting better.

All your answers will remain confidential.

Instructions

Please read these instructions carefully. Answer ALL the questions and check that the sections are complete

- If you are asked to fill in a box please just give a single answer

For **example**: Did you come to hospital on the bus? Yes [ ] No [X]

- If you are asked to circle a number to identify your views, please just circle one number.

For **example**:

How often do you use the bus?

Never				Always
(1)	2	3	4	5

Please turn the page to start

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Participant number	
Date of attendance	
Date entered onto EDGE	

Version No: 1.2 **Date:** 24/02/20

Part 1: ABOUT YOU

This information will help us understand the impact your wrist injury has on you.

A. DATE OF BIRTH Day ☐☐ Month ☐☐ Year ☐☐☐☐

B. JOB ……..
(Please state if you are a student, are currently unemployed or retired)

C. DOMINANT HAND ☐ Right ☐ Left

D. PAIN RELIEF

Do you usually take regular painkillers (for any reason)? ☐ Yes ☐ No

If YES what type(s) …….

How often …….

E. FOLLOW UP

If you require follow up care (including telephone calls from a researcher) please confirm the best telephone number to contact you on:

Preferred contact number: …….

When is it best to contact you? ☐ Daytime ☐ Evening
(Select one or both)

Please turn the page to continue

Version No: 1.2 **Date:** 24/02/20

Part 2: BEFORE YOUR INJURY

The next questions are a Patient Related Wrist Evaluation and relate to health **BEFORE YOUR INJURY**

A. PAIN

Please circle the number which best represents the pain in your wrist BEFORE YOUR INJURY. A zero (0) means you had NO pain and a ten (10) means that you had the worst pain you had ever experienced or could not do the activity because of the pain.

	No Pain										Worst ever
At rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with a repeated wrist movement	0	1	2	3	4	5	6	7	8	9	10
When lifting a heavy object	0	1	2	3	4	5	6	7	8	9	10
When it is at its worst	0	1	2	3	4	5	6	7	8	9	10
	Never										**Always**
How often do you have pain?	0	1	2	3	4	5	6	7	8	9	10

B. FUNCTION

Please state the difficulty you had BEFORE YOUR INJURY in performing each of the items listed below by circling ONE number. A zero (0) means did not experience any difficulty and a ten (10) means that it was so difficult you could not do it at all.

	No Difficulty										Unable to do
Cut meat using a knife in affected hand	0	1	2	3	4	5	6	7	8	9	10
Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

C. USUAL ACTIVITIES

Rate the difficulty you had performing your usual activities in the areas below. A zero (0) means did not experience any difficulty and a ten (10) means that it was so difficult you could not do it at all.

	No Difficulty										Unable to do
Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

Please turn the page to continue

Version No: 1.2 **Date:** 24/02/20

These questions relate to your quality of life **BEFORE YOUR INJURY**.

D. MOBILITY

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking about
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

E. SELF CARE

- ☐ I have no problems washing or dressing myself
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

F. USUAL ACTIVITIES (work, study, housework, family or leisure activities)

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

G. PAIN / DISCOMFORT

- ☐ I have no pain or discomfort
- ☐ I have slight pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have severe pain or discomfort
- ☐ I have extreme pain or discomfort

H. ANXIETY / DEPRESSION

- ☐ I am not anxious or depressed
- ☐ I am slightly anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am severely anxious or depressed
- ☐ I am extremely anxious or depressed

Please turn the page to continue

We would now like to know how good or bad your health was **BEFORE YOUR INJURY**

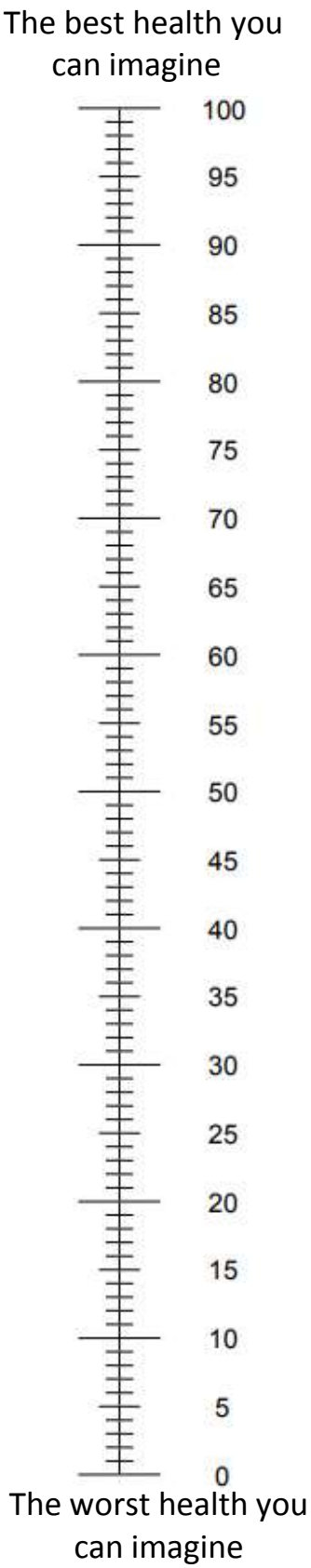
The scale is numbered 0 to 100

- 100 means the BEST health you can imagine
- 0 means the worst health you can imagine

Mark a cross X on the scale to indicate how good or bad you think your health is BEFORE YOUR INJURY

Now please write the number you marked on the scale in the box below

Your health before your injury = ☐



Please turn the page to continue

Version No: 1.2 **Date:** 24/02/20

Part 3: TODAY

This set of questions relate to your health **TODAY**, you will see they are a repeat of earlier questions, but you should now tell us how you feel since your wrist injury.

A. PAIN

Please circle the number which best represents the amount of pain in your wrist today. A zero (0) means you had NO pain and a ten (10) means that you have the worst pain you had ever experienced or can not do the activity because of the pain.

	No Pain										**Worst ever**
At rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with a repeated wrist movement	0	1	2	3	4	5	6	7	8	9	10
When lifting a heavy object	0	1	2	3	4	5	6	7	8	9	10
When it is at its worst	0	1	2	3	4	5	6	7	8	9	10
	Never										**Always**
How often do you have pain?	0	1	2	3	4	5	6	7	8	9	10

B. FUNCTION

Please state the difficulty you have TODAY in performing each of the items listed below by circling ONE number. A zero (0) means do not experience any difficulty and a ten (10) means that it is so difficult you can not do it at all.

	No Difficulty										**Unable to do**
Cut meat using a knife in affected hand	0	1	2	3	4	5	6	7	8	9	10
Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

C. USUAL ACTIVITIES

Rate the difficulty you have (or expect to have) performing your usual activities in the areas below. A zero (0) means did not experience any difficulty and a ten (10) means that it was so difficult you could not do it at all.

	No Difficulty										**Unable to do**
Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

Please turn the page to continue

These questions relate to your quality of life **TODAY**

D. MOBILITY

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking about
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

E. SELF CARE

- ☐ I have no problems washing or dressing myself
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

F. USUAL ACTIVITIES (work, study, housework, family or leisure activities)

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

G. PAIN / DISCOMFORT

- ☐ I have no pain or discomfort
- ☐ I have slight pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have severe pain or discomfort
- ☐ I have extreme pain or discomfort

H. ANXIETY / DEPRESSION

- ☐ I am not anxious or depressed
- ☐ I am slightly anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am severely anxious or depressed
- ☐ I am extremely anxious or depressed

Please turn the page to continue

The best health you can imagine

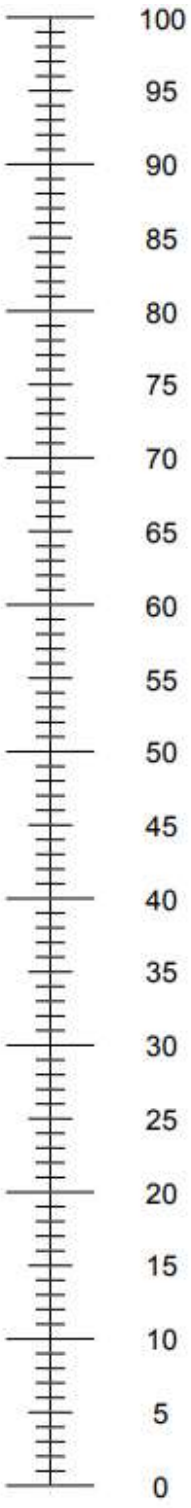
We would like to know how good or bad your health is

SINCE YOUR INJURY

The scale is numbered 0 to 100

- 100 means the BEST health you can imagine
- 0 means the worst health you can imagine

Mark a cross X on the scale to indicate how good or bad you think your health is TODAY



Now please write the number you marked on the scale in the box below

Your health TODAY = ☐

Thank you for your time. Please return the questionnaire to the person looking after you in the Emergency Department

The worst health you can imagine

Version No: 1.2 **Date:** 24/02/20

Appendix 2 – Baseline CRF – For Researcher Completion

Baseline Questionnaire – For Researcher Completion

This should be completed as soon as possible following participant discharge from the ED.

PART 1: EMERGENCY DEPARTMENT OUTCOMES

Site ☐ Dewsbury ☐ Pontefract ☐ Wakefield

Clinician ☐ ENP ☐ Jnr Doc ☐ Middle Grade/ SpR ☐ Cons ☐ GP

ED Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state …….

Immobilisation ☐ None ☐ Splint ☐ Cast

ED disposal ☐ Research Follow-Up ☐ Virtual Fracture Clinic ☐ Other

If Other state …….

Also enter screening tool information onto EDGE

For office use only

Participant number	
CRF completion date	
Date entered onto EDGE	
Researcher name	

PART 2: IMAGING INVESTIGATIONS

Baseline X-Ray ☐ Scaphoid ☐ Wrist & Scaphoid

X-ray Room ……. **X-Ray DAP** ……. **No. Exam repeats……**

X-ray Exposures

DP	…… kVP	……..mAs
Oblique	…… kVP	……..mAs
Lateral	…… kVP	……..mAs
Zitters	…… kVP	……..mAs

X-Ray report ☐ Immediate (Hot) ☐ Delayed (Cold)

X-ray Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state ……

CBCT performed ☐ Yes ☐ No

Date CBCT performed …….

CBCT Exposure …… kVP ……..mA **CBCT DLP** ……

Time to CBCT report ……Hours

CBCT Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state ……

Appendix 3 – 2-Week follow up CRF

2-Week Questionnaire – For Researcher Completion

This should be completed within 12-16 days following ED discharge. Please have a copy of the BASELINE CRFs available.

PRIOR TO FOLLOW-UP CALL

Prior to call ensure the researcher must check:

Has the patient re-attended the ED with wrist problems?	Yes	No
Has the patient re-attended for further imaging investigations?	Yes	No
Has the patient been admitted to hospital?	Yes	No
Has the patient died?	Yes	No

If the answer to any question is YES, you must discuss this with the CI or PI before attempting to make contact.

BASELINE POST INJURY PRWE SCORE	**/100**
BASELINE POST INJURY EQ-5D-5L	**/100**

INSTRUCTIONS

- Check the baseline CRF and identify any missing demographic data (e.g. Job)
- Check you have the correct information – preferred contact details listed on the Baseline CRF
- Ensure when make call that you confirm patient/carer identity
- Confirm that the answers will remain confidential but you will be making notes to be able to see how well they are doing.

For office use only

Participant number	
Completion date	
Date entered onto EDGE	
Researcher name	

Part 1: TODAY – GENERAL QUESTIONS

This set of questions relate to your health **TODAY**, you will note that they are a repeat of those you filled in when you were at the hospital. You should now tell us how you have been feeling since being discharged for your wrist injury.

- Have you been to see anyone about your wrist since you were at the ED?

  ……..

- Are you still wearing your splint?

  If YES ☐ All the time ☐ Just for certain activities?

- Are you currently taking any pain relief taking for your wrist

  If YES - Dose/how often ……

- Have you had any time off work because of your wrist injury?

  If YES state……..

Part 2: PRWE

1. PAIN

Please state the level of pain in your wrist today from 0-10. A zero (0) means you had NO pain and a ten (10) means that you have the worst pain you had ever experienced or can not do the activity because of the pain.

	No Pain										**Worst ever**
At rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with a repeated wrist movement	0	1	2	3	4	5	6	7	8	9	10
When lifting a heavy object	0	1	2	3	4	5	6	7	8	9	10
When it is at its worst	0	1	2	3	4	5	6	7	8	9	10
	Never										**Always**
How often do you have pain?	0	1	2	3	4	5	6	7	8	9	10

TOTAL PAIN ☐ /50 SCORE

2. FUNCTION

Please state the difficulty you have TODAY in performing the following tasks by stating a number between 0-10. A zero (0) means do not experience any difficulty and a ten (10) means that it is so difficult you can not do it at all.

	No Difficulty										**Unable to do**
Cut meat using a knife in affected hand	0	1	2	3	4	5	6	7	8	9	10
Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

B. USUAL ACTIVITIES

Rate the difficulty you have (or expect to have) performing your usual activities from 0-10. A zero (0) means do not experience any difficulty and a ten (10) means that it is so difficult you could not do it at all.

	No Difficulty										**Unable to do**
Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

TOTAL FUNCTION SCORE	Sum=	**Divide by 2 =**

2-WEEK PRWE SCORE	Pain + Function	/100

Part 3: EQ-5D-5L

These questions relate to your quality of life **TODAY**

A. MOBILITY

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking about
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

B. SELF CARE

- ☐ I have no problems washing or dressing myself
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

C. USUAL ACTIVITIES (work, study, housework, family or leisure activities)

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

D. PAIN / DISCOMFORT

- ☐ I have no pain or discomfort
- ☐ I have slight pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have severe pain or discomfort
- ☐ I have extreme pain or discomfort

E. ANXIETY / DEPRESSION

- ☐ I am not anxious or depressed
- ☐ I am slightly anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am severely anxious or depressed
- ☐ I am extremely anxious or depressed

We would like to know how good or bad your health is **TODAY**

The scale is numbered 0 to 100

- 100 means the BEST health you can imagine
- 0 means the worst health you can imagine

Health TODAY = ☐

Part 4: OTHER QUESTIONS

Any other questions or comments?

……

……

……

Part 4: OUTCOME

Is PRWE total score (or any sub-section) ≥ Baseline POST INJURY? ☐ Yes ☐ No

Is the analgesia ≥ Baseline POST INJURY? ☐ Yes ☐ No

If the answer to either of the above questions is **YES** inform patient that you will arrange a follow up hospital appointment (ED MSK clinic for doctor review).

Decision ☐ Recall to clinic ☐ Follow up at 6 weeks

Appendix 4 – 6-Week follow up CRF

6-Week Questionnaire – For Researcher Completion

This should be completed within 12-16 days following ED discharge. Please have a copy of the BASELINE and 2-Week CRFs available.

PRIOR TO FOLLOW-UP CALL

Prior to call ensure the researcher must check:

Has the patient re-attended the ED with wrist problems?	Yes	No
Has the patient re-attended for further imaging investigations?	Yes	No
Has the patient been admitted to hospital?	Yes	No
Has the patient died?	Yes	No

If the answer to any question is YES, you must discuss this with the CI or PI before attempting to make contact.

BASELINE POST INJURY PRWE SCORE /100 **2-WEEK SCORE** /100

BASELINE POST INJURY EQ-5D-5L /100 **2-WEEK SCORE** /100

INSTRUCTIONS

- Check you have the correct information – preferred contact details listed on the Baseline CRF
- Ensure when make call that you confirm patient/carer identity
- Confirm that the answers will remain confidential but you will be making notes to be able to see how well they are doing.

For office use only

Participant number	
Completion date	
Date entered onto EDGE	
Researcher name	

Part 1: TODAY – GENERAL QUESTIONS

This set of questions relate to your health **TODAY**, you will note that they are a repeat of those you were asked before. You should now tell us how you have been feeling since we last contacted you.

- Have you been to see anyone about your wrist since you were at the ED?

  ……..

- Are you still wearing your splint?

  If YES ☐ All the time ☐ Just for certain activities?

- Are you currently taking any pain relief taking for your wrist

  If YES - Dose/how often ……

- Have you had any time off work because of your wrist injury?

  If YES state……..

Part 2: PRWE

3. PAIN

Please state the level of pain in your wrist today from 0-10. A zero (0) means you had NO pain and a ten (10) means that you have the worst pain you had ever experienced or can not do the activity because of the pain.

	No Pain										**Worst ever**
At rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with a repeated wrist movement	0	1	2	3	4	5	6	7	8	9	10
When lifting a heavy object	0	1	2	3	4	5	6	7	8	9	10
When it is at its worst	0	1	2	3	4	5	6	7	8	9	10
	Never										**Always**
How often do you have pain?	0	1	2	3	4	5	6	7	8	9	10

TOTAL PAIN ☐ /50 SCORE

4. FUNCTION

Please state the difficulty you have TODAY in performing the following tasks by stating a number between 0-10. A zero (0) means do not experience any difficulty and a ten (10) means that it is so difficult you can not do it at all.

	No Difficulty										**Unable to do**
Cut meat using a knife in affected hand	0	1	2	3	4	5	6	7	8	9	10
Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

B. USUAL ACTIVITIES

Rate the difficulty you have (or expect to have) performing your usual activities from 0-10. A zero (0) means do not experience any difficulty and a ten (10) means that it is so difficult you could not do it at all.

	No Difficulty										**Unable to do**
Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

TOTAL FUNTION SCORE	Sum=	Divide by 2 =

6-WEEK PRWE SCORE	Pain + Function	/100

Part 3: EQ-5D-5L

These questions relate to your quality of life **TODAY**

A. MOBILITY

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking about
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

B. SELF CARE

- ☐ I have no problems washing or dressing myself
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

C. USUAL ACTIVITIES (work, study, housework, family or leisure activities)

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

D. PAIN / DISCOMFORT

- ☐ I have no pain or discomfort
- ☐ I have slight pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have severe pain or discomfort
- ☐ I have extreme pain or discomfort

E. ANXIETY / DEPRESSION

- ☐ I am not anxious or depressed
- ☐ I am slightly anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am severely anxious or depressed
- ☐ I am extremely anxious or depressed

We would like to know how good or bad your health is **TODAY**

The scale is numbered 0 to 100

- 100 means the BEST health you can imagine
- 0 means the worst health you can imagine

Health TODAY = ☐

Part 4: OTHER QUESTIONS

Any other questions or comments?

……

……

……

Part 4: OUTCOME

Is PRWE total score (or any sub-section) ≥ 2 WEEK? ☐ Yes ☐ No

Is the analgesia ≥ 2 WEEK? ☐ Yes ☐ No

If the answer to either of the above questions is **YES** inform patient that you will arrange a follow up hospital appointment (ED MSK clinic for doctor review).

Decision ☐ Recall to clinic ☐ Discharge, thank patient for taking part

Appendix 5 – Recruitment poster content (Trust format on corporate template)

InSPECTED Research Study

Do you have a wrist injury?

Then you might be eligible to take part in the InSPECTED research project.

Your nurse or doctor may talk to you about the research and provide you with an information pack.

The research is an evaluation of standard care of suspected scaphoid fractures and we are keen to see if our new pathway is better for patients and more efficient.

If you want to know more:

- Ask the nurse or doctor looking after you
- Email: midyorks.radiology.research@nhs.net

Version No: 1.1 **Date:** 18/02/2020

Appendix 6 – Scaphoid fracture screening tool

Suspected scaphoid fracture protocol checklist

Patient details (or affix sticker)

First name_____ Grade of person initially assessing patient:

FY1/2 [ ] CT or ST1-3 [ ]

Last name_____ ST4-6 [ ] SAS or Ass. Spec [ ]

Consultant [ ] ENP/ANP [ ]

Date of injury_____

Patient has sustained trauma compatible with scaphoid fracture [ ]
(e.g. Fall onto outstretched hand)

AND one or more of the following (Please tick all that apply):

Tenderness in the anatomical snuffbox with the wrist in ulnar deviation [ ]
Tenderness over the scaphoid tubercle with the wrist slightly extended [ ]
Pain on axial compression of the thumb [ ]

X-rays including scaphoid views that are normal or insufficient to explain symptoms/signs. [ ]

If fracture -refer to appropriate specialty e.g. Orthopaedics, VFC or plastics [ ]

CT requests on ICE: [ ]

- CT Wrist- Clinical information to include "Exclude scaphoid fracture on ED pathway". Phone Radiology Hub on 51636 to book next available appointment.

Patient discharged with: [ ]

- Futura wrist splint.
- Scaphoid injury information leaflet.
- Appropriate analgesia.

Please ensure this checklist is complete and scanned into CITO alongside patient notes.

Version No: 1.1 **Date:** 10/02/2020

Appendix 7 - Participant information sheet

Improving the Scaphoid Pathway with Extremity CT in the ED

Chief Investigator: Professor Bev Snaith

Why are we inviting you to take part in this research?

You have had a wrist injury and are suspected of having a scaphoid fracture and we would like to inform you of a research study evaluating the standard pathway for suspected scaphoid fractures at this Trust. We would like to invite you to take part in the research but before you make your decision it is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully. You may want to talk to others about the study before taking part. Please ask us if you would like any more information. A telephone number is also provided at the end of this information sheet.

What is the purpose of the InSPECTED study?

The scaphoid is a small bone in the wrist commonly broken during falls. Unfortunately, many fractures are not visible on initial x-rays and there can be a delay before the fracture is identified. Other imaging tests such as MRI and CT can be used but practice varies across the UK. The Mid Yorkshire Hospitals NHS Trust is sponsoring this study, which aims to find out if the extremity CT scanning we have introduced for suspected scaphoid fractures enables earlier diagnosis and increased efficiency for both patients and the hospital services.

Do I have to take part?

We are offering all patients on the pathway the opportunity to participate in the research but you do not have to take part if you do not want to. You are consenting to the research team recording routinely collected information about your emergency department visit and imaging examinations from standard NHS hospital systems. We would ask you to complete a questionnaire today about your pain and function before and after your injury. If the initial scaphoid x-ray is normal, you will have an extremity CT scan of your wrist. If this is also normal you will be contacted by a member of the research team after 2 weeks (in line with standard follow up) and again at 6 weeks to see you have recovered as expected. They will ask you many of the same questions again.

If you decide that you do not want to participate in the research, you will still be treated as you would normally with x-rays and if necessary a CT scan. None of your care or rights will be affected. Based on the result of your tests, you will be referred to a specialist clinic or be discharged from ED with

immobilisation and appropriate advice with follow up as standard at 2 weeks. The important thing is that no information will be collected about your ED visit or follow up.

Are there any risks or benefits from being involved?

There are no expected risks from taking part in the study as the x-ray and CT wrist scan are delivered as part of routine care. If you take part in this study, you will not undergo any additional imaging procedures to normal. These procedures use ionising radiation to form images of your body and provide us with clinical information. Ionising radiation can cause cell damage that may, after many years or decades turn cancerous. The chances of this happening to you are the same whether you take part in this study or not.

Follow up telephone calls will be kept as short as possible and we will work with you to perform them at a time that is convenient to you. There are no advantages to taking part in the study but being part of the research will provide you with reassurance in ongoing management of your injury and will allow you to alert the clinical team of any on-going symptoms. If there are ongoing problems, we will arrange review in a hospital clinic. The information we get from the study will help us improve care of patients with similar injuries in the future and provide valuable information on the use of NHS resources.

What if there is a problem?

This study only included tests and care that you would receive normally. If at any stage, you have any questions about the study or concerns about the way it has been carried out please contact a member of the local research team (contact details below) who can advise. You can also contact the Mid Yorkshire Hospitals Patient Advice and Liaison Service (PALS) on 01924 542972, or email: myh-tr.palsmidyorks@nhs.net

Will my taking part in InSPECTED be kept confidential?

We will need to use information from you and your hospital records for this research project. This information will include your name, hospital number and contact details. The research team will use this to ensure that the research is done properly but no one outside of the direct research team will be able to see your name or contact details, instead your data will have a code number. We will keep all information about you safe and secure. Most of your data will be analysed at the Trust but anonymised information relating to health economics will be sent to the University of Leeds. This information will be analysed by a health economist but they must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

For more information about how we use your information is available

- at www.hra.nhs.uk/information-about-patients/
- at https://www.midyorks.nhs.uk/privacyfair-processing-notice
- by asking or calling one of the research team (contact details below)
- by sending an email to heathercook1@nhs.net who is the Trusts data protection officer

What will happen to the results of the research study?

The research study is expected to last 5 months. We will publish the findings in medical journals and at appropriate conferences. The outcomes will also be shared locally through the Trust communications team and available to participants at the end of the study if they want to see it. You have the option to allow us to retain your x-rays and extremity CT images to support future research in this area.

Who has reviewed InSPECTED?

The Leicester Central Research Ethics Committee has reviewed this study and approval was given on 25/02/2020. The study is supported by Carestream Health who have provided the scanner equipment required to perform this evaluation within the NHS setting.

What if a change my mind and decide to withdraw from the InSPECTED study at a later date? You can stop being part of the study at any time without giving a reason, but we will keep information about you that we already have. The same is true if you lose the capacity to consent during the study. If you chose to opt out at the 2-week telephone call, you will still need a review at this time and so will get a further telephone call from a hospital doctor.

We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

Thank you for reading this leaflet about the InSPECTED study; if you have any questions please ask the doctor or nurse who is looking after you in the emergency department.

Research contact	**Local Principal Investigator**	**Local Research Nurse**
Martine Harris 01924 542297	Dr Sarah Robertshaw 07912 775407	Sarah Buckley 01924 543769

Version No: 1.2 **Date:** 24/02/2020

Appendix 8- Consent form

CONSENT FORM

Study ID number:

Improving the Scaphoid Pathway with Extremity CT in the ED (InSPECTED)

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet (version....., dated…….) for the above research study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and am satisfied with the answers to my questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw my data up to data analysis without giving any reason and without my medical care or legal rights being affected. ☐
3. I give permission for routine hospital data about my ED attendance, including images, to collected, recorded, analysed and used in research dissemination. ☐
4. I understand that individuals may look at data collected during the study, from organisations involved in developing and running this research study, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records but understand that my confidentiality will be maintained. ☐
5. I agree to take part in the above study. ☐
6. I would like to receive a copy of the summary of findings for this study or to be sent the details of a link to the location of the findings. ☐
7. I give permission for the scaphoid x-rays and extremity CT images obtained as part of this study to be retained and used to support future research (optional). **YES / NO** (Please circle)

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature
Name of Witness (If applicable)	Date	Signature

Version No: 1.1 **Date:** 24/02/2020

Appendix 9 – Retrospective cohort CRF

Retrospective data Questionnaire – For Researcher Completion

This should be completed for all patients included in the retrospective cohort.
Where information is not available please state *MISSING DATA* .

Also enter information onto EDGE

Part 1: ABOUT THE PATIENT

	Day	Month	Year
F. DATE OF BIRTH	☐☐	☐☐	☐☐

G. JOB ……
(Please also state if the patient is a student, is currently unemployed or retired)

H. DOMINANT HAND ☐ Right ☐ Left

I. PAIN RELIEF

Does the patient take regular painkillers (for any reason)? ☐ Yes ☐ No

If YES what type(s) …… How often …….

For office use only

Participant number	
CRF completion date	
Date entered onto EDGE	
Researcher name	

PART 2: BASELINE EMERGENCY DEPARTMENT OUTCOMES

Date of attendance Day ☐☐ Month ☐☐ Year ☐☐

Time of presentation (24 hour) Hour ☐☐ Minutes ☐☐

Site ☐ Dewsbury ☐ Pontefract ☐ Wakefield

Clinician ☐ ENP ☐ Jnr Doc ☐ Middle Grade/ SpR ☐ Cons ☐ GP

Clinical symptoms ☐ Pain ASB ☐ Pain tubercle ☐ Pain axial loading

Injury mechanism .....

ED Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state .....

Immobilisation ☐ None ☐ Splint ☐ Cast

ED disposal ☐ ED Clinic review ☐ Fracture Clinic ☐ Discharge ☐ Other

If Other state .....

PART 3: BASELINE IMAGING INVESTIGATIONS

Baseline x-ray ☐ Scaphoid ☐ Wrist & Scaphoid

X-ray Room **….**…… **X-ray DAP** ……. **No. Exam repeats.....**

X-ray Exposures

DP	…… kVP	……..mAs
Oblique	…… kVP	……..mAs
Lateral	…… kVP	……..mAs
Zitters	…… kVP	……..mAs

X-Ray report ☐ Immediate (Hot) ☐ Delayed (Cold)

X-ray Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state ……

PART 4: PLANNED FOLLOW UP

Date of first ED clinic Day ☐☐ Month ☐☐ Year ☐☐

Site ☐ Dewsbury ☐ Pontefract ☐ Wakefield

ED Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state ……

Immobilisation ☐ None ☐ Splint ☐ Cast

ED disposal ☐ ED Clinic review ☐ Fracture Clinic ☐ Discharge ☐ Other

If Other state ……

Date of second ED clinic Day ☐☐ Month ☐☐ Year ☐☐

Site ☐ Dewsbury ☐ Pontefract ☐ Wakefield

ED Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state ……

Immobilisation ☐ None ☐ Splint ☐ Cast

ED disposal ☐ ED Clinic review ☐ Fracture Clinic ☐ Discharge ☐ Other

If Other state ……

PART 5: UNPLANNED FOLLOW UP

Total number of unplanned attendances during this period .....

Dates of unplanned attendances since injury.....

Reasons for unplanned attendances (In date order).....

.....

.....

ED disposal 1 ☐ ED Clinic review ☐ Fracture Clinic ☐ Discharge ☐ Other

ED disposal 2 ☐ ED Clinic review ☐ Fracture Clinic ☐ Discharge ☐ Other

PART 6: IMAGING FOLLOW UP

Follow up X-Ray 1 ☐ Scaphoid ☐ Wrist & Scaphoid

Date x-ray performed .....

X-ray Room ..... **X-ray DAP** ..... **No. Exam repeats.....**

X-ray Exposures

DP	..... kVP	.....mAs
Oblique	..... kVP	.....mAs
Lateral	..... kVP	.....mAs
Zitters	..... kVP	.....mAs

X-Ray report

☐ Delayed (Cold) ☐ Immediate (Hot)

X-ray Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state …….

Follow up X-ray 2 ☐ Scaphoid ☐ Wrist & Scaphoid

Date x-ray performed ……..

X-ray Room **……** ……. **X-Ray DAP** …….. **No. Exam repeats……**

X-ray Exposures			
	DP	…… kVP	……..mAs
	Oblique	…… kVP	……..mAs
	Lateral	…… kVP	……..mAs
	Zitters	…… kVP	……..mAs

X-Ray report ☐ Immediate (Hot) ☐ Delayed (Cold)

X-ray Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state …….

CT scan performed ☐ Yes ☐ No

Date CT scan performed ……..

CT Exposure CT …… kV ……mA **DLP** ……..

Time to CT report ……Hours

CT Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state …….

MRI scan performed ☐ Yes ☐ No

Date MRI scan performed ……..

Time to MRI report ……Hours

MRI Diagnosis ☐ NBI ☐ # Scaphoid ☐ Other

If Other state …….