

Quality Improvement Project for FRCEM

**Standard Operating Procedure (SOP):
Sedation of Adult Patients in the Emergency Department**

Executive Summary

A Quality Improvement Project to enhance the Quality and Safety of Adult Procedural Sedation in the Emergency Department in a busy District General Hospital.

Following an RCEM National Audit, a Standard Operating Procedure (SOP) was developed. This SOP included a detailed explanation of the expectations when undertaking Adult Procedural Sedation in the Emergency Department, along with a Sedation Proforma, printable Discharge Information and a Pre-Procedural Time-Out check list.

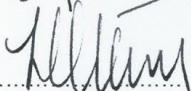
The Proforma section was piloted in draft format, and analysed after 3 months. The SOP was formally ratified by the Patient Safety and Quality Committee and then by the Executive Board.

Pilot data analysis has shown a significant improvement in meeting the fundamental Quality Standards outlined by RCEM for Adult Procedural Sedation. This QIP has been embedded in the culture of both the Trust and the Emergency Department.

Dr James C Klewe

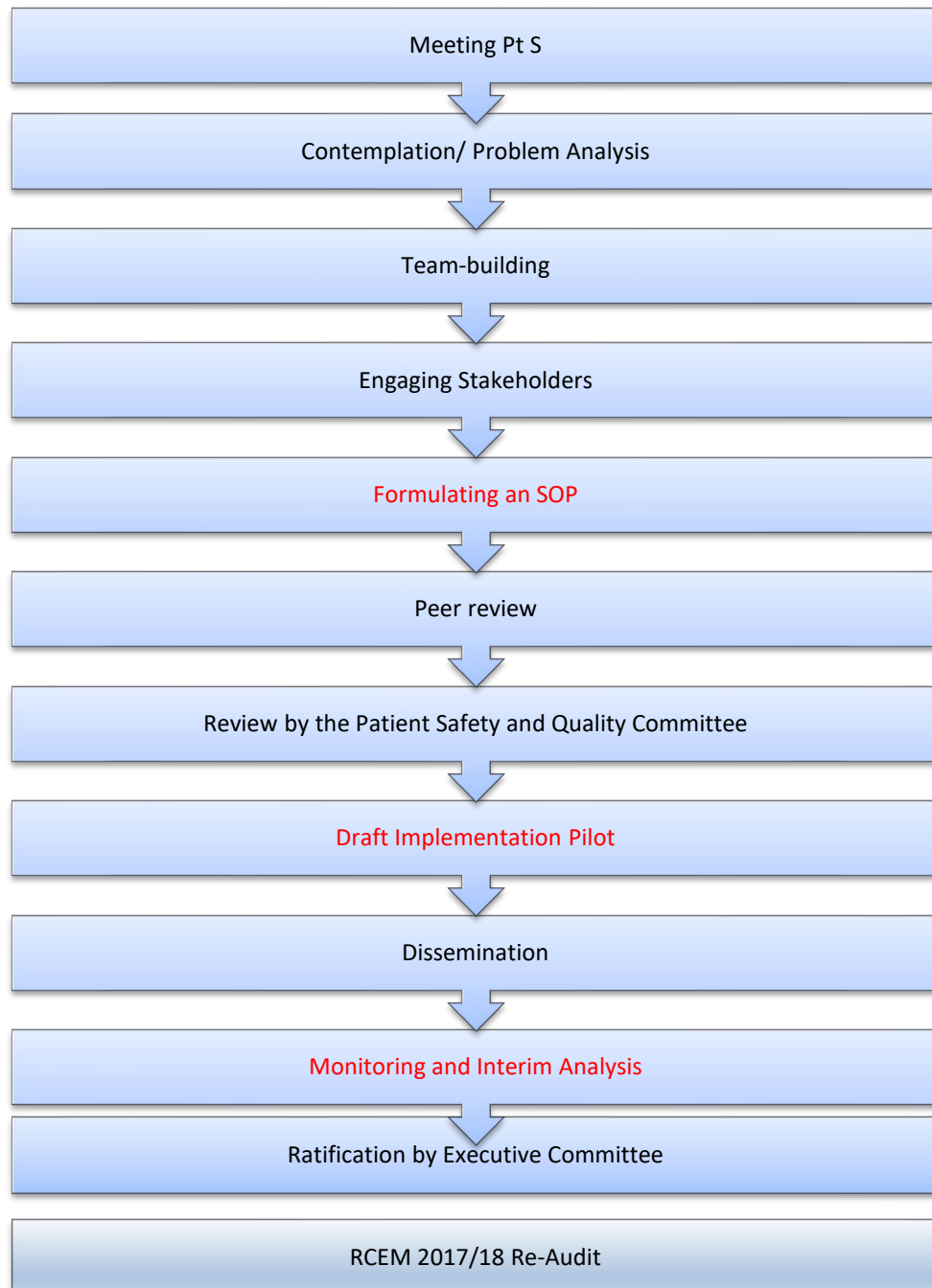
January 2018

Dr Curtis Emordi..........(Trainer)

Dr James Klewe..........(Candidate)

Overview of the project

This outlines the processes involved in the QIP.



It was a Saturday morning a week after my arrival to Princess Alexandra Hospital (PAH) as an ST4. Hand-over was completed and the middle grade on nights asked me to undertake procedural sedation on Mr. S who had attended the ED with a dislocated shoulder. I was pleased to undertake my first sedation in this new ED.

I did my usual patient assessments to ascertain suitability for procedural sedation and asked the resus nurse for the monitoring for sedation and how documentation was undertaken. I was asked what monitoring I would like as “everyone does it differently here”, and informed that the patient notes were used for documenting the procedure. I was slightly perturbed at this point having worked the previous year in a tertiary MTC with paperless systems including “narrators” for trauma and sedation documentation.

I completed my procedural sedation and a colleague reduced the patient’s shoulder. Everything went well, Mr. S fully recovered uneventfully and despite the delays went home happy. I printed a discharge information leaflet from the RCEM website as the ED did not have one, and arranged follow-up.

I was not quite so pleased. In fact, I was very concerned primarily regarding how adult procedural sedation was being undertaken without the safeguards of the standards specified by the Royal College of Emergency Medicine instituted in 2012 to ensure ED procedural sedation is as safe as possible for patients.

Introduction

PAH is a DGH on the outskirts of London, seeing 101,910 ED attendances per annum and led by 6.5 WTE Consultants. Additional Medical Staff include 2 training STRs and 4 ACCS trainees. Adult Procedural Sedation is undertaken by 3 of the ED Consultants, with a longstanding informal arrangement of support from the Anaesthetic Department to help in the ED should a patient need sedation. None of the regular Middle Grade doctors procedurally sedate patients and intermittently a MG Locum may undertake such a procedure with Consultant (and patient!) consent.

The Resuscitation Room is a 3-bedded unit with new monitors capable of capnography. There are generally 1-2 nurses based in resus per shift and others may be allocated if needed, according to a Nursing Flexibility Protocol.

Adult Procedural Sedation (APS) in the ED is the administration of sedatives with or without analgesics to alter the conscious level of the patient so that a procedure may be undertaken that would otherwise be unpleasant (painful, distressing or difficult to perform when a patient is fully conscious). Undertaking specific safeguards mitigate the associated risks and minimise potential harm to the patient. This is achieved by meticulous preparation by appropriately trained staff and combined continuous monitoring of vital functions until the patient is restored to their normal conscious state.

These safeguards relate to the location of the procedure, patient assessment and selection, appropriate monitoring and staff, continuous oxygen provision, with recovery and disposition of the patient. The practice of APS in the Department needed to be streamlined and comply with national standards of care¹. This included improving patient safety by ensuring that all aspects of the patient preparation and the environmental set up were optimised to ensure the safe undertaking of a procedure known to have the potential to harm patients

Discussion and Change Plans

The Trust Guidelines on the Intranet did not include a clinical policy relating to APS. Discussion with the ED Consultant Lead confirmed the absence of a policy covering this procedure. Initial engagement with the Clinical Lead resulted in the mutual recognition that this certainly was an area of clinical concern, which had yet to be addressed. Further discussions highlighted there were no financial resources available for a costly project and a low-tech approach was necessary to instigate any change of practice.

During a progress meeting with my Educational Supervisor discussion turned to how to effectively address these concerns and how to potentially formulate a Quality Improvement Project (QIP). Changes made to the practice of APS in the ED would enhance safety, quality, accountability and governance. Demonstrating an improvement in Quality would be challenging solely based on a Policy.

Concept/Plan

Good practice and the initiation of a Standard of Care in the form of a Standard Operating Procedure (SOP) governing the requirements to undertake APS in the ED would standardise care. Encompassing separate sections of this SOP which would be incorporated into the patient clinical record would further strengthen clinical governance with improvements in data collection and accountability.

The use of a proforma for contemporaneous documentation of procedures requiring APS is supported by RCEM. Discharge information and advice are available on the RCEM websiteⁱⁱ as are the expected standards to maintain patient quality and safety.

This SOP should outline all expected standards pertaining to APS and include printable discharge patient information leaflets, a sedation proforma printed and kept separately in an accessible folder, along with a time-out style checklist. This would if achieved, demonstrate quantifiable change and aim to show an improvement in patient care.

Simultaneously the RCEM audit of current practice in 2015/16 was undertaken whilst initiating engaging with the relevant Stakeholders.

Stakeholders

Engagement with the Associate Medical Directorⁱⁱⁱ (AMD) who held responsibility for quality and safety within the Trust and the Clinical Director for the Surgical and Anaesthetic Directorate was key. A relationship had already been established during my placement for ST2 Anesthetic training in PAH.

Communication was initially through face to face meetings with the sound boarding of ideas and inclusions for the project. Perspectives from both an anaesthetic and management standpoint complemented the ED view, thus providing a more detailed objective view of any problematic areas. Support and progress assessment were then undertaken via email.

Support for the QIP was clear, with the AMD seeing the potential to utilise this 3-part SOP model to address other Quality and Safety issues within the Trust, primarily to improve the safety, quality and governance to many different invasive and non-invasive patient procedures.

NatSSIPs was introduced in 2015 by NHS England Patient Safety Domain^{iv}. This strives for

improved patient safety whilst invasive procedures are undertaken. This programme aims to introduce a “Time Out” prior to, during and after all invasive procedures. The implementation of this into the SOP ensures compliance with NatSSIPs and the local Trust variance called LocSIPPs.

The STOP! CHECK process introduced in the SOP, where a “time-out” is mandated to ensure the situation is optimised prior to undertaking a procedure. The AMD was involved in implementing the NatSSIPs to the Trust and “time-out” is an important part improving safety. This revolutionary model conceived by Gawande et al for the World Health Organisation(WHO.^v) Such meetings resulted in the proposal to incorporate this process in to the SOP, as a STOP! CHECK. Facilitating essential ‘think time’ to ensure availability of appropriate resources to perform the procedures and manage any complications.

Processes

After the initial plan to undertake all the work required single-handedly, pressures mounted it became apparent that a team approach was not only necessary but essential. The team comprised: myself as completer/ finisher and an FY2 as monitor/ evaluator with the Chairperson as the overseeing consultant.

The QIP was to have a SMART^{vi} structure, based on the mnemonic where each letter represents Specific, Measurable, Achievable, Results orientated, and Time bound. This format was first mentioned in 1954! For this project our SMART structure is outlined below.

S- Improving the Quality and Safety of Adult Procedural Sedation.

M- Using the RCEM APS Audit as the Pre-QIP Reference, the Proforma would be implemented as a Pilot and then interim analysis would be undertaken following the identical structure and format as the RCEM Audit showing the impact of the Pilot introduction

A- Assignment of roles within the Project team.

R- RCEM National Audit on APS will be repeated in 2017/18 which should support our outcomes.

T- introduction of Pilot Proforma as part of the QIP and interim analysis after 3 months. Whole project completed within a year.

Royal College of Emergency Medicine

RCEM^{vii} published 7 Quality Standards relating to APS, in 2012, after consultation with the Royal College of Anaesthetists and the AAGBI^{viii}, which recommended the minimum safe Standards necessary to undertake APS in the ED. They outlined standards as fundamental (F) where “mandatory requirements which providers are expected to achieve at all times” and developmental (D) where “ED should be working towards achieving these standards in the future if not met already.”

STANDARD	GRADE
1. Patients undergoing procedural sedation in the ED should have documented evidence of pre-procedural assessment, including a) ASA grading b) Prediction of difficulty in airway management c) Pre-procedural fasting status	F
2. There should be documented evidence of the patient's informed consent unless lack of mental capacity has been recorded	D
3. Procedural sedation should be undertaken in a resuscitation room or one with dedicated resuscitation facilities.	F
4. Procedural sedation requires the presence of all the below a) a doctor as sedationist b) a second doctor, ENP or ANP as procedurist c) a nurse	F
5. Monitoring during procedural sedation must be documented to have included all the below a) Non-invasive blood pressure b) Pulse oximetry c) Capnography d) ECG	F
6. Oxygen should be given from the start of sedative administration until the patient is ready for discharge from the recovery area.	D
7. Following procedural sedation, patients should only be discharged after documented formal assessment of suitability, including all the below a) Return to baseline level of consciousness b) Vital signs within normal limits for the patient c) Absence of respiratory compromise d) Absence of significant pain and discomfort e) Written advice on discharge for all patients	F F F F D

Data Identification and collection

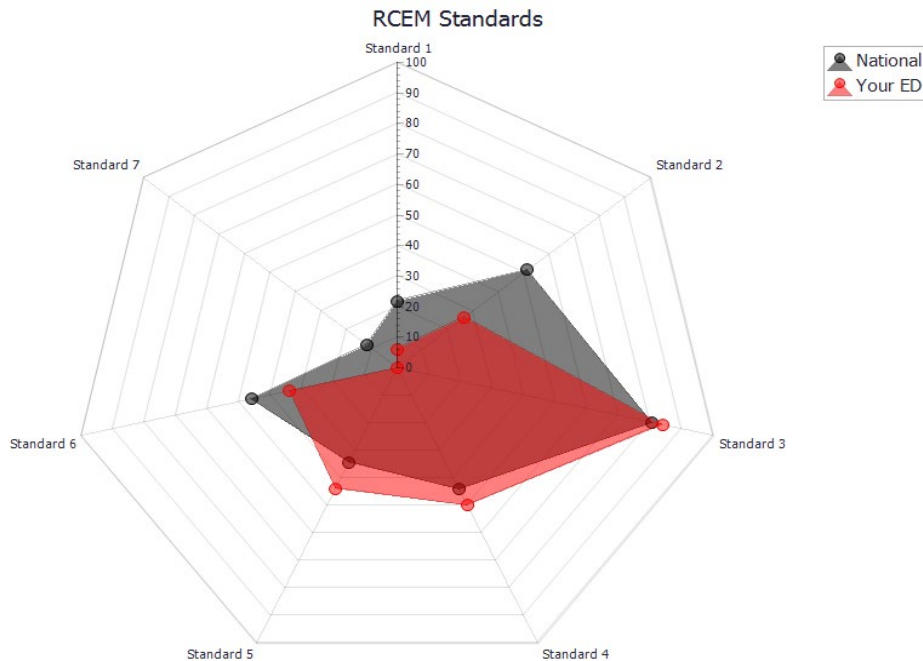
Undertaking, collecting and submitting the data to the 2015/16 RCEM APS National Audit was to serve as the baseline data in this QIP.

Patient cases included for data collection for the 2015/16 RCEM audit of APS were identified primarily from the controlled drug (CD) book, IT coding searches for 'dislocation;' "manipulation" and a search of the plaster technician's logbook, as they would attend to plaster any fracture manipulations.

The CD book proved useful for searches of ketamine, fentanyl, midazolam and morphine, However the use Propofol as a sedative could not be tracked this way. Coding of patients using the computerised system looking for dislocation/ sedation/ fracture dislocation/ plaster

cast/ with the help of the IT team picked up a more cases, this however generated an enormous volume of data which needed evaluating for inclusion by manually reviewing each case.

The data was submitted to RCEM in December 2015 with a report issued in April showing the National Outcomes and those for PAH. The benchmark for each of the 7 Quality Standards as set out in 2012 by RCEM was 100%. The outcomes are shown in the graph below for each Quality Standard.



The Executive Summary is shown below for the standards achieved nationally and for PAH for 2015/2016^{ix}

SOP Development

Decisions were finalised regarding the purpose of the final SOP. An Standard Operating Procedure for Adult Procedural Sedation would be written and submitted through the Policy Teams for incorporation into Trust Guidelines. This would include a full description of the procedure and expected standards to be adhered to whilst undertaking APS. The SOP would also contain discharge advice, a STOP! CHECK and the Proforma. The inclusion of extractable clinical sections as a Sedation Proforma and Patient information leaflet which would simply be printed out and utilised.

As clinicians we chose to develop a clinically educational document which would act as a point reference outlining the expected methods for undertaking APS in the Resus at PAH. The formatting needed in terms of the layout, contents and structure was considered jointly by the team.

Resources were identified using standard search parameters primarily initially commencing from the RCEM site and following the search strings. This provided documents specifically relevant published by the Heart of England Foundation Trust (HEFT), Bristol Royal Infirmary and Manchester Royal Infirmary amongst many others. Colleagues were approached at

Addenbrooke's and Broomfield Hospitals and kindly engaged in the process by sharing documents and procedures.

The availability of a suitable Proforma, which for me was the crux of the project, was more challenging to identify. Having reviewed all that came from the searches, none encompasses all that the team felt should be included. Some were too long and cumbersome, others lacked the clarity and flow of safe processes. Thus, the formulation of an original Proforma was necessary to progress. This entailed some creative application by the Monitor/Evaluator to create a unique and specific styled document. Patient discharge information included was sourced directly from the RCEM Guidelines.

Once this was completed the SOP underwent peer review informally by the ED Consultants to identify any obvious errors or omissions. Once amended, the document was formally Peer Reviewed by 3 ED Consultants in addition to the ED Lead acting as chairperson, 2STRs, the AMD, and 2 ST1s. This formal Peer Review formed part of the submission to the PS&Q Committee.

All the relevant stakeholders agreed on the format of the finalised document as submitted to the Policy team prior to submission to the PS&Q Committee. Representation at this meeting was led by the Chairman. The SOP was accepted and passed through to the next stage of formal submission to the Trust Executive Committee.

Following acceptance by the PS&Q Committee, the tools in the SOP could be clinically implemented in draft format. A red A4 binder was placed in Resus with a copy of the STOP! CHECK (SOP, Appendix 3) attached to the inside left cover. The locale for had been agreed by the Matron and ED Lead Consultant with this information disseminated via email to the Departmental Team members.

Implementation

Primarily, discussion amongst the team focused on the mechanisms of implementation and sustainability. There followed multidisciplinary discussion involving representatives of all grades of nursing and medical staff regarding how to maintain the enthusiasm and impetus of a newly developed project.

A review of the literature regarding the models of change management and associated processes relating to the implementation and sustainability of a new working system was educational and powerful. Policy implementation and change management is demonstrated succinctly by the 4 stages of the 'Change Curve' by Kubler-Ross^x. Underpinning this project was the overwhelming feeling that the Status Quo was not providing the safest or best care so Stages 1 and 2 of the Kubler-Ross Model were simple to overcome, and immediately getting valuable support from colleagues. Thus, change in the form of this QIP was readily accepted, progressing soon after to commitment.

The Change Curve^{xi}



Information dissemination and the challenges involved.

The subject of information dissemination within an organisation is complex and multifaceted. The medical profession needs to consider how industry and other similar businesses disseminate vital information to workers in a way that is purposeful and measurable^{xii}.

Healthcare related dissemination of information occurs generally via the blanket email with or without a read receipt for “important” messages or via the face-to-face format. The utilisation of email is quick but does not guarantee information has been digested. Interpersonal verbal communication with a phased repetition is thought to be a better. Nursing and Medical staff handovers, safety huddles, teaching sessions and direct contact were chosen for this project. Personal explanation with active learning were the planned outcomes of these brief interventions. Anaesthetic Departmental teaching sessions held for their Trainees were attended. These were the very Anaesthetic team members who might be called to and may attend the ED to be involved in APS. They were specifically integrated into the process to promote engagement across the teams and to address any queries or concerns.

This was also followed up by a reminder email after the learning sessions, which included a point of reference for any queries or questions which may have arisen since. Plans were initiated to include Medical and Nursing Staff Inductions as specific forums for education and further dissemination.

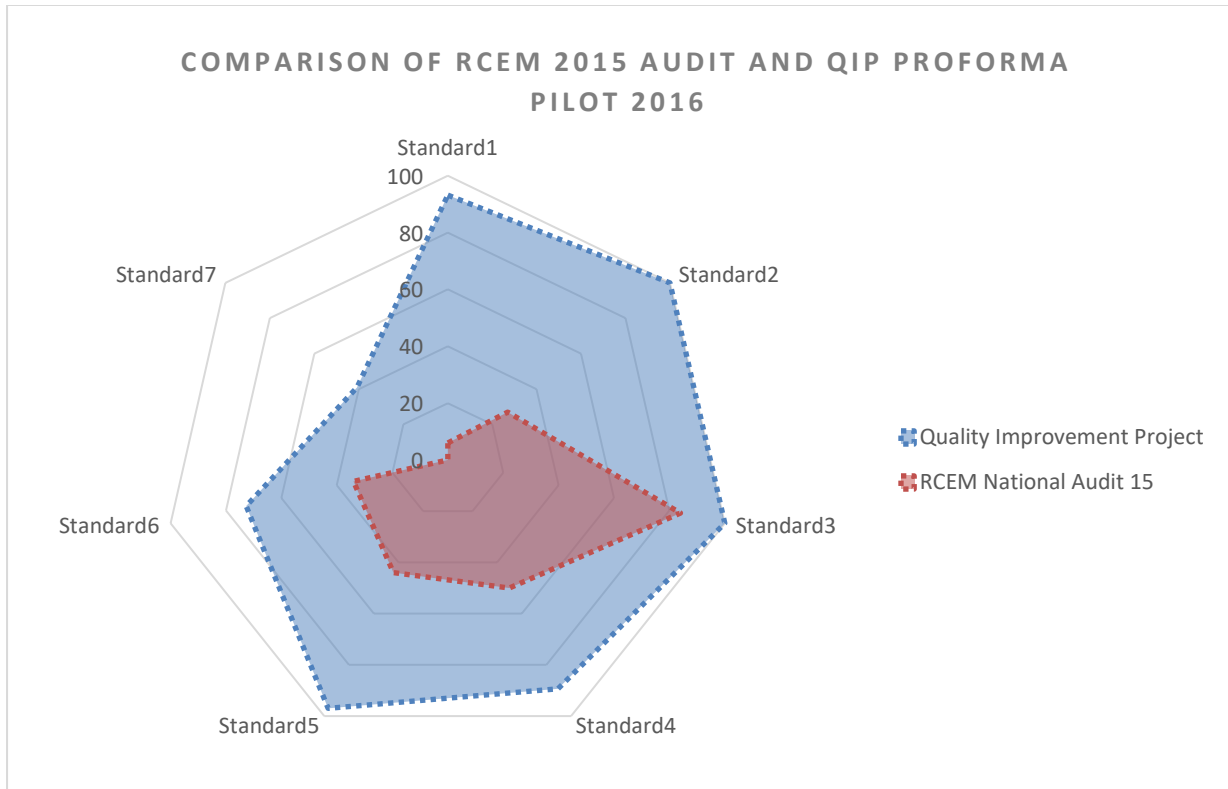
Measuring and outcomes

Due to the RCEM National Re-audit occurring just outside the timescale of this project in 2017/18 and alternative method of analysing the impact of the project was sought. An interval audit utilising the same data collection methods and analysis as the RCEM Audit, was planned to assess effectiveness of introduction of the subsections of the SOP, primarily the Proforma.

After 3 months of piloting the project, the completed draft proformas were analysed to determine the effectiveness of the change and the degree of uptake and completion. The

same process was undertaken as for the RCEM 2015/16 National Audit. All patients undergoing APS and not just those with a completed proforma needed to be identified for the Pilot Review. This is as outlined in the section on data collection above, to avoid selection bias.

Analysis of the second data set obtained from the Pilot Review of was conducted utilising the same model that RCEM used in the evaluation of practice for the National Audits. This resulted in two comparable data sets relating directly to PAH from before and after the implementation of the draft proforma. (Refer to Appendix A for data.)



The differences between the pre-and post- pilot proforma audit are highlighted in the above chart.

The practice changes since implementation over a short few months shows absolute compliance with Standards 2 and 3 and greater than 90% with Standards 1, 4 and 5. Standard 7 has changed from 0 to 40.9%.

Scrutiny of the Pilot Proformas indicated completion dates were as would be expected for the number of procedural sedations undertaken in the PAH ED. This suggested that uptake of using the Proforma was almost universal, as identified by case analysis, using the identical methods undertaken for data identification and collection in the first audit (RCEM 2015/16 APS Audit.) Failing to identify all occurrences of sedations and incorporating them into the study is an unavoidable but equal bias which should be applicable to both data sets (e.g. selection bias.) Until the time of searchable informatics are functional and available incorporating a complete data set this problem is as such unavoidable.

The step of implementing the Pilot Proforma as part of the SOP, whilst awaiting full

ratification and publication on the Intranet, has shown that people really engaged with the whole process.

Formal re-audit of the APS National RCEM cycle is currently underway for the cycle 2017/2018. This data will be incorporated into this document to complete the process. Expectation is that the outcomes should support the Pilot Analysis of a significant improvement in quality.

Reflection

Having worked alongside staff at PAH ED in ST2 and ST4 training years, I have personally witnessed a commitment to offer patients the best care possible. There is also awareness of the flaws and constraints with the current working practices and a drive to change. When I broached the concept of the planned changes with multiprofessional colleagues in the ED, there was an immediate shift to stage 3 of the Change Curves^{xiii}. They could envision what I could and how this QIP had the potential for improving the safety of clinical care for patients almost immediately. I was exceptionally fortunate that this positive change from the status quo was welcomed following brief interactive sessions. Mainly these involved a face-to-face discussion with the staff on the shop floor explaining the purpose and role of the sedation file, use of the Proforma and 'STOP! CHECK' timeout.

Support was enhanced by the recognition that the change of process standardised monitoring in the resus room, record keeping, improved communication as well as being a cognitive prompt whilst not impacting greatly upon the nursing staff workload other than locating the "sedation file." Occasionally prompting clinicians to complete the proforma, with obvious clear benefits to patient safety and improvement in clinical quality following the consistent use of STOP! CHECK timeout. Actually, there was no opposition to this project at any time with engagement of the Medical and Nursing Staff at all levels to be unchallenging. I found immense professional and personal satisfaction upon witnessing members of the nursing staff educating clinicians prior to undertaking procedural sedation. I saw nurses on several occasions applying the appropriate monitoring and oxygen prior to starting the procedure and then engaging during the STOP! CHECK timeout.

These simple steps, introduced via this QIP, immediately had a direct impact on improving safety, care and risk minimisation. Furthermore, these actions also ensured shop floor compliance with 4 of the 7 quality standards.

There was suggestion based on the outcomes of this project as to whether this could be developed Trust wide as part of the NatSSIPs^{xiv} project by using the model developed of proforma, SOP and STOP! CHECK to increase the safety for every invasive procedure undertaken. RCEM has since generated a generic Procedural Checklist^{xv}.

I found the initial contemplation phase valuable in evaluating how to maximally improve patient safety and quality of care whilst undergoing APS. I wanted to implement a robust and enduring process., Writing a policy or SOP incorporating the extractable tools would be a way of achieving this. I recognised that the QIP needed substance and support at every level and actively sought this. With both the Executive Board and PS&Q Committee ratifying the SOP it would have the support and backing to ensure longevity and thus ensure embedding of the processes into Trust culture.

Having registered the RCEM Adult Sedation Audit as per Trust protocol I engaged with the Patient Safety and Quality Team regarding how to write and present a formal Trust document. I was sent the "document" template after trying to explain to them what I was

hoping to write. Although I knew what and how to write it I was not certain until the submission as to what type of document this would be: A Policy, Guideline, SOP or Toolkit.

Initially I was reluctant for others to be involved in 'my project' however once accepting that alternative skills, influences and opinions were beneficial to the project I found working within a team to be instrumental in the project's success particularly around areas such as data collection, representation at stakeholder meetings and dissemination of information.

Writing the SOP was significantly harder and timelier than I had anticipated, something that certainly increased the pressure and stress of the situation. With countless drafts and many hours applied to the writing and formatting of the document until it was acceptable to the team. At this point I realised the value of including my F2 colleague as monitor-evaluator as her IT talents, expert eye for detail and minute corrections and graphic design skills came to the forefront.

The process of peer review was both enlightening and frustrating. During the informal review several appraisers felt a need to find a miniscule grammatical error or something insignificant which they would change. The final review revealed a consensus opinion agreeing that the final SOP was developed to a satisfactory level. I felt it was invaluable to have the input and support of my colleagues as I feel this contributed to the success of the project and ultimately benefited the transition of working practices surrounding APS.

Unfortunately, I was unavailable to attend the PS&Q Committee meeting when the SOP was presented and approved, something that I regret but however was unavoidable. I was so proud to have even achieved this step, moving forwards we went live with the DRAFT Proforma as a pilot.

The Meredith Belbin model^{xvi} for fulfilling team roles was utilised with roles and responsibilities assigned. This became a fluid dynamic with interchanging of the many roles enacted due to the size and nature of the team. Ensuring all members were aware of their responsibilities at specific points in the project was paramount. Roles tended to morph from one to another individual with several roles being undertaken by a single team member. This naturally occurs in a smaller team.

The 'STOP! CHECK' was explained to staff at the various forums and was secured inside the A4 sedation binder where the APS proformas were kept. Having another A4 binder in the Resus room was not an ideal location. This was initially frequently tidied away or moved until its purpose, and the necessity of the location was understood by all. This aspect of the project enabled the SOP to achieve compliance with NatSSIPs and the local version (LocSIPPs) of standardising patient safety whilst undergoing invasive procedures.

Personally, I have come to understand the processes of change management, stakeholder engagement and policy writing within an NHS Trust.

Seeing the figures of the post-QIP analysis is hugely rewarding and a testament to our hard work and dedication. Finally having the SOP available on the Trust Intranet, as a reference tool, for anyone undertaking APS in the ED has been immensely rewarding. Trust and professional colleague buy-in was essential to the SOP safeguarding this implemented process, ensuring it was sustained even after I rotated on from this ED.

I returned to PAH a year later to undertake a locum shift. I was ecstatic to find my file with several recently completed and spare blank proformas in the Resus room. I have been informed by the Chairman of the team that the Trust Executive Committee formally ratified the SOP and is now a policy document as of November 2017. I await with interest the results of the RCEM 2017/18 APS audit from PAH.

I planned that the project was formally adopted by a named Consultant upon my leaving the trust in July 2016. I verbally handed responsibility to the incoming STR to ensure copies of the Proforma and the discharge information could be kept available. A commitment to the ongoing success and evidence of embedding into the Trust culture at a Corporate level is that this project is mentioned in the Quality Report for year ending 2016 at PAH^{xvii15}.

We have gained enormous pride in having created this project as a cohesive team.

Learning Points

The addition of a patient satisfaction score to the Proforma, underneath the discharge advice for completion upon discharge from the ED or as a delayed encounter/ email/ questionnaire follow-up. Patient satisfaction is paramount.

A sedation book recording all undertaken APS could also have been part of the implementation is part of the QIP giving a clear audit trail of data. This would improve Governance and data collection; however, it was felt that the progress should be toward a paperless system and the same issue of ensuring proper use in a contemporaneous manner as the Proforma would apply. It was felt that the implementation of the QIP as decided at the beginning would be an appropriate start with other additions later if felt necessary.

A 41% improvement in Standard 7 may have an association with QIP but indicates that further work is needed to consolidate the dissemination of information. Medical Induction to the Emergency Department now includes highlighting standardised sedation practices as developed by this QIP.

Summary

A Quality Improvement Project was undertaken to address concerns regarding Patient Safety, Quality and Governance whilst undertaking Adult Procedural Sedation in the ED. This included documentation, monitoring, adherence to RCEM Quality Standards, accountability and governance. An SOP was developed which encompassed a Sedation Proforma to complete contemporaneously, a timeout checklist to follow and written patient information leaflet for presentation upon discharge from the ED.

A 3 month follow up Pilot Analysis following introduction of the Sedation Proforma has already shown significant improvements in the way APS is undertaken in the ED as a response to the implementation of this QIP and significantly improved fulfilment of the RCEM Quality Standards for Adult Procedural Sedation in the ED.

This QIP also ensured compliance at PAH for both the NatSSIPs and LocSIPP directives from NHS England for invasive patient procedures.

The SOP was incorporated into Trust policy in November 2017 with the proforma still being utilised as an essential tool when undertaking adult procedural sedation. I am confident that in Spring 2018 the outcomes of the National RCEM Adult Procedural Sedation Audit will clearly demonstrate the value and importance of the work undertaken.

Appendices

Appendix A

Outcome Measure	RCEM 2015/16-%	QIP Pilot Audit 2016 - %
QS1	6	93.2
QS2	27	100
QS3	84	100
QS4	50	89.4
QS5	44	97.0
QS6	34	72.7
QS7	0	40.9

Appendix B

Examples of actions taken following review of national clinical audit reports

Name of national audit	Actions completed
Adult Asthma	Two respiratory nurses have been employed and a specialty doctor has been appointed to review all respiratory patients including COPD/Asthma in Emergency Assessment Unit (EAU).
National COPD Audit Programme	Two respiratory nurses have been employed and a specialty doctor has been appointed to review all respiratory patients including COPD/Asthma in EAU.
National Diabetes Audit - Adults	To improve recording of care processes, in particular ensuring that all patients have urine microalbumin level recorded, further training in diabetes outpatient clinics has been delivered. A new electronic medical record form has been introduced which auto-calculates BMI for ease of recording.
Elective Surgery (National PROMs Programme)	The Trust has reviewed its Enhanced Recovery Programme, standardising the anaesthetic techniques and analgesia regimes, and introduced physiotherapy follow-up classes to take ownership of patients' rehabilitation post hip replacement.
Falls and Fragility Fractures Audit Programme (FFFAP)	A dedicated escalation bed has been assigned.
Procedural sedation in the emergency department (ED)	A new procedural sedation proforma for adults in ED has been locally produced and introduced.

Appendix C

TRUST POLICY GROUP MEETING COVER SHEET

Date of Meeting		
Document Title	<u>Standard Operating Procedure (SOP): Sedation of Adult Patients in the Emergency Department</u>	
Lead Director/Manager	Dr C Emordi	
Document Author	Dr James Klewe	
Consultation and Communication with Stakeholders, please list:		Date:
Committee / Group Document approved by:		Date:
Freedom of Information (FOI) Status	Unrestricted <input checked="" type="checkbox"/> Restricted <input type="checkbox"/> (select using <input checked="" type="checkbox"/>)	
Action Required	Note <input type="checkbox"/> Ratify <input checked="" type="checkbox"/> Discuss <input type="checkbox"/> Inform <input type="checkbox"/> Assure <input type="checkbox"/> Other <input type="checkbox"/> (specify) (select using <input checked="" type="checkbox"/>)	
Executive Summary	SOP and Procedural Guidelines for the safe sedation of adults in the Emergency Department. Introducing a sedation STOP! CHECK list, proforma, equipment list and discharge advice sheet.	
Recommendation		
Trust Strategic Goal		
NHS Constitution	All staff	
Implications		
Risk		
Legal/Regulatory		
Resources		
Appendices to Cover Sheet		

Standard Operating Procedure (SOP):

Sedation of Adult Patients in the Emergency Department

PAHT document reference	<i>State policy reference</i>
Version	<i>V0.04</i>
Author / Reviewer	<i>Dr James Klewe</i>
Date ratified	<i>State the date of ratification (dd.mm.yyyy)</i>
Ratified by	<i>Trust Policy Board / Board of Directors / state other</i>
Issue Date	<i>State date the policy will be in force (dd.mm.yyyy)</i>
Review date	<i>State the review date (dd.mm.yyyy)</i>
Target audience	<i>All clinical staff</i>

The current version of any policy, procedure, protocol or guideline is the version held on Trust Public Folders. It is the responsibility of all staff to ensure that they are following the current version

Signed.....
..... Chair of Trust Policy Group

Emergency Department

Standard Operating Procedure (SOP): Sedation of Adult Patients in the Emergency Department

Dr James Klewe

20/3/2016

Abstract

This document outlines the accepted standards for Adult Procedural Sedation in the Emergency Department at PAH. It has been developed using the RCEM standards with the emphasis on safeguarding excellent patient care and maintaining patient safety.

From initial assessment with a mandated and documented specific sedation history and examination through to compulsory levels of equipment and monitoring.

Procedural guidelines for medications to be used to ensure gold standard patient care. Included are Pre-Sedation STOP! CHECK challenge and respond safety lists, a proforma to support governance and pre-discharge advice for the clinician and the patient.

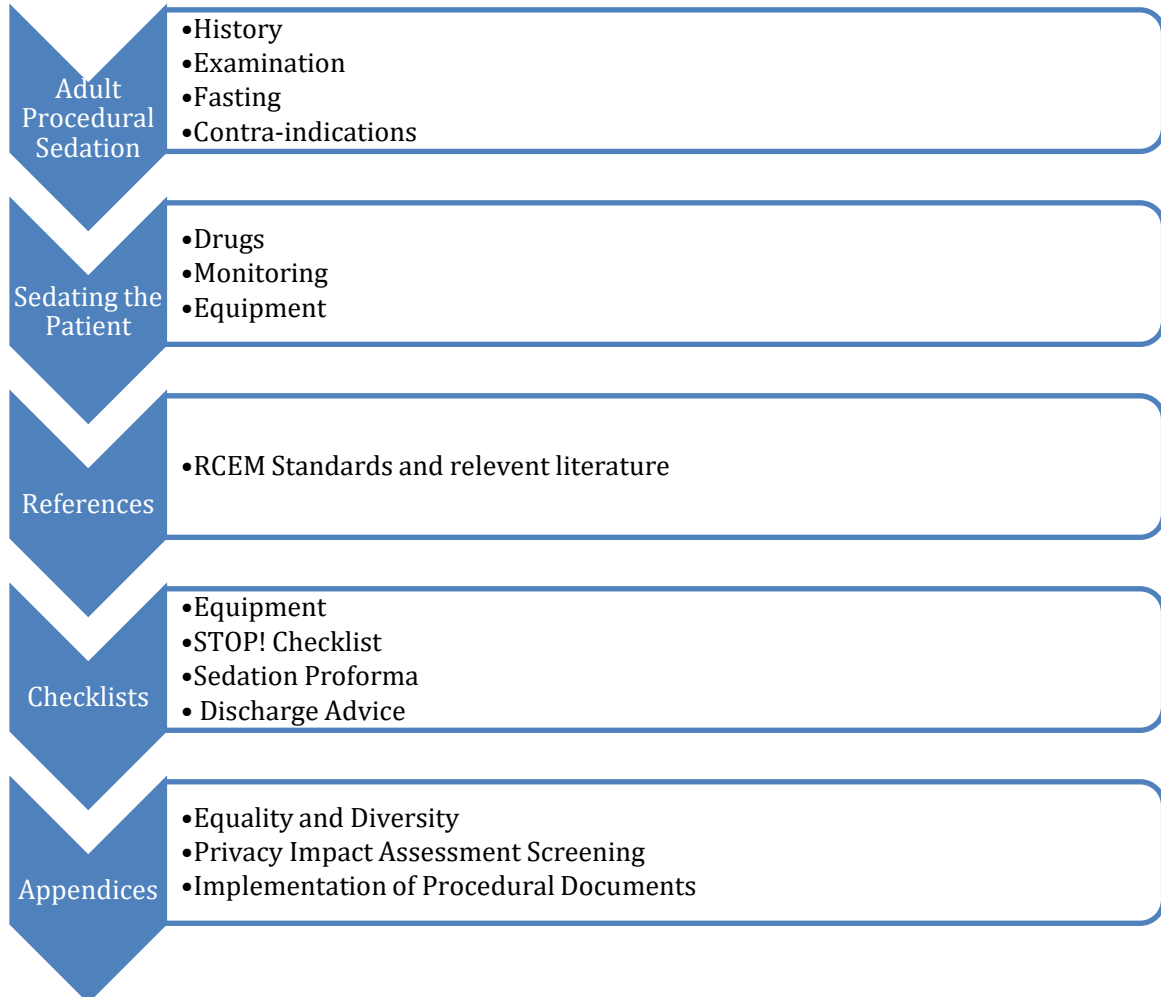
This document has arisen following concerns upon completing an RCEM National Audit on the Procedural Sedation of Adults in the ED.

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1. QUICK REFERENCE GUIDE

Use this SOP for undertaking SAFE Procedural Sedation in the Emergency Department



2. Definitions

SOP	-	Standard Operating Procedure
PAH	-	Princess Alexandra Hospital
RCEM	-	Royal College of Emergency Medicine
ED	-	Emergency Department
Resus	-	Resuscitation Room in the ED
ASA	-	American Society of Anesthesia
ECG	-	Electrocardiograph
BP	-	Blood Pressure
HR	-	Heart Rate
SpO2	-	Oxygen Saturations
IV	-	Intra-venous
GABA	-	Gamma Amino Butyric Acid
mg	-	milligrams
kg	-	kilograms
mls	-	millilitres
ET CO2-	-	End Tidal Carbon Dioxide
BVM	-	Bag-Valve-Mask
LMA	-	Laryngeal Mask Airway
NP	-	Nasopharyngeal
OP	-	Oropharyngeal

Emergency Department Standard Operating Procedure

Sedation of Adult Patients in the Emergency Department

1. Reason for Development

- To standardise/improve patient care.
- Risk reduction in the Emergency Department
- To enhance audit and governance.

2. Introduction

Procedural Sedation is a common practice in Emergency departments and is often performed in conjunction with clinicians from other specialties. The aims are to relieve anxiety, reduce pain, facilitate a procedure and provide amnesia. Sedation can produce a continuum of states, ranging from minimal sedation (anxiolysis) through to general anaesthesia. This document specifically applies to moderate sedation (i.e. "conscious sedation"). The drugs used can produce both cardiovascular and respiratory complications.

Using a standard driven SOP with guidance along with knowledge and familiarity of the drugs involved are vital to minimise the potential risks to the patient.

It is not acceptable for single operators to be sedating and performing a procedure in the ED. The minimum personnel required are two doctors and one nurse. The doctor supervising sedation should be familiar with this document and be trained to recognise and have the skills to deal with potential complications, including advanced airway skills.

3. Scope/ Purpose

Adult patients requiring Procedural Sedation in the Emergency Department.

This SOP is to guide the clinicians (ED or other specialty) safely deal with adults who need procedures requiring sedation in the emergency department e.g. joint reduction, fracture manipulation.

Some components are SOP and MUST be undertaken whilst others are a procedural guide.

3.1 Sedationists

Sedationists must have ideally attained Initial Assessment of Anaesthetic Competence (IAC) during formal anaesthetic placement and subsequently have completed 3 supervised Sedations in the ED. In lieu of the IAC, the completion of 5-10 supervised Sedations overseen by competent Senior Clinicians and being "signed off" as competent. This list is in the Adult Sedation file in the Resus Room and includes members of the Anaesthetic team with provisions (as noted below.)

3.2 Anaesthetists

Anaesthetic colleagues holding the IAC and deemed competent by the Duty Anaesthetic Consultant may undertake Procedural Sedation in the Resus Room in the Emergency Department in keeping with this SOP and the completion of the Sedation Protocol.

3.3 Pre-Sedation Equipment Checklist

(See Appendix 1)

This document outlines the expected pre-sedation checklist, peri-sedation observations required and post-sedation management.

4. History

A full history, including drugs, previous sedation or anaesthesia, allergies and fasting time must be undertaken and documented.

Procedural Sedation is contraindicated if any one of these applies

- Procedures involving stimulation of the posterior pharynx.
- Procedures that are more appropriately performed under general anaesthesia or in sterile operating theatre conditions.
- Patient is ASA grade >2.
- History of airway instability, tracheal surgery, or tracheal stenosis or abnormal facial anatomy.
- Active pulmonary infection or disease (including upper-respiratory infection, exception is for asthma).
- Head injury associated with loss of consciousness, altered mental status, or vomiting.
- Central nervous system masses, abnormalities, or hydrocephalus.
- Poorly controlled seizure disorder.
- Glaucoma or acute globe injury.
- Psychosis, porphyria, thyroid disorder, or thyroid medication.
- High predicted risk of being difficult to ventilate or with significantly abnormal physiological parameters.

4.1 Fasting

- Table 1 below outlines the current recommendations regarding patient fasting. ED Procedural Sedation must only be undertaken as an emergency or urgent procedure in the unfasted patient.

Oral intake in the prior 3 hours	Procedural Urgency ^b			
	<i>Emergent Procedure</i>	<i>Urgent Procedure</i>	<i>Semi-Urgent</i>	<i>Non-Urgent</i>
<i>Nothing</i>	All levels of sedation	All levels of sedation	All levels of sedation	All levels of sedation
<i>Clear liquids only</i>	All levels of sedation	Up to and including brief deep sedation	Up to and including extended moderate sedation	Minimal sedation only
<i>Light snack</i>	All levels of sedation	Up to and including dissociative sedation; non-extended moderate sedation	Minimal sedation only	Minimal sedation only
<i>Heavier snack or meal</i>	All levels of sedation	Up to and including dissociative sedation; non-extended moderate sedation	Minimal sedation only	Minimal sedation only

Table 1- Fasting Recommendations

4.2 Examination and Observations

The patient's airway must be assessed to identify features associated with increased risk of difficult intubation and/or ventilation:

- Obesity.
- Short neck, limited neck movements, dysmorphic face, reduced hyoid-mental distance (<3cm).
- Small mouth opening, protruding incisors, large tongue.
- Small jaw.

A focused physical examination including auscultation of the heart and lungs. Vital signs and observations-12 lead ECG (if over 60 years of age or any history of ischaemic heart disease), BP, HR and SpO₂ must be documented.

4.3 Environment and Staff

- Procedural Sedation should only take place in the Resuscitation room.
- There must be a tilting trolley, suction, oxygen, and equipment for advanced airway management.
- Senior Clinician present who has advanced airway management skills (3.1, 3.2)
- One Clinician for sedation while another Clinician performs the procedure.
- Intravenous access (ideally 2 cannulae) and supplemental oxygen administered.
- Nursing staff in attendance throughout and specifically during sedation and recovery.

4.4 Consent

- Written consent to be completed for the sedation in line with Trust Policy.
- Document verbal sedation consent on the proforma prior to any sedative administration.
- Separate consent for the procedure.

Section 4 points are MANDATORY PRACTICE and are essential for all Procedural Sedation

5. Administration of Sedation- Procedural Guideline

Intravenous sedative/analgesic drugs should be given in small, incremental doses that are titrated to the desired end-point of analgesia and sedation. In general, single agents are safer than polypharmacy though no one agent or regime is conclusively more effective than another. Clinician familiarity and experience with these drugs and potential side effects are most important.

5.1 Choice of Sedative Agent

The choice of Sedation agent depends on the type of procedure undertaken, familiarity of the user and patient characteristics. As a guide the following are appropriate Procedural sedatives:

- | | |
|-----------------------------|---|
| • Joint reduction: | Propofol with preceding analgesia |
| • Fracture manipulation | Propofol preceded by opioid or Ketamine |
| • Colles' fracture | Haematoma block with small dose Propofol/
Ketamine |
| • Cardioversion | Propofol or Ketamine |
| • Laceration suturing | Propofol, Ketamine, Midazolam |
| • Chest drain insertion | Ketamine, Propofol, Midazolam |
| • Transthoracic / IJ Pacing | Midazolam |

Propofol:

- A GABA receptor agonist with sedative and amnesic properties.
- 1% solution ONLY should be drawn up into a 10ml syringes, so 100mgs in 10mls.
- Starting dose: 0.25- 0.5mg/kg (usually 3mls of 1%), up to 10mls if titrated carefully to Sedation level and blood pressure. Less propofol is often required if given slowly. Loss of verbal contact is a key sign of the level of sedation/anaesthesia.
- Anaesthetic induction may be at only 0.5mg/kg, especially in elderly i.e. could be only 3mls for 60kg patient.
- Beware backflow from the octopus connector.
- Caution using propofol with opioids (respiratory depression).

Ketamine:

- A dissociative sedation/anaesthetic agent with analgesic and amnesic properties.
- Contraindicated in patients with cardiovascular disease, thyroid disease or if agitated and sympathetically stimulated.
- Beware different concentrations available.
- Intravenous: 0.25-1.0 mg/kg give slowly; add 0.5mg/kg as needed for prolonged procedures.
- Atropine 0.01mg/kg (min 0.1mg, max 0.5mg) should be made ready in case of bradycardia.
- Smaller doses of ketamine (e.g. 20mg, sometimes repeated) can be used to facilitate short procedures e.g. radial fracture manipulation, where a haematoma block has already been given.
- Beware emergence phenomena.

Midazolam:

- A short acting water-soluble benzodiazepine which at higher doses causes intense sedation (anaesthesia) and retrograde amnesia.
- Vial of 5mg Midazolam drawn up into a 10ml syringe with 5mls of normal saline (10mls in total) and labelled accordingly (0.5mg per ml).
- Dosage intravenously is initially 0.1 mg/kg (usually up to 5mg): small and elderly patients may require smaller first dose e.g. 1-2mg.
- Onset of action 30-60 seconds with peak action at 12min.
- Half-life of Midazolam is approx. 2hrs.
- May cause hypotension.
- Respiratory depression may be reversed with Flumazenil. The respiratory depression may be particularly pronounced if combined with an opioid e.g. fentanyl. Beware that re-sedation may occur if a reversal agent is used.

5.2 Patient monitoring- MANDATORY

- Close observation of airway and respirations by an experienced health care professional until recovery well-established.
- Drapes positioned such that airway and chest motion can be visualised at all times.
- Availability of oxygen supplementation with pulse oximetry and ECG.
- Supplemental oxygenation **MUST** be administered throughout the entire procedure. Oxygen should be initiated before any sedative is administered until after full recovery. **End tidal CO₂ monitoring is ESSENTIAL FOR ALL SEDATIONS**
- Blood pressure measured every 5 minutes.

- Level of consciousness must be continuously assessed throughout the procedure. Deep Sedation (level 3) is not appropriate for ED Procedural Sedation (See Appendix 2).

5.3 Possible complications- CALL FOR SENIOR HELP EARLY

- Laryngospasm/stridor (0.3%) – treat with adrenaline nebs (5ml of 1:1000); maintain airway with tight fitting mask, consider use of BVM, may need deepening of sedation/anaesthesia.
- Hypoxia from respiratory depression ($\text{SpO}_2 < 92\%$)- high flow O_2 with ETCO_2 monitoring.
- Hypotension (BP $< 90\text{mmHg}$)- trolley tilt, IV fluids, patient stimulation or pressors.
- Bradycardia (HR $< 50\text{bpm}$)- stimulate patient, atropine 500mcg IV.
- Increased level sedation (general anaesthesia)- protect the airway, oxygenate.
- Specific drug side effects (especially Ketamine)- secretions, give atropine 500mcg, keep calm and dim lights for emergence, 0.5-1mg lorazepam IV for extreme agitation.
- Vomiting or aspiration - tilt and suction.

5.4 Associated Analgesia

Consider if the patient has already received IV opiates pre-hospital.

Where possible, sedation should be augmented by local anaesthesia or pre-procedure analgesia (IV paracetamol). For severe pain (e.g. fracture/dislocation ankle) morphine should be given at least 10 minutes before Sedation. If this is not possible fentanyl can be used; see below

Fentanyl:

- A potent synthetic opiate with a rapid onset of action and short half-life.
- Stocked in 2ml ampoules of 50 $\mu\text{g/ml}$.
- Should be drawn up into a 2ml syringe (100 μg in total) and labelled accordingly.
- Dosage intravenously of 0.25-1.5 $\mu\text{g/kg}$ over 30 – 60 seconds.
- Beware apnoea if given with Propofol.
- May cause significant respiratory depression and hypotension.
- Give at least 3 minutes before sedation.

See Appendix 4- Procedural Sedation Proforma in the ED

6. Post-Sedation Management

6.1 Recovery Area

- Minimal physical contact or other psychic disturbance. Quiet area with dim lighting if possible (Ketamine Sedation).
- Advise parents or caretakers not to stimulate patient prematurely.
- Continue oxygen saturation monitoring.

- Will need continuous nursing observation until fully alert and responsive – beware if the patient has required a reversal agent as may become re-sedated.

6.2 Discharge Criteria

- Recovery depends on drug(s) used.
- Return to pre-treatment level of verbalisation, awareness and mobility.
- Normal vital signs and ability to take oral fluids.
- Give discharge instructions (see Appendix 5 advice sheet).
-
- Responsible adult to accompany patient if discharged.
- Written/ printed discharge advice sheet.

6.3 Audit and Governance

- The Emergency Department will regularly audit the use of Sedation against national standards. Any serious complications or near misses will be reported through the hospital incident reporting system and discussed at the quarterly ED clinical governance meetings.
- The accompanying Sedation proforma will be completed and copied with the original kept in the Sedation file for purposes of audit. The copy should be placed in the patients notes.
- Proformas will be completed for each Sedation undertaken.
- To implement changes following the Royal College of Emergency Medicine core audit December 2015 regarding Adult Procedural Sedation.
- Audit will be cycled every 6-12 months.

7. Training

Procedural Sedation training is beyond the remit of this SOP. Competency must be attained prior to undertaking Procedural Sedation (see section 2.2.) Standard mandatory training of healthcare providers working in the ED is appropriate to assist with Procedural Sedation.

8. Equality and Diversity Statement

This document complies with the PAH NHS Trust Service Equality and Diversity statement.

(See Appendices 6 & 7)

9. Disclaimer

It is **your** responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

11. Duties

The Chief Executive is responsible for:

- Governance compliance for the SOP and procedures.

Directors, Managers or Consultants must ensure that:

- Staff are made aware of the SOP and how to access it.
- The SOP is implemented correctly.
- Staff understand the importance of issues regarding Procedural Sedation in the ED
- Staff are trained and updated in Sedation
- The SOP is audited, and the audit details are fed back to staff.
- Ensure that Sedation Proforma, patient leaflets and SOP are available as required.

Clinical staff delivering care must:

- Adhere to the SOP and procedure.
- Notify their line manager of any training needs.
- Participate in the audit process.

Dissemination

- Through ED network to all clinical nursing and medical staff.
- Trust group emails.
- Joint ED/ Anaesthetic Meetings.
- Trust induction.

Storage

Accessed via the x-drive in the Emergency Department Policies and Procedural Guideline file.

Per Trust SOP and Procedural Guideline file.

Implementation

- Emergency Department clinical lead with the Anaesthetic Lead
- Emergency Department Registrars and Middle Grade Doctors at induction
- ED nursing staff working in Resus

12. RELATED TRUST POLICIES

There are no Trust related policies associated with this document.

13. References

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- Weaver CS et al. Emergency department Procedural Sedation with propofol: Is it safe? *J Emerg Med*. Nov 2007, 33(4):355-61.
- Short acting Agents for PSAA in Canadian Emergency Departments: A Review of clinical outcomes and Economic Evaluation. March 2008. Canadian Agency for Drugs and Technologies in Health.
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Appendix 1

Sedation Equipment Checklist

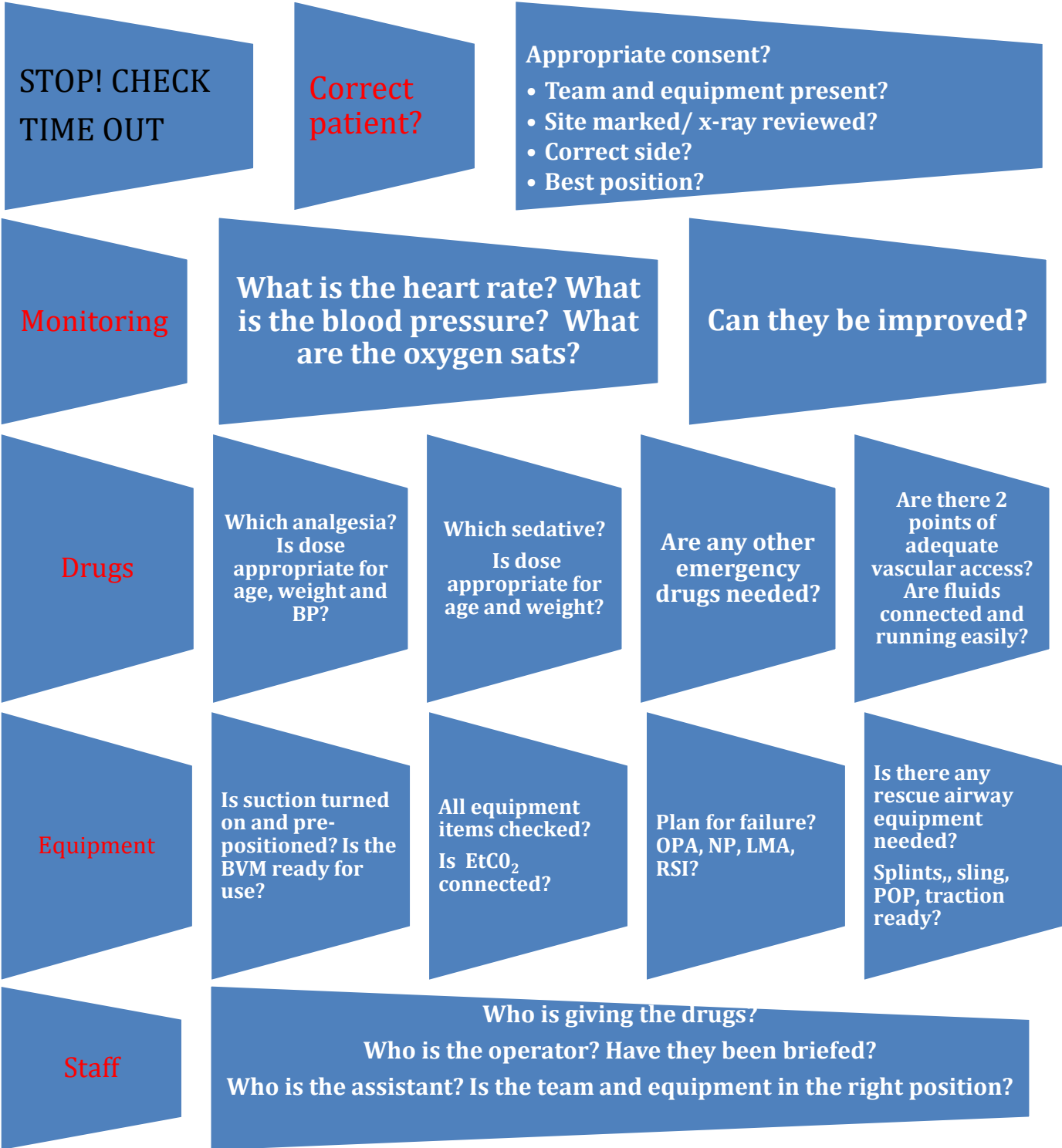
- Experienced Resus Nurse.
- Consent form.
- Sedation Proforma- please copy and original to the file and copy to patients notes.
- Oxygen via face mask and/or nasal prongs.
- 2x endotracheal tube checked and sized.
- LMA 4&5.
- NPx2 and OP airways.
- Mac 3 and 4.
- McCoy blade.
- Tube tie.
- BVM.
- Cricothyroidotomy set nearby.
- Pillow or blanket.
- End tidal CO₂ monitoring.
- Cardiac/ sats/ BP /RR monitor.
- I.V. access - flushed.
- Running crystalloid infusion.
- Analgesia.
- Sedation drugs of choice.
- Flumazenil out but not drawn up for midazolam.
- Atropine for ketamine induced bradycardia.
- Tilting trolley.

Appendix 2

- Level of consciousness, using the American Society of Anaesthesia guidelines (see below) will need regular communication with the patient to assess.
- ED Procedural Sedation should **not** exceed Level 2.

	Responsiveness	Airway	Ventilation	CVS
Minimal Sedation (anxiolysis) Level 1	Normal response to verbal communication	Unaffected	Unaffected	Unaffected
Moderate Sedation/Analgesia Level 2	Purposeful response to verbal or tactile stimulation	No intervention required	Adequate	Usually maintained
Deep Sedation/Analgesia Level 3	Purposeful response following repeated or painful stimulation	Intervention may be required	May not be adequate	Unusually maintained
General Anaesthesia	Unarousable even with painful stimulation	Intervention usually required	Usually not adequate	May be impaired

Appendix 3
Adult Sedation Checklist- Challenge and Respond



Note the time and commence Sedation

Procedural sedation proforma for adults in ED

(Use this form in conjunction with the PAH Emergency
Department sedation policy)

Patient details/sticker

Date: _____ Time: _____

Planned procedure:

TIME OUT STOP!CHECK completed

Staff involved

- Procedure doctor.....
- Sedation doctor.....
- Dedicated nurse.....
- Consultant (on call).....

Relevant co-morbidities:

Drug history:

Allergies:

Estimated body weight: kg

SEDATION CHECKLIST

- Consent: written / verbal
- Procedure explained
- Airway assessment
- Last meal/drink hours ago
- Equipment check
- Appropriate monitoring on
(see overleaf)
- Drug doses calculated
- ASA grade: 1 2 3 4 5
(see below)

Any adjuncts to sedation
(e.g. regional block/LA infiltration)

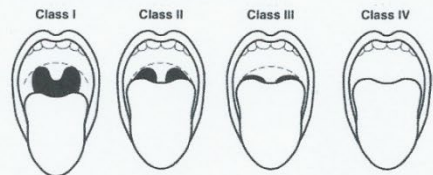
Airway assessment

- **Look:** short neck, large tongue, small jaw, beard, buckteeth
- **Evaluate:** Mouth opening >3 fingers, thyro-mental distance >7cm
- **Mallampati:** III/IV = difficult airway → Call anaesthetist
- **Obstruction, Obesity**
- **Neck movement**

ASA Classification

- 1 Healthy patient
- 2 Mild systemic disease, no functional limitation
- 3 Severe systemic disease with function limitation
- 4 Severe systemic disease that is a constant threat to life
- 5 Moribund patient not expected to survive without operation

Mallampati Grading



Monitoring:			
HR	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If no, give reason.....
BP	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If no, give reason.....
O ₂ saturation	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If no, give reason.....
RR	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If no, give reason.....
ETCO ₂	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If no, give reason.....
ECG	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If no, give reason.....
GCS	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If no, give reason.....

Observations to be documented every 2-5 minutes on separate chart
Use 15l O₂ if no contraindication

Drug	Route	Dose	Time given	Subsequent doses + time	Signed
Oxygen					

Any complications:

Reversal agents used:

DISCHARGE CHECKLIST	
- Fully conscious	<input type="checkbox"/>
- Observations normal for patient	<input type="checkbox"/>
- No nausea or vomiting	<input type="checkbox"/>
- Adequate analgesia	<input type="checkbox"/>
- Follow up arranged	<input type="checkbox"/>
- Verbal/written advice given (incl. leaflet) (No driving/alcohol/important decisions for 24 hrs)	<input type="checkbox"/>
- Discharged to care of responsible adult/Admitted	<input type="checkbox"/>
- Copy of proforma in notes	<input type="checkbox"/>
Destination on discharge.....	

SIGN OUT HANDOVER COMPLETED EQUIPMENT CHECK/ COUNT

Signed..... Print name..... Date.../.../..... Time.....

Appendix 5

Post Sedation Discharge Advice Sheet for the Patient and Carer.

Sedation

Patients discharged following the use of sedation

As part of your treatment you have been given medication that relieves anxiety and helps relaxation. You may experience a short period of memory loss during the time that the sedation is working.

We advise that you observe the following for the next 12 hours.

Do:

- ✓ Remain with a responsible adult
- ✓ Drink plenty of fluid and eat a light diet

Do not:

- ✗ Drive a car or any other vehicles including bicycles
- ✗ Operate any machinery or appliances such as cookers or kettles
- ✗ Drink any alcohol
- ✗ Lock the bathroom or toilet door, or make yourself inaccessible to the person looking after you
- ✗ Make any important decisions or sign any documents

Please telephone the Emergency Department (*********) should you have any worries or concerns following discharge from hospital.

Appendix 6

VERSION CONTROL SUMMARY

Document Title: Standard Operating Procedure (SOP): Sedation of Adult Patients in the Emergency Department

Version Number	Purpose / Changes	Author	Date Changed
Draft 1: V0.01	Initial draft document	Dr J Klewe	11/12/15
Draft 2: V0.02	Addition of the proforma	Dr J Klewe	20/1/2016
Draft 3: V0.03	Addition of STOP! CHECK	Dr J Klewe	24/2/2016
Draft 4: V0.04	Completion of Trust Documentation	Dr J Klewe	29/3/2016

Appendix 7

CHECKLIST FOR PROCEDURAL DOCUMENTS

To be completed by the author and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval / ratification*.

Document Title and Version No.

SOP and Procedural Guideline: Sedation of Adult Patients in the Emergency Department. Version V0.04

		Yes/No/ Unsure	Comments
1.	Title		
	Is the title clear and unambiguous?	y	
	Is it clear whether the document is a guideline, policy, protocol or standard?	y	SOP
2.	Rationale		
	Are reasons for development of the document stated?	y	Area of interest, FRCEM QIP and recent audit of sedation for RCEM
3.	Development Process		
	Is the method described in brief?	y	
	Are individuals involved in the development identified?	y	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	y	
	Is there evidence of consultation with stakeholders and users?	y	
4.	Content		
	Is the objective of the document clear?	y	
	Is the target population clear and unambiguous?	y	
	Are the intended outcomes described?	y	
	Are the statements clear and unambiguous?	y	
5.	Evidence Base		
	Is the type of evidence to support the document identified explicitly?	y	
	Are key references cited?	y	
	Are the references cited in full?	y	
		Yes/No/ Unsure	Comments

	Are local/organisational supporting documents referenced?	y	
6.	Approval		
	Does the document identify which committee/group will approve it?	y	SOP Group
	If appropriate, have the joint Human Resources/staff side committee (or equivalent) approved the document?		
7.	Dissemination and Implementation		
	Is there an outline/plan to identify how this will be done?	y	
	Does the plan include the necessary training/support to ensure compliance?	y	
8.	Document Control		
	Does the document identify where it will be held?	y	x-drive, proforma in Resus file
	Have archiving arrangements for superseded documents been addressed?	y	
9.	Process for Monitoring Compliance		
	Are there measurable standards or KPIs to support monitoring compliance of the document?	y	Midazolam apnoea is a " never event"
	Is there a plan to review or audit compliance with the document?	y	Audit July 2016
10.	Review Date		
	Is the review date identified?	n	Not needed currently
	Is the frequency of review identified? If so, is it acceptable?		12-18 months review
11.	Overall Responsibility for the Document		
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?	y	Dr J Klewe, Dr C Emordi

Completed by			
Name	Dr James Klewe	Date	23/3/2016
Job Title	Specialist Registrar in Emergency Medicine		

*Acknowledgement: Cambridgeshire and Peterborough Mental Health Partnership NHS Trust

Appendix 8

EQUALITY IMPACT ASSESSMENT

The organisation aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. The Equality Impact Assessment Tool is designed to help you consider the needs and assess the impact of your policy.

Name of Document:	<u>Standard Operating Procedure (SOP): Sedation of Adult Patients in the</u>		
Completed by:	Dr James Klewe		
Job Title:	Specialist Registrar Emergency Medicine	Date:	21/3/2016

		Yes/No
1.	Does the document/guidance affect one group less or more favourably than another on the basis of:	N
	• Race	N
	• Ethnic origins (including gypsies and travellers)	N
	• Nationality	N
	• Gender (including gender reassignment)	N
	• Culture	N
	• Religion or belief	N
	• Sexual orientation	N
	• Age	N
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	N
2.	Is there any evidence that some groups are affected differently?	N
3.	If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?	N
4.	Is the impact of the document/guidance likely to be negative?	N
5.	If so, can the impact be avoided?	N
6.	What alternative is there to achieving the document/guidance without the	N
7.	Can we reduce the impact by taking different action?	N

If you have identified a potential discriminatory impact of this procedural document or the answer to any of the above is Yes, please refer it to the Head of Patient Experience, Tel 01279 444455 – Extn 2358 complaints@pah.nhs.uk, together with any suggestions as to the action required to avoid/reduce this impact. In this case, ratification of a procedural document will not take place until approved by the Head of Patient Experience.

Date of approval by Head of Patient Experience:	<i>Evidence of approval must be available if requested</i>
--	--

Appendix 9

PRIVACY IMPACT ASSESSMENT SCREENING

Privacy impact assessments (PIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet individual's expectations of privacy. The first step in the PIA process is identifying the need for an assessment.

The following screening questions will help decide whether a PIA is necessary. Answering 'yes' to any of these questions is an indication that a PIA would be a useful exercise and requires senior management support, at this stage the Information Governance Manager must be involved.

Name of Document:	Standard Operating Procedure (SOP): Sedation of Adult Patients in the Emergency Department		
Completed by:	Dr James Klewe		
Job title	Specialist Registrar Emergency Medicine	Date	21/03/2016
			Yes or
9. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.			N
10. Will the process described in the document compel individuals to provide information about themselves? This is information in excess of what is required to carry out the process described within the document.			N
11. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information?			N
12. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?			N
13. Does the process involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.			N
14. Will the process result in decisions being made or action taken against individuals in ways which can have a significant impact on them?			N
15. Is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.			N
16. Will the process require you to contact individuals in ways which they may find intrusive?			N
<p>If the answer to any of these questions is 'Yes' please contact the Information Governance Manager, Tel: 01279 444455 - Extn: 1272 / Mobile: 07908 632215 tracy.goodacre@pah.nhs.uk / tracy.goodacre@nhs.net. In this case, ratification of a procedural document will not take place until approved by the Information Governance Manager.</p>			
IG Manager approval Name:			
Date of approval			

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