

A novel Caldicott-compliant hospital imaging protocol for open fracture photography

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Abstract

Open fractures incur significant morbidity and mortality, and as such have standardised guidelines for their management. Photography of open fractures is an essential component of documentation in the treatment of open fractures as per the British Orthopaedic Association Standards of Trauma and National Institute for Health and Care Excellence guidelines. Smartphones have made photography easily accessible to the clinician, but serious concerns exist regarding data security and the consent process around the use of sensitive clinical images. This project sought to overcome this issue by developing a Caldicott-compliant hospital imaging protocol that allows clinicians to use their smartphone to upload open fracture images into the patient's permanent record. Implementation of the protocol was audited and resulted in the increase of safe and secure open fracture photographic storage to inpatient medical records. This protocol would be transferrable to other hospital trusts and could be adopted across major trauma networks.

Key words: BOAST; Caldicott; Medical photography; Open fracture; Quality improvement

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Background

Open fractures

An open fracture is defined as a fracture that has direct communication with the external environment (Figure 1). Open fractures are associated with significant morbidity and mortality, since the combination of bone fracture and soft tissue injury results in significantly increased risk of neurovascular injury, infection and non-union (Garner et al, 2020). The priorities of treatment are to stabilise the fracture, reconstruct soft tissues, re-vascularise as required and prevent infection. Achieving these outcomes requires the combined efforts of orthopaedic, plastic and vascular surgeons. Photography of open fractures allows for visual assessment of soft tissue injuries by multiple teams, without the need for painful and contaminating repeat exposures of the patient's wound.

The British Orthopaedic Association Standards of Trauma (BOAST) guideline number 4 (British Orthopaedic Association, 2017) and the National Institute for Health and Care Excellence (2017) guideline NG37 highlight that hospitals have a responsibility to ensure that there is a protocol in place for the photography of open fractures 24 hours a day. The protocol needs to be robust, not only to ensure patient safety but also to protect the clinicians in recording patient confidential information as per the Caldicott principles (see below). The open fracture guidelines instruct that injuries should be photographed at first clinical presentation and again at subsequent key stages of management. These photographs should be stored within the patient's permanent medical record to ensure best clinical practice (British Orthopaedic Association, 2017; National Institute for Health and Care Excellence, 2017).

Limitations to photography of open fractures and instant messaging

Until recently there was no practical protocol in place for photography of open fractures in the authors' major trauma centre. Healthcare professionals were encouraged to use a departmental digital camera, which had significant practical limitations (Table 1) and meant that few photos were taken.

Modern technology has superseded the practical need for a departmental camera, where the almost ubiquitous ownership by clinicians of smartphones (Mobasher et al, 2015)

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Figure 1. Open fracture of ankle.

Table 1. Practical and data security limitations for photography		
	Practical limitations	Data security limitations
Departmental digital camera	Misplacement of digital camera Uncharged batteries Difficult to transfer to image storage system	Digital cameras are not encrypted Digital cameras have no password function Digital camera memory cards retain other patient photographs unless deleted
Smart phone photography (including using WhatsApp)	Difficult to transfer to image storage system	Images are stored next to other non-clinical photos Photos are not deleted No password protection for particular application

with high-quality cameras makes taking photos very easy. However, serious concerns exist regarding data security and consent when using personal telephones to take clinical images (Abbott et al, 2018). This is particularly true when using the most common messaging application WhatsApp (WhatsApp Inc. Dublin, Ireland)(Mobasheri et al, 2015; Rimmer, 2017a; Morris et al, 2018), where infringements of patient confidentiality, particularly surrounding inappropriate discussion of patients, have resulted in General Medical Council investigations (Rimmer, 2017b).

Any intervention must therefore address data security, but also be practical and simple to use, particularly in the context of the high-pressure environment of open fractures and major trauma.

Information governance and Caldicott principles

Information governance provides a framework in which organisations such as the NHS handle patient and employee data. The legal framework governing the use of personal confidential data in health care is complex, with legislation including the Human Rights

Act 1998, the NHS Act 2006, the Health and Social Care Act 2012, the Data Protection Act 2018 and General Data Protection Regulation (GDPR) 2018.

Implementation of robust information governance uses the Caldicott principles. The original six principles (Caldicott, 1999) reference the fundamentals that an organisation should use to protect sensitive data such as patients names or their photographs. They also ensure that this information is only used and shared when it is appropriate to do so. A seventh principle was added in the most recent review (Caldicott, 2013) that stated ‘The duty to share information can be as important as the duty to protect patient confidentiality’ and that ‘Health and social care professionals should have the confidence to share information in the best interests of their patients and within the framework set out by these principles’. This should also be ‘supported by the policies of their employers, regulators, and professional bodies’.

Photography of open fractures needs to respect both early and more recent Caldicott guidelines; there is a duty to share photographs of open fractures and professionals should be able to do this confidently, but it needs to be done while also protecting confidentiality. The authors therefore describe the development of a Caldicott-compliant hospital imaging protocol – a C-CHIP. A C-CHIP could be relevant not just to the authors’ department but could also act as a template for adoption within different departments and hospitals.

Aims of project

The primary aim was to produce a Caldicott compliant hospital imaging protocol for open fractures. The secondary aim was to meet BOAST guidelines by ensuring that photos of open fractures were recorded as a permanent part of a patient’s record.

Implementation of protocol

The C-CHIP for open fractures was developed in combination with trauma and orthopaedic, radiology and clinical governance teams. It was registered and authorised with the hospital’s clinical governance board by the Chief Clinical Information Officer. The protocol was implemented in August 2019. Before implementation the protocol was demonstrated to the orthopaedic team at departmental meetings, and posters (Figure 2) were also displayed throughout the hospital. No other specific training was needed to be given to clinicians regarding the uploading of images to PACS, apart from these demonstrations.

In broad terms the protocol used a secure messaging application (Siilo, Amsterdam, The Netherlands) for photography and transfer to the trust computers. Images were transferred to the hospital PACS (Intellispace PACS Enterprise v4.4, Philips, Foster City, USA) using Radiology+ (Soliton IT, Hemel Hempstead, UK)

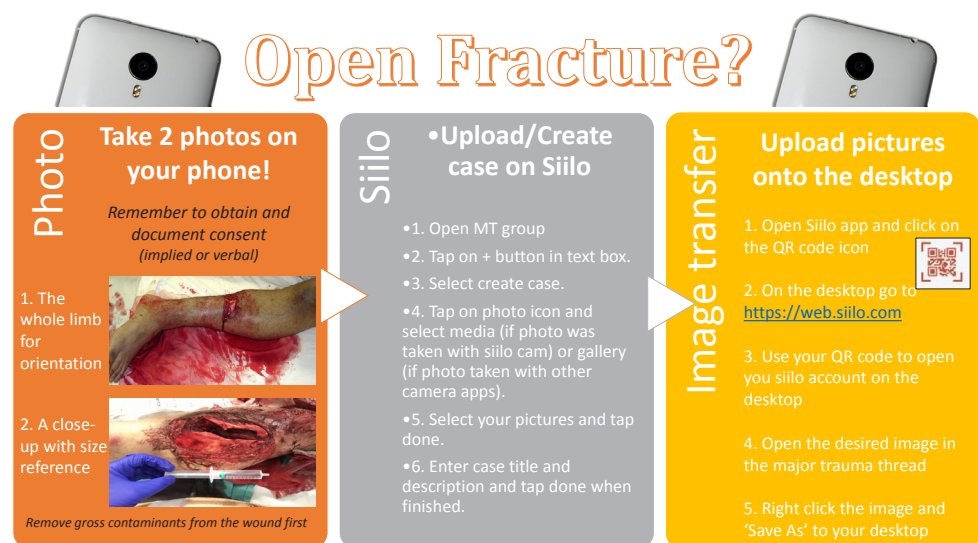


Figure 2. Open fracture photography protocol poster distributed within the orthopaedic department.

Assessing the effectiveness of the intervention

A retrospective review was performed of a prospectively collected database of all trauma patients presenting to the authors' hospital over a 6-week period (15/09/2018–31/10/2018), before implementation of the open fracture photography protocol. The patient's medical record and the medical photography database were reviewed to ascertain if any photographs of their open fractures were recorded.

A second review was completed of all open fracture patients over a 6-week period (15/09/2019–31/10/2019) following the introduction of the protocol in early August 2019. The patient's medical record was again reviewed to establish if photographs of their open fracture had been stored as per the protocol.

Inclusion criteria were patients of all ages presenting directly to the major trauma centre. Exclusion criteria were any patients who were transferred to the major trauma centre after being first assessed in a local trauma centre.

Results

Similar numbers of patients presented with open fractures over the two 6-week periods. There were five exclusions from the 2018 cohort and four exclusions from the 2019 cohort, all as a result of being transferred following emergent management at a local trauma centre. Numbers of open fractures, basic patient demographics and proportion of open fracture photographs documented on PACS are shown in [Table 2](#).

Discussion

This project aimed to provide a practical solution to a complex persisting problem within major trauma centres. As far as the authors are aware this is the first published solution that is cost neutral to the hospital, safe for the patient and compliant with relevant governance principles.

Adherence to Caldicott principles

Seven Caldicott principles need to be justified in a C-CHIP (Caldicott, 2013) ([Table 3](#)).

Consent

The General Medical Council (2008) states clearly the considerations a clinician must make for consent when performing a medical procedure. The General Medical Council state that consent can be given orally, in writing or be implied. When performing a low risk, minor or routine investigation or treatment, providing the clinician is satisfied that the patient understands the details and implications of what is proposed, then oral or implied consent is appropriate (The Royal College of Radiologists, 2012). The importance of the use of photography in open fractures for the best clinical management of patients has been established. Therefore, the benefit of taking a photograph of an open fracture outweighs any potential risks in this situation. As photography is a widely used media and therefore conceptually well understood by patients and has no risk to the patient's health, oral or implied consent would be an appropriate form of consent for clinicians to use.

This protocol, in keeping with General Medical Council (2011) guidance, stated that clinicians should obtain consent to take a photograph of an open fracture. If the patient has

Table 2. Number of open fracture photographs recorded on PACS pre- and post-protocol implementation

	Time frame	Number of open fractures	Age (years) (range)	Male sex (%)	Number of open fracture photographs on PACS (%)
Pre-implementation of protocol	15/09/2018–31/10/2018	20	45 (14–88)	16 (80%)	0 (0%)
Post-implementation of protocol	15/09/2019–31/10/2019	20	33 (4–83)	10 (50%)	16 (70%)

Table 3. Caldicott principles and steps taken in the protocol to adhere to principles	
Caldicott principle	Protocol adherence to principle
Justify the purpose for using confidential information	There is a clinical need for open fracture photography and sharing of images between surgical specialties associated with the patient's care as detailed in British Orthopaedic Association Standards for Trauma and National Institute for Health and Care Excellence guidelines
Do not use personal confidential data unless absolutely necessary	Photographs of open fractures are taken with any identifying features minimised
Use the minimum necessary personal confidential data	Photographs restricted to open fractures as per the patient's clinical need. Basic personal data are used to form a case presentation in the application which prevents confusion with other patients
Access to personal confidential data should be on a strict need-to-know basis	Open fractures uploaded to PACS system as part of patient's medical record are only able to be accessed by professionals with access as per hospital information governance protocols. Access to the major trauma group within the application is only granted to professionals working with major trauma
Everyone with access to personal confidential data should be aware of their responsibilities	Staff who were part of this project were trained on the importance of Caldicott principles when handling patients' data
Understand and comply with the law	The smartphone application Siilo adheres to NHS England (2018) guidance on instant messaging software
The duty to share information can be as important as the duty to protect patient confidentiality	The protocol embraces the sharing of essential clinical data, to abide by British Orthopaedic Association Standards for Trauma and National Institute for Health and Care Excellence guidance to give optimal care to patients with open fractures

capacity then verbal consent is deemed sufficient. If the patient does not have capacity or is unable to give consent then implied consent is appropriate. Documentation of verbal or implied consent should be recorded in the patient's clerking.

Confidentiality

The General Medical Council (2017) offers guidance to clinicians on the issue of patient confidentiality. Doctors have a legal and ethical responsibility to ensure that patient confidentiality is maintained. However, the General Medical Council (2017) also emphasises that appropriate sharing of patient information is an essential role of a clinician to give best care for their patients. Hence, the sharing of open fracture photographs on a patient's medical record between the multidisciplinary team directly involved in their care is in keeping with the General Medical Council (2017) guidance.

Data protection in messaging applications

With the introduction of GDPR in May 2018, patients are now able to request access to, location of, amendment to, and erasure of their data (John, 2018).

NHS England has produced a document for guidance on the use of instant messaging software. It highlights features in a smartphone application that are required to enable patient confidentiality through secure data sharing (NHS England, 2018).

1. Encryption – NHS end-to-end encryption standard AES 256
2. End-user verification
3. Passcode protection
4. Remote wipe
5. Message retention.

Additional security concerns with the use of photography of patients on clinicians' smartphones include:

1. Photographs saved directly to phone's camera roll
2. Active cloud photograph storage.

In this project, a smartphone application was required that met all the NHS England recommendations for data security and also addressed the smartphone photograph storage security concerns. An application called Siilo was used, which is a free (to user) messenger

application that is designed exclusively for medical professionals. To meet guidelines, it has the following attributes (Bruggeman et al, 2018):

1. AES 256 end-to-end encryption
2. Requires verification of all users as medical professionals
3. PIN code/fingerprint recognition access to the app (independent of phone protection)
4. Remote wipe function. Ability to wipe all Siilo data from phone remotely in case of theft
5. All messages are automatically deleted after 30 days
6. Photographs taken through the app are not saved to the regular phone camera roll or accessed or synchronised with the user's cloud storage service
7. Secure European servers for messaging data (based in Frankfurt, Germany and user information stored in secure servers in Dublin, Ireland – servers within the European Economic Area).

Case creation allowing individual patient identifiers and communication that can be individually exported as a non-editable file.

This application therefore meets the information governance requirements for confidentiality set out by the General Medical Council (2017), NHS England (2018) and GDPR (John, 2018) for a messenger service, ensuring that patient confidentiality is maintained and the clinician is protected from having patient data on their personal device. This application should be used as an alternative to WhatsApp in healthcare.

Limitations

The C-CHIP for open fractures is an ongoing programme and will be subject to further iterations. The responsibility for photography and uploading the images has rested with the on-call clinicians on the day, which has meant training approximately 30 staff in the department on how to perform this task. As new staff join the department, extra demonstrations will be needed to ensure people know how to perform the protocol. The authors are aware that 100% upload was not achieved. There could be a variety of reasons for this that includes patients who were transferred immediately to theatre and new staff not being aware of the protocol. The results do not include patients who were transferred from other trauma centres. These patients often have emergent management, including casting of the fracture done at the local trauma centre. Further development of the protocol could include a facility to transfer photographs of the open fractures within the trauma network.

The results demonstrated require an intervention to be made by staff (physical uploading) and therefore are not in any way a result of bias or chance. The project could be extended to photography in the operating theatre at initial debridement. The protocol could also be expanded across different departments within the hospital that also need to take clinical photographs; this article provides a template for other units to follow.

Further qualitative research could be performed to assess the value of these images that had not been previously available to healthcare professionals and of the benefits of real-time communication within the major trauma setting.

This protocol uses Siilo, although other messaging applications are available. However, not all mobile applications meet the necessary guidelines to be used in a C-CHIP. This is particularly true of WhatsApp (Morris et al, 2018). Caution must be exercised by healthcare professionals when using WhatsApp, particularly when other applications are available. With regard to sharing data, Lord Darzi has highlighted (Ghafur et al, 2020) the importance of engaging with patients with consent, and educating front-line staff on their responsibilities. This C-CHIP is therefore a positive step in the engagement of patients and staff to ensure a safe and secure way to achieve best clinical practice.

Conclusions

The establishment of this protocol has led to the simple, safe and secure transfer of clinical images from clinicians' smartphones to the hospital medical record. The protocol is adherent to Caldicott, General Medical Council and NHS guidelines and has improved the documentation of open fracture photography in a major trauma centre.

The authors suggest this C-CHIP would be transferrable to other trusts and could be adopted across trauma networks. It requires coordination between clinical staff, governance

Key points

- Photography of open fractures is an essential component of management as per British Orthopaedic Association and National Institute for Health and Care Excellence guidelines.
- The development of a Caldicott-compliant hospital imaging protocol (C-CHIP) requires adherence to relevant General Medical Council, NHS and Caldicott guidelines.
- Certain instant messaging applications can be used to develop a C-CHIP although this does not extend to WhatsApp.
- Implementation of this protocol has led to the simple, safe and secure transfer of clinical images from clinicians' smartphones to the hospital medical record.
- This or a similar protocol would be transferrable to other trusts and could be adopted across trauma networks.

structures, radiology and IT departments. The successful implementation of this protocol would ultimately achieve improved patient care in keeping with national guidelines for the management of open fractures.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical approval

All procedures were performed in compliance with relevant laws and institutional guidelines as well as being approved by appropriate institutional committees.

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