

Legal Aspects of Virtual Fracture Clinics

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Introduction

There is wide interest in the redesign of orthopaedic trauma outpatient services and the adoption of a "virtual fracture clinic" model. The evidence base for the clinical safety and cost-effectiveness of the model continues to grow. This article discusses the medico-legal aspects related to redesign of outpatient fracture clinic services.

When a person sustains orthopaedic trauma they usually undergo initial management in an Emergency Department (ED) or a Minor Injuries Unit (MIU). In most cases they are discharged home following treatment such as splintage and analgesia. The nature of the injury and treatment is explained. They are usually also given an appointment to return to an Orthopaedic Fracture Clinic in the next few days. A patient is discharged from fracture clinic follow-up when the injury is healing and they are regaining function.

Fracture clinics are often busy and rely on the presence of junior medical staff to deal with the large number of patients. The present system of managing these injuries arose from poor and uncoordinated fracture management in the early 20th century¹. With improved primary emergency care, along with the understanding of the nature and natural history of minor trauma, this ongoing utilisation of resources is of questionable efficiency and efficacy. Although the system provides clinic attendees with "face to face" encounters, due to the large number of patients this will often be with a doctor in training, or may be outwith the specialist training of the consultant in charge of that clinic. Complex cases that would benefit from specialist senior assessment may have suboptimal care due to this unfocused system. At the same time there may be needless review of minor injuries that would resolve satisfactorily with no further medical input.

The Virtual Fracture Clinic

As knowledge of the natural history and management of orthopaedic injuries has improved, it has become apparent that many have been unnecessarily medicalised, which leads to over-investigation and unnecessary follow-up. This can result in prolonged treatment in plaster casts, further x-rays and attendance at repeat appointments²⁻⁸. In response to these deficiencies, the Virtual Fracture Clinic (VFC) system was introduced at Glasgow Royal Infirmary in 2011. The aim was to improve the clinical effectiveness and the patients' experience by standardising treatment pathways. This system has spread in a sustainable fashion, based on evidence that we have published in peer-reviewed literature analyses of its safety and patient satisfaction.

Several types of injury were identified that could be completely managed by the emergency department or minor injuries unit without onward referral. These injuries included occult and undisplaced radial head and neck fractures⁹, mallet finger injuries¹⁰, fifth metacarpal and metatarsal fractures². Simple, patient-removable, splintage was provided to relieve pain. Return to everyday activities was advised as early as comfort allowed. Standardised information was provided verbally and via patient information leaflets. A telephone hotline was provided so that if the patient experienced any problems or had any subsequent problems, they could obtain direct, high quality, advice. This process relied on the existing skills of the ED and MIU to diagnose and manage these conditions. All other injuries were referred for review at the following day's VFC. This runs seven days a week. It consists of consultant review of radiographs and information documented in the ED records. It is conducted in a similar manner to any other multidisciplinary team (MDT) meeting. A provisional management plan is formulated during the meeting and the patient is contacted afterwards by telephone by a nurse who discusses this plan. Several management options are available: discharged with advice but no further physical review, or review in a subspecialty clinic at the optimal time point for the particular injury. If there are problems with communication, diagnostic or treatment uncertainty, or strong patient preference, physical review is offered. Physical review is also offered for more complex injuries or injuries where different treatment options are available. In these cases patients are invited for a more detailed discussion in a traditional clinic setting. The results of the VFC discussion and subsequent communication with the patient, is recorded via an electronic pro forma in our electronic patient record (EPR; Bluespier International, Worcester, UK).

Concerns about the VFC pathway are occasionally voiced by clinicians and include worry that there may be an increase in delayed, missed and erroneous diagnoses, inadequate treatment, and medico-legal claims. Since the introduction in our unit in 2011 there have been no complaints or medico-legal actions arising from diagnosis or management in the virtual clinic. During this period the VFC has managed approximately 7,000 to 8,000 patients per year.

Medico-legal principles applied to the VFC

Facilitation of good quality treatment, consented to by the patient, is a prerequisite for any acceptable model of healthcare. The primary purpose of such a model must be to secure the well-being of the patient. Where systemic or casual departures from acceptable care occur, and the patient has sustained harm, legal claims may result. The VFC pathway should therefore seek to minimise both the risk of unnecessary injury to the individual patient and the risk to healthcare providers of litigation: the two being complimentary aims.

Care in a modern UK hospital is delivered by individual practitioners (including doctors) working in a multidisciplinary manner in complex health systems. Protocols and guidelines are increasingly used with a view to providing consistent and evidence-based care. However, the source and status of protocols and guidance may vary. For example, General Medical Council guidance may be advisory or mandatory. Guidelines issued by bodies such as SIGN, NICE, the Royal Colleges and specialist associations may require local adoption and implementation in Unit protocols. The evidence basis of Guidelines, and of individual recommendations within Guidelines, may differ: in

some instances guidance may, in the absence of a reliable evidence base, rest only upon the consensus of current guideline committee members.

Professional Negligence

The foundation of the modern law of medical negligence is in Scotland the case of *Hunter v Hanley*¹¹ and in England *Bolam v Friern Hospital Management Committee*¹²: the cases being to similar effect. A practitioner is negligent if he or she acts in a manner which no equivalent practitioner of ordinary skill would if exercising reasonable care. Where the practitioner acts in accordance with a standard practice, or with a practice that a responsible body of relevant professional opinion supports, then this will normally be sufficient to discharge the duty of care - unless the practice is not applicable to the circumstances of the patient, or the practice can be shown to be irrational, unreasonable or illogical¹³. In applying the test, regard will be had to the type and grade of the practitioner alleged to have been negligent: in practice a higher standard of knowledge and skill, and thus of care, may be required, for example, of a doctor than of a nurse, and of a consultant than of a junior doctor. The application of the “Bolam test” has been removed from the issue of informed consent after the *Montgomery* ruling in the Supreme Court in 2015 and may still be removed from other aspects of treatment if the lawyers have their way¹⁴.

What considerations require to underpin an acceptable professional practice in the management of fractures? The General Medical Council provides general professional guidance relating to the primary interaction between doctors and patients in its “Good Medical Practice” guideline¹⁵: particularly 15a/b, 16b, 19, 22a, 32 and 45.

15a. adequately assess the patient’s conditions, taking account of their history..., their views and values; where necessary, examine the patient

15b promptly provide or arrange suitable advice, investigations or treatment where necessary...

16b provide effective treatments based on the best available evidence...

19 Documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events you are recording or as soon as possible afterwards...

22a taking part in regular reviews and audits of your work and that of your team, responding constructively to the outcomes taking steps to address any problems and carrying out further training where necessary...

32 You must give patients the information they want or need to know in a way they can understand. You should make sure that arrangements are made, wherever possible to meeting patients’ language and communication needs...

45 When you do not provide your patients' care yourself, for example when you are off duty or you delegate the care of a patient to a colleague, you must be satisfied that the person providing care has the appropriate qualifications, skills and experience to provide safe care for the patient.

The British Orthopaedic Association is the professional body for orthopaedic surgeons in the United Kingdom. It publishes Standards for Trauma (BOAST) to give national professional guidance. It issued BOAST 7 in August 2013, covering Fracture Clinic Services¹⁶. There has been little research performed on the provision of outpatient fracture clinic services and BOAST 7 includes the statement, "this guideline is based upon professional consensus as there are very few scientific studies in the area". It states that, "following acute traumatic orthopaedic injury, patients should be seen in a new fracture clinic within 72 hours of presentation with the injury. This includes referrals from emergency departments, minor injury units and general practice". The guideline also recommends that "all new fracture clinic appointments must lead to a management plan, including any clinical interventions, which is communicated to both the general practitioner and patient in writing.", and that, "there must be a system in place that allows patients rapid access back to the fracture clinic if they have problems related to their initial presenting injury."

The BOAST guideline also states that "there should be local referral guidelines for fracture clinics and any re-design that deviates from these recommendations should be prospectively evaluated to support the change of practice.' [Para 13].

Consent

Informed consent is required for any episode of medical investigation and treatment (whether conservative or active). The General Medical Council produced their current guidance on consent, *Consent: patients and doctors making decisions together* in 2008¹⁷: Paragraph 2 sets out an over-riding duty or principle that requires to be complied with ("you must"). Further paragraphs (2, 5, 7 and 46) set out how the over-riding duty should be implemented ("you should").

"2. Whatever the context in which medical decisions are made, you must work in partnership with your patients to ensure good care. In so doing, you must:

- a) listen to patients and respect their views about their health
- b) discuss with patients what their diagnosis, prognosis, treatment and care involve
- c) share with patients the information they want or need in order to make decisions
- d) maximise patients' opportunities, and their ability, to make decisions for themselves
- e) respect patients' decisions.

5. If patients have capacity to make decisions for themselves, a basic model applies:

a The doctors and patient make an assessment of the patient's condition, taking into account the patient's medical history, views, experience and knowledge.

b The doctor uses specialist knowledge and experience and clinical judgement, and the patient's views and understanding of their condition, to identify which investigations or treatment are likely to result in overall benefit for the patient. The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice

c The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one. They also have the right to accept or refuse an option for a reason that may seem irrational to the doctor, or for no reason at all.

d If the patient asks for a treatment that the doctor considers would not be of overall benefit to them, the doctor should discuss the issues with the patient and explore the reasons for their request. If, after discussion, the doctor still considers that the treatment would not be of overall benefit to the patient, they do not have to provide the treatment. But they should explain their reasons to the patient, and explain any other options that are available, including the option to seek a second opinion.

....

7 ...you should tailor your approach to discussions with patients according to:

a their needs wishes and priorities

b their level of knowledge about, and understanding of, their condition, prognosis and the treatment options

c the nature of their condition

d the complexity of the treatment, and

e the nature and level of risk associated with the investigation or treatment.

....

46 In the case of minor or routine investigations or treatments, if you are satisfied the patient understands what you propose to do and why, it is usually enough to have oral or implied consent.

The information that requires to be provided to a patient in order to secure their valid consent was clarified by the Supreme Court in the recent case of *Montgomery v Lanarkshire Health Board* and merits detailed consideration¹⁸.

Paragraphs 87-91 are particularly relevant

"[87] ... An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would

be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

[88] The doctor is however entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient's health. The doctor is also excused from conferring with the patient in circumstances of necessity, as for example where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision. It is unnecessary for the purposes of this case to consider in detail the scope of those exceptions.

[89] Three further points should be made. First, it follows from this approach that the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.

[90] Secondly, the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form.

[91] Thirdly, it is important that the therapeutic exception should not be abused. It is a limited exception to the general principle that the patient should make the decision whether to undergo a proposed course of treatment: it is not intended to subvert that principle by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests."

Achieving High Quality and Consent in the VFC

The VFC pathway allows us to comply with the standards set out in BOAST 7¹⁵. Locally agreed protocols, that are regularly reviewed, govern which injuries can be directly discharged and which need referred to the VFC for further consideration.

Information leaflets ensure that patients receive locally agreed information about their injury, recommended treatment, and anticipated recovery. There are no standards as yet recommending the level of information to be provided by such leaflets. We aimed to provide a readable document that focused on what the patient should expect and who to contact if there were any problems. Patients have reported satisfaction with the information provided. In the future, we anticipate the provision of nationally agreed advice leaflets supported by national specialty and sub-specialty organisations.

All radiographs are also reviewed by a radiologist, or reporting radiographer, within 24 hours and discrepancies are rapidly investigated. The actual treatment (analgesia and splintage) provided through the virtual clinic system is

identical to that which would be provided in a traditional system. The telephone discussion with the patient is similar to that which would occur face-to-face. The nature of the injury is explained and the treatment option outlined. The patient can ask questions. Where no further face-to-face review is recommended there must be certainty as to the expected outcome. The patient must also fully understand when and whom to contact when the outcome fails to match expectations. Patients are given hospital contact details for use if they have any problems, or if questions arise in the future.

Our VFC is also attended by a nurse from the fracture liaison service to identify patients at risk of osteoporosis and offer them targeted investigation and management. This assists with compliance with a separate standard for trauma (BOAST 9)¹⁹.

A provisional management plan is decided during the VFC, and then discussed with the patient by telephone by the nurse. Where there is insufficient information to formulate a satisfactory management plan, either because of lack of information from the ED, or suitable radiographs, a physical review is arranged. If there are communication difficulties (for example, if the nurse making the telephone call is unsure that the patient fully understands the information they have been given), again, further review is arranged. When different treatment options are available and feasible, decision making can be complex. These patients are therefore offered face-to-face review in a sub-specialist clinic. When face-to-face review is necessary the VFC process ensures that it is with the most appropriate specialist to provide all the information that is required for the patient to make an informed decision. Finally, if at any point from the phone-call, up to six months following the injury, the patient requests physical review, this is arranged at an appropriate time point depending on the problem encountered.

The decisions of the VFC and the follow-up telephone discussions are recorded contemporaneously in our electronic patient record (EPR) which generates a letter to the patient, that is copied to the general practitioner. The use of an EPR allows regular audit, and we have examined the clinical effectiveness, safety and satisfaction with this process^{2,9,10,20}.

We have introduced a special pathway within the virtual fracture clinic system to manage the “suspected scaphoid fracture”. Traditional management of the “suspected scaphoid fracture” results in a large number of attendances in traditional fracture clinics. This is usually for re-examination and repeat x-rays at two weeks. There is concern that a missed scaphoid fracture will result in nonunion and long term wrist dysfunction. Although the “missed” scaphoid fracture is perceived as an area of significant litigation, the prevalence of claims is in fact low. A recent paper considered the burden of legal action in the area of wrist and scaphoid injuries²¹. The authors used a Freedom of Information (FOI) request to obtain data over a seventeen year period from the NHS Litigation Authority (NHSLA) covering litigation in the English NHS, and classified the type of claim. There were 73 claims relating to scaphoid fractures that were “settled lost”, and 170 relating to the distal radius. The reported incidence of actual scaphoid fractures in the UK is 29 per 100,000²². In the same population, the prevalence of true fracture in the overall “suspected” fracture group is 16%²³. Assuming a population of England of 53.01 million (2011 Census Data), the

expected number of actual scaphoid fractures in this time period was 15,373. Therefore the proportion of all suspected scaphoid fracture cases “settled lost” was approximately 0.07%. In a similar way, the incidence of distal radius fractures is estimated at 195 per 100,000²⁴, and the number of “settled lost” cases was 170²¹. The proportion of “settled lost” cases to total injuries was therefore 0.16%. In our service, a patient suffering wrist pain following an injury, and having examination findings consistent with an occult scaphoid fracture, has cross-sectional imaging (MRI) arranged directly by the ED. The VFC staff monitor for the results. When results are available, the patient is contacted: where there is no injury, they can mobilise without delay, and if there is a fracture, they can return to clinic for a specialist review. This protocol accelerates access to definitive diagnosis and treatment. We believe that the use of the VFC as a hub for the investigation and management of these injuries reduces variation and the risk of misdiagnosis and management.

Conclusions

VFCs have the potential to improve the safety of management through the use of standardised protocols, consultant-led management and release of time to devote to the management of complex patients. VFCs also have the potential to improve the coordination of management of injuries at higher medico-legal risk, such as the suspected scaphoid fracture.

When setting up a VFC, adequate attention should be paid to the protocols introduced, information provided in verbal and written formats, recording of discussion and decisions, and application of the principles of good patient care and consent. Professional negligence claims can be avoided by the use of robust, up-to-date protocols that are based on national standards. Following the Montgomery ruling it is clear that where valid treatment choices exist, a clinician should provide the risks and benefits of each option that that patient would reasonably want to be informed of when making that choice.

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