

Dear Sir,

Open fractures can be severe life-changing events and therefore, a multidisciplinary approach towards treatment has been advocated to optimize long-term outcomes. Clinical guidelines on the management of these injuries have aimed to provide evidence-based recommendations, offering a framework that optimizes utilization of resources and establishing norms for future audit and research. However, the development of these documents is an expensive and tedious process.

We compared the 2009¹ and 2020² *British Orthopaedic Association (BOA) – British Association of Plastic, Aesthetic and Reconstructive Surgeons (BAPRAS) Standards for the Management of Open Fractures*, *National Institute for Health and Care Excellence (NICE) 2016 Complex Fracture Guidelines*³ and *Dutch Federation of Medical Specialists 2017 Lower Extremity Fracture Guidelines*⁴ to examine on their content, recommendations, associated time investment and costs.

We found that there was extensive overlap in the topics covered by the studied documents. In regard to interventions meant to take place during the first week following injury, overlap was 89% (Table 1). Recommendations were equivalent, with differences largely confined to areas for which there is a lapse in the evidence.

The AGREE II grading tool involves 7 different domains, including scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. This tool assesses the risk of bias in clinical guidelines. We found that the quality of the studied guidelines has improved over time (Figure 1). The BAPRAS/BAO 2009 the NICE 2016 and Dutch 2017 scored higher than the BAPRAS/BAO 2009 standards. The use of systemic review protocol is one of the important causes which results in this improvement. Contributing, more value is attached to the applicability, stakeholders and editorial independence. However, higher quality and more robust methodology of the former comes at an expense. The cost of developing the Dutch and NICE guidelines was £60,608 and £311,434 respectively, if only the lower limb recommendations are

considered. This was the sum of expenses associated with literature research, process supervision, office space, secretarial costs, catering, travel expenses, and the support of focus groups. The production cost of the BAPRAS/BOA guideline in 2009 was £20,000 and 2020 £17,252, as these scientific societies covered organizational expenses and authors were not paid for their contribution. The publication costs were paid by private companies to cover Open Access costs. The time invested for the development of the studied guidelines ranged from 24 up to 60 months.

National guidelines on the management of open extremity fractures are relatively uncommon. For example, Italy and Spain are countries with well-established health systems that, despite considerable efforts, at present do not have their own national guideline on open extremity trauma. In 2016 the Italian Orthopedic (SIOT), Plastic Surgery (SICPRE), Hand (SICM) and Microsurgery (SIM) Societies agreed to work together to produce an upper and lower limb open fractures guideline, using the BAPRAS/BOA 2009 document as a starting point. Unfortunately, this joint effort has come to a halt due to the lack of financial resources to cover the administrative costs of the process required by the Italian National Centre for Clinical Excellence, Quality, and Security (CNEC). In Spain, the management of these injuries is variable across units. Nevertheless, some efforts for standardization have been noted, such as the participation of the Spanish Orthopaedic Surgery Society (SECOT) in the development of an International Consensus on Musculoskeletal Infections,⁵ which includes open fractures. Additionally, in the absence of an interconnected major trauma network, regional ambulance services in Madrid (SAMUR), Valencia (SAMU) and Barcelona (SEM) have developed protocols for the transfer patients to the most appropriate trauma centre in their area.

Considering that more than £500,000 have been spent in The Netherlands and the United Kingdom to produce these guidelines, resulting in wide overlapping and matching recommendations, we propose that societies in other countries consider cost and time-saving alternatives. International cooperation may result in the production of high-quality guidance that could be applied across national borders once transparent methodology and aims are agreed whilst taking into account differences in

healthcare systems and structures. If available, robust previous guidelines could be used as a starting point to further reduce the time and effort associated with development of a completely new document. Different healthcare systems and availability of recourses have to be contemplated but considerable costs can be avoided by means of international collaborating, adapting existing guidelines, whilst remaining cognisant of local needs and limitations. The examples we provide from Italy and Spain illustrate the hurdles for each country if they try to proceed alone. We should build on examples of successful collaboration such as those provided by the AO Foundation to improve for the benefit of patients sustaining severe open fractures.

Declarations

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None.

Conflicts of Interests

Jagdeep Nanchahal participated in the development of the BAPRAS/BOA 2009 and 2020, and NICE guidelines for the management of open limb fractures. Hinne Rakhorst was part of the working committee for the Dutch guideline for open lower limb fractures. The remaining authors do not have any conflicts of interest to declare.

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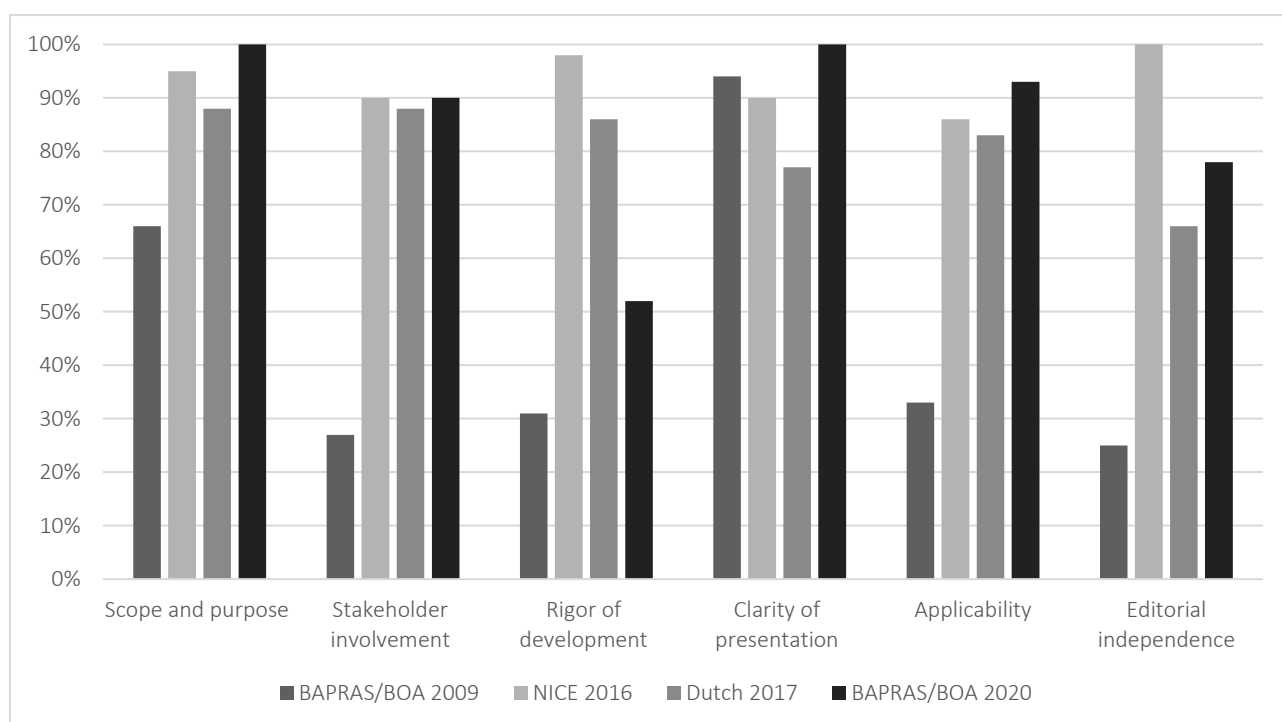


Figure 1: AGREE II scores for the open fracture guidelines. This grading tool involves 7 different domains, including scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. These are divided into 23 items rated on a 7-points Likert scale. Supplemental documents about the development were requested from the authors. Each domain was assessed in parallel by two authors in a blinded fashion (EV, KO). Consensus was reached by means of discussion with a third author (JEB). An overall score for each heading was calculated by summing individual items and converting these to percentages according to the AGREE II methodology. The grading tool can be achieved from 'www.agreetrust.org'.

Table 1: Recommendation comparison across the open fracture guidelines. Major differences are underlined. A Cross means not described in the guideline.

	<i>BAPRAS/BOA 2009</i>	<i>NICE 2016</i>	<i>Dutch 2017</i>	<i>BAPRAS/BOA 2020</i>
Prehospital management and transfer	X	Airway management, controlling haemorrhage, pain control, saline soaked dressings, prophylactic antibiotics, and splinting. Transport to major trauma/specialized centre.	Follow Netherlands National Protocol of Ambulance Care and Prehospital Trauma Life Support principles. Saline soaked dressings, align fractures, pressure bandage, and splinting. Transport to specialized centre.	Prehospital Trauma Life Support principles, Antibiotics, splinting, documentation of neurovascular status and saline soaked dressings. Transport to major trauma/specialized centre.
Multidisciplinary approach	Orthopaedic and plastic surgeons in specialized centres.	Orthopaedic and plastic surgeons in specialized centres.	Trauma/orthopaedic and plastic surgeons and rehabilitation physicians in specialized centres.	Orthopaedic and trauma surgeons, medical microbiologists, rehabilitation specialists in specialized centres.
Management in the Emergency Department	ATLS principles. Photographs and X-rays. Avoid wound exploration or irrigation. Antibiotics and tetanus prophylaxis. Cover wounds with saline soaked dressings and splinting.	ATLS principles. Photographs and X-rays. Avoid wound exploration or irrigation. Antibiotics and tetanus prophylaxis. Cover wounds with saline soaked dressings and splinting. Whole-body CT only in adults (16 or over) with major trauma.	ATLS principles. Photographs and X-rays. Avoid wound exploration and irrigation, remove only large (none perforating) foreign bodies. Antibiotics and tetanus prophylaxis. Cover wounds with saline soaked dressings and splint if not done previously. Administer pain relief. CT only on indication.	Photographs and X-rays. Antibiotics and tetanus prophylaxis. Avoid wound exploration or irrigation, remove only large foreign bodies. Cover wounds with saline soaked dressings and impermeable membrane, splinting. For multilevel injuries or polytrauma: head to toe CT, incl. angiogram if indicated. DVT prophylaxis.
Antibiotic administration	Within 3 hours of injury, preferably co-amoxiclav or cephalosporin. Add gentamicin at time of debridement. At time of definitive fixation and soft tissue coverage administer. Continue antibiotics until soft tissue cover or 72 hours.	Within 1 hour of injury, either pre-hospital or in emergency department.	As soon as possible, cefazolin is preferred. Adding gentamycin for high energy injuries. Continue until soft tissue closure or 72 hours. Contact microbiologist if unusual contaminations.	Within 1 hour of injury, preferably co-amoxiclav or cephalosporin. Add gentamicin at time of debridement and continue for 24 hours. At time of definitive fixation and soft tissue coverage administer single dose of glycopeptide (teicoplanin).
Wound excision (Debridement)	<u>Within 24 hours</u> , performed by senior plastic and orthopaedic surgeon.	Immediately for highly contaminated injuries. <u>Within 12 hours for high-energy injuries and within 24 hours for other injuries</u> . Performed jointly by consultant plastic and orthopaedic surgeons.	Immediately for highly contaminated injuries. As soon as possible, ideally <u>within 12 hours</u> by consultant plastic surgeon and trauma/orthopaedic surgeon.	Immediately for highly contaminated injuries, <u>within 12 hours for high-energy injuries and within 24 hours for other injuries</u> . Performed jointly by consultant plastic and orthopaedic surgeons.
Temporary wound dressings	<u>Negative pressure wound therapy</u> (NPWT), not a substitute for definitive wound cover. Antibiotic impregnated beads pouch.	<u>Consider NPWT</u> after debridement if immediate definitive soft tissue coverage is not possible.	<u>NPWT</u> , not a substitute for definitive wound cover. Second choice are saline-soaked gauze dressings.	<u>Use a simple non-adherent dressing (no benefit of negative pressure dressings over conventional dressings)</u> . NPWT not a substitute for definitive wound cover.
Skeletal stabilisation	Spanning external fixation if immediate definitive fixation and soft tissue cover is not possible.	Definitive skeletal stabilisation and soft tissue cover at the same time as wound excision, if possible. Within 72 hours if soft tissue coverage not possible in first instance.	Spanning external fixation if immediate definitive fixation and soft tissue cover is not possible. Intramedullary nail is the preferred fixation method.	Spanning external fixation if immediate definitive fixation and soft tissue cover coverage is not possible. Definitive internal fixation only if there is minimal contamination and if definitive soft tissue cover can be achieved immediately. Otherwise ideally within 72 hours. Use multiplanar circular fixator if there is significant contamination or bone loss.
Soft tissue reconstruction	<u>As soon as possible, within 1 week</u> . At same time as internal fixation.	Definitive skeletal stabilisation and soft tissue cover at the same time as wound excision (debridement) if possible. <u>Otherwise within 72 hours</u> .	<u>As soon as possible, within 1 week</u> . Should be performed at same time as definitive fixation.	Definitive skeletal stabilisation and soft tissue cover at the same time as wound excision if possible. Otherwise definitive soft tissue coverage <u>within 72 hours</u> . Use local flaps only for patients with limited zone of injury.
Early amputation	Perform emergency amputation if limb is source of uncontrollable life-threatening bleeding or if limb unsalvageable. Decision should be taken by two consultant surgeons with patient and family involvement if possible. Preferred amputation level is transtibial, followed by transfemoral.	Perform emergency amputation if limb is source of uncontrollable life-threatening bleeding or limb unsalvageable. Decision made jointly by orthopaedic and rehabilitation team, patient and relatives. When indicated, amputate within 72 hours.	Preferred amputation level is transtibial, followed by through-knee. Involve rehabilitation specialist early.	Perform emergency amputation if limb is source of uncontrollable life-threatening bleeding or limb unsalvageable. Decision should be taken by two consultant surgeons (orthopaedic and plastic) with patient and family involvement if possible. When indicated, ideally amputate within 72 hours. Preferred amputation level is transtibial, followed by through-knee

Management of vascular injuries	Immediate surgical exploration and revascularisation within 4 hours. Capillary refill can be misleading. Preoperative angiography can lead to wasting valuable time.	Use hard signs for assessment and diagnosis. Do not rely on Doppler signal or capillary refill. Perform immediate surgical exploration if hard signs persist after re-alignment of limb. Do not delay surgery to obtain imaging. Use a vascular shunt to restore circulation before skeletal stabilisation.	Perform immediate surgical exploration and revascularisation. Keep ischaemia time to a minimum. Only conduct CT-angiography if distal pulses are present.	Use hard signs for assessment and diagnosis. Do not rely on Doppler signal or capillary refill. Perform immediate surgical exploration if hard signs persist after re-alignment of limb. Do not delay surgery to obtain imaging. Use a vascular shunt to restore circulation within 4 hours of injury and before skeletal stabilisation.
Compartment syndrome	Surgical emergency that must be diagnosed and treated promptly. In adults, the threshold is a perfusion pressure of <30mmHg. Decompression of 4 compartments via 2 incision technique.	Maintain awareness in the first 48 hours post injury or surgery. Regularly assess for symptoms. Teach patients to self-monitor. Consider continuous compartment pressure measurements.	Pay attention to the development of compartment syndrome.	Surgical emergency that must be diagnosed and treated promptly. Accurate diagnosis is facilitated by serial assessment and intra-compartmental pressure measurements. In adults, the threshold is a perfusion pressure of <30mmHg for 2 consecutive hours. Decompression of 4 compartments via 2 incision technique.
Degloving injury	Degloving can occur superficial to the deep fascia, extent of injury difficult to estimate. Thrombosis of the subcutaneous veins usually indicates the need to excise the overlying skin. Circumferential degloving often indicates that involved skin is not viable. Serial wound excision may be necessary.	X	X	Degloving can occur superficial to the deep fascia, extent of injury difficult to estimate. Thrombosis of the subcutaneous veins usually indicates the need to excise the overlying skin. Circumferential degloving often indicates that involved skin is not viable. Serial wound excision may be necessary. Large volume (>50ml) Morel-Lavalle lesions may be better treated surgically instead of drainage.
Management and avoidance of complications: flap failure, bone loss, deep infection.	Necrosis, deep infection, or suspected circulatory compromise requires early exploration and revision surgery. Antibiotics should be started for suspected deep infection. Limited flap congestion can respond to leech therapy. Perform free flap anastomoses out of zone of injury. Common causes of complications include inadequate wound excision, haematoma formation, inappropriate or delayed soft tissue cover, and unstable fixation.	X	X	Reconstructive options for bone loss include autologous bone graft, distraction osteogenesis, or free vascularised bone. Infection should be managed by multidisciplinary team. Diagnosis is based on radiological appearances and bone and deep tissue sampling after stopping antibiotics. Treatment includes removal of internal fixation, aggressive wound excision, and culture-specific anti-microbial therapy. Retention of internal fixation may be considered in early infection with low virulence organisms suppressed with targeted antibiotics, and closely monitored.
Open fractures in children and older patients	Wound excision and principles of soft tissue reconstruction in children are same as for adults. The use of medullary devices limited by the presence of growth plates. It is likely that patients under the age of 12 will have a shorter union time.	Use clinical judgement to limit CT to the body areas where assessment is needed. Elaborate a definitive management plan involving a paediatric orthopaedic trauma specialist within 24 hours of diagnosis. Allocate a dedicated member of the staff if a child is unaccompanied. Consider the age, developmental stage, and cognitive function, and include siblings when offering support to family and carers.	X	Initial management of children is same as for adults. Fracture fixation needs to consider the presence of growth plates. Small areas of bone loss in under 6 years of age can be managed expectantly. Skeletal injuries in those aged 12 or older behave like adults. Management for older patients should include falls prevention, rehabilitation and mental health support. Coordination with primary care and social services is important. Regional anaesthesia and angle-stable skeletal fixation devices should be considered. In frail patients unsuitable for lengthy surgical procedures alternative surgical techniques may be used, incl. skeletal shortening, secondary healing and pre-conditioning of local flaps.

Blast injuries and mass casualties	X	X	X	The tissue damage is often greater than suggested by the size of the wound, that evolves over time. Initial surgery should be performed as soon as possible, and wound excision often needs to be repeated. Blast and complex ballistic injuries should not be closed directly, and early complex reconstruction should be undertaken cautiously. For mass casualties standard orthopaedic care pathways may need to be modified to provide a population-based approach. It may be necessary to preserve evidence for future forensic examination.
Patient centred approach and rehabilitation	X	Manage expectations and answer questions honestly, do not speculate. Provide a point of contact and ask the patient if they want someone with them. Provide information about what is happening, injuries, investigations, treatment, and time-schedules. Offer people the opportunity to see images of their injury. Give verbal and written information on the management plan.	Discuss the definitive treatment plan with the patient and relatives. Point out the possible treatment options, risks, and expected results. Start exercise therapy as quickly as possible post-operatively. Set treatment targets in consultation with patient and surgeon. Adapt exercise therapy targets over time to the requirements of the patient.	Offer psychological support to express emotions, manage pain, adjust to wounds and to mobility changes. Cognitive Behavioural Therapy can be used and referral to mental health clinicians considered. Rehabilitation should be led by a consultant in rehabilitation medicine. A rehabilitation prescription should be provided within 2 days. Weight bearing status should be documented immediately after skeletal and soft tissue reconstruction. Screen for PTSD and refer to the specialist pain team if patients develop chronic pain. Make a peri-operative pain plan before undergoing a delayed amputation. Poorly functioning patients should be referred for dynamic orthotics. Patients with high transfemoral amputations should be referred for consideration of osseointegration if not tolerating standard prosthetics.
Documentation	X	Follow a structured process when handing over care and make sure this is documented. Ensure all documentation goes with the patient when transferring. The written summary contains diagnosis, management plan, and expected outcome. Send it within 24 hours to the GP, write it in plain English for the patient and family, and make sure it is readily available in the patients' record.	X	Keep photographic documentation of the wound in the key stages of management in the patients' record. Document neurovascular status for both limbs: nerve function, sensibility, and motor function (MRC grading system). Presence of pulses, or how circulation has been assessed when pulses are not accessible.
Classification of open fractures	The Gustilo and Anderson grading is widely used and is relatively simple but has poor interobserver reliability and is best applied after wound excision.	Gustilo-Anderson open fracture classification is used for clarity. High-energy injuries = Gustilo IIIA and IIIB.	Classify the injury in accordance with the Gustilo and Andersen open fracture classification.	The Gustilo-Anderson classification: High-energy lower limb fractures are likely Gustilo-Anderson Type IIIA and IIIB.
Organisation of the ortho-plastic service	Essential components include orthopaedic trauma surgery, plastic, and microvascular surgery, with facilities for simultaneous debridement for these teams. Provide dedicated theatre sessions for the combined ortho-plastic management during the normal working day. Have access to microbiology, radiology, artificial limb fitting, rehabilitation, physical, and psychosocial rehabilitation services. Include audit of outcome as part of the care pathway. Aim to reach 30 cases per annum. Possess intensive care and other trauma facilities for the multiply injured patient.	Essential components include combined service for orthopaedic and plastic surgery in which consultants from both specialties work simultaneously to treat open fractures as part of regular, scheduled, combined orthopaedic and plastic surgery operating lists. Consultants are supported by combined review clinics and specialist nursing teams. Ensure that healthcare professionals have up-to-date training and the right skills for interventions they required to give.	The multidisciplinary team should see the patient preoperatively and make a treatment plan. Assign a primary treating physician. Make local or regional arrangements regarding the organisation of care for patients with a grade III open fracture of the lower limb and register this in a protocol.	Essential components include a joint service provided by orthopaedic and plastic surgery consultants, with sufficient combined operating theatre lists to meet timely treatment as per this guideline. There should be combined review clinics and specialist nurses to care for both fractures and flaps. There should be regular audit meetings and case data submitted to the Trauma Audit Research Network.

Measuring outcomes in clinical practice	<p>Patient health status questionnaires such as the Sickness Impact Profile and Medical Outcomes Study Short Form-36 provide a valuable overall assessment of the patient. Other recommended outcome measures are union time of diaphyseal, complication rates and limb function scores (i.e. Enneking Score).</p>	X	<p>For quantification of physical functioning, six-weekly WOMAC and Short Form-36 are recommended. Return to work and quality of life are determined by personal and environmental factors.</p>	<p>The core outcomes are quality of life, return to life roles, walking, gait and mobility, pain and discomfort. They also should include EQ-5D-5L and the Lower Extremity Functional Scale.</p>
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