QUALITY IMPROVEMENT REPORT

A multifaceted strategy for implementation of the Ottawa ankle rules in two emergency departments

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EDITORIAL by Thomson
See also PRACTICE, pp 400, 402

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Abstract

Problem Despite widespread acceptance of the Ottawa ankle rules for assessment of acute ankle injuries, their application varies considerably.
Design Before and after study.
Background and setting Emergency departments of a tertiary teaching hospital and a community hospital in Australia.
Key measures for improvement Documentation of the Ottawa ankle rules, proportion of patients referred for radiography, proportion of radiograph showing a fracture.
Strategies for change Education, a problem specific radiography request form, reminders, audit and feedback, and using radiographers as "gatekeepers."
Effects of change Documentation of the Ottawa ankle rules improved from 57.5% to 94.7% at the tertiary hospital, and 51.6% to 80.8% at the community hospital (P<0.001 for both). The proportion of patients undergoing radiography fell from 95.8% to 87.2% at the tertiary hospital, and from 91.4% to 78.9% at the community hospital (P<0.001 for both). The proportion of radiographs showing a fracture increased from 20.4% to 27.1% at the tertiary hospital (P=0.069) and 15.2% to 27.2% (P=0.002) at the community hospital. The missed fracture rate increased from 0% to 2.9% at the tertiary hospital and from 0% to 1.6% at the community hospital compared with baseline (P=0.783 and P=0.747).
Lessons learnt Assessment of case notes has limitations. Different groups of clinicians seem to differ in their capacity and willingness to change their practice. A multifaceted change strategy that includes a problem specific radiography request form can improve the selection of patients for radiography.

The Ottawa ankle rules

An ankle radiographic series is required only if there is pain in the malleolar zone and any of these findings:
- Bone tenderness at the posterior edge or tip of the lateral malleolus (distal 6 cm), or
- Bone tenderness at the posterior edge or tip of the medial malleolus (distal 6 cm), or
- Inability to bear weight both immediately and in the emergency department

A foot radiographic series is required only if there is pain in the mid-foot zone and any of these findings:
- Bone tenderness at the base of the fifth metatarsal, or
- Bone tenderness over the navicular bone, or
- Inability to bear weight both immediately and in the emergency department

Problem

Radiography is ordered for virtually all patients with blunt ankle trauma, and typically 85% of these examinations do not find a fracture.[1] According to clinical research findings, a radiograph is not always needed to exclude an ankle or foot fracture.[1 2] The Ottawa ankle rules (box) are a clinical decision tool that aids the efficient use of radiographs in acute ankle injuries.[2]

In the emergency departments in this study, the Ottawa ankle rules were either not being used or their application varied considerably. We aimed to identify strategies to improve the uptake of the Ottawa ankle rules in the emergency departments, and to determine if these strategies were effective in improving selection of patients with ankle injuries for radiography.

Background and setting

This study began at a major tertiary referral hospital serviced by a public radiology provider. After 12 months, the implementation strategies developed at the tertiary hospital were transferred to a community hospital serviced by a private radiology contractor, to assess if they would work in another setting. The study continued for a total of 20 months at the tertiary hospital and six months at the community hospital.

The target group were all clinicians working in the emergency departments who were able to order radiographs—that is, triage nurses who had completed accreditation to order radiographs, nurse practitioners, and all medical staff. Over the study period, the target group comprised 315 clinicians at the tertiary hospital and 62 at the community hospital.

Strategy for change

The study was underpinned by concepts for changing clinical practice and the implementation of evidence based guidelines.[3-7]

A baseline audit established the evidence-practice gap and provided a starting point from which to measure the extent of practice change. The audit

included all consecutive eligible patients over a retrospective six month period who presented to the emergency departments with an ankle or mid-foot injury.

Barriers analysis

An initial analysis identified potential barriers to evidence being used in routine clinical practice. We completed process mapping of several ankle patients from triage to discharge or admission, along with key informant [8] interviews of emergency department and radiology staff.

Barriers fell into three groups:

- *Individual clinician*—Knowledge of the Ottawa ankle rules, concern about missing a fracture, lack of confidence in clinical ability to exclude a fracture without a radiograph, and lack of knowledge about which radiograph to order.
- *Social context*—Many staff felt obliged to order a radiograph if patients were unhappy with lengthy waits to be seen.
- *Organisational context*—High staff turnover due to rotating staff, staff on shift work, no negative consequences of ordering unnecessary radiographs, and, at the tertiary hospital, triage nurses ordering radiographs without clinical examination at busy times to improve flow of patients within the emergency department.

Engaging the target group

At the tertiary hospital, the results of the baseline audit and barrier analysis were presented to an emergency department consultants' meeting to gain support in principle. We identified change champions and clinical opinion leaders in both the emergency department and radiology, and convened a multidisciplinary steering group, which helped design the change strategies and drive the changes.

At the community hospital, we presented the results of the baseline audit and barrier analysis to a general staff meeting with the director and acting manager of the emergency department present, to provide support and endorsement.

Linking change strategies to barriers

The change plan was a multifaceted change strategy designed to deal with the identified barriers.

Barriers at the individual clinician level and in the social context were met by education during in-service tutorials. Barriers within the organisational context were met by introducing a new request form incorporating the Ottawa ankle rules (see figure in the long version on bmj.com), reminders via posters and lanyard cards, audit and feedback, and empowering the radiographers to reject the old request forms or any incomplete new request forms ("gatekeeping"). Strategies were tailored to each hospital, and apart from audit and feedback, were all introduced simultaneously (table 1).

Evaluating outcomes

Assessment of documentation of the Ottawa ankle rules on the request form and in the case notes was used as a marker of the use of the rules in clinical practice. The hospital's radiology imaging system was searched to determine if imaging had occurred for

Table 1 | **Multifaceted implementation**

	Tertiary hospital	Community hospital
Education		
Tutorials were organised to:- Teach the Ottawa ankle rules- Improve examination skills with hands-on teaching by an emergency physician- Provide instructions on how to use the new request form- Discuss verbal and written "prescription" to give to patients for whom radiography is not indicated. If the patient insisted on radiography, staff were advised to respect the patient's wishes	- Multiple tutorials were run over a two month period, separately for medical and nursing staff at their regular in-house training sessions- Over the next four months, tutorials were run for each medical staff rotation, but no extra sessions were run for nursing staff because of the stability of the workforce- After the initial six months, education about the rules was left to the discretion of the emergency department consultants responsible for training	- Multiple sessions were run over a one month period, both at scheduled staff meetings and opportunistically when the emergency department was quiet- Additional sessions were arranged on an "as needed" basis
New request form		
- Design and implementation of a problem specific radiography request form incorporating the Ottawa ankle rules as a decision tree	- Feedback was sought regularly from all stakeholder groups, resulting in iterative improvements- Version 3 was used at the end of the study (pregnancy was removed from the form as few pregnant women present to the tertiary hospital; it does not have an obstetrics department)	- Version 2 (developed at the tertiary hospital) was used without modification
Reminders		
- Posters about the rules were placed around the emergency department- Each member of staff was given a paper guideline and a lanyard card containing the rules- The posters, guideline, and lanyard card all looked identical, and colours matched the new request form to "brand" the study and provide an instantly recognisable product	- Information about the rules was updated on the intranet- Occasional small features about the study were placed in the emergency department newsletter	- No additional reminders
Audit and feedback		
	- Feedback to emergency department staff on outcomes and practice change at a midpoint review	- Feedback to emergency department staff on outcomes and change in practice at a midpoint review
Radiographers as "gatekeepers"		
- Radiographers were taught about the Ottawa ankle rules and how the new request form was to be used- Radiographers were empowered to reject the old request form	- Senior radiographers enlisted to help maintain and drive the change in their work groups- Multiple sessions run over a one month period at the start of the study to all available radiography staff- Communication book left in radiography work area to document any implementation problems or queries	- The "gatekeeping" role was not requested of the radiographers working for the private radiology contractor

each ankle presentation. If there was no record, case notes were reviewed to confirm that no imaging had been performed. Request forms were reviewed for all presentations throughout the study. Case notes were reviewed for all patients in the baseline audit. Case notes were only reviewed in the implementation period for patients who had no imaging requested or no documentation of the Ottawa ankle rules criteria on the request form.

The proportion of patients sent for radiography in each emergency department was assessed, and we calculated fracture rates as the proportion of radiographs showing a definite fracture.

See the full version on bmj.com for a full description.

Effects of change

During the study, 1561 patients with ankle injuries presented to the two hospitals. Age and sex of the patients at each hospital were similar, with most injuries occurring in the 20-29 year old age group in both sexes.

Table 2 shows that documentation of the Ottawa ankle rules criteria increased significantly on request forms and in the case notes. The proportion of patients referred for radiography fell by 8.6% at the tertiary teaching hospital and by 12.5% at the community hospital compared with the baseline audit. The increase in the proportion of radiographs that demonstrated a fracture was not significant at the tertiary hospital (6.7%) but was statistically significant at the community hospital (12.0%). In the baseline period no patients re-presented with a missed fracture. However, during the implementation period, three (2.9%) patients re-presented at the tertiary hospital, and one (1.6%) re-presented at the community hospital with a missed fracture.

Compared with baseline, a greater proportion of patients were seen during the implementation period by nurse practitioners at the tertiary hospital (30/215 *v* 252/813) and by resident medical officers at the community hospital (6/244 *v* 70/289), and a smaller proportion of patients was seen by triage nurses in both emergency departments (56/215 *v* 126/813 at the tertiary hospital, 8/244 *v* 8/289 at the community hospital).

The greatest reduction in the proportion of patients referred for radiography was in the nurse practitioner groups (30/30 *v* 208/252, decreased by 17.5% at the tertiary hospital; 11/11 *v* 19/28, decreased by 32% at the community hospital) and resident medical officers at the community hospital (6/6 *v* 55/70, decreased by 21%), but these reductions were not statistically significant. Radiography referrals by triage nurses were not reduced at either site, with all patients being sent for radiography in both study periods (data not shown).

The proportion of referrals made on the new request form was 88% at the tertiary hospital and 41% at the community hospital. The proportion of new request forms completed correctly was 85.7% and 87.1% at the tertiary and community hospital respectively (table 2).

Discussion

Guidelines that recommend the elimination of an established behaviour (such as ordering radiographs) are more difficult to implement than guidelines that recommend adding a new behaviour.[9] Despite this, the change strategies implemented in this study achieved a significant increase in the use of the Ottawa ankle rules at both the tertiary hospital (37.2%) and the community hospital (29.2%). This change was three to four times higher than in a systematic review of 235 guideline dissemina-

Table 2 | Documentation of Ottawa ankle rules, fracture rate, and use of new request form. Values are numbers (percentages) unless otherwise indicated; varying denominators indicate availability of request forms and case notes

	Tertiary hospital				Community hospital			
Key measures	Baseline period (n=215)	Implementation period (n=813)	% difference (95% CI)	P value	Baseline period (n=244)	Implementation period (n=289)	% difference (95% CI)	P value
Patients referred for radiograph	206/215 (95.8)	709/813 (87.2)	−8.6 (3.9 to 13.3)	<0.001	223/244 (91.4)	228/289 (78.9)	−12.5 (6.4 to 18.7)	<0.001
"Positive" documentation†:								
Request form	84/205 (41.0)	588/707 (83.2)	42.2 (35.3 to 49.0)	<0.001	76/223 (34.1)	147/225 (65.3)	31.2 (22.0 to 40.5)	<0.001
Case notes	123/214 (57.5)	767/810 (94.7)	37.2 (32.1 to 42.3)	<0.001	126/244 (51.6)	231/286 (80.8)	29.2 (21.1 to 37.1)	<0.001
Radiograph	115/205 (56.1)	665/707 (94.1)	38.0 (32.5 to 43.4)	<0.001	123/223 (55.2)	186/225 (82.7)	27.5 (18.9 to 36.1)	<0.001
No radiograph	8/9 (88.9)	102/103 (99)	10.1*	>0.05	3/21 (14.3)	45/61 (73.8)	59.5*	<0.001
Fracture identified on radiograph	42/206 (20.4)	192/709 (27.1)	6.7 (−0.3 to 13.3)	0.0686	34/223 (15.2)	62/228 (27.2)	12.0 (4.6 to 19.8).	0.002
Missed fractures	0/9 (0)	3/104 (2.9)	2.9	0.783	0/21 (0)	1/61 (1.6)	1.6	0.747
Referrals on new request form	NA	622/707 (88.0)	—	—	NA	93/225 (41.3)	—	—
Forms completed correctly	NA	533/622 (85.7)	—	—	NA	81/93 (87.1)	—	—

CI = confidence interval; NA = not applicable.
*95% confidence intervals could not be calculated because the number within each cell for Fisher's exact test was less than 5.
†Complies with consensus criteria for adequate documentation of Ottawa ankle rules.

tion and implementation strategies, which showed a median 10% improvement.[4]

The reason for the greater impact of the change strategy on documentation than reduction in radiography referrals is not entirely clear.

The number of missed fractures at both sites was small and not statistically significant. A more robust measurement of missed fracture rates could be achieved with longer periods of data collection.

The greatest change in practice was seen with the nurse practitioners at both sites and the resident medical officers at the community hospital. Nurse practitioners became champions of the implementation of the Ottawa ankle rules, and among the junior medical staff, uptake may have increased because the new request form gave a clear, evidence based framework for clinical assessment. The reason for lack of change in radiography referral patterns by triage nurses is not entirely clear. The shift in radiography referrals away from the triage nurses could account for some of the outcomes, but not for change in practice in other clinician groups.

The new request form was well adopted at the tertiary hospital (88% of referrals were made on the new form). The staff acknowledged that it served not only as a memory aid but also described the appropriate population in which the Ottawa ankle rules should be used. Given the large volume of staff and the small proportion of permanent staff in the tertiary hospital's emergency department, the new request form worked well as a change strategy and was used successfully by both rotating and shift working staff. At both sites, the new form was used correctly in over 85% of radiography referrals.

The reduction in unnecessary ankle radiographs was greater at the community hospital, even though the problem specific radiograph form was used in less than half of presentations (41%). This may be due to the smaller size and stability of the community emergency department workforce.

A key strategy for implementing the new request form at the tertiary hospital was assigning a "gatekeeper" role to the radiographers. The radiographers accepted and performed this role, but for some it was confrontational and challenging.

Limitations

The observational nature of this study limits interpretation of the data. In addition, the study period was limited to the duration of the lead author's fellowship.

Assessing change in practice by assessing documentation of the Ottawa ankle rules in the case notes was hampered by inconsistencies in the quality of documentation. Although most clinicians will carefully document the results of an electrocardiogram, they seem to be less motivated to document examination findings for an injury that is not life threatening.

The rate of missed fractures may have been higher than reported, as patients who subsequently presented to their general practitioner may have been referred to community based private radiology contractors; this would not be captured by the hospital's electronic clinical information system. The differing lengths of implementation periods and external factors such as seasonality may also have influenced these findings.

It is impossible to disentangle the outcome effects of the separate components of the change strategy when all, apart from audit and feedback, were commenced concurrently.

A cost benefit analysis would further evaluate this multifaceted change strategy. The effect of this change strategy on length of stay in the emergency department, change in practice in requesting of other radiographs, and patient satisfaction could also be considered

Lessons learnt

There were several key learning experiences that arose from this study.

Using documentation as a surrogate measure for clinical practice has limitations and is both time consuming and prone to error, but in clinical practice is often the only way of evaluating practice.

Clinician groups seem to differ in their capacity or willingness to change their practice.

A multifaceted change strategy including education; a new problem specific radiography request form; reminders; audit and feedback; and using radiographers as "gatekeepers", can result in improved selection of patients for radiography.

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1 Stiell IG, McKnight RD, Greenberg GH, McDowell I, Nair RC, Wells GA, et al. Implementation of the Ottawa ankle rules. *JAMA* 1994;271:827-32.
2 Stiell IG, Greenberg GH, McKnight RD, Nair RC, McDowell I, Reardon M, et al. Decision rules for the use of radiography in acute ankle injuries: refinement and prospective validation. *JAMA* 1993;269:1127-32.
3 Grol R, Wensing M, Eccles M. *Improving patient care: the implementation of change in clinical practice*. Edinburgh: Elsevier Butterworth Heinemann, 2005.
4 Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess* 2004;8(6):iii-iv.
5 Grol R. Successes and failures in the implementation of evidence-based guidelines for clinical practice. *Med Care* 2001;39(suppl 2):46-54.
6 Lomas J. *Health services research and evidence-based decision making*. Ottawa: Canadian Health Services Research Foundation, 2000.
7 Wilson RM, Harrison BT, Gibberd RW, Hamilton JD. An analysis of the causes of adverse events from the quality in Australian health care study. *Med J Aust* 1999;170:411-5.
8 National Institute of Clinical Studies. *Identifying barriers to evidence uptake*. Melbourne: NICS, 2006.
9 Winkler JD, Lohr KN, Brook RH. Persuasive communication and medical technology assessment. *Arch Intern Med* 1985;145:314-7.

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DIAGNOSIS IN GENERAL PRACTICE

The injured ankle and foot

Dan Mayer

In this pair of articles, **Dan Mayer** shows how a clinical prediction rule, the Ottawa ankle rules, is applied and **Gavin Falk** and **Tom Fahey** set out what to consider when using such rules

See also PRACTICE, pp 396, 402

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ABSTRACT

While playing basketball, a 26 year old student went up for a shot and came down inverting his ankle. He heard a loud pop and felt severe ankle pain. He was unable to get up for a few minutes, but his friends helped him up and he was able to limp off the court. He saw his primary care physician the next day, limping badly.

Diagnostic dilemma

Injuries to the ankle and mid-foot are commonly seen in primary care and hospital emergency departments. Only 15% of these are fractures,[1] and the diagnostic dilemma for the clinician is thus to identify patients with such fractures, as these require plaster immobilisation or referral to an orthopaedic specialist. Most other injuries are treated for ligamentous stretch or disruption with dynamic stabilisation, rest, and physical therapy.

In the past, the decision making process for ankle and mid-foot injuries involved subjective elements of the history and physical examination, followed almost always by an x ray, a process that is potentially harmful and wasteful. Historical clues included asking patients whether they heard a pop at the time of injury and were able to walk after the injury. Examination findings suggesting fracture were the presence of swelling, ecchymoses, stability when the ankle or mid-foot was moved, and ability to dorsiflex or plantar flex against resistance. However, such clinical findings were found to be unreliable, with poor inter-rater reliability.[2]

Thus clinicians need a more accurate method to identify high risk injuries that require radiographic examination.

The diagnostic approach: clinical prediction rules

Ankle and mid-foot injuries are caused by the disruption of only a few structures: the lateral and medial malleoli, fibulotalar ligament laterally and the deltoid ligament medially (see figure). In the ankle, the lateral and medial malleoli are the bony structures that maintain medial and lateral stability and alignment. The fibulotalar ligament laterally and the deltoid ligament medially maintain soft tissue stability and flexibility of the ankle. These four structures allow us to freely flex and extend our foot at the ankle but limit eversion and inversion. Injuries to these structures most commonly occur with an inversion injury of the ankle either in a sports setting or simply while walking.

In the mid-foot, the navicular bone is part of the arch transmitting weight from the upper body to the forefoot. This and the other bones of the mid-foot allow us to plantar flex our foot and push off while walking.

In 1992 the emergency medicine group at the University of Ottawa evaluated the clinical findings in ankle and mid-foot injuries. The only aspects of the examination with reasonable inter-rater reliability were ability of the patients to walk four steps at the time of the accident and in the emergency department, and tenderness over the bony portions of the lateral and medial malleoli, the navicular, and the proximal fifth metatarsal.

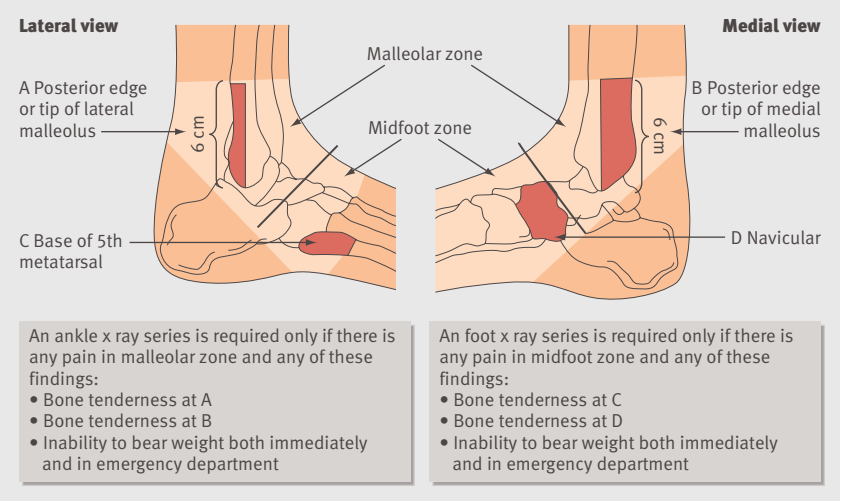
When these findings are combined, forming the Ottawa ankle rules (figure), they have 98% sensitivity and 40% specificity for excluding fractures, based on the initial derivation study[2] and several validation studies[3-5] and summarised in the pooled sensitivity and median specificity in a systematic review.[1] Calculating the likelihood ratios from these gives a negative likelihood ratio of 0.05. Starting with a pretest probability of 15% will lead to a post-test probability of fracture of less than 1% if the result on applying the rule is negative and about 22% if it is positive. A negative result on applying this rule means an x ray of the ankle is not necessary.

Similar findings for the mid-foot found that the presence of tenderness on the proximal head of the fifth metatarsal or navicular is associated with the presence of a fracture. The Ottawa foot rules had 99% sensitivity and specificity about 38%. The pooled results for the ankle and foot rules have a sensitivity of 97.8% and specificity of 31.5%, giving a negative likelihood ratio of 0.08.[1]

LEARNING POINTS

- Ankle injuries are extremely common but many features on history and physical examination are unreliable
- The combined Ottawa ankle and foot rules have a sensitivity of 97.8% and a specificity of 31.5%, giving a negative likelihood ratio of 0.07; this will yield a post-test probability of about 1% for fracture of the ankle if test results are negative (not requiring x ray)
- Treatment for ligament injuries should include dynamic splinting and RICE (rest, ice, compression, and elevation)
- Rule out a complete tear of the ligaments by doing drawer testing of the ankle before discharging the patient or at the first follow-up visit

This series aims to set out a diagnostic strategy and illustrate its application with a case. The series advisers are Kevin Barraclough, general practitioner, Painswick, and research fellow in community based medicine, University of Bristol; Paul Glasziou, professor of evidence based medicine, Department of Primary Health Care, University of Oxford; and Peter Rose, university lecturer, Department of Primary Health Care, University of Oxford.



Ottawa ankle and foot rules. Used with permission[4]

Using the Ottawa ankle rules to rule out patients with ankle injuries who will not require x rays of the ankle reduces the number of ankle x rays by an estimated 25%.[6] A before and after cohort study of the rules in eight hospitals of varying sizes found the actual saving was a 21.9% absolute reduction in ankle x rays, giving a number needed to test of 5 to avoid one x ray (95% confidence interval 4 to 5). The sensitivity of the rules in this study was 99.4%.[7]

Case review

Our patient had a negative result on the Ottawa ankle rules. He was able to walk four steps even though he was limping and he had no tenderness over either the medial or lateral malleoli. His primary care physician explained that the likelihood of having any fracture was extremely low, less than 1%, and almost certainly such a fracture would be a small "chip" or avulsion fracture that could be treated in the same way as a sprained ankle. The patient was placed in a dynamic splint and sent home to rest for a few days with RICE instructions (rest, ice, compression, and elevation). On follow-up he was prescribed exercises to strengthen inversion and eversion and advised to increase mobility gradually. Three months later, his ankle felt back to normal, but he noticed it was slightly unstable and was more likely to twist on uneven ground.

Patients able to walk four steps and with no tenderness over either the lateral and medial malleoli can be diagnosed as having an ankle sprain. Ankle sprains can be classified into three levels of severity: grade I is stretching with minor tear of the ligament and with no signs of laxity; grade II is a partial tear; and grade III is a complete tear of the ligament. All but the most severe can be placed in a dynamic splinting device such as the Aircastand treated as in our case.[8-11] A new randomised single blind (to outcome only) study performed by the CAST group compared tubular dressings, the Bledsoe boot (complex immobilisation boot), Aircast, and below knee cylinder cast in 584 patients with severe ankle sprains. Those treated by plaster immobilisation with a below knee cast or either of the dynamic immobilisation devices had more rapid healing of their ankle sprains at three months than did those treated with a tubular bandage, and the costs of the cast or Aircast were minimally higher than the plaster cast. Nine months after injury, all groups had equal functional outcomes. One problem was a 25% dropout rate in each group, which could have biased the end results.[12] With more serious injury, physical therapy may be helpful.

Serious injuries that should not be missed are complete disruption of the fibulotalar or deltoid ligaments, mortise, or interosseous ligament, which could require surgical repair to restore a functional and stable ankle. Suspect these if patients continue to have severe pain after a few days of rest and if they have laxity or severe pain when the ligaments are under stress. Ligamentous laxity is tested for with the "drawer test," which looks for appreciable movement of the forefoot relative to the ankle or severe pain when the ligaments are stressed, leading to suspicion of complete ligamentous disruption.

Other serious injuries should be suspected if the patient has severe pain after a period of resting, and patients with these injuries should be referred to an orthopaedic specialist.

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1 Bachmann LM, Kolb E, Koller MT, Steurer J, Ter Riet G. Accuracy of Ottawa ankle rules to exclude fractures of the ankle and mid-foot: systematic review. *BMJ* 2003;326:417-9.
2 Stiell IG, Greenberg GH, McKnight RD, Nair RC, McDowell I, Worthington JR. A study to develop clinical decision rules for the use of radiography in acute ankle injuries. *Ann Emerg Med* 1992;21:384-90.
3 Stiell IG, McKnight RD, Greenberg GH, McDowell I, Nair RC, Wells GA, et al. Implementation of the Ottawa ankle rules. *JAMA* 1994;271:827-32.
4 Stiell I, Wells G, Laupacis A, Brison R, Verbeek R, Vandemheen K, et al. Multicenter trial to introduce the Ottawa ankle rules for use of radiography in acute ankle injuries. Multicenter Ankle Rule Study Group. *BMJ* 1995;311:594-7.
5 Pigman EC, Klug RK, Sandord S, Jolly BT. Evaluation of the Ottawa clinical decision rules for the use of radiography in acute ankle and midfoot injuries in the emergency department: an independent site assessment. *Ann Emerg Med* 1994;24:41-5.
6 Perry JJ, Steill IG. Impact of clinical decision rules on clinical care of traumatic injuries to the foot and ankle, knee, cervical spine, and head. *Injury* 2006;37:1157-65.
7 Stiell I, Wells G, Laupacis A, Brison R, Verbeek R, Vandemheen K, et al, for the Multicentre Ankle Rule Study Group. Multicentre trial to introduce the Ottawa ankle rules for use of radiography in acute ankle injuries. *BMJ* 1995;311:594-7.
8 Kerkhoffs GMMJ, Marti RK, Struijs P, Blankevoort L, Assendelft WJJ, Van Dijk CN. Functional treatment for acute ruptures of the lateral ankle ligament: a systematic review. *Acta Orthop Scand* 2003;74:69-77.
9 Boutis K, Willian AR, Babyn P, Narayan UG, Alinan B, Schuh S. A randomized controlled trial of a removable brace versus casting in children with low-risk ankle fractures. *Pediatrics* 2007;119:e1256-63.
10 Beynnon BD, Renström PA, Haugh L, Uh BS, Barker H. A prospective, randomized clinical investigation of the treatment of first-time ankle sprains. *Am J Sports Med* 2006;34:1401-12.
11 Boyce SH, Quigley MA, Campbell S. Management of ankle sprains: a randomized controlled trial of the treatment of inversion injuries using an elastic support bandage or an aircast ankle brace. *Br J Sports Med* 2005;39:91.
12 Lamb SE, Marsh JL, Hutton JL, Nakash R, Cooke MVV. On behalf of the Collaborative Ankle Support Trial (CAST Group). Mechanical supports for acute, severe ankle sprain: a pragmatic multicentre, randomised trial. *Lancet* 2009;373:575-81.

DIAGNOSIS IN GENERAL PRACTICE

Clinical prediction rules

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This series aims to set out a diagnostic strategy and illustrate its application with a case. The series advisers are Kevin Barraclough, general practitioner, Painswick, and research fellow in community based medicine, University of Bristol; Paul Glasziou, professor of evidence based medicine, Department of Primary Health Care, University of Oxford; and Peter Rose, university lecturer, Department of Primary Health Care, University of Oxford.

What are they?

Clinical prediction rules quantify the contribution of symptoms, clinical signs, and available diagnostic tests, and stratify patients according to the probability of having a target disorder.[1] The outcome of interest can be diverse and be anywhere along the diagnostic, prognostic, and therapeutic spectrum. Developing and validating a clinical prediction rule is a form of observational epidemiological research that requires referring to specific methodological standards.[2 3]

These rules usually go through three distinct stages before they are used in a clinical setting:

- Development of the rule—establishing the independent and combined effect of explanatory variables (or clinical predictors), which can be symptoms, signs, or diagnostic tests
- Narrow and broad validation—the explanatory variables or clinical predictors in the derivation set are assessed in separate populations
- Impact analysis—a randomised controlled trial measures the impact of applying the rule in a clinical setting in terms of patient outcome, health professionals' behaviour, resource use, or any combination of these.

The CAGE score (box) is a clinical example of a rule developed to aid in the diagnosis of alcohol abuse.

When are they used?

Clinical prediction rules are most commonly used at the stage of refining a diagnosis alongside quantifying the probability of a target disorder (fig 1). Applying a rule often requires a bayesian approach to diagnosis: estimating a clinically likely pretest probability for a target disorder, then applying a likelihood ratio derived from the presence or absence of the clinical features of the rule (similar to applying a test result), which in turn enables a revised estimate of clinical probability.[4] Whether a clinician wishes to "rule in" or "rule out" a disorder is likely to be specific to the setting of care and the nature and severity of the target disorder. For instance, clinical prediction rules may be used in primary care to rule out a disorder, provide reassurance, or adopt a "watchful waiting" strategy. In these instances rules with a high sensitivity and low negative likelihood ratio (ratio of false negative to true negative in patients with a negative test result) are preferred.[5] In the same way, ruling in a diagnosis is desirable in secondary care settings where the emphasis is usually on establishing a firm diagnosis and starting appropriate treatment or conducting more expensive and invasive diagnostic tests.[5] In these settings rules with a high specificity and high positive likelihood ratio (ratio of true positive to false positive in patients with a positive test results) are preferred.[5]

This quantitative approach applied to a clinical example—that of alcohol abuse—is shown in figure 2.[6] The pretest probability of alcohol abuse in general practice is estimated as about 5%; if the CAGE questionnaire is administered and the patient scores 3, then the positive likelihood ratio is 13.1.[6] Applying this positive likelihood ratio to the pretest probability produces a post-test probability of alcohol abuse of 41.3%, which warrants intervention in terms of more detailed assessment, counselling, and management.[4] Other examples of clinical prediction rules are provided in the table on bmj.com.

How do they go wrong?

Clinical prediction rules, like diagnostic tests, are subject to biases that affect their validity and application in clinical practice.[5 7] Heuristic reasoning (cognitive strategies people learn or adopt when making decisions or solving problems) usually works well when the rule is relatively simple (with few clinical variables) but when the situation is complex, heuristic reasoning may produce errors.

Common errors when applying rules include:

- Incorrect estimates of pretest probability of disease (for example availability bias overestimates the probability of vivid or easily recalled events, such as rare but memorable disease)
- Inaccuracy due to methodological problems in

The CAGE questionnaire

Each positive answer scores one point.

1. Have you ever felt you should **C**ut down on your drinking?
2. Have people **A**nnoyed you by criticising your drinking?
3. Have you ever felt bad or **G**uilty about your drinking?
4. Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover (**E**ye-opener)?

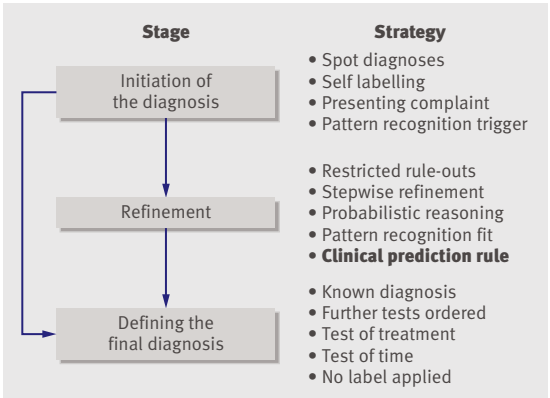

Fig 1 | Stages and strategies in arriving at a diagnosis

Positive likelihood ratio estimate[7]

Positive likelihood ratio for CAGE score of 3 = 13.3

Pretest probability = p_1 = 0.05 = 5%

Pretest odds = $o_1 = p_1/(1-p_1)$ = 0.05/0.95 = 0.053

Post-test odds = pretest odds x likelihood ratio

Post-test odds = o_2 = 0.053 x 13.3 = 0.705

Post-test probability = $o_2/(1+o_2)$ = 0.705/1.705 = 0.413 = 41.3%

Nomogram

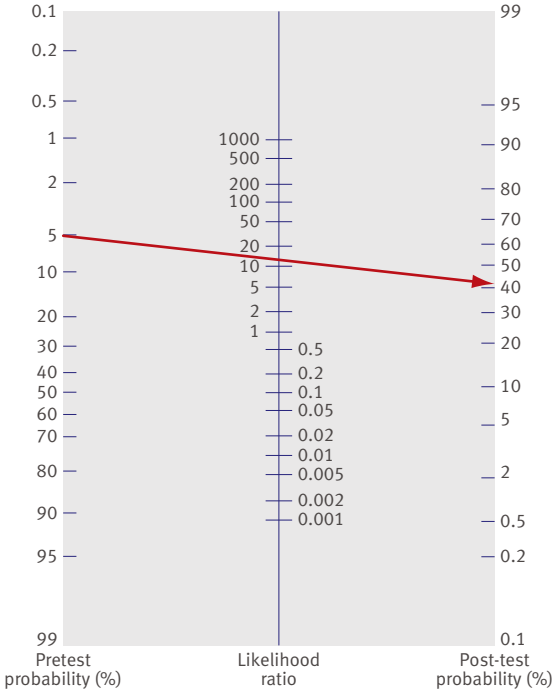

Fig 2 | **Calculating post-test probability of alcohol abuse using positive likelihood ratio estimate,[6] and equivalent method with nomogram**

their derivation (spectrum bias occurs when the study population from which the accuracy of a rule is derived has a different clinical spectrum, usually with more severe or advanced disease, than the population of patients to which the rule is applied, and can lead to the sensitivity and specificity of a clinical feature or diagnostic test incorporated in a rule being exaggerated[7])

- Imprecise quantitative estimates in rules (when sample size considerations are not reported clearly [7 8]) make the precision of the diagnostic, prognostic, or therapeutic recommendations of a rule less certain.

An example of the challenges of applying a rule to a primary care setting is the CRB-65 score, which is used to predict 30 day mortality in patients with community acquired pneumonia.[9] The score, (representing confusion, respiratory rate, blood pressure, and age over 65) was derived and validated in three cohorts of patients admitted to hospital in the United Kingdom, New Zealand, and the Netherlands.[9] Subsequent validation in a separate, community based cohort in the Netherlands showed lower 30 day mortality across all strata of risk than in hospital based patients.[10] Low risk patients can be accurately identified with CRB-65, but the optimal referral threshold for a patient with suspected community acquired pneumonia, and how it might affect their subsequent management and survival, is unclear.[4 10]

How can we improve?

Methodological standards concerning the conduct and reporting of clinical prediction rules are well documented.[1 2] STARD (Standards for Reporting of Diagnostic Accuracy) is likely to provide a framework for improved conduct and reporting of published rules, particularly in combating spectrum bias and selection bias in the populations of patients used in these studies.[11]

Recent initiatives aim to increase sample size substantially and improve precision by means of simplified study protocols and web based recruitment. For example, a study of clinical prediction rules (www.descarte.co.uk) is currently under way in UK primary care, aiming to recruit 18 000 patients with a sore throat in general practice and assess the clinical features that predict further complications.

Lastly, the accurate recall and implementation of rules can be facilitated by computer based clinical decision support systems (CDSSs) that quantify diagnostic and prognostic information and provide clinicians with patient specific recommendations.[12]

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1 McGinn T, Guyatt G, Wyer P, Naylor CD, Stiell I. Diagnosis: clinical prediction rules. In: Guyatt G, Rennie D, eds. *Users' guides to the medical literature: a manual for evidence-based clinical practice.* Chicago: American Medical Association, 2002:471-83.
2 Laupacis A, Sekar N, Stiell I. Clinical prediction rules: a review and suggested modifications of methodological standards. *JAMA* 1997;277:488-94.
3 McGinn TG, Guyatt GH, Wyer PC, Naylor CD, Stiell IG, Richardson WS. Users' guides to the medical literature XXII: How to use articles about clinical decision rules. *JAMA* 2000;284:79-84.
4 Grimes DA, Schulz KF. Refining clinical diagnosis with likelihood ratios. *Lancet* 2005;365:1500-5.
5 Fahey T, Van der Lei J. Producing and using clinical prediction rules. In: Knottnerus A, Buntinx F, eds. *Evidence base of clinical diagnosis*. Oxford: Blackwell Scientific, 2008:213-36.
6 Buchsbaum DG, Buchanan RG, Centor RM, Schnoll SH, Lawton MJ et al. Screening for alcohol abuse using CAGE scores and likelihood ratios. *Ann Intern Med* 1991;115:774-7.
7 Reilly BM, Evans AT. Translating clinical research into clinical practice: impact of using prediction rules to make decisions. *Ann Intern Med* 2006;144:201-9.
8 Bachmann LM, Puhan MA, ter Riet G, Bossuyt PM. Sample sizes of studies on diagnostic accuracy: literature survey. *BMJ* 2006;332:1127.
9 Lim WS, van der Eerden MM, Laing R, Boersma WG, Karalus N, Town GI, et al. Defining community acquired pneumonia severity on presentation to hospital: an international derivation and validation study. *Thorax* 2003;58:377-82.
10 Bont J, Hak E, Hoes AW, MacFarlane JT, Verheij TJH. Predicting death in elderly patients with community-acquired pneumonia: a prospective validation study reevaluating the CRB-65 severity assessment tool. *Arch Intern Med* 2008;168:1465-8.
11 Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, et al. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. *BMJ* 2003;326:41-4.
12 Garg AX, Adhikari NKJ, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *JAMA* 2005;293:1223-38.