

Independent evidence-based health care

ON CARE PATHWAYS

We hear a lot about guidelines, which are supposed to ensure that the right patients gets the right treatment. This is a rather glib statement, but is underpinned by some interesting ideas, including:

- ◆ **Diagnosis:** Treating the right patient
- ◆ **Treatment:** Treating the right patient right
- ◆ **Organisation:** Treating the right patient right at the right time
- ◆ **Pathway:** Treating the right patient right at the right time and in the right way

Guidelines are supposed to cover this, but they mostly cover just the first two steps. There is more to delivering good care than that. It requires good organisation - what one might call management, except that many of us now see that word as meaning anything but organisation. And it requires that we perform actions in ways that are known to deliver good quality care.

A care pathway would, in the industrial world, be a manufacturing guide, for instance. There may be many different ways of assembling a television or car, but every one is assembled in the same way on a production line, because that is the best and cheapest way of doing so, with a product that works and which the customer wants.

Care pathways, or treatment protocols, should be the quality-assessed and evidence-based way of consistently delivering high quality care for a particular circumstance. This essay will examine the evidence that they do, and see if there are any lessons to be learned about how to prepare a care pathway. First, though, a quick lesson about the perils of guidelines.

Guideline evidence [1]

Today guidelines are supposed to be evidence-based, meaning that they have used or apply the very best contemporary evidence available. The problem is that many do not.

On the face of it guidelines seem like a good idea because they should condense all the best knowledge and experience to give any individual practitioner the confidence that, within limits, they can aspire to the same level of practice as the best in their field. Bandolier's Internet pages have examples of good guidelines [1].

Variability of guidelines [2]

Not all guidelines are created equal and there are examples of great variability between the advice of guidelines. One revelation from Newcastle was that of guidelines for anticoagulation for atrial fibrillation in the UK [2].

In 1996 various people and organisations in England, Wales and Scotland were contacted about the existence of guidelines for anticoagulant treatment of atrial fibrillation. These included regional and national NHS bodies, professional and charitable institutions, and members of mailing lists of audit organisations. They represented purchasers and providers of healthcare and relevant national organisations.

Guidelines were defined as a document produced to help clinicians decide which patients should be given anticoagulant drugs. Drafts, or documents designed for single specialised units, or to provide guidance once warfarin treatment had begun were not included. Where possible, guideline developers were interviewed using a semistructured method about how guidelines had been developed.

All included guidelines were applied to 100 consecutive patients with atrial fibrillation aged 65 years or older identified in a community survey. Details of risk factors for stroke or contraindications for treatment were obtained.

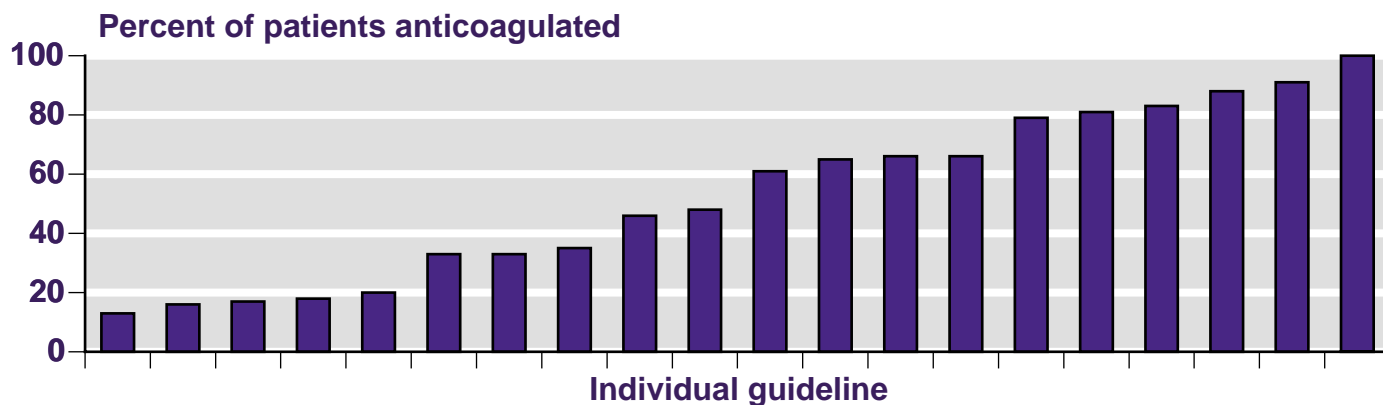
Results

The overall response rate was 66% (350/534), yielding 48 documents of which 20 fulfilled the requirements for definition of a guideline. They varied from a single page to 28 pages, were primarily for use by general practitioners, and affected populations from 12,000 to 500,000.

Guidelines were not systematically developed. A group of people developed about half, and the other half were developed by a single individual. About half had some outside consultation, but about a quarter had no external review. Distribution was haphazard and few had educational meetings to introduce the guideline. Only one was explicitly claimed to be evidence-based, and had outside consultations from a health economist and clinician, with external review and local consultation, with wide distribution and an educational meeting to introduce the guideline.

When applied to 100 consecutive patients, the number recommended for anticoagulation by the guidelines ranged

Figure 1: Anticoagulation guidelines in the UK applied to the same 100 consecutive patients



from 13 to 100 (Figure 1). Only one patient would have had anticoagulant treatment recommended by all guidelines, but every patient would have been recommended for anticoagulation by at least two guidelines (but not the same two). Target INR values varied between 1.2 to 1.5 and 2.5 to 3.0.

Evidence-base of guidelines [3]

Another examination of the evidence-base of guidelines comes from Greece [3]. Researchers looked for guidelines published in 1979, 1984, 1989, 1994 and 1999 in six prestigious English language journals (Annals of Internal Medicine, BMJ, JAMA, NEJM, Lancet and Pediatrics). The definition of what constituted a guideline was specific and included all articles containing the words guideline or recommendation or other characteristic words in title or abstract and which had a main focus on prevention or therapeutic interventions.

For each guideline, the reference lists were scrutinised and characterised as randomised trial, systematic review, meta-analysis, or neither. All cited articles were searched in MEDLINE and full records and abstracts were scrutinised. The full paper was retrieved and read in the case of any uncertainty about whether it was a randomised trial. This also applied to articles published before 1966.

Where guidelines had references, contained fewer than two citations of randomised trials, and cited no systematic reviews, a full MEDLINE search was performed up to the year of publication of the guideline.

Results

There were 191 guidelines identified in these six journals for the years searched, predominantly from the USA (86%). Group authorship was most common (84%). Of the 191 guidelines only 12 (6%) had performed a systematic review, but 130 (68%) made no mention about a lack of evidence. Thirty-six guidelines (19%) had no references.

Randomised trials made up a minority of the citations (Table 1). Only 8% of the citations were randomised trials, and fewer than 1% were systematic reviews or meta-analyses of randomised trials or epidemiological studies. The proportion of guidelines not citing any randomised trials fell from 95% in 1979 to 53% in 1999 (Figure 2). Only about one guideline in 10 had a systematic review or meta-analysis.

Thirty-nine guidelines had fewer than two randomised citations with no systematic review. Because 30 were in Pediatrics, 10 of these were chosen at random, and 19 in all were the subject of specific searches. In 12 of the 19, additional relevant randomised trials were found. The number of additional randomised trials was 1 to 194 per topic.

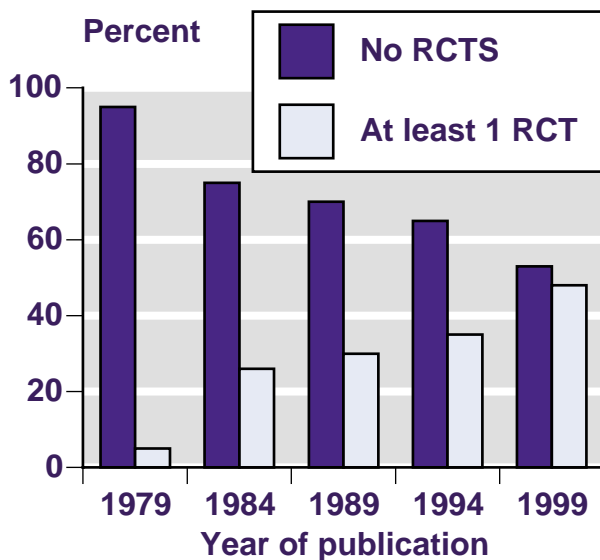
Comment

Guidelines are important, and are proliferating. They can be individual, local, regional or national, and often many variants of the same guidelines exist at the same time. Guidelines should be updated regularly. Most importantly, they should be based on the best available evidence. The evidence is that many, perhaps most, are not.

Table 1: Citations in 191 guidelines in six prestigious medical journals

Citations	Number	Percent of total citations	Mean citations per guideline
Total from 191 guidelines	4853	100	25.4
Randomised trial	393	8.1	2.1
Systematic review	19	0.4	0.1
Meta-analysis of randomised trials	23	0.5	0.1
Meta-analysis of epidemiological studies	11	0.2	0.1
Books/pamphlet/brochure	719	14.8	3.8
Abstract	122	2.5	0.6

Figure 2: Evidence from RCTs in guidelines



These two papers look at a particular clinical condition exclusively in the UK, and more widely at material that turned out to be predominantly from the USA. They give the same answer, that when examined guidelines are not good enough. The Greek review [2] interestingly looks at parameters associated with citing randomised evidence in guidelines. Those funded by government and professional bodies were worse than those with university and private (usually pharmaceutical) sources of funds. The lesson is that we should not take any guideline on trust, without a sceptical examination of how it has been arrived at, and whether it has followed good practice for guideline development.

Care pathways/treatment protocols

The unique biology of the patient, with their special circumstances, drives diagnosis and treatment. Yet individuals are often sufficiently similar one to another to make a treatment protocol, based on evidence, seem worthwhile. Even if it ensures that nothing important is missed, it should reduce error and might improve results. To that end treatment protocols, or clinical pathways, critical pathways or care paths have been developed and are used.

Do they deliver? This is not just being precious about evidence, but has real importance. Treatment protocols often require more front-end resources. Where the biggest constraint is one of capacity, as in the NHS right now, we need to know that professionals' time is likely to be used to the best advantage.

Treatment protocols are often used in hospital, where the advantage might be reduced length of stay. Where beds are restricted or waiting times long, more throughput could be a major efficiency benefit.

Looking for evidence from randomised trials that care pathways or treatment protocols deliver the goods is not easy, but PubMed has been searched using a variety of free-test terms, and reference lists and reviews scanned. What follows is not an exhaustive systematic review, but the papers

we found. There are a number of examples, in different situations with different goals and outcomes, all in secondary care. For each we give a brief outline of the method and results.

Hip and knee replacement [4]

This study in Australia randomised patients admitted for standard hip or knee replacement to:

- standard reactive treatment where the treating team responded to the will and condition of the patient in providing postoperative care
- proactive treatment in a care pathway where specific goals were set each day for the patient and treating team, using a special written protocol listing milestones to be achieved, tests ordered, and daily tasks for patient and team members.

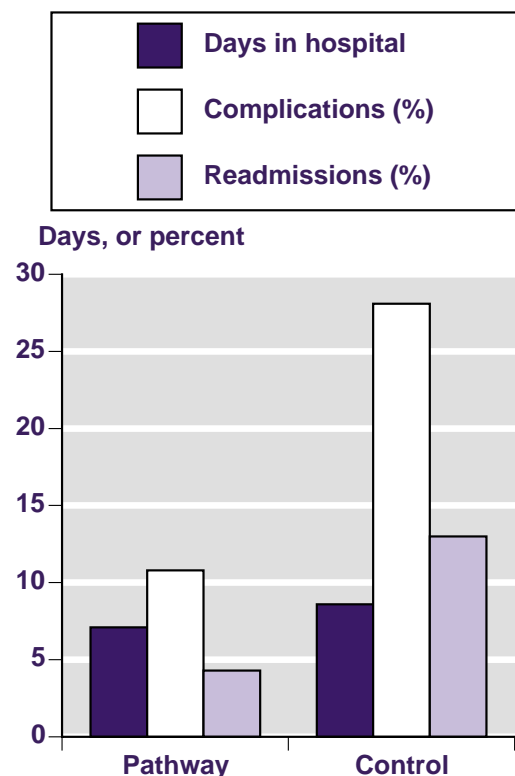
The main outcome was length of stay, but others collected included complications (wound infection, chest infection, deep vein thrombosis, for instance) and readmission rates.

Results

The 92 patients randomised to the pathway and 71 to control were similar in age, weight and co-morbid conditions. Those treated in the pathway sat out of bed and were ambulant earlier, and were discharged after 7.1 rather than 8.6 days (Figure 3). There were fewer complications, and the proportion readmitted within three months was 4% for the pathway, against 13% for controls.

Reduced length of stay did not increase the complication rate. This might have been a concern, perhaps, about

Figure 3: Outcomes in knee and hip replacement



whether the patients were having too little time in hospital with more complications and higher readmissions later on. Readmissions did not increase, but fell. No costs or resource allocation are given in the paper, but there is no indication that this care pathway should cost more to provide better quality of care.

Fractured neck of femur [5]

Another Australian study randomised (by date of birth) uncomplicated patients with fractured neck of femur to usual care or to a clinical pathway. The main components of this pathway included an admission information checklist, specific pathway documentation specifying responsibilities and time, with a discharge package, and with discharge planning begun on admission.

Results

The 55 patients randomised to the pathway and 56 to control were similar in age and weight. Those treated in the pathway had earlier mobilisation, and were discharged after 6.6 rather than 8.0 days. There were fewer in-hospital complications (24% versus 26%), and the proportion readmitted within one month was 4% for the pathway, against 11% for controls, though these last two were not statistically different.

This was a small study in a unit already operating with an on-site rehabilitation unit and quite short background length of stay. Patients included those who, on admission, were confused (40%), had a co-morbid condition (33%) or who did not speak English (26%), so that the population studied was not over-selected. Their mean age was 83 years.

Inpatient asthma management [6]

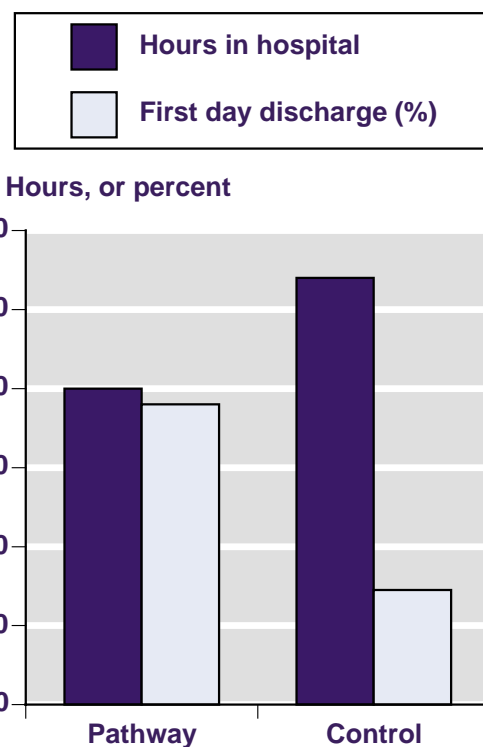
In this study from Johns Hopkins a paediatric multidisciplinary team combined to create the care pathway, plus a weaning protocol designed for asthma patients between two and 18 years of age. Patients being admitted with a primary diagnosis of asthma exacerbation were randomised to a bed on the intervention unit (in which staff had been trained in the pathway) or a control unit in which they received standard care.

Results

There were 55 patients treated using the clinical pathway, and 55 usual care controls. Patients were similar apart from clinical path children being slightly older. The duration of hospital stay was significantly shorter using the clinical pathway (40 versus 54 hours, Figure 4) with a larger percentage discharged in the first day (38% versus 15%). The pathway also resulted in less use of beta-agonists. The average cost was almost US\$1,000 per patient lower for patients in the clinical pathway.

A particularly detailed and interesting paper, this. It shows shorter stay, better outcomes, and lower cost. One problem was that only a quarter of eligible patients could be enrolled in the study because of bed shortages.

Figure 4: Outcomes in asthma management in children



Community-acquired pneumonia [7]

A critical pathway for treating patients had three main components: use of a clinical prediction rule to assist admission decisions, treatment with levofloxacin (a fluoroquinolone antibiotic with good oral bioavailability and broad antimicrobial activity), and practice guidelines for care of inpatients. Nineteen hospitals were randomised to continue conventional management or implement the critical pathway.

Results

Over six months 1,743 patients were evaluated. Hospitals using the critical pathway had an 18% reduction in the admission of low-risk patients (31% versus 49% of admissions were low risk). Those treated in hospitals using the pathway spent 1.7 fewer days in hospital (5.0 versus 6.7 days), despite having more severe disease. Patients at hospitals implementing the pathway were also much more likely to be treated with a single antibiotic (64% versus 27%). There was no difference in the rate of adverse clinical outcomes (intensive care admission, mortality, readmission, complication), or quality of life indicators.

Combining the lower admission rate and reduced hospital stay, this care pathway, the authors computed a reduced cost of treating each case of US\$1,700. This was at no reduction in quality of care or clinical outcomes.

Stroke rehabilitation [8]

An integrated care pathway based on evidence of best practice and professional standards was developed and coordinated by an experienced nurse in London. Eligible patients were those with persistent impairment within two weeks

of the event. Exclusions were those with severe premorbid conditions or cognitive disability, or who had only mild deficits not needing rehabilitation. The stroke rehabilitation unit had two independent teams of carers, and the care pathway was introduced in one of them.

Results

There were 76 patients in each group, with a mean age of 75 years and no difference at baseline. There was no difference between the groups in outcomes or length of stay, institutional admission, or mortality.

This negative result could, of course, be due to the fact that care was already so good that it could not be bettered. The average length of stay was about 50 days, but the standard deviation was a huge 20 days, indicating the large variations between patients. This may have been influenced by issues other than those in the study. And there could have been cross-over between the two teams. Whatever, the additional cost of a coordinating nurse made the pathway more expensive at no benefit.

Use of laboratory tests [9]

Prospective randomised studies of patients undergoing elective surgery or acute medical admissions using clinical pathways were examined for use of laboratory tests in this Australian study.

Results

In the elective surgery study of 224 patients, use of laboratory tests was reduced by about 70% using the care pathway (1 versus 3 tests per patient for hernias, 3 versus 7 tests per patient for cholecystectomy). For acute medical admissions, there were 12 versus 16 tests per patient using the care pathway. These were mainly haematology and clinical chemistry tests. Estimated cost reductions were of the order of A\$68 (£26) per patient.

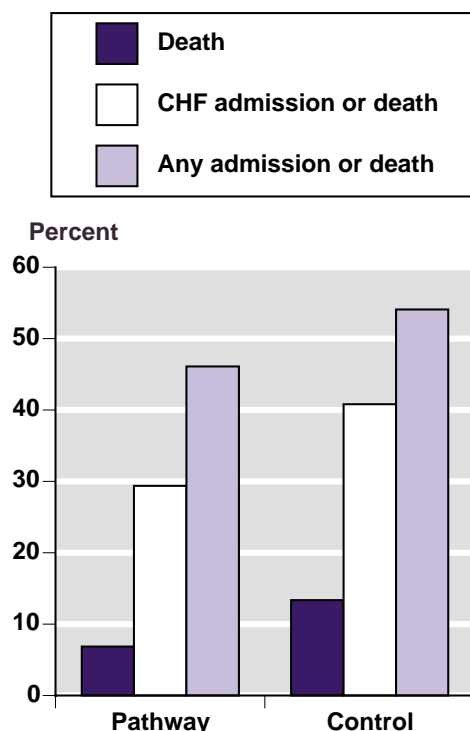
There was no suggestion that patient care was in any way impaired by this reduction in laboratory testing. As laboratory tests have often been shown to be over-used, this outcome is a beneficial effect from using a care pathway.

Heart failure [10]

This randomised study from Johns Hopkins concerned patients at high risk of coronary heart failure readmission. This was defined by the presence of one or more of a rather long list that included age over 70 years, low left ventricular ejection fraction, at least one admission for heart failure in the previous year. An intervention team involved a telephone nurse coordinator, a heart failure nurse, heart failure cardiologist and the patient's primary physician.

The cardiologist designed and documented a treatment plan for all study patients before randomisation and saw patients at baseline and after six months. The primary care physician delivered the interventions and looked after all non heart failure problems. The heart failure nurse visited patients on a monthly basis, and the telephone coordinator

Figure 5: Outcomes in heart failure management in the community



also kept in contact. In the usual care control group the cardiologist's plan was documented without further intervention.

Results

Two hundred patients were enrolled, and the two groups were similar at baseline. There were fewer heart failure hospital admissions or death over six months using the care pathway (49% versus 73%; Figure 5). Patients in the care pathway group were more likely to hit targets of treatment (weight, diet, vasodilators), and have stable or improved symptoms. Inpatient and outpatient resource use had similar costs, though the care pathway group tended to have lower costs and shorter lengths of stay.

For every 10 patients treated in the care pathway, one fewer would have died or had a hospital admission for heart failure compared with usual care. Better quality was delivered at the same cost.

Community acquired lower respiratory tract infection (LRTI) [11].

The study was conducted in the medical wards of a single hospital in Antrim. All adult patients admitted with a primary diagnosis of LRTI during December 1994 to February 1995 formed the control group. Diagnoses were made on clinical grounds supplemented with X-rays in most cases. Patients received empirical treatment before development of a treatment protocol.

After development and institution of a treatment protocol in November 1995, all patients admitted with a primary diagnosis of LRTI from December 1995 to February 1996 formed the intervention group.

The treatment protocol consisted of measuring the severity of the condition according to age more than 60 years, respiratory rate above 30 breaths/minute, diastolic blood pressure below 60 mmHg, white cell count below 4 or above 20 billion cells/L, new confusion, new atrial fibrillation and multiple lobe involvement on X-ray. One point was given for the presence of each of these, and treatment instituted depending on severity:

- ◆ Moderate (score 2 or less): oral amoxicillin/clavulanic acid every 8 hours.
- ◆ Severe (score 3 or more): intravenous cefuroxime every 8 hours.
- ◆ Very severe (score 3 or more and pO₂ less than 8 kPa on 28% oxygen): intravenous cefuroxime every 8 hours and intravenous erythromycin every six hours.

Protocol construction was with involvement and support of all consultant physicians. Introduction involved presentations, seminars and ward discussions, involvement of new junior medical staff, distribution of written summaries of the protocol, posting the algorithm in all wards, encouragement of implementation by clinical pharmacists.

Details of patients and outcomes were collected on a customised data collection form. Treatment success was a major improvement or complete resolution of all signs and symptoms, and failure persistence or progression of signs and symptoms, or development of new clinical findings, or death from the primary diagnosis, or discontinuation of medicines because of adverse reaction.

Results

There were 112 patients in the control group, and 115 in the treatment protocol group. Their mean age was about 68 years, with a mean onset of about five days at admission. Two thirds were moderate and one third severe on admission. There were no differences between the groups, and no patient was very severe on admission. Most patients (99%) had an X-ray. The only significant difference in laboratory testing was that 98% of patients on the protocol had a sputum cultured, while only 55% of controls had this test.

There were 35/112 treatment failures (31%) on control and 9 (8%) on the protocol. The reasons for the failures are shown in Figure 6. Protocol was better than control for every reason for failure. For every four patients on the protocol there

was one fewer treatment failure than if the protocol had not been used (NNT 4.3, 95% CI 3.0 to 7.4).

Control patients had a mean length of stay of 9.2 days. Those on the protocol had a mean length of stay of only 4.5 days. The overall average cost per control patient was £2,024 and £1,020 for a protocol patient, a saving of £1,000 per patient. Most savings came from lower bed costs and lower antimicrobial costs (£11 protocol vs £54 control).

Adopting a treatment protocol delivered better care at lower cost. Protocol construction and implementation was exemplary. This is a study worth reading, though individual hospitals may want to institute different regimens because of local differences.

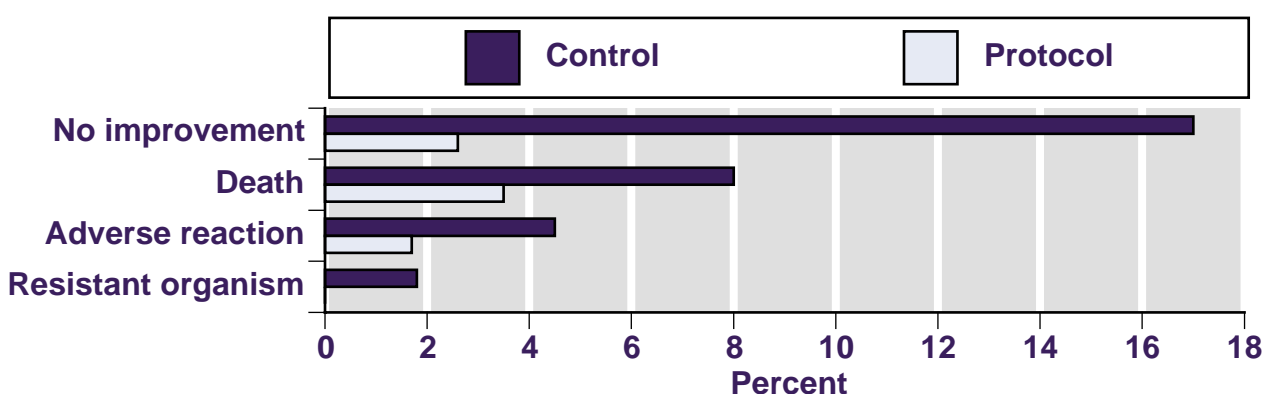
Emergency admission with pneumonia [12]

A similar study to that in Antrim had been conducted before in Pennsylvania. This retrospective time series study looked at three cohorts of patients admitted to an emergency department with community-acquired pneumonia, before and after the introduction of a critical pathway.

A multidisciplinary group established a pneumonia pathway detailing the recommended sequence of clinical actions and decisions from the time of arrival in the emergency department, and through hospital admission to discharge. It recognised the need for a standardised set of antibiotic regimens, depending on where the patient came from, and based on national US guidelines. A key feature of the pathway was early recognition, diagnosis and prompt antibiotic treatment of pneumonia.

All patients admitted with pneumonia during a three month period immediately before the introduction of the pathway, over the period 10-12 months afterwards, and over the period 34-36 months afterwards formed the subjects in the survey. Each period was for three months, and the same inclusion criteria were applied. These were age 18 years or more, admission to emergency department with primary diagnosis of pneumonia and radiologic evidence at time of admission, and a discharge diagnosis of pneumonia. Not included were patients with antibiotics administered before admission, with HIV infection, extensive stay in hospital because of another diagnosis, or repeat admission with the three months assessment period.

Figure 6: Results in Antrim before and after protocol for LRTI



Results

In the three periods were admitted 63, 96 and 122 patients respectively. The mean age of patients was mid 70s, about equally distributed between the sexes. Vital signs were similar between the three cohorts, as was the frequency with which symptoms were reported.

One of the process of care goals was decreasing time to antibiotic administration in the emergency department. In the cohort admitted before pathway initiation, the mean time was 315 minutes, and 58% of patients had antibiotic administered in the emergency department. The proportion administered antibiotics in the emergency department increased to over 90% in both post initiation cohorts, with mean time to antibiotics down to 170 minutes.

The main gains were in mortality in hospital, which fell from 10 to 5% (Figure 7), and in length of stay, which fell from 10 to six days (Figure 7). The decline in mortality was not statistically significant, given the small number of deaths that actually occurred.

There are several interesting things about this paper. Unusually, it has assessed the effect of the care pathway not just in the period immediately after introduction, when effects might be expected to be greatest, but one and three years later. The findings were that, if anything, results continued to improve, showing that initial benefits can be maintained.

It sought rapid diagnosis and treatment using standardised antimicrobial therapy, treating the right patient right in the right way and at the right time. This not only improved the quality of care (fewer deaths), but must have reduced costs. Four fewer days in hospital is between £800 and £1,000 less cost per patient, just as was seen in Antrim.

There is more too it than that, though. Fewer days in hospital means less stress on a capacity constrained system. In reality, we should increase the cost savings to take account of this very important finding.

Clinical pathway for bronchiolitis [13]

A multidisciplinary team generated this guideline for infants of one year or younger admitted with a first time episode of typical bronchiolitis. The method of guideline development was described in detail, and included exact information from hospital data systems about children admitted with the condition, and a systematic review of literature relating to the condition. A series of order sheets and scoring instruments were developed, and subjected to peer and institutional review before being implemented.

The guideline was not formally made into a clinical pathway, and specifically clinicians did not have to document when guideline goals were met or recommendations not followed.

Evaluation of the guideline was by a retrospective comparison of children admitted in the first eight or nine weeks after it had been implemented and children admitted in the same eight-week period over four years before the guideline was introduced.

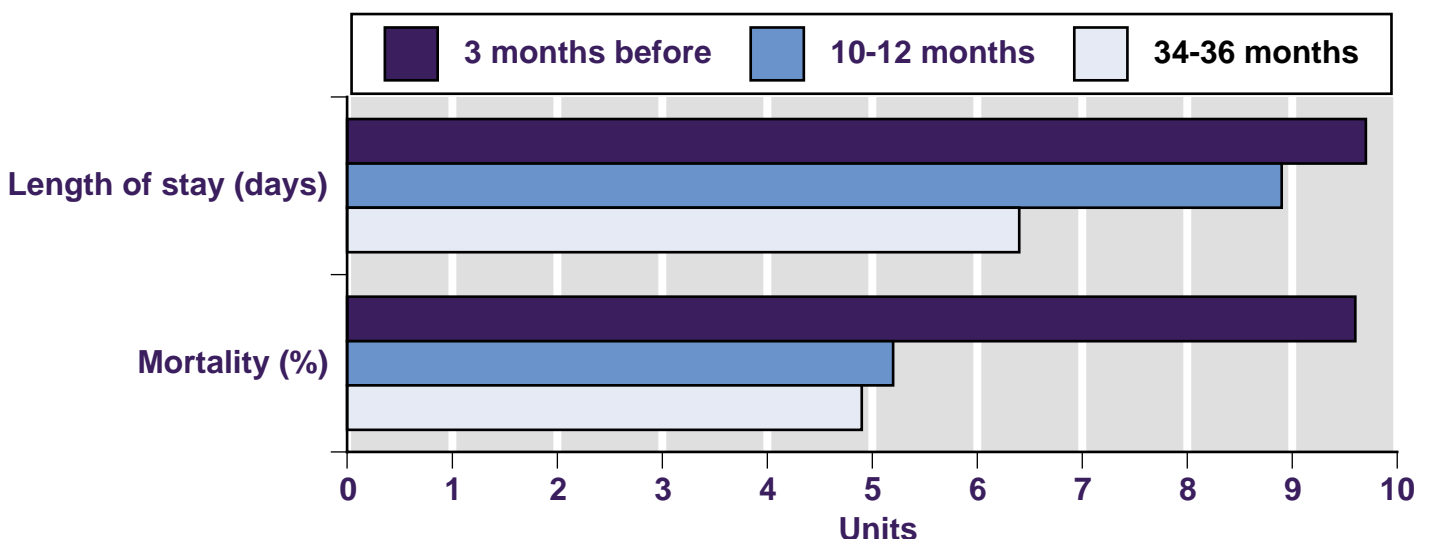
Results

There were 1,300 records for children admitted before implementation, and 229 admitted after implementation, of whom 181 had a guideline admission order. There were no differences between the two groups for a number of characteristics.

The main results of the pathway implementation was a reduced length of stay (by an average of half a day) and a reduction in overall cost (by US\$400, or 37%). Use of beta-agonists was reduced, but not antibiotics, where use was high at 56%.

A later report [14] extended the observations for two additional years, and confirmed the reduction in costs, especially bed occupancy and respiratory care. This guideline was so very close to being a clinical pathway that it is included in this essay. It has been used as the basis of other pathways.

Figure 7: Effect of a clinical pathway for pneumonia on length of hospital stay and mortality



Another clinical pathway for bronchiolitis [15]

Many children are admitted to hospital with bronchiolitis, and it is known that bacterial infection requiring antibiotics is a factor in only a very small proportion. Despite this, many children receive unnecessary antibiotics. This adds to costs, has the possibility of adverse reactions, and could serve to increase microbial resistance to antibiotics. Reducing this unnecessary antibiotic prescribing is thus a goal for a quality service.

The development of the clinical pathway is not well described, but its intent was to reduce inappropriate antibiotic use. It consisted of a detailed order set, inclusion and exclusion criteria, criteria for admission and discharge, educational material on bronchiolitis and the specific goals of the pathway. Parent and family material was included, explicitly emphasising the evidence that antibiotics are rarely indicated in this condition.

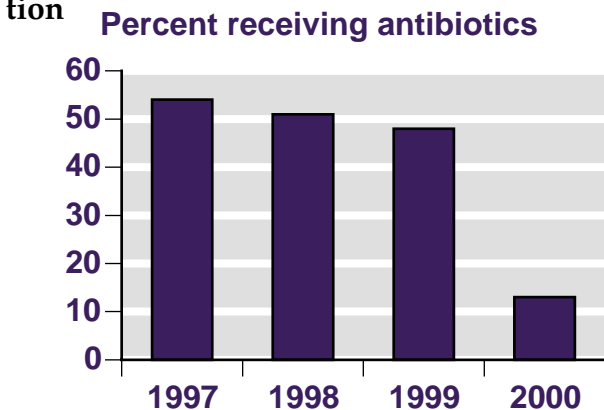
All patients admitted through one complete winter season after the introduction of the pathway formed the patient cohort. The review was by an involved investigator, and children on the pathway were matched to a group of children who met the inclusion criteria for pathway use but who were not managed on the pathway. Inclusion was viral respiratory infection with wheezing and respiratory distress in children over four weeks of age. Matching was done on the basis of age, disease severity, and socioeconomic status.

Results

There were 96 children treated on the pathway and 85 not treated on the pathway. The two groups were indistinguishable in terms of severity indices. Antibiotics were used in just 9% of children on the pathway, compared with 27% off the pathway. Length of stay was half a day shorter on average on the pathway, and average cost was reduced by US\$1,000 (from \$3,200 to \$2,200). There was no increased unplanned admission after discharge on the pathway.

For the three years before the implementation of the clinical pathway, antibiotic use occurred in about half of children with the condition. In the year after implementation this fell to 13% (Figure 8).

Figure 8: Antibiotic prescribing for three years before and one year after pathway introduction



This may not be the very best of study architectures, and we do not know why some children were treated on the pathway and others off it. Though they appeared to have very similar characteristics, the non-random approach may have led to the introduction of some biases.

Clinical care pathway for colon resection [16]

Here we have a straightforward before-after study. The intervention was a care pathway for patients undergoing colon resection. It involved at-home bowel preparation before admission, pre-operative patient education about length of stay and return of bowel function, standardised anaesthetic, and, to some extent, surgery, and standardised postoperative care, discharge, and post-discharge education for patients.

A strength of this study was that it involved all patients undergoing this surgery with a single surgeon at one hospital, from start of practice. It was therefore comprehensive, and the comparison was with patients operated on before the new pathway and those operated on after the care pathway was initiated.

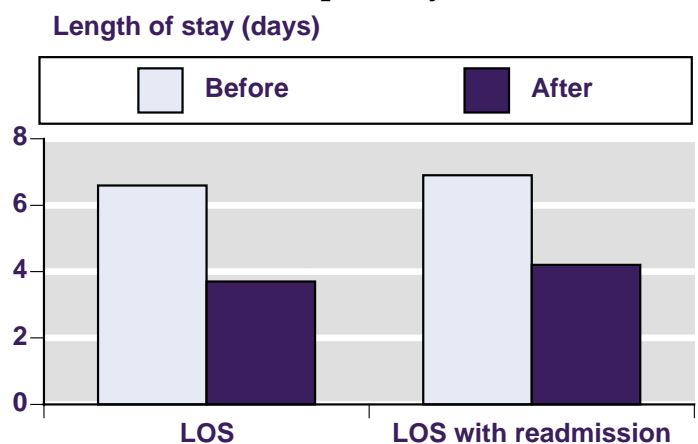
Results

There were 138 patients, 52 before and 86 after pathway initiation. The two groups were broadly similar, though the after group were somewhat younger, at 62 years, than the before pathway group, with an average age of 69 years.

The length of hospital stay was reduced from an average of seven days before the pathway to 3.7 days after the pathway. There were somewhat more re-admissions (10% vs 2% before) after the pathway, but including this additional time in hospital made no difference to the average length of stay saved (Figure 9). There were fewer complications in patients treated on the pathway (12% vs 25% before).

Hospital costs fell with the new pathway. Before these averaged US\$8,800 and afterwards they averaged \$6,500, an average saving for each patient of \$2,300. When the costs of readmissions were added, the before and after costs rose to \$9,300 and \$7,100, and the average saving was still \$2,200.

Figure 9: Length of stay for colon resection before and after care pathway introduced



The implementation of a comprehensive care pathway resulted in no loss of quality of care. It was cheaper because patients spent less time in hospital. Of course, elective surgery lends itself to the use of care pathways, given that the environment in which it occurs is well managed, and not constantly assailed by the vagaries of bed crisis, blocking, or emergency surgery.

Improving pain control after Caesarean section [17]

In Warwick, a baseline audit involving case note review and interviews with 30 mothers suggested that pain control was not always satisfactory. Pain was not being routinely assessed, and it limited function, stopping some mothers from feeding and bathing their babies.

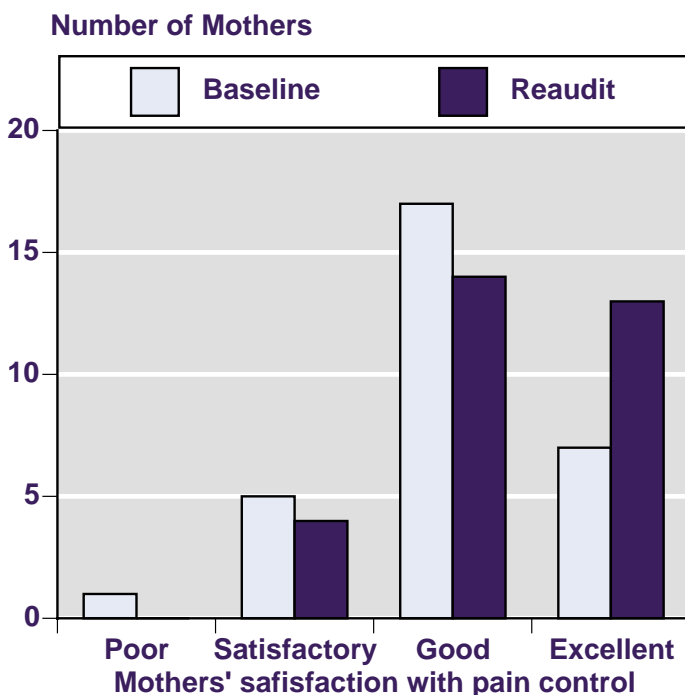
This prompted the formulation of a local protocol for the management of post-Caesarean pain, with input from different professions. Key features of the protocol were the introduction of formal pain assessments, the use of pre-printed prescription labels to apply to drug charts and the introduction of self-medication by mothers. The introduction of self-medication was supported by intensive on-one education and discussion for professionals, and a patient information leaflet. Reflecting the three-step approach, the leaflet explained how mothers should handle mild, moderate and severe pain and how to seek advice if needed.

Results

A re-audit in 31 mothers showed that:

- ◆ Maternal function was much improved. Only seven mothers were not caring for their babies with just one giving pain as the reason (the other six were in SCBU). In the baseline survey, the numbers were 13 and 10 respectively.

Figure 10: Pain control pathway for mothers



- ◆ The incidence of severe pain at rest and on movement was down by about 30%.
- ◆ Mothers were more satisfied with their pain control. Over 40% (13) rating pain control as excellent compared with about 20% (7) in the baseline.

The length of stay of mothers was not recorded in the baseline audit but subsequent examination of hospital records revealed an encouraging reduction of one day between the baseline and re-audit. Based on the hospital's average number of Caesarean sections (438 a year), the average reduction of one postoperative day suggests a saving of about £95,000 per annum or 438 bed days. It could be argued that these savings are a direct consequence of the new protocol because there have been no other policy or operational changes in the care of mothers after Caesarean section.

What is interesting about the Warwick experience is that, though small, it demonstrates what can be achieved in even relatively small institutions by simple management techniques. Again, the result is better quality of care delivered at a lower cost.

Treating the right patient right

All of the examples we have looked at so far have in common that patients entering the care pathways had well defined conditions. The right patients were clear, and it was mainly the right treatments and their organisation that was being examined. Finding the right patients to treat is a somewhat different matter, and there are examples of where finding the right patient to give the right treatment is the key.

Two examples follow, both randomised trials, that demonstrate the importance of giving the right treatment to the right patient, a defining issue for care pathways. One examines rehabilitation for back pain, and the other treatments for acute migraine.

Back pain rehabilitation [18]

There were two studies in one in this example. The main study looked at different levels of intervention for people off sick from work with musculoskeletal problems for more than eight weeks. The subsidiary study examined the effectiveness of treatment depending on an initial prognosis determined by a screening instrument.

The setting was the area around Bergen, with a population of 270,000. Participants were recruited from sickness insurance records if they were off work for eight weeks or more. The total approached was 1,988 (0.74% of the total population). Because some people did not accept the invitation to participate, the final sample was 654 individuals (33% of the total).

A screening instrument consisted of a questionnaire and a structured examination by a physiotherapist. The details are too many to explain here, but in a fairly simple process participants were graded as having a good, medium or poor prognosis to return to work.

A properly randomised open study involved three treat-

ments:

1. Ordinary treatment described referral back to a general practitioner.
2. Light multidisciplinary treatment and follow up comprised a lecture on exercise and lifestyle and fear avoidance advice, with information and feedback. Patients were encouraged gradually to increase their activity level. Patients received individual exercise programmes. Some were referred to physiotherapists. Over a year each patient received an average of three individual follow ups.
3. Extensive multidisciplinary treatment and follow up involved a more intensive treatment programme lasting for four weeks, with six hour sessions five days a week. It involved cognitive-behavioural modification, education, exercise and occasional workplace interventions. Patients were encouraged to take responsibility for their own health and lifestyle. Follow up over one year with individual pain management programmes.

The outcome was return to work by one year after the intervention, which took place about two months after screening. A cost benefit analysis was also carried out for the light and extensive multidisciplinary treatments. Economic returns were measured in terms of productivity gain when patients returned to work minus the costs of the treatment programmes.

Results

At baseline the three treatment groups were well matched. The mean age was 44 years, about two thirds were women, and three quarters of patients had back pain or neck or shoulder pain. About half were considered to have a medium prognosis for return to work, 22% had a good prognosis and 28% a poor prognosis. More patients had returned to work at one year with a good prognosis or medium prognosis than with a poor prognosis.

Ordinary treatment led to fewer patients at work at one year

(50%) than either the light or extensive multidisciplinary treatments (60%).

- ◆ For patients with a good prognosis, there was no difference between treatments.
- ◆ For patients with a medium prognosis there was no additional effect of extensive over light multidisciplinary treatment. Ordinary treatment for these patients gave poor results (Table 2).
- ◆ For patients with poor prognosis extensive multidisciplinary treatment was superior to ordinary or light multidisciplinary treatment (Table 2).

Most patients returned to work if they were given treatment appropriate to their screening category (Figure 11). Between 55% and 64% returned to work when given the right treatment.

If screening results rather than randomisation had been the determining factor for the type of treatment, then productivity gains would have outweighed the cost of treatment by \$800 per treated patient.

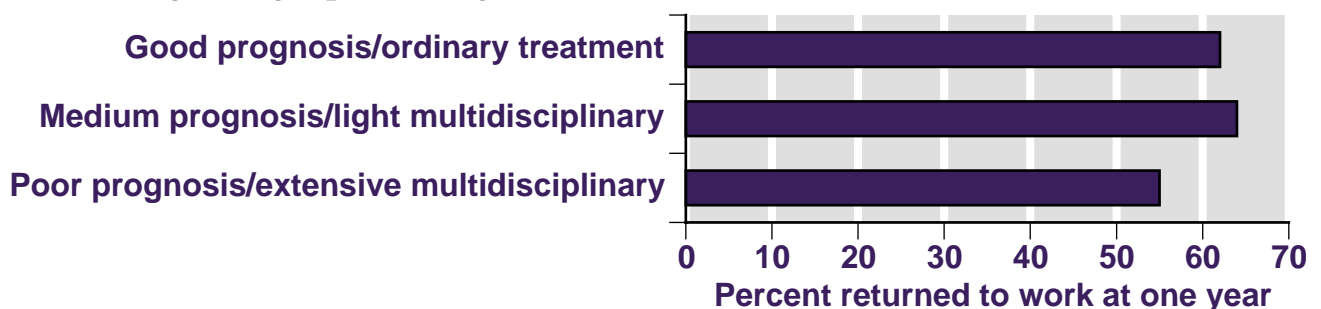
What we have here is a demonstration from a randomised trial that doing the right thing for the right patient pays dividends. The benefits are to the patients who get back to work, and benefit because of it, and society, which benefits because the productivity gains outweigh the costs of getting people back to work. Whether this would be true in societies other than Norway is another matter.

The general principle seems sound. One size does not fit all, and the average results from studies need not apply to individuals. It sounds more complicated, but actually is not. It comes down to a greater appreciation of the benefits of triage, or diagnosis, or prognosis. All topics where evidence is painfully thin.

Table 2: Results of different treatment strategies with medium and poor prognosis

Initial prognosis	Percent in work at one year		
	Ordinary treatment	Light multidisciplinary	Extensive multidisciplinary
Medium	48	63	62
Poor	37	44	55

Figure 11: Treating the right patients right



Acute migraine attacks [19]

A number of strategies can be used to treat acute migraine attacks, each utilising some part of the evidence base.

- ◇ For instance, the initial attack could be treated with aspirin or simple analgesic, and if or when that fails, a triptan could be used. That is a **step strategy within an attack**.
- ◇ A different approach may be to try aspirin or simple analgesic for a few attacks. It will work for some, but for those for whom it does not work, a triptan may be an alternative treatment. That is a **step strategy across attacks**, and is probably the strategy most likely to be used in the UK as it is probably seen as the cheapest.
- ◇ A third way would be to assess the individual patient for the severity of the disorder, and then to treat appropriately: mild disease might be treated with aspirin or simple analgesics, while more severe disease might be treated with a triptan. This would be **stratified care**.

It just so happens that a randomised controlled trial indicates that stratified care produces the best results.

The trial was randomised, but open-label, and examined multiple migraine attacks for patients with established diagnosis of migraine according to International Headache Society criteria. Patients completed the MIDAS questionnaire [20], that measures lost time in three domains of activity. Patients were assigned a grade of disability from I (little or infrequent disability), grade II (mild or infrequent disability), grade III (moderate disability) to grade IV (severe disability). Patients with grade II-IV disability were included.

Randomisation was to:

- 1 **Stratified care:** grade II patients received aspirin 800 to 1000 mg plus metoclopramide 10 mg for all six attacks. Those with grade III or IV received zolmitriptan 2.5 mg.
- 2 **Step care across attacks:** Patients treated the first three attacks with aspirin 800 to 1000 mg plus metoclopramide 10 mg. Those without adequate relief took zolmitriptan 2.5 mg for the next three attacks.
- 3 **Step care within attacks:** Patients treated all attacks with aspirin 800 to 1000 mg plus metoclopramide 10 mg first. If adequate relief was not obtained by two hours, they then took zolmitriptan 2.5 mg.

Results

In the three treatments groups, 1062 patients were randomised. Twenty percent of patients withdrew or were lost for various reasons, mostly innocuous. Only 3% withdrew because of an adverse event, and 0.2% because of deteriorating condition. Groups were well balanced.

More patients had a two-hour headache response in the stratified care strategy than for either step care strategy (Figure 12).

Figure 12: Two-hour headache response for up to six migraine attacks with different treatment strategies

Percent of patients with headache response at 2 hours

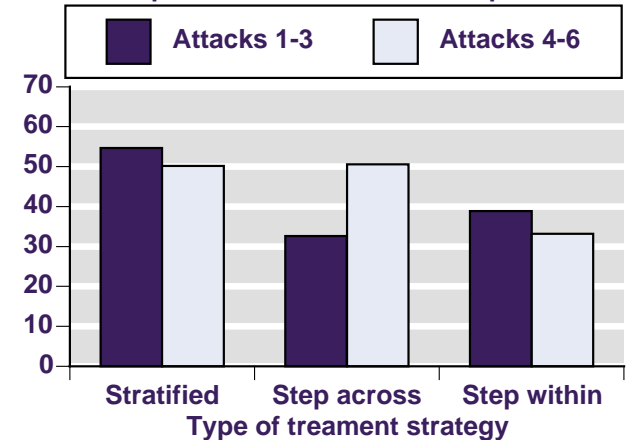
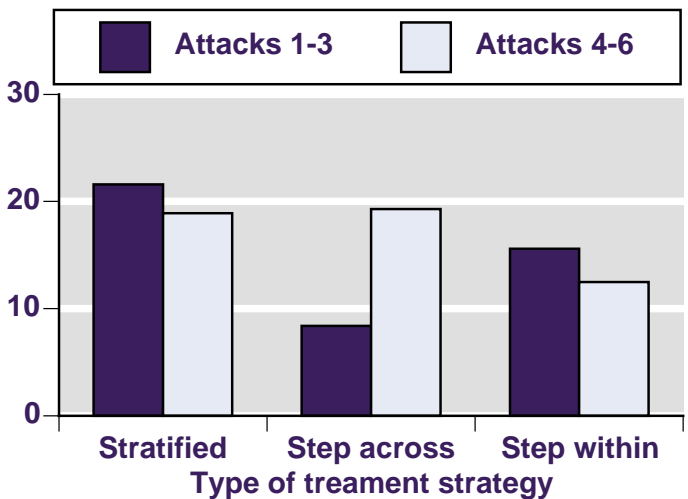


Figure 13: Two-hour pain free for up to six migraine attacks with different treatment strategies

Percent of patients pain free at 2 hours



More patients were pain free at two hours in the stratified care strategy than for either step care strategy (Figure 13).

Adverse events were equally common in all three groups, and were predominantly mild and transient. Adverse event study withdrawals were evenly distributed across the groups.

Most guidelines would probably accept a step up approach, similar to that of step up across attacks, but with many more steps. Because of the time involved, and because of repeated failure of treatment, some patients simply become disenchanted and seek other forms of treatment.

Treating the appropriate patient appropriately from the beginning is a better bet. It takes less time, is more effective, and is without the "hassle factor" for patient and doctor. This is exactly what evidence-based medicine was supposed to be about, and reading the definition of EBM in the context of this trial is rewarding.

Care pathways do not start from nowhere and nothing. It is not as if what we do usually is badly awry, and our experience in modern healthcare systems is the opposite. These large, complex, organisations looking at millions of individual people do a simply marvellous job for most people most of the time.

While recognising that, none of us could or would claim that everything is perfect. There is always room for improvement as our technology, experience, and support services improve. The issue is often not one of no change, but often one of too much change, but of the wrong sort.

In industry, care pathways would be called something else. A mix, perhaps, of good practice and quality control, plus a large helping of ongoing quality improvement. After all, care pathways involve not one action, but many, often in a complex package of care. In these complex packages, it is the combining of individual interventions in a management framework suited to local needs and abilities that is the critical factor.

Many of the examples cited here have things in common. They frequently:

- ◆ Examine the external evidence for individual technologies.
- ◆ Combine this with local knowledge and experience and conditions.
- ◆ Involve a number of different disciplines of people, in a team decision and creating ownership of the product.
- ◆ Measure the results of the actions.
- ◆ Have information systems feeding back to the team on a timely basis.
- ◆ Amend the pathway in the light of results.

They also have in common that they deliver a better quality of care, and almost always manage to do this at lower cost. That is perhaps the single most important result - better quality at lower cost.

This goal is exactly the one most sought after by commissioners and the folk who hold the purse strings.

Of course, care pathways cannot and will not work in an environment of chaos, and they demand a certain basic structure that is reasonably constant. That may be obvious, but is still worth saying.

This brief review cannot be comprehensive. Finding examples of care pathway evaluation in the literature is not easy, without a lengthy searching exercise. If readers know of good or better examples, *Bandolier* would love to hear about them.

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