

CON: encouraging resistance to rule-based medicine is essential to improving outcomes

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Know the rules well, so you can break them effectively.—Dalai Lama XIV

The golden rule is that there are no golden rules.—George Bernard Shaw

Of course my rules are necessary, proportionate and flexible, it is *your* rules that are the problem, being arbitrary in nature, excessive in force and of course far too numerous, all of which lead to unintended consequences.

Rules like so much else in medicine are a quantitative science and until the far off day of every fact being known allows reliable rules to be formulated, then like an elevator in a skyscraper, the trick is knowing on which floor to get off when the current known rules stop applying to a situation. Hence this article opposes at least in part the paper in this issue by Blakey *et al.*¹

PubMed yields 18 962 results where 'rule' or rules' are in the title and in our comparatively enlightened trust there are about 160 clinical guidelines varying from 2 to 274 pages and some 475 other trust policies and guidelines. Despite this, there are so many situations where there simply are no rules.

The first reference by Blakey *et al* concluding that algorithmic predictions are superior to clinical judgement² is based on studies from 1944 to 1989 only and covers everything from the prediction of coupon utilisation from mail order catalogues via the risk of malingering to the 'diagnosis' of homosexuality! Of the few papers cited published between 1980 and 1989, clinicians predicted intensive care unit mortality and the diagnosis of abdominal pain better than algorithms but clinicians were worse on diagnosis of myocardial infarction and chest pain. The enthusiasm of Blakey *et al* for new technology and the papers they cite undoubtedly shows better capture of data nowadays but the outcomes remain the same i.e. 'the August effect 'remains despite no increase in work load';³ it is just the work of the most junior doctor is

of a lesser standard due to less experience even *with* rules. The reader is strongly recommended to read Stephen Green on the problems with more up to date clinical decision rules (CDRs).⁴ He states 6 considerations (dare I say rules) before a CDR should be used:

1. Is it a clinically relevant question
2. Has the rule been rigorously derived
3. Has the rule been validated in a second population—this is where decision rules most often fail.
4. Does the rule permit one way or two way application—one way is when criteria are met and then an action or inaction follows but the rule does not allow the opposite. The example used are the PE rule out criteria (PERC) where patients with no criteria should *not* have a PE work up but the presence of criteria does *not* mean they should have a PE workup. A two way application rules for both presence and absence e.g. the Ottawa Ankle rules. *Clinicians are likely to wrongly assume decision rules are two way and use them as such when they are only one way.*
5. Does the rule apply to your practice setting and your target population or indeed target patient
6. Does the rule improve on current clinical practice.

In the same journal, there are 3 articles,^{5–7} one looking at usage of abdominal CT in children after trauma where the decision rule missed 6 children with trauma and the physicians missed one.⁵ In the second, the physicians performed better than the Wells criteria and the modified Geneva score⁶ in predicting who should be worked up for PE and in the third the conclusion was the Alvarado score for adult appendicitis could not be replicated in another setting and ought to be abandoned.⁷ There are many other examples: Delebarre *et al* examined the 12 CDRs produced in the last 16 years for paediatric febrile neutropenia.⁸ They all failed for many reasons especially a failure to be reproduced in another group and to be clinically sensible! The ability to correctly identify the tumour, nodes, metastases (TNM) stage of multifocal

lung cancers according to international rules was tested on 360 physicians and surgeons⁹ in two thoracic oncology networks and there was universal inconsistency in the results putting in doubt the validity of outcome data as a result.

The praise by Blakey *et al* of the BTS guidelines are worthy for the time and effort put in on them and there are indeed lots of rules but for example in the case of paediatric empyema¹⁰ there are essentially three high grade facts known from evidence: Urokinase is good; small drains may be better than big ones; and video assisted thoracoscopy is no better than drains and is more expensive. The rest are the great and the good sitting around a table stroking their chins. Rules inevitably cover common situations with plenty of data available so asthma, chest pain, abdominal pain etc. The BTS asthma guidelines¹¹ are criticised by Blakey *et al* for inertia (why do not they like these rules?) of the step charts. I have seen worse and the only adjustment to them would be for each step to add 'are they taking their treatment' at step 2, 'are they really taking their treatment' at step 3, 'I am pretty sure they are not taking their treatment' at step 4 to 'I am virtually certain they are not taking their treatment'¹² at step 5, since despite 50 years of research into asthma it is still a blue and a brown inhaler, measuring the urinary cotinine and looking menacingly at the pet cat regardless of the 151 pages of BTS asthma guidelines.

My opponents' notion of rules has been confined purely to clinical decision making and ignores the plethora of other rules whose benefits are scarcely discernable. An excellent example is the orgy of rules now surrounding research.

Regarding rules governing research, as the offspring of a refugee from Nazi Germany, I am well aware of the horrors due to a lack of oversight in medical research although in this instance there was not only plenty of oversight but active encouragement in addition. However, the pendulum has inevitably swung far too far in the other direction all in the name of minimising risk. I note that the debacle of the Northwick Park TGN1412 trial in 2006 does not help my cause on the alleged grounds that on not knowing a dose, the researchers 'guessed' and gave it to 8 adults simultaneously. Again, I wonder whether the plethora of rules got in the way of common sense i.e. not sure of the dose from the animal/lab data so come up with a dose, divide by 10 or 100 and give it to one person, preferably the principle investigator as that concentrates the mind wonderfully.

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Kantarjian *et al*¹³ bemoan the rules hampering cancer research in the USA. No Belmont principles have changed in the past 30 years (respect for persons—proper understanding of research, free will participation; beneficence—maximise benefits and minimise risk; and justice—avoidance of prejudices) but in this period:

- A. the protocols have increased from an average of 15 pages to up to 200 pages
- B. consent forms have increased from 3 to 30 pages leading to a **reduction** in patient understanding with 'just show me where to sign' as a result.
- C. The cost per patient in a phase III trial has risen eightfold
- D. the growth of clinical research organisations (turnover >\$20 billion)
- E. between 300 and 600 regulatory steps to even start a trial
- F. all leading tragically to <5% of adult cancer patients participating in trials and 40% of national cancer institute sponsored protocols not achieving their minimum patient recruitment objectives.

The authors estimated, using lung cancer as an example, that the increased regulatory delay of 5 years as a result of all this may save 16 life years due to increased safety but loses 2 000 000 life-years worldwide due to patient deaths caused by the delay even if the new drug only increased the cure rate by a measly 1%! They claim that trials are moving to Europe which is easier although my personal experience of the bureaucratic and financial quagmire of a clinical trial¹⁴ even 16 years ago, and it is way worse now,¹⁵ made me draw one fundamental conclusion as an National Health Service (NHS) clinician—*never again...* which is sad. The much vaunted clinical rigour of patient recruitment has the danger of a trial in which the conclusions are based on such a narrow group of patients that they virtually do not exist and are therefore valueless.

Just when I thought that writing a CON article was a truly uphill struggle the PRO authors hand me victory on a plate by not using evidence and relying on propaganda. They state: 'As a simple example, we all agree hand hygiene is essential'. The evidence for this is what exactly? The literature review of all the studies by Silvestri *et al*¹⁶ shows no effect on intensive care mortality since Semelweis' original 1861 publication,¹⁷ and estimates that only 40% of such infections are nosocomial almost entirely in those staying longer than 7 days. Even the

huge randomised trial¹⁸ of glove and gown use on intensive care units showed no benefit in the primary endpoint of MRSA and vancomycin resistant enterococcus (VRE) isolation despite the glove and gown group having a statistically significant improvement in room exit hand hygiene. A further randomised crossover trial of enhanced cleaning again showed no change in patient MRSA acquisition¹⁹ and yet my opponents are proposing censure and even suspension for contravention. That most effective propagandist, Josef Goebbels, said 'It would not be impossible to prove with sufficient repetition and a psychological understanding of the people concerned that a square is in fact a circle. They are mere words, and words can be moulded until they clothe ideas and disguise.' We do not need a repeat!

My opponents cite deference as a problem between juniors and a rule 'free' consultant, but there is nothing more irritating than an obsequious, deferential junior doctor. Robust, although civilised, debate over patients is essential as even I do not have a monopoly of either knowledge or wisdom.

The programme 'House' cited disappearing by Blakey *et al* was popular for many reasons but one was that the medical cases did not lend themselves to rules. In fact rules *were* followed at the beginning of each episode by the 'diligent juniors' but did not throw up the answer. It illustrated well the danger, best expounded in the past by geneticists especially dysmorphologists, of forcing a constellation of findings into a single syndrome shoebox ignoring the inconvenient findings that do not fit and 'hung over the side' of the box.

Just as troubling for me is when litigation ensues after a perceived medical error. I, as a so-called medical expert, was recently drowned in local guidelines over triage criteria, temperature measurements, National Institute of Health and Care Excellence symptom algorithms, re-presentation guidelines all of which got in the way of: If infants/toddlers re-present to casualty with the same presentation 48 h later at 03:00 after an additional seizure/rigor, *you admit them...* and that is it. This toddler was sent home and died 48 h later. The attempt to manage everything with guidelines (also known as rules) loses sight of the real issues and confuses priorities.

In the real world, medicine in general and especially paediatrics is a messy, inconvenient business full of the unexpected, guaranteed to skewer the unwary

—that is what keeps it interesting. Overspecific rules are rarely superior and far too often get in the way, especially in research. They are slavishly followed at your peril.

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