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Dr. R. Dale, London, UK:

Philosophy behind Guidelines

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GUIDELINES and PROTOCOLS

Philosophy behind them

Richard F. Dale M.B., B.S., F.R.C.S. (Engl) F.R.C.S. (Ed)

I have been asked to address some of the issues and philosophy behind guidelines and also to consider the relationship between evidence and guidelines.

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What are they?

- Practice Policies
 - Guidelines
 - Standards (Protocols)
 - Options

 Dr. David Eddy of Duke University in the US wrote a series of articles in JAMA¹ that defined a group of instruments as Practice Policies dividing them into these 3 categories.

Options are simply a list of choices and I do not wish to dwell on them.

Guidelines we will deal with and I will distinguish them from what he defines as standards but I would define them as protocols.

Distinguishing between guidelines and protocols I believe helps to understand and to overcome some of the fears that people have about them.

¹Eddy D. Practice Policies: guidelines for methods. JAMA 1990;263:1839-41

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Practice Policies

Performed recommendations issued for the purpose of influencing decisions about health interventions

Practice Policies he defines as:

Performed recommendations issued for the purpose of influencing decisions about health interventions.

In essence a practice policy is designed in a similar way to making a decision for an individual patient:

- firstly - identify the available options
- secondly - estimate the consequences of the different options
- thirdly - determine the desirability of those outcomes from the perspective of the patients.

There are important differences, namely:

- there may be a range of uncertainty about the outcomes
- the comparisons may be difficult
- there may be varying degrees of conviction about which is the best option

Thus practice policies increase the stakes;

- if the decision is wrong then many patients will be harmed
- the higher stakes increases the degree of uncertainty and mistakes are mainly due to uncertainty
- the variability of patients makes simple predictions difficult

These added complexities and higher stakes are the reason for requiring three types of practice policies.

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Guidelines

systematically developed statements to assist practitioners' and patients' decisions about appropriate care for specific clinical circumstances

Guidelines are defined on this slide as:

Systematiccalle developed statements to assist Practitioners' and patients' about appropriate care for specific circumstances.

 They are envisaged as addressing the problem of the higher stakes because they are intended to allow flexibility and should be followed in *most* cases. Deviations will be *common* and can be *justified*; deviation from them will not itself imply malpractice.

It is important to note that they are designed to help the patients to choose as well as the practitioners. Thus the concept involves patients in decisions and acknowledges that it is not possible to predict the response of patients accurately. The word systematically is important because it emphasises that the guideline must be methodologically sound; it means that they must be evidence based and the guideline development must be open to scrutiny and based on sound principles.

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Protocols I am suggesting are the same as the Standards as defined here. They are rules or formalities necessitating how something is done.

Protocols

are the rules or formalities necessitating how something is done

This language is very different to that used in defining guidelines; exceptions will be rare and these rules should be applied rigidly.

The term violation is spawned with the introduction of protocols and if not adhered to then thoughts of malpractice will arise and defence will be difficult. The language does not include patient choice in the formalities, they thus assume that the patients' response is known with surety.

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Why have Practice Policies?

- Unnecessary care
- Uncontrolled costs
- Effectiveness
- Quality

The pressure to introduce Practice Policies are various and they have a different look according to where you stand in the health system.

- To the Politician, unnecessary care and variance are difficult to understand; Guidelines and Protocols appear to offer opportunities to ensure that care is provided equitably and better value for money.
- To the Purchaser, the opportunity to control costs is attractive.
- The Professional sees the issues of improving effectiveness of care as an important issue.
- The Patient on the other hand may see these policies as opportunities for improved quality of care.

There is nothing new in such policies, the clinical professions have been using them for decades. What is new is that the political, economic and social pressure to introduce guidelines and protocols, particularly from outside the profession, is increasingly important.

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Unnecessary Care

- Significant variations between geographic areas
 - overutilisations
 - underutilisation

This desire to see better cost effectiveness is driven in part from the observation that there are marked differences between geographic areas for the uptake of health interventions. There are well known studies showing that variations in the use of health services are in part due to the fact that in some areas patients are receiving

- unnecessary care,
- whilst in other areas they are denied care that they should have.

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Variance

- A major cause of variance is: *due to decision making under conditions of uncertainty*

This is emphasised by the parallel observation of variation in outcomes seen for many conditions not only in the UK but also in the US and Europe.

A major cause of this variance is due to both professional and patient uncertainty over the decisions that have to be taken.

The role of guidelines in particular is to reduce this uncertainty in decision making.

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Uncontrolled Costs

- Rising costs
- Inappropriate care
- Coste effectiveness
 - are outcomes worth the cost?
 - do benefits outweigh the harms?

The main stimulus, however, for practice policies comes from the desire of control costs. This comes from the impact of rising costs of health care, the recognition that some care is inappropriate and the move towards considering cost effectiveness.

Thus practice policies may help by:

- including cost as an integral part of medical decision making and recommend a treatment only if the health outcomes are deemed to be worth its costs;
- or they can recommend a practice if the benefits outweigh its harms without considering the cost that will have to be paid to obtain them.

The former will control costs but will result in some beneficial practices not being recommended, i.e. rationing!

The latter does not constrain beneficial practices but costs will still rise.

This highlights the conflict between whether it is ethical to give the best treatment to the individual or what can be afforded by society. A debate that has not been adequately aired, with

- health economists on the one side demanding that cost effectiveness must be considered and
- the traditional professional view that clinical effectiveness is paramount.

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Uncontrolled Costs

- Efficacy
 - what can be achieved
- Inappropriate care
 - what is achieved

The professional stimulus promoting guidelines hinges around the concept of clinical effectiveness. There has been in our lifetime an explosion in new knowledge emanating from research, but this knowledge does not reach clinical practice as quickly as it might. Thus the potential, of efficacy, of treatment is not being realised and there are several well known examples of treatments that have taken a long time to reach general acceptance.

The effectiveness of care lags behind the potential.

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Quality

The quality of medical care depends upon:

- what can be achieved
- the quality of the decisions that determine what actions are taken;
- the quality with which those actions are executed

I use this quote, again from Eddy as it emphasises an important distinction between decision making and conducting the process of care, this is particularly relevant for surgeons.

- The quality of care depends upon the quality of the decision making that determine what actions are taken.
- And the quality with which those actions are executed.

Though this is self evident in many ways, it misses out a crucial factor

- the quality of care also depends upon the systems that support the clinician.

There is no doubt that the environment in which we work and the structures that support us are critical in determining the quality of medical care. So often the skill of clinical medicine comes in the decision making and once the decision is made the actions that follow are often less uncertain and the process more clear cut, on the other hand if the process, or operation, is not done well, the patient may be harmed. From the patient's perspective quality may be viewed differently to that of the professional who may be more concerned with the results of the treatment. The patient on the other hand is more concerned with how he lives with the outcomes and is certainly concerned as to whether he lives. The development of guidelines should, therefore, include patient representation and the best guidelines have a version written for patients.

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Decision Making

- Medical decisions are complex
- New knowlwdge requires
 - distillation - too much *noise*
 - dissemination

We have to recognize that medical decision making is complex and to make a coherent medical decision one has to know and understand:

- the likely outcomes of the available alternatives and;
- the desirability of the outcomes of each of the options.

To understand the likely outcomes one needs an analysis of the available evidence regarding benefits, harms and costs but this evidence is never perfect and, therefore, some judgement will be necessary.

To assess the desirability three types of comparisons are necessary:

- benefits compared with harms [risks, side effects, inconvenience, anxiety];
- health outcomes compared to costs;
- with limited resources, benefits and resources consumed must be compared with other practices to give priority to highest yield.

In a climate that is fast moving it is very difficult to keep up to date and this has spawned the movement of Evidence Based Medicine that attempts to distill the knowledge and cast aside irrelevant information. The dissemination of this knowledge, however, requires a strategy and the use of practice policies is one of the ways to achieve this.

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Practice Policies seek to:

- Improve Decision Making

and

- the Execution of Care

Thus, practice policies seek to improve decision making and can be drawn up to:

- reduce uncertainty about appropriateness of care
- reduce the costs
- improve the effectiveness towards the potential efficacy and
- improve the quality of care

in so doing they should reduce risk. Decision making does, however, require flexibility because so often the knowlwdge of outcomes is not sufficiently hard to provide rules that can be followed in the vast majority of cases. To write rules that have to be followed the main health and economic consequences of the intervention must be known sufficiently well to permit these rigid decisions and there must be virtual unanimity among patients about the overall desirability of these outcomes. The concept of virtual unanimity of preferences implies that at least 95 % or, even better, 99 % of patients should be known to agree about the desirability of the outcomes.

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Patient Care

- Complex process
- Many individuals/professionals involved
- Traditionally based on medical model
- Quality uncertain
- Patient/staff satisfaction uncertain

Patient care is a complex process and nowadays the patient will pass through a hospital meeting many individuals from many professions. The process of care tend to be based upon the traditional medical model with the added complexity that has ensued from greater specialisation. This has lead to the quality of care being uncertain in too many cases which leaves both the professional and the patient becoming dissatisfied too often.

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Objectives

The objective of practice policies should be to deliver higher quality patient care that is also predictable in the majority of cases. If achieved this can lead to an increase in patient satisfaction and also in staff satisfaction. The evidence from industry and commerce is that a policy that pursues quality leads to cost control through greater efficiency. This can be achieved in medicine.

- Higher quality patient care
- Predictable patient care
- Increased patient satisfaction
- Increased staff satisfaction
- Possible cost control
- Improved competitive position of hospital

In these days of provider competition this can be important for individual hospitals or their units.

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Tools or Rules?

- Guidelines are:
 - Tools to help decision making
- Protocols are:
 - - rules to control actions

So what is needed? Do we need Tools or do we need Rules? Eddy suggests that we need guidelines and protocols as well as simple lists of options.

It may be better to consider that guidelines are tools designed to assist in decision making, they allow for subjective interpretation.

To use them demands an understanding of the science behind their writing and they are not suitable for people with delegated responsibility.

Protocols, however, are rules and as such have a mechanistic approach. Protocols do not, by their very nature, permit those following them to deviate from the paths described.

The difference between guidelines and protocols, therefore, lies in the fact that guidelines free the individual from the burden of having to estimate and weigh the pros and cons of each decision. In so doing they bring order and discipline to their decisions but allow interpretation for differing clinical situations. Whereas protocols force a discipline that has to be followed.

Protocols are rules and I would suggest are mainly suitable as instruments to control actions once those decisions are made. This distinction between decisions and actions is perhaps arbitrary but it does highlight the differences between the indications for the potential of guidelines and protocols.

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Judging guidelines

- Guidelines can be judged on:
 - their validity
 - their effectiveness

Russell & Grimshaw

If we accept that protocols and guidelines are a good thing, how do we judge them. One of the problems is that anyone can sit down and write a guideline but are they all going to improve the quality of care and the clinical effectiveness or lead to cost control?

Russell and Grimshaw highlight that guidelines should be judged against the concepts of:

- validity and
- effectiveness.

They also point out the necessity for using hard evidence.

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Likelihood of scientific validity

- High if:
 - based on systematic review
 - using national external groups
 - all key disciplines represented
 - evidence based development

Firstly if we take scientific validity the next three slides demonstrate some of the attributes that tend to determine the degree of validity into high, medium or low.

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Scientific validity

- Medium if:
 - Unsystematic review
 - intermediate group with some end users
 - some key disciplines represented
 - formal consensus development

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Scientific validity

- Low if:
 - based on expert opinion
 - internal group only end users

Guidelines are more likely to be valid if they are based on rigorous scientific evidence specially if based upon a systematic review. Less so if the only papers used are those preferred by the reviewers; and worst if based on expert opinion.

It appears that when people develop guidelines that they themselves will use, they tend to be influenced more by their current practice than by scientific evidence. Those guidelines, on the other hand, developed by national or regional groups are more likely to be valid. The more key groups represented in the development, the higher the likelihood of validity.

If the guidelines are written with the recommendations linked to the available evidence they are more likely to be valid and least likely to be valid when an informal consensus is used where the

- one key disciplines represented
- informal consensus

loudest voice wins.

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Likelihood of effectiveness

- High if:
 - internal group
 - specific education intervention
 - patient specific reminder at time of consultation

That is only half the picture because one also needs to judge whether the guideline is adopted and that it influences practice in the way that the guideline directs.

These three slides highlight the factors that influence effectiveness.

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Effectiveness

- Above average if:
 - intermediate group
 - continuing medical education
 - patient specific feedback
- Below average if:
 - local external group
 - mailing to targeted groups
 - general feedback

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Effectiveness

- Low if:
 - national external group
 - publication in professional journal
 - general reminder of guidelines

Thus the guidelines that are developed by the end user are more likely to change practice than those emanating from national groups meaning that effectiveness is not related to validity. The dissemination strategy is important and if the unit puts aside an entire half-day for the education of all the staff then the guidelines are more likely to be effective. Use of Continuing Medical Education is the next most useful approach whereas posting the guidelines or simply publishing them have much less effect. The strategy is also important with the best option being prompts about appropriate patient management in the health record. Simply providing general feedback or a general reminder is less effective.

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Validity and Effectiveness

- A high scientific validity leads to guidelines that have a low level of effectiveness
- A highly effective guideline is likely to have a low level of scientific validity

There is thus a conflict between the some of the important factors that influence validity and the influence on effectiveness. These two statements emphasis this conflict.

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Disadvantages

- Freeze practice on unsound treatment
 - get the treatment wrong
- Evidence changes
 - get out of date
- Exclusions not defined adequately
 - get the wrong patient
- Increase costs

The obvious disadvantages of guidelines and protocols are:

- that they freeze practice on unsound treatment. A dogma is established which may take years to debunk and in the meantime all the patients have been harmed
- practice may initially be frozen on a sound basis but new knowledge appears and it may be very difficult to incorporate change.

This is true of the practice of medicine anyway and the use of practice policies may help overcome this inertia.

However, people must have confidence in guidelines and one of the factors that promote confidence is to determine a review mechanism and a date for that review to be decided on publication of the guideline.

Other disadvantages are:

- get the sums wrong

- exclusions are not defined properly and the wrong patients are included
- the policy does not consider cost effectiveness in which case a guideline can increase costs.

The danger here is in the separation of budgets. There must also be an assessment of the organisational complexity e.g. it is easier to administer a drug once a day than several times a day and something that is simple to administer may be performed more reliably and thus risk from non performance is reduced.

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Guidelines for Guidelines

- Identify Key Decisions & Consequences
- Review valid evidence for alternatives on:
 - benefits
 - risks
 - costs
- Present evidence in accessible format

Finally, it is important to look at the standards of the guidelines themselves. In a recent article in the BMJ² a simple pragmatic strategy was put forward. This highlighted three key components of a useful clinical guideline.

Firstly it is important to concentrate on key decisions and their consequences. If guidelines do not limit themselves to what is important they become unwieldy. These key decisions usually relate to

- the diagnosis,
- estimating prognosis,
- assessing relevant outcomes including benefits and risks.

Secondly the relevant valid evidence needs to be brought together on each of the key decisions. This remains difficult because the necessary research evidence is frequently lacking.

Thirdly is the need to present the evidence and recommendations in a concise, accessible format and probably different formats to the various stakeholders for the guideline.

² Jackson R, Feder G. Guidelines for Clinical Guidelines. BMJ 1998,317:427-8