

Don't sideline the guidelines

How to ensure clinical guidelines translate into better treatment

→ Emma Mason

Many patients are still being let down by a failure to follow clinical guidelines. It's all very well to blame know-it-all doctors, but if the guidelines are hard to access and tricky to use, and if treatment centres don't take steps to ensure new guidelines are implemented and continue to be observed, then what should we expect?

AS international experts meet in St Gallen to consider the best treatments for breast cancer and to disseminate their accumulated knowledge to the world with the 2007 St Gallen consensus statement, the focus is again on clinical guidelines.

The argument these days tends to be less about whether they improve patient outcome – there's now plenty of evidence in literature that they do – and more about how widely they are implemented, which ones are best for which cancers in which countries, their purpose (standardisation of care or treatment rationing), and how to help and encourage clinicians to implement guidelines and to do it effectively.

Guidelines for the treatment of cancer in clinical practice are intended to give physicians around the world up-to-

date information and recommendations on the best prevention, diagnosis and treatments for every cancer, in order to improve patient care. In other words, to provide the *right care*, at the *right time*, for the *right person*, in the *right way*.

However, clinicians and guideline writers face a number of barriers to successful implementation of clinical practice guidelines, and these vary in different countries, with some easier to surmount (e.g. lack of knowledge) than others (e.g. lack of resources or systems).

The picture is further complicated by the array of guidelines available to clinicians. These range from guidelines produced by several different organisations for the treatment of individual cancers from diagnosis through to palliative care, to guidelines (again, from several organisations) on one particular aspect of care, such as radiation, chemotherapy, or control of anaemia, neutropenia or vomiting, for instance.

So how is the busy oncologist expected to choose from amongst this plethora of guidelines, and find and use those that work best for them? Is it any surprise that, faced with such a choice, many fall back on their personal experience, perhaps supplemented by information they have picked up at conferences and their hospital's standard practice?

Bruce Barraclough, medical director of the Australian Cancer Network (ACN), has a wide experience of developing and implementing guidelines. He and his colleagues have written "evidence-based guidelines on how to implement guidelines", and he warns that producing and implementing them is not a simple or easy process.

"To make it simplistic is to underrate how difficult it is to change practice in humans," he says. "It's the same in any human organisation, from hospitals right through to families.

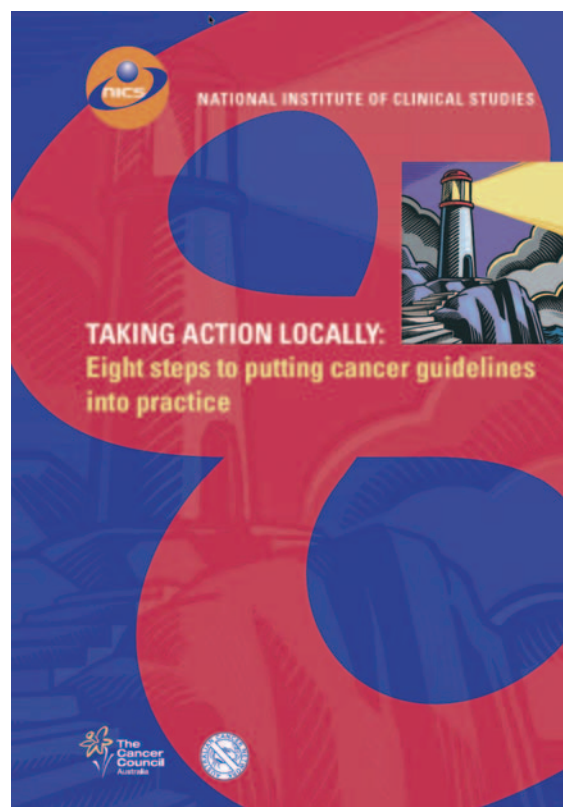
"Change is not simple, change is not

PUTTING GUIDELINES INTO PRACTICE

The Australian Cancer Network's eight-step guide has been disseminated widely throughout the Australia, and its general principles are applicable everywhere.

1. Appoint the team – clinical champions and executive sponsor
2. Decide which recommendation to tackle first – size and importance of evidence/practice gap
3. Is current practice in line with guideline recommendation? – audit
4. Understand why we are not achieving best practice – individual and system
5. Prepare for change – engage stakeholders
6. Choose the right approach
7. Put your theories to the test – plan, do, study, act
8. Keep things on track – communication – change takes time

The guide can be downloaded at www.cancer.org.au/content.cfm?randid=352233.



“A simplistic approach to guidelines underrates how difficult it is to change practice in humans”

quick, change is not the same in every place, because systems might be different, leadership lacking in some places and good in others. In some smaller, more remote places where people don't get enough interaction with their peers, there may be lack of knowledge.”

The ACN and the Australian National Institute of Clinical Studies (NICS) have produced a short booklet called *Taking action locally: eight steps to putting cancer guidelines into practice* (see box). “When we first put the booklet out, we were inundated with requests for it. It is aimed at leaders and managers looking to encourage their people to put guidelines into practice and arming them with the information to do so,” says Barraclough.

OVERCOMING OBSTACLES

In the sixth step of the booklet, “choose the right approach”, some of the key barriers to successful implementation are identified, together with strategies to overcome them.

Barraclough says, “There are number of issues here. If we are going to improve cancer care through guidelines, we need to review and understand the literature, and then write guidelines that people who are very busy at work can use.” The guidelines need to be easy to read so that clinicians can absorb the essential information in “a quick flick through while at the coal face”, he explains.

“Work has to be done on understanding change, and when you are

changing long-established practices, this requires a change management process.”

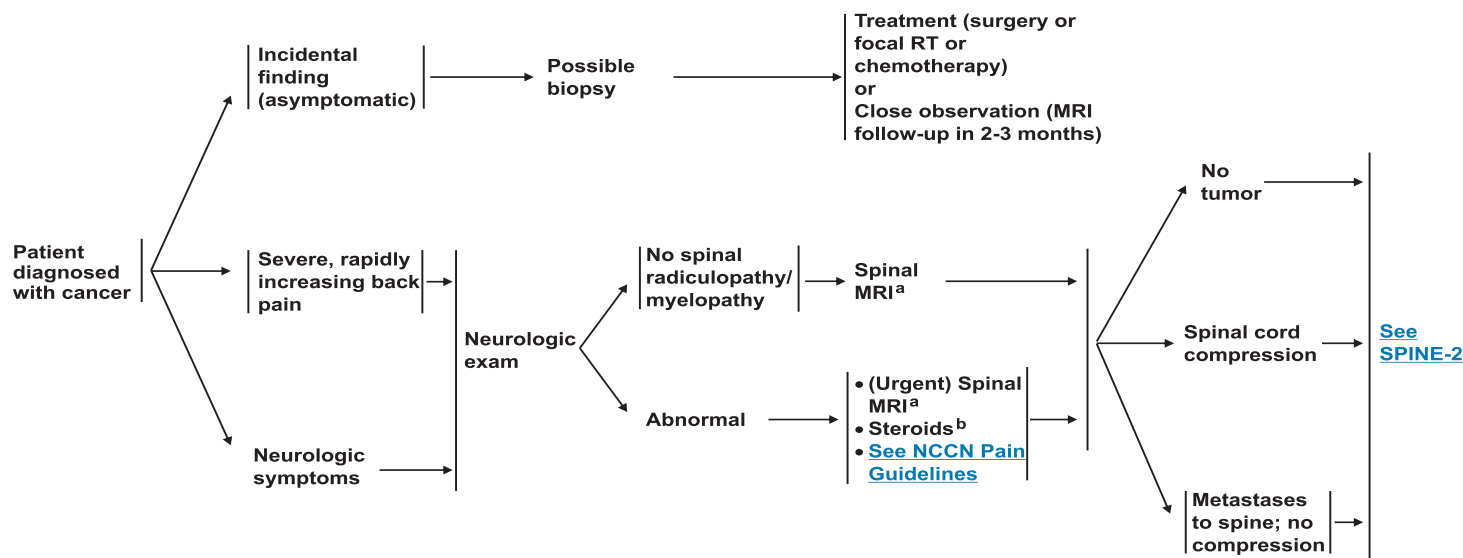
He identifies barriers and suggests interventions to deal with them:

- Lack of knowledge – supply educational courses and provide aids to decision-making
- Mismatch between perception and reality – audit and feed back the results. “If they think differently, you need to explain the evidence and audit the work so that people are confronted with what they are doing, rather than what they think they are doing”
- Lack of motivation – provide leadership and have a system of incentives and sanctions

PRESENTATION

WORKUP

TREATMENT



^aIf the patient is unable to have an MRI, then a CT myelogram is recommended.

^bThe recommended minimum dose of steroids is 4 mg of dexamethasone every 6 hours, although dose of steroids may vary (10-100 mg). Methylprednisolone can be used instead of dexamethasone. For rapid neurologic deterioration or significant myelopathy, a stat MRI is recommended. A randomized trial supported the use of high-dose steroids (Sorensen PS, Helweg-Larsen S, Mouridsen H, Hansen HH. Effect of high-dose dexamethasone in carcinomatous metastatic spinal cord compression treated with radiotherapy: A randomized trial. Eur J Cancer 1994;30A:22-27). Steroid use should be tapered within 3 days.

Note: All recommendations are category 2A unless otherwise indicated.
 Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

Easy to use. The US National Comprehensive Cancer Network presents its guidelines in the form of decision trees, making it easy for doctors to track their patient's specific problem and work out the recommended treatment*

Source: Reproduced with permission from the NCCN 2.2006

Central Nervous System Cancers Clinical Practice Guideline in Oncology, The Complete Library of NCCN Clinical Practice Guidelines in Oncology [CD-ROM]. Jenkintown, Pennsylvania:© National Comprehensive Cancer Network, June 2006. To view the most recent and complete version of the guideline go online to www.nccn.org

- Attitudes and lack of belief in benefits – use peer influence and opinion leaders
 - Systems of care – “If the system of care makes implementation of guidelines difficult, there needs to be a process redesign (involving managers etc)”
- Other oncologists identify additional barriers, including the availability and accessibility of guidelines, whether they have been translated into other languages, lack of resources (including lack

of funding, drugs, training, people and equipment, and problems associated with geographically remote locations), as well as the very practical issue of how easy the guidelines are to read and use.

Shortly before he died in a plane crash in December, Christopher Desch, National Medical Director of the US National Comprehensive Cancer Network (NCCN), spoke to *CancerWorld*. The NCCN is an alliance of some of the leading US cancer centres, dedicated to

improving the quality and effectiveness of care provided to patients with cancer. The organisation creates clinical practice guidelines appropriate for use by clinicians, patients and others involved in cancer care. All the NCCN guidelines are on its website and available to anyone to download.

Desch identified the format and the availability of guidelines as two of the barriers. “There are plenty of reasons why doctors may or may not use guide-

*These Guidelines are work in progress that will be refined as often as new significant data becomes available. The NCCN Guidelines are a statement of consensus of its authors regarding their views of currently accepted approaches to treatment. Any clinicians seeking to apply or consult any NCCN Guidelines is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. The NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. These Guidelines are copyrighted by the NCCN. All rights reserved. These Guidelines and the illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN.

“Some guidelines are long documents of text and it’s difficult to work out what the solution is”

lines. The format is very important. The NCCN guidelines use an algorithm, or decision tree, that enables the physician to track the specific problem your patient has and work out what the treatment should be. Some guidelines from other organisations are long documents of text and it’s more difficult to work out what the solution is.

“Some guidelines are available only in paper copies and not on the web. This is a problem for doctors, because if you cannot get them exactly when you want them, it doesn’t help. Also, the amount of time available during the clinical interaction [between the doctor and the patient] can be a problem,” he said.

Often, cancer patients can find themselves being treated by clinicians who are not necessarily cancer specialists. Desch said, “The less training the clinician has had in cancer care, the less likely they are to use guidelines, sometimes because they do not even know of their existence.”

However, like every other oncologist interviewed for this article, Desch was in no doubt about the usefulness of guidelines. “I still practice oncology. I use the guidelines to help me manage patients with unusual cancers, such as thyroid cancer. They help me to find the right treatment and also the experts, as the members of each guidelines panel are listed at the front of the NCCN guidelines. As a user I use them almost every day in practice.”

He continued, “Ten years ago people were not sure what they should do with guidelines. Today, there are a number of factors that make people appreciate them more:

- They are associated with quality care
- Guidelines are now used in training programmes; so in every programme, guidelines are put up [on slides] to show where the patient fits along the pathway
- Young physicians have incorporated them within the training process, so they see them as a tool that helps, rather than as ‘cook book’ medicine. Fewer and fewer doctors look on guidelines as a constraint.”

THE COOK BOOK CHARGE

The charge that guidelines can be dictatorial, inflexible and a way of delivering cancer care through ‘cook book’ medicine is one that most of those involved in formulating or implementing guidelines have frequently had to counter. Barraclough argues that, “Even if the guidelines are not perfect, the evidence shows that they still improve patient outcome. We do better by making care standardised, than by changing care to take account of the latest and most incremental advances.”

They are a tool to be used, said Desch. “They don’t define what *has* to be done, because many patients don’t fit exactly into them because of age, comorbidity, patient preference and so on.” He also believed that guidelines could be used to re-assure patients that they were being treated in accordance with the best advice, even if their particular circumstances required some variations.

Barraclough agrees. “Guidelines are not some holy writ. They need to be interpreted for the patient in front of you, with patient preference taken into account.”

He refers to the theory of evidence-based medicine as propounded by David Sackett: that clinicians need evidence of what treatment works best, but then there needs to be clinical expertise to apply it to the patient and patient preference is also important and needs to be taken into account.

In Australia, the huge distances can also have an impact and influence on patients’ preferences, as some may not wish to travel hundreds of miles to receive a treatment that might have only a marginal benefit.

“As the leader of a cancer team, you say ‘this is the evidence, these are the results we have and this is how we can interpret it for our environment,’” says Barraclough.

Nicholas Pavlidis, chairman of the European Society for Medical Oncology (ESMO) guidelines group and professor of medical oncology at the University of Ioannina, Greece, says, “There will always be people who are against guidelines and say they are oversimplifying things and that they lead to ‘cook book’ medicine. In a recent systematic survey of clinicians’ attitudes to clinical practice guidelines, 70%–75% of clinicians agreed that guidelines are helpful sources of advice, good educational tools and intended to improve quality. However, 30%–52.8% of them also considered that guidelines are impractical and too rigid to apply to individual patients; they reduce physician autonomy, they oversimplify medicine, they would increase litigation and are intended to cut healthcare costs.”

He says that physicians from countries in Europe that are less organised

ESMO decided to do something very short, so the practitioner can read them and make a decision fast

and have fewer resources are more likely to say guidelines are not good for them to use. "But if you're talking about organised societies and health systems, then I think the majority of doctors are in favour of them."

Pavlidis has been a member of the ESMO guidelines group since 1997 and chair since 2006. The society publishes the 'ESMO clinical recommendations' which, until recently, were called the 'minimum clinical recommendations.'

The idea for the ESMO clinical recommendations originated with Heine Hansen (Copenhagen, Denmark) to meet the needs of Eastern Europe. The recommendations are no more than three pages long and all are available on the ESMO and *Annals of Oncology* websites.

Pavlidis says, "ESMO decided to do something very, very short, so that it would be convenient for the practitioner to go through them and make a decision fast. That's why they were originally called the 'minimum clinical recommendations'. Other guidelines have a huge amount of information in many, many pages, which are less easy to use."

He continues, "The principle of the guidelines are:

- to create a statement of the basic standards of care
- to be disease- or topic-orientated
- to be evidence-based
- to have an emphasis on medical oncology
- to be regularly updated every year

"They have informed thousands of people. Between January and August 2006 there were 57,887 downloads from the

Annals of Oncology website. The most frequently downloaded were the common cancers: lung, breast, colorectal, gastric, ovarian and prostate cancers."

Updating all the guidelines annually ensures that they keep abreast of medical advances. While Pavlidis makes no claims that doctors should choose to use the ESMO guidelines instead of, or in preference to, other guidelines, he says, "We do hope that the ESMO guidelines could become the most practical, easy-to-use, annually updated guidelines, not only in Europe, but worldwide."

But clinicians can choose from guidelines produced not only by ESMO, but the European Organisation for Research and Treatment of Cancer (EORTC), the Multinational Association of Supportive Care in Cancer (MASCC), the UK's National Institute for Health and Clinical Excellence, the American Society of Clinical Oncology (ASCO) and the NCCN, to name but a few.

Of the NCCN guidelines, Desch said that although he couldn't put a precise figure on it, he was sure they were widely used. "Doctors all over the country say how useful they are, and when we count the number of times they are accessed on the Internet, it's over a million times a year. We also know that insurance companies in the States use them to ensure that the care that doctors are giving is within reason."

Matti Aapro, director of medical oncology at the Clinique de Genolier, Switzerland, and co-author of several EORTC and MASCC guidelines, believes that there is a problem with

too many over-lapping guidelines, and that the different guidelines need to be harmonised. The way to do this is through collaboration.

"If you look at the MASCC guidelines, for example, we called on all organisations to send a representative to join the guidelines committee, in order to harmonise the guidelines. I think that's been very successful for the anti-emetic guidelines. ASCO [who had a representative on the MASCC guidelines committee], acknowledged the MASCC guidelines and the work that had been done by the MASCC when they started to formulate their own guidelines.

"If you look at members of the EORTC group that wrote the guidelines on the use of G-CSF [to reduce neutropenia in patients with lymphomas and solid tumours], you will realise that there are members of the ASCO G-CSF group on this committee. We try to have members from Europe and the USA so that we don't have conflicting messages."

ONE GUIDELINE FITS ALL?

But can guidelines formulated in one country be useful in another country that may have a different system of health services and funding? Is it possible to have guidelines that are universally applicable? What about the differences between developed and developing nations, both in terms of resources and structures?

These are questions that appear to have complicated answers, but the simple message is that, although it's possible for doctors to follow guidelines written in



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another part of the world, they have to adapt and supplement them to suit their local situation. Aapro, for instance, points out that one of the main differences between the US and Europe is the availability and the use of drugs – the US Food and Drug Administration (FDA) has not approved certain drugs that are available for use in Europe, while other drugs are not available for certain uses in some European countries that are available in the US. In some European countries, government policy dictates that there should be national guidelines, which physicians have to, or are expected to, follow. The use of Herceptin to treat early breast cancer is a good example of differences between countries.

There are other differences too. Aapro says, “There are differences in priorities

and the way the results of studies are looked at in Europe and the States. In the States, they concentrate a lot on North American studies and ignore the European studies, and this can make a difference to the content of the resulting guidelines, while in Europe we tend to look at data that comes from phase three studies from all over the world. The St Gallen consensus statement is a good example of the differences that exist in the treatment of breast cancer between the two continents. It places a lot of weight on the evaluation of the tumour, and whether it is endocrine responsive or not, and that drives thinking about the use of adjuvant treatment. The Americans use too much chemotherapy without consideration of data that show that the advantage of chemotherapy can be

minimal in certain situations.”

Knowing these political, financial and structural constraints that have influenced the formulation of guidelines is crucial. Barraclough says, “Provided that you know how the guidelines were produced, you can share them with other countries. A number of guidelines in different countries are evidence-based to an extent, but then there appear to be variations depending on the resources of the country. If a certain medication is not going to be available for a particular treatment, then it’s not included in the guidelines. Some countries seem to use guidelines in this way to help allocate resources because there’s not endless supplies of money to do everything for every patient, every time.”

Benjamin Anderson is director and

chair of the Breast Health Global Initiative (BHGI) at Fred Hutchinson Cancer Research Center (Washington, Seattle, USA) and professor of surgery at the University of Washington School of Medicine. The BHGI international alliance, co-sponsored by the Hutchinson Center and the Susan G. Komen Breast Cancer Foundation, develops evidence-based, economically feasible guidelines that can be used in developing countries with low resources to improve outcomes for women with breast cancer (*Breast Journal*, vol 12 suppl.1, 2006). He believes that guidelines written for well-resourced countries are likely to be unworkable in countries with limited resources and inadequate systems for delivering healthcare. But guidelines written for developing nations could be useful to developed nations.

“Many of the obstacles observed in developing countries are also present in under-served regions or populations in developed countries. In particular, the social and cultural boundaries among ethnic groups that may limit women’s access to care appear to have a commonality,” he says.

Developing countries struggle with a number of barriers to providing adequate healthcare, let alone following guidelines. “Availability of resources is one limitation,” says Anderson. “But I would suggest that information and organisation are more commonly the obstacles to early detection and adequate treatment. Many of the basic therapies that we provide, such as surgery, radiation therapy and basic drug therapy, are reasonably affordable, if provided in a system where patients can be reached in a timely and ade-

quate fashion. Social and cultural barriers can be major, unanticipated obstacles for improving healthcare, especially when the care is being imported from outside communities that may not appreciate the cultural beliefs that shape a woman’s willingness to undergo diagnosis and/or treatment.”

Therefore, structures rather than individual clinicians and their ability or willingness to follow guidelines, can be a major barrier. “It is overly simplistic to view healthcare delivery as being defined by physician knowledge and communication. Clearly, proper education of physicians and the public is mandatory. However, the delivery system needs to be organised in such a way that this knowledge can be acted upon.

“In many circumstances, the obstacle is not the clinicians at all, who may be well aware of the ideal tools and therapies. Rather, the problem has to do with the healthcare system’s capacity to provide the sustainable resources for healthcare delivery, despite the fact that resources are inevitably being spent on patients with the disease. More often, the obstacles are system-wide and beyond the clinicians’ scope of control. These issues are prevalent in developed and developing countries alike, because in all settings, there are populations where healthcare fails to penetrate,” says Anderson.

The BHGI approach is described in the US Institute of Medicine publication, *Cancer control opportunities in low- and middle-income countries*, in a chapter on resource-level-appropriate interventions (*National Academy Press*, 2007). Anderson says that one of the issues that the BHGI considers is whether a country’s resources could be

re-allocated in a way that makes better use of them, and involves the people in the country, rather than solutions being handed down from outside, which is an approach that will fail.

“The BHGI international guidelines provide a framework for an integrated, cohesive system for breast healthcare and cancer treatment by which these solutions could be brought about in a sequential manner, taking into account real resources.” Different countries have different levels of resources, and so the BHGI suggests a tiered, step-wise system of resource allotment, defined using four levels: basic, limited, enhanced and maximal. These levels are based on the contribution of each resource to improving clinical outcomes. So, for instance, in the poorest countries, surgery might be the only available treatment, while better resourced countries might be able to afford chemotherapy, and so on.

“This is an economically stratified approach for the real world to frame how limited-resource countries can ‘step up the ladder,’” says Anderson. By approaching the formulation of guidelines from this different direction, and biennially revisiting and refining them, he hopes that the BHGI will be simultaneously learning where the problems lie and implementing solutions in order to fill in the missing rungs of the ‘ladder’.

ALLOCATION OF RESOURCES

The issue of resources is a recurring theme in relation to guidelines. In the US, private health insurance finances most medical treatments, and here, as Desch pointed out, insurance companies find guidelines useful for establishing standards of care, but also for ensuring that

Guidelines written in another part of the world must be adapted to suit the local situation

Guidelines can be used to ration treatments, but they can also ensure all patients are treated equally

they don't have to pay out for treatments that have little evidence of efficacy. In other countries, where the state provides healthcare, funded either through taxation, or a combination of taxation and insurance, guidelines can also be about the allocation of resources, or rationing.

Ingvar Karlberg, professor of health services research at Gothenburg University, Sweden, has been interviewing politicians, health service managers and clinicians for his research into guidelines. He believes that guidelines need to be formulated by all the parties or 'stakeholders' involved with them; this includes not only managers, clinicians and patients, but also what he calls the 'third party payer' – the organisation that pays for the healthcare.

"In all economic systems, whether it's a tax-based system or whether it's an insurance-based system, there's always a third party payer. The problem is that doctors and patients meet, discuss, decide on treatment and then send the bill to the third party payer, who has not been involved in the discussions. One way to involve the third party payer in these discussions is through clinical practice guidelines. If they are based on scientific evidence and take account of priorities, finances and incentives, they will probably work well and make the third party payer part of the process," says Karlberg.

He believes that a consensus needs to be reached between all parties on issues such as cost, treatments and priorities, otherwise guidelines are in danger of appearing to be 'wish lists' of what clinicians think are the best treatments, without any regard for how they are to be financed – at which point arguments break out between the different stakeholders.

Media coverage of the latest 'break-through' or 'wonder drug' helps to create patient pressure for treatments, and "politicians want everyone to have everything available, and that's a political pressure," says Karlberg. "Guidelines need to be used to support political management in order to restrict care in some cases, but you can also turn that argument around and say guidelines enable political management to ensure equity and accountability in the delivering of healthcare."

In other words, guidelines can cut both ways: they can be used by funders to ration treatments, but also to ensure

that all patients are receiving an equal standard of care.

This may be a message that some people will be reluctant to hear, particularly clinicians and patients. But in this day and age when more and more treatments are being developed for more and more diseases, the fact that there is not a bottomless pit of money to pay for all patients to receive the very latest treatment relevant to them is an important one, especially for nations with fewer resources. Guidelines could be a way of building consensus on these thorny issues, but only if all the different parties are involved in their formulation.

TIPS FOR WRITING AND IMPLEMENTING GUIDELINES

FORMULATING GUIDELINES:

- Involve multi-disciplinary teams (clinicians, radiotherapists, nurses etc) and a wide range of stakeholders, such as funders, managers, advocates, patients
- Develop an evidence-based, consensus approach
- Be aware of existing guidelines – try to harmonise with them to create an integrated, cohesive approach
- Keep guidelines concise, in an easy-to-use format so that a busy clinician can see at a glance recommended strategies (use of algorithms/decision trees)
- Non-profit/NGO retains total control of guidelines publication to avoid conflict of interest with for-profit organisations
- Update guidelines annually or biennially

IMPLEMENTING GUIDELINES:

- Provide vision, leadership, organisation, internal support and appropriate structures to ensure the guidelines are introduced and continue to be used in day-to-day practice
- Educate health professionals about the value of guidelines (via training, peer pressure etc)
- Make the guidelines easily and freely accessible via the Internet
- Publicise the availability and down-loadability of guidelines
- Provide translations of guidelines if possible
- Regularly remind health professionals that guidelines exist and should be used (via training, conferences, use of incentives, debates, discussions etc)