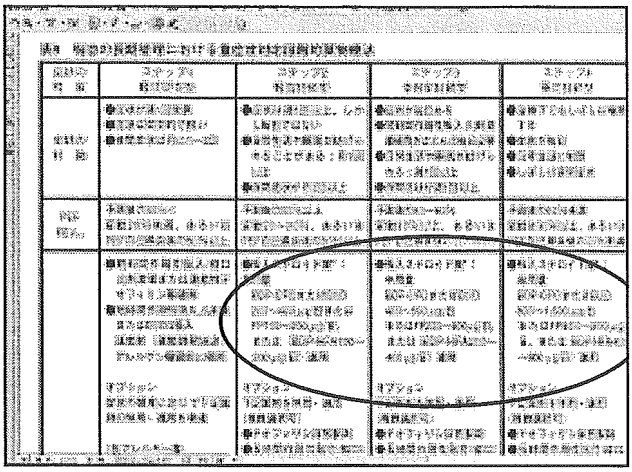
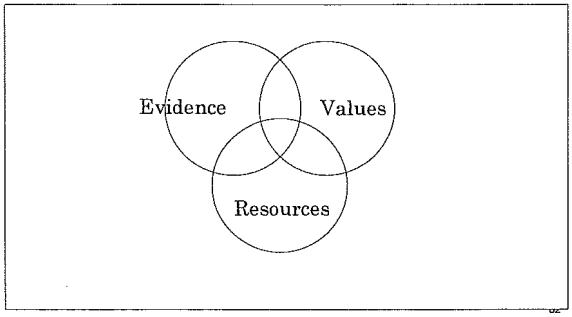


患者と集団における意思決定に影響する要因：
エビデンス、価値観、資源



振り返って・・・

- 以下のことについて基本的な知識を学び、医療におけるエビデンス（または情報）を理解する基礎つくりを目指します。
  - 診療ガイドラインの役割について
  - 診療ガイドラインの基盤にある根拠に基づく医療（EBM）、疫学の考え方について
  - 実際の臨床研究論文を患者の立場でどう読むか、それを利用するか。
- 医療の専門家からの一方的な講義ではなく、参加者の皆様からの率直なご意見、ご感想を期待します。

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どうもありがとうございました。

Adoption of structured abstracts by general medical journals and format for a structured abstract*

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Background: The use of a structured abstract has been recommended in reporting medical literature to quickly convey necessary information to editors and readers. The use of structured abstracts increased during the mid-1990s; however, recent practice has yet to be analyzed.

Objectives: This article explored actual reporting patterns of abstracts recently published in selected medical journals and examined what these journals required of abstracts (structured or otherwise and, if structured, which format).

Methods: The top thirty journals according to impact factors noted in the "Medicine, General and Internal" category of the ISI Journal Citation Reports (2000) were sampled. Articles of original contributions published by each journal in January 2001 were examined. Cluster analysis was performed to classify the patterns of structured abstracts objectively. Journals' instructions to authors for writing an article abstract were also examined.

Results: Among 304 original articles that included abstracts, 188 (61.8%) had structured and 116 (38.2%) had unstructured abstracts. One hundred twenty-five (66.5%) of the abstracts used the introduction, methods, results, and discussion (IMRAD) format, and 63 (33.5%) used

the 8-heading format proposed by Haynes et al. Twenty-one journals requested structured abstracts in their instructions to authors; 8 journals requested the 8-heading format; and 1 journal requested it only for intervention studies.

Conclusions: Even in recent years, not all abstracts of original articles are structured. The eight-heading format was neither commonly used in actual reporting patterns nor noted in journal instructions to authors.

INTRODUCTION

To assist clinicians in quickly finding articles that are both scientifically sound and applicable to their practices, the Ad Hoc Working Group for Critical Appraisal of the Medical Literature proposed, in 1987, a seven-heading format for informative abstracts in clinical articles [1, 2]. Accepting Altman's proposal [3], Haynes et al., in 1990, revised the format and content requirements for structured abstracts to an eight-heading format (objective, design, setting, patients, intervention, main outcome measures, results, and conclusions for original articles) [4]. In 1993, the International Committee of Medical Journal Editors (the so-called "Vancouver group") recommended, in the "Uniform Requirements for Journals Submitted to Biomedical Journals," the use of structured abstracts [5]. Following these proposals, medical journals in Europe and the United States have tried to provide more informative abstracts for articles of clinical interest.

Whether the adoption of structured abstracts could improve the quality of articles continues to be controversial [6, 7]. However, it is certain that structured abstracts make it easier for clinical readers to select appropriate articles more quickly and facilitate peer review before publication. Secondary journals like the *ACP Journal Club,* published by the American College of Physicians, are recognized as valued information resources for practicing evidence-based medicine [8] and have adopted structured abstracts. Harbourt et al. [9] reviewed articles listed on MEDLINE from 1989 to 1991 and found 3,873 articles that included structured abstracts; both the number of articles with structured abstracts and the number of journals publishing them had increased. Kulkarni [10] reported that 28.5% of clinical trial reports listed on MEDLINE in the first half of the 1990s included structured abstracts and that number continued to increase to 71% by the latter half of 1995. Even in non-English-speaking countries, increasingly more journals are adopting structured abstracts; however, the number of structured abstracts provided by journals differs significantly between countries [11, 12].

The introduction, methods, results, and discussion (IMRAD) format [13, 14] and the eight-heading format are well known for structured abstracts in original articles. However, no recent data exist on how many journals provide structured abstracts and what abstract format is required. No systematic research has been conducted on the content of the journals' instructions for authors regarding structured abstracts.

This study was conducted to find out how many original articles published in well-known medical journals included structured abstracts, to identify the formats of such structured abstracts, and to see what abstract format the journals required, structured or otherwise, and, if structured, which format.

METHODS

The top thirty journals according to impact factors noted in the "Medicine, General and Internal" category of ISI's Journal Citation Reports (2000) were selected. Although impact factors are not directly related to journal quality [15, 16], they can be used as an objective selection criteria for journals given that they reflect a journal's impact in terms of how often it is cited.

An investigation was conducted to identify how many of these journals provided structured abstracts as of January 2001. Because four journals (*Annual Review of Medicine, Amyloid, Annals of Medicine,* and *British Medical Bulletin*) had an insufficient number of original articles in the January 2001 issue, the investigation continued into February 2001. PubMed was used to extract the abstracts to examine their formats.

To eliminate manuscripts that were not original, the following categories were excluded from the search: "review," "meta-analysis," "historical article," "legal cases," "consensus development conference," "comment," "guideline," "practice guideline," and "biography." "Meta-analysis" articles resemble original contributions more than traditional narrative reviews. A six-heading format of structured abstracts for review research [4], which is nearly equivalent to a "systematic review" or a "meta-analysis," was assessed independently from original articles. The authors excluded "meta-analysis" in the present examination to focus on the format of structured abstracts in original articles. A search formula was created as follows:

Journal name [ta] AND 2001/01[dp] NOT (review[pt] OR meta-analysis[pt] OR historical article[pt] OR legal cases[pt] OR consensus development conference[pt] OR comment[pt] OR guideline[pt] OR practice guideline[pt] OR biography[pt])

To classify the abstract patterns objectively, the authors conducted a cluster analysis (Ward's method) of

* This study was supported by a grant from the Ministry of Health, Welfare and Labor, Japan.

the structured abstracts extracted from PubMed using statistical software (JMP, SAS Institute). The journals' instructions for authors concerning the format of abstracts were obtained from each journal or collected from Websites in February 2002.

RESULTS

We retrieved a total of 467 hits from 27 journals. No original articles were retrieved from the *Annual Review of Medicine, Proceedings of the Association of American Physicians,* or *Archives of Family Medicine* using the above search. The first two journals mainly published papers other than original contributions, and the *Archives of Family Medicine* ended in 2000. Among them, 304 articles included abstracts, 188 (61.8%) of which were structured, while 116 (38.2%) were unstructured (Table 1). Abstracts provided by the *New England Journal of Medicine, British Medical Journal,* and 2 other journals were structured, and 70% or more of those in the *Journal of American Medical Association (JAMA), The Lancet,* and 7 other journals were structured. Twenty of the 21 abstracts provided by *JAMA* were structured (formats with 8 headings), and 19 of the 21 abstracts provided by *The Lancet* were structured (IMRAD format). In 5 of the journals, fewer than 70% of the abstracts were structured. All abstracts provided by *Medicine, Amyloid,* and 6 other journals were unstructured.

Various patterns were observed in the 188 structured abstracts retrieved from our search, and the structured formats varied even in the same journal. Thirty-one headings were identified from the structured abstracts, which were examined and summarized into 11 categories (Figure 1). Headings such as "method and results," which obviously included 2 different headings in 1, were counted as 2 different headings. Using a dendrogram built by cluster analysis, the structured abstracts were categorized into formats with 8 headings (and their variations) and the IMRAD format (and its variations). Results showed that 125 (66.5%) of the 188 structured abstracts adopted the IMRAD format, and 63 (33.5%) adopted the format with 8 headings.

Examination of the journals' instructions for authors indicated that eight journals, including *JAMA* and *Annals of Internal Medicine,* used the eight-heading format, while thirteen journals, including the *New England Journal of Medicine* and *The Lancet,* used the IMRAD format. Six other journals, including the *Annual Review of Medicine* and *Medicine,* did not specifically recommend the use of a structured format. No articles were retrieved via PubMed from the following three journals: *Proceedings of the Association of American Physicians, Archives of Family Medicine,* and *British Medical Bulletin;* their instructions for authors were also not available. Twenty-six of the twenty-seven journals examined provided abstracts conforming to the instructions for authors. The *Journal of Family Practice* indicated eight-heading abstracts were to be used, but three out of the four abstracts retrieved were IMRAD format.

DISCUSSION

The relationship between the 8-heading format and the IMRAD format is shown in Figure 2. The 8-heading format requests authors of articles to specify and detail their research design and results [4]. In structured abstracts, authors are asked to describe their research's limitations [17], which are occasionally obscured in the traditional narrative format of abstracts. Accordingly, diffusion of structured abstracts in medical journals, to rapidly convey necessary information for clinical application, can be said to reflect readers' needs rather than those of authors. For a medical librarian or an informationist, structured abstracts are easier to read and facilitate a quicker assessment of relevant clinical articles expected by clinicians. In light of the proposals noted in the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" [5], more journals are expected to adopt structured abstracts. However, more than 30% of articles from the top 30 journals did not include structured abstracts in this study. One possible reason for journals not adopting structured abstracts is traditional space constraints for a single article, as narrative abstracts generally increase in length once modified to conform to the structured format [1]. Another reason may be that journals are reluctant to obligate authors to present their study's weak points by writing structured abstracts.

A limited number of journals had only structured abstracts. Among the 304 articles that included abstracts, 61.8% were structured. Sixty-seven percent of the structured abstracts used the IMRAD format, while the 8-heading format was not widely used. Results of the cluster analysis indicated that the IMRAD format mainly included the headings "method(s)," "results," and "conclusion." Variations of the IMRAD format also included "objective(s), aim, or purpose"; "patients, participants, population, subjects, and material(s)"; and "discussion, recommendation, or interpretation." As for the format with 8 headings, "results" and "conclusion(s)" were the only categories generally used. Three additional categories were also identified among those using variations of the 8-heading format; these included "context," "patient," and "main outcome measures"; "objective(s)," "intervention(s)," and "main outcome measure(s)"; and "objective(s)," "patients," and "main outcome measure(s)."

Structured abstracts, particularly those with an eight-heading format, are assumed to be more suitable for interventional studies than for observational studies [7]. However, when our search was limited to "clinical trials" by using PubMed's publication type, we retrieved only a few clinical trials (Table 1). Therefore, we could assume that the eight-heading format, if modified appropriately, could also be applied to abstracts for observational study reports. When the heading of "intervention" is not applied in a cohort study that aims to explore the risk factors of a certain disease, "none" or "not applied" can be included. However, it may be rather difficult to describe the "main outcome measures" in an observational study, which

Table 1
Abstracts of original articles published in top 30 journals according to the rank of impact factors (Medicine, General and Internal): frequency and patterns of structured abstracts (2001)

No.	Journal	Articles with abstracts/ articles retrieved	Clinical trials	Structured abstract		Format of structured abstract (with their variations)				Instruction for authors about abstract form*†
				n	%	IMRAD	%	8-heading format	%	
1	*New England Journal of Medicine*	18/32	10	18/18	100.0	18/18	100.0	0/18	—	IMRAD
2	*Journal of American Medical Association*	21/59	3	20/21	95.2	0/20	—	20/20	100.0	8-heading
3	*The Lancet*	21/51	3	19/21	90.5	19/19	100.0	0/19	—	IMRAD
4	*Annual Review of Medicine*	0								
5	*Annals of Internal Medicine*	12/14	2	9/12	75.0	0/9	—	9/9	100.0	8-heading
6	*Archives of Internal Medicine*	29/37	8	26/29	89.7	24/26	92.3	2/26	7.7	IMRAD
7	*American Journal of Medicine*	22/31	1	7/22	31.8	7/7	100.0	0/7	—	IMRAD
8	*British Medical Journal*	12/37	5	12/12	100.0	0/12	—	12/12	100.0	8-heading
9	*Medicine (Baltimore)*	3/3	0	0/3	—					No specific instruction
10	*Amyloid*	35/40	0	0/35	—					No specific instruction
11	*Proceedings of the Association of American Physicians*	0								
12	*Journal of Family Practice*	5/18	0	4/5	80.0	3/4	75.0	1/4	25.0	8-heading
13	*Annals of Medicine*	4/4	0	4/4	100.0	4/4	100.0	0/4	—	IMRAD
14	*Journal of General Internal Medicine*	7/7	0	6/7	85.7	0/6	—	6/6	100.0	8-heading
15	*Canadian Medical Association Journal*	5/12	1	3/5	60.0	3/3	100.0	0/3	—	IMRAD
16	*Journal of Internal Medicine*	8/8	0	7/8	87.5	1/7	14.3	6/7	85.7	8-heading
17	*Archives of Family Medicine*	0								
18	*Journal of Investigative Medicine*	10/11	0	9/10	90.0	9/9	100.0	0/9	—	IMRAD
19	*QJM: Monthly Journal of the Association of Physicians*	5/5	0	0/5	—					IMRAD
20	*Mayo Clinic Proceedings*	10/12	0	6/10	60.0	6/6	100.0	0/6	—	IMRAD
21	*American Journal of Preventive Medicine*	15/17	0	9/15	60.0	8/9	88.9	1/9	11.1	IMRAD‡
22	*European Journal of Clinical Investigation*	10/10	0	10/10	100.0	9/10	90.0	1/10	10.0	IMRAD
23	*Palliative Medicine*	7/7	0	0/7	—					No specific instruction
24	*The Journal of Laboratory and Clinical Medicine*	8/9	2	0/8	—					No specific instruction
25	*The Medical Journal of Australia*	6/8	2	5/6	83.3	0/5	—	5/5	100.0	8-heading
26	*British Medical Bulletin*	2/4	0	0/2	—					No specific instruction
27	*Journal of Pain and Symptom Management*	9/9	1	0/9	—					No specific instruction
28	*British Journal of General Practice*	9/9	2	4/9	44.4	4/4	100.0	0/4	—	8-heading
29	*Preventive Medicine*	10/11	1	10/10	100.0	10/10	100.0	0/10	—	IMRAD
30	*American Journal Medical Science*	1/2	0	0/1	—					IMRAD
Total		304/467	41/304	188/304	61.8	125/188	66.5	63/188	33.5	

* Instructions for authors of the journals were examined on the Websites in February 2002.
† Introduction, methods, results, and discussion (IMRAD) format; 8-heading format: objective, design, setting, patients, intervention, main outcome measures, results, and conclusions.
‡ Eight-heading format is requested only for intervention studies.

are more exploratory in nature than hypothesis testing. Further discussion is needed to address this issue.

In only eight journals of the present study did the instructions for authors recommend the use of the eight-heading format, and, for the most part, abstract formats conformed to the journals' instructions for authors. In light of differences in time of submission, acceptance, and publication and time of examination of the instructions for authors (February 2002), the present findings did not address the question of whether

Figure 1
Integration of similar headings of the 188 structured abstracts of the original articles

1. Objective(s), aim, purpose
2. Design, design of study, study design
3. Setting
4. Patients, patients/participants, population, subjects, participants, material(s), cases, data source(s)
5. Intervention(s)
6. Main outcome measure(s), outcome, outcome measures, measurements
7. Results, main results, findings
8. Conclusion(s)
9. Context, background, introduction
10. Discussion, recommendation, interpretation
11. Method(s)

Figure 2
The relationship between the introduction, methods, results, and discussion (IMRAD) format and the eight-heading format of the structured abstracts

IMRAD format	Eight-heading format
1. Introduction	1. Objective: the exact question(s) addressed by the article
2. Methods	2. Design: the basic design of the study 3. Setting: the location and level of clinical care 4. Patients or participants: the manner of selection and number of patients or participations who entered and completed the study 5. Interventions: the exact treatment or intervention, if any 6. Main outcome measurement: the primary study outcome measure as planned before data collection began
3. Results	7. Results: the key findings
4. Discussion	8. Conclusions: key conclusions including direct clinical application

the abstract formats of published articles were consistent with the instructions for authors.

Because abstract formats are influenced by the publishing journal, the instructions for authors and processes of review and editing play important roles in promoting appropriate abstract formats. As for those abstracts that do not conform to the instructions for authors, two possibilities exist. One is that the abstract was submitted, reviewed, and edited before the instructions for authors had been revised and released, and the other is that the abstract format recommended in the instructions for authors might have been inappropriate for the abstract's contents. Although instructions for authors are essential for controlling the quality of abstracts, their limitations result from being provided prior to article submission. Pitkin and Branagan [18] conducted a study to find out whether giving specific instructions to authors after submission of articles could improve the quality of abstracts in the next submission but were unable to prove the effectiveness of such instructions. Nevertheless, their study emphasized the importance of giving specific and detailed attention to abstracts during the editing process.

Abstracts summarize the information provided in original articles. Improvement in the quality of abstracts would be beneficial to authors, readers, and editors. Further possible studies in this area are: attitudes of journal editors, readers, and authors toward using structured abstracts; reasons why some abstracts do not conform to journals' instructions for authors; desirable abstract formats for observational studies, qualitative research, or case reports; possibilities of incorporating information standardized in structured abstracts into a larger database or a decision-support system; and more. We believe that it would be valuable for established journals to recognize how structured abstracts can improve the quality of their publications.

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Under the new policy, BCG vaccination will be offered to infants in communities with an average incidence of tuberculosis of at least 40 per 100 000 and to unvaccinated individuals who come from, or whose parents or grandparents come from, countries where the incidence exceeds 40 per 100 000. Most people born in the United Kingdom will thus probably never receive BCG vaccination, and most will not be exposed to mycobacteria. This means that tuberculin testing will become increasingly efficient as a means of identifying people exposed to and latently infected with the tubercle bacillus, who may be given prophylaxis.

The change from routine to targeted vaccination is accompanied by technical changes. The Glaxo BCG vaccine has been replaced by one from the Danish Statens Seruminstitut and the multipuncture "Heaf" technique for tuberculin testing is being replaced by the intradermal injection "Mantoux" technique, which is the standard in the rest of the world. All of these changes bring the UK's approach to preventing infection with tuberculosis in line with policies and practice in many other countries.

BCG vaccination will continue to have an important role in protecting children in high risk populations from tuberculosis. Coupled with vigorous efforts to identify and appropriately treat cases, and to ascertain and offer prophylaxis to people with latent infection, the new policy should allow more efficient control of tuberculosis in the entire UK population.

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Competing interests: PF is a member of the BCG Subcommittee of the Joint Committee on Vaccination and Immunisation and took part in discussions leading to this policy change.

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The Japanese healthcare system

The issue is to solve the "tragedy of the commons" without making another

The Japanese medical insurance system has a unique combination of characteristics that has led to the overuse of tests and drugs, unconstrained demand from patients, and an explosion of costs. Unless the system of medical insurance and reimbursement of healthcare providers changes, the combination of increasing technological advances, an ageing population, and unconstrained demand will produce a crisis in Japanese health care. Japan is only belatedly waking up to this crisis.

The Japanese medical insurance system has four characteristics that lie at the root of the problem. Firstly, Japanese citizens are covered comprehensively and exclusively by either national medical insurance (for the self employed) or social insurance (for employees). Beneficiaries have to make some co-payments, which are capped depending on income.[1] Secondly, mixed private and insurance payments are prohibited—that is, beneficiaries cannot pay privately for medical services that are covered by their medical insurance. Thirdly, beneficiaries have guaranteed access to any healthcare providers, from general practitioners to specialists, without being charged a premium fee. Finally, healthcare providers and institutions are reimbursed through fees for service.

Fuelled by economic growth after the second world war and facilitated by the healthcare system, Japan has become one of the most medically advanced nations in the world, especially in its service quantity. Compared with other developed countries in the Organisation for Economic Cooperation and Development (OECD), Japan is the runaway leader in the number of magnetic resonance imaging and computed tomography scanners per head of population.[2] Because they are paid for each prescription or test rather than time spent with patients, healthcare providers, both private and public, are driven to prescribe more drugs and to order more imaging and tests.

Japanese patients visit outpatient clinics more often and stay in hospitals longer than patients in other OECD countries.[2] Profits gained from a "three-hour wait, three-minute contact" consultation (with an emphasis on ordering tests and prescribing drugs during the three minutes) primarily benefit pharmaceutical and medical equipment companies. Healthcare expenditures, both per head and as a percentage of gross domestic product, continue to increase despite the economic growth rate remaining low throughout the past 10 years. In Japan's ageing society, the economic burden rests with the insurers, who ultimately raise their funds from the working population and their employers.

Japanese health care is therefore a typical case of the "tragedy of the commons."[3] The name relates to grazing land: free access to common grazing land drives each herdsman to maximise his own take from the commons, even when it becomes overcrowded with grazing animals. Ultimately this behaviour ruins the common land, as well as those who depend on it for survival. In the Japanese system patients are the herdsmen, and specialists, medical resources, and health insurance coverage comprise the commons. A more

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cynical view holds that doctors and pharmaceutical and medical equipment companies are the herdsmen while patients and health insurance reimbursement comprise the commons. What can be done to avoid ruin? A variety of different players have made proposals for reform.

In December 2002, the council of advisers to the Cabinet Office, composed of business leaders and academic economists, recommended that the ban on mixed payments should be abolished. Private payments should be allowed for any medical services not covered by medical insurance at any medical institution which fulfilled certain conditions.[4 5] The council argued that the ban deprived Japanese patients of the chance to receive a higher or more advanced level of medical services. It also deprived the Japanese medical industry of chances to market its new technologies and drugs, thus impeding its international competitiveness. Indeed, the big three university hospitals, well known for their research activity, as well as the Japan Surgical Society expressed their agreement with this proposal.

The Japan Medical Association, commonly regarded as an interest group for private office based practitioners, campaigned against the proposal, claiming that it would deprive people with low incomes of necessary medical services. The Ministry of Health, Labour, and Welfare opposed the recommendation on the same grounds, claiming also that patient safety would be at risk if new medical technologies and drugs were used prematurely.

Last December Prime Minister Junichiro Koizumi agreed not to adopt the council's recommendation, but instead decided to expand the existing exceptional approvals system for highly advanced medical technologies.[6] Under this system private payments are expected to be allowed for selected medical technologies that are not covered by medical insurance at any hospitals that fulfil certain conditions (some 2000). For new drugs that have not yet been approved, especially those approved in other developed countries, measures will be taken to ensure steady implementation of bridging short term and long term clinical trials. But no one believes that the business leaders, who have a mission to vitalise the Japanese economy, have given up their objective.

The Ministry of Health, Labour, and Welfare is currently making changes to the healthcare system. In a scheme that started in 2003 with 82 hospitals providing advanced treatments, an increasing number of acute hospitals have adopted a system of reimbursement for inpatient care based on diagnosis-procedure combinations (DPC).[7] Hospitals are paid daily fees proportionate to the length of stay for each condition and treatment, irrespective of actual interventions.[8] Therefore, this system gives an incentive to healthcare institutions to provide a better service in a shorter period while ordering fewer tests and prescribing fewer drugs.

The ministry is also promoting protocol based medicine. It has provided support for the development of evidence based clinical practice guidelines by academic medical societies since 1999.[9] The dissemination and implementation of these guidelines is expected to improve the quality of medical care and drive the distribution of limited resources to effective treatments. But, as in other developed countries, this remains a challenging task. The government's attempts have often been challenged by the Japan Medical Association, on the grounds of "professional autonomy." But the association is currently renewing its stance on professional autonomy,[10] to a positive, self regulated commitment to patient welfare based on sound clinical evidence and expertise.[11]

The problem is that neither the new reimbursement system nor protocol based medicine will change patients' behaviour as "herdsmen." Previously patients and physicians were driven in the same direction: more tests, more drugs. The new reimbursement system drives only physicians in the opposite direction. Indeed, conflict between patients and physicians could cause a separate tragedy. To encourage shared decision making between patients and doctors based on sound clinical evidence, including an understanding of the need to avoid unnecessary tests and drugs, the ministry has set up a task force to investigate the possibility of patients participating in the development, dissemination, and implementation of clinical practice guidelines. This task force is also working on strategies to popularise the concept of patient-physician partnership.

To date, no countermeasures for the tragedy of the commons have been found other than restricting free access to the commons. If effective actions are not soon taken to change the behaviour of both patients and healthcare providers, some restriction on Japan's free access to health care will become inevitable. Withdrawing the ban on mixed payments—and allowing patients to pay privately for extra treatments—is equivalent to giving up an important part of the commons, and could cause the worst tragedy for patients.

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Competing interests: TN is the chair and HN is a member of the task force on the improvement of the development, usage, and dissemination of evidence based practice guidelines with special attention to patient and carer involvement.

1 Fukawa T. *Public health insurance in Japan.* Washington, DC: World Bank Institute, 2002.
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ORALS

O-4-4
Do guidelines include relevant information to support communications among patients, care givers and physicians? : a content analysis of clinical practice guidelines developed in Japan

2

2005.12.7

The 3rd Guideline International Network at Lyon, France

Do guidelines include relevant information to support communications among patients, care givers and physicians? : A content analysis of clinical practice guidelines developed in Japan.

Takeo Nakayama, MD, PhD
Department of Health Informatics,
Kyoto University School of Public Health, Japan
Hiromichi Suzuki
International Medical Information Center, Japan.

3

Background 1

- In Japan, the official movement to develop evidence-based clinical practice guidelines began in 1999 with the financial support of the Ministry of Health and Welfare (presently, the Ministry of Health, Labour and Welfare).
- Since then, practice guidelines in various fields have been developed or are now under development.
- Methods using the principles of evidence-based medicine are becoming popular.

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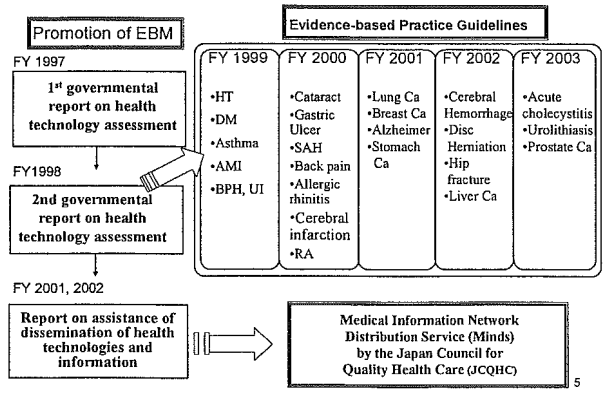
EBM related governmental activities in Japan.



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Working Groups funded by the Ministry of Health, Labour and Welfare in Japan

- A study on the acceptability and developmental methodology of 'structured abstracts' to be used for medical databases and EBM-oriented 'Clinical Practice Guidelines (FY 2001-2003)
- A study on the infrastructure development for the appropriate development, use, and distribution of Evidence-based Guidelines (FY 2004-).

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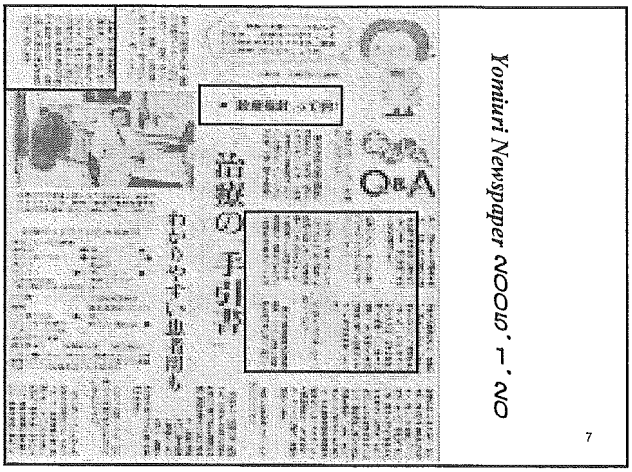

Yomiuri Newspaper 2005・1・20

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Yomiuri Newspaper 2005・9・27

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Asahi Newspaper 2004・6・13

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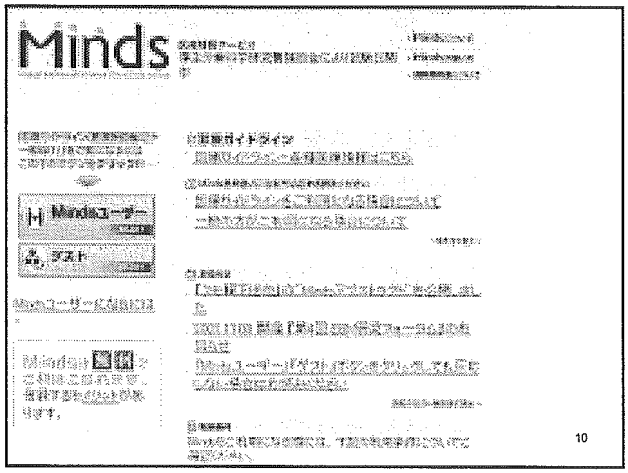

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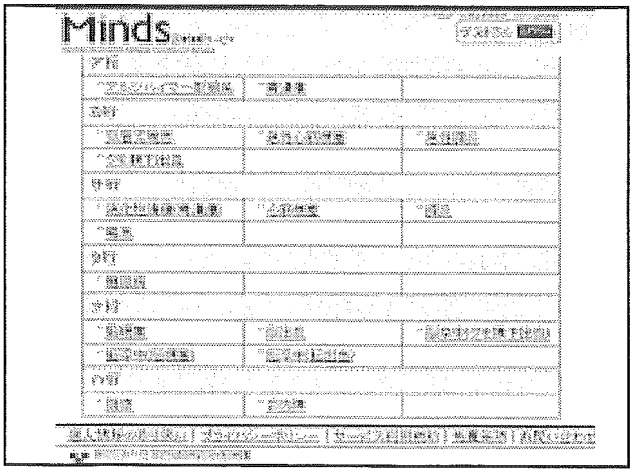

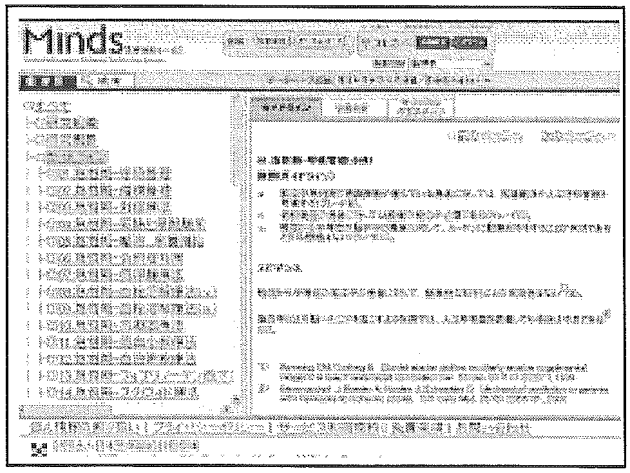

Background 2

- Practice guidelines are expected to assist decision making by practitioners, patients and care givers as well as to facilitate communications among them.
- However, the contents of practice guidelines have not been fully examined concerning whether or not they include relevant information for these purposes.

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Objectives

- We aimed to analyze the contents of practice guidelines in terms of including relevant information to support communications among patients, care givers and physicians.

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Methods 1

- Both electronic and manual search were conducted to retrieve existing practice guidelines developed in Japan.
- Reports, academic literature and books were searched.
- Out of the retrieved guidelines, well-formulated ones were selected if they met the following criteria:
  - defining clinical questions to be addressed
  - reviewing evidence
  - determining grade of recommendation

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Methods 2

- The practice guidelines that were identified accordingly were analyzed for their contents in terms of patients' preferences, informed consent, and patients' quality of life (QOL).
- HS and TN independently reviewed the contents of the guidelines selected.
- Inconsistencies were resolved by discussion.

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Results 1

- 369 clinical practice guidelines that were developed and available in Japan were found (February 2005).
- Among these guidelines, 23 guidelines, such as pain control for cancer patients (2000), asthma (2001), acute myocardial infarction (2001), met the criteria for the present analysis.

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Results 2

- Out of 23 guidelines examined...
- Only guidelines for pain control for cancer patients explicitly included considerations of patient preferences.
- 3 guidelines (breast cancer, cerebral infarction and cataract) included relevant information about informed consent.
- Only guidelines for asthma dedicated a chapter specifically to informed consent.
- 11 guidelines did not include any description about patients' QOL.

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Conclusions

- At present, there are few Japanese guidelines that include relevant information to support communications among patients, care givers and practitioners.
- In setting clinical questions to be addressed in the guidelines, concerns and questions in terms of patients and care givers ("patient questions: PQ") should be considered appropriately.

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Present activities

- Our working group is
  - developing support program for patient representatives to act in guidelines developmental group.
  - promoting interview survey of patients and/or care givers to know "patient questions".
  - facilitating the review of articles that include patients' concern.
- (...These approaches are also recommended in the AGREE instrument.)

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New Zealand GUIDELINES GROUP Te Rōpū Rorangi Tohutohu

医療情報サービス Minds

Improving Care by Implementing Guidelines

The New Zealand Experience

Catherine Marshall

Chief Executive, NZGG

Honorary Patron,

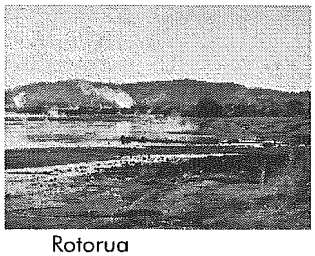
Guidelines International Network

Guidelines International Network

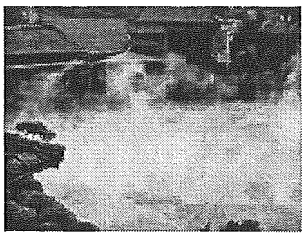
Shared World Views

Mount Ngarahoe

Mount Fiji



Rotorua



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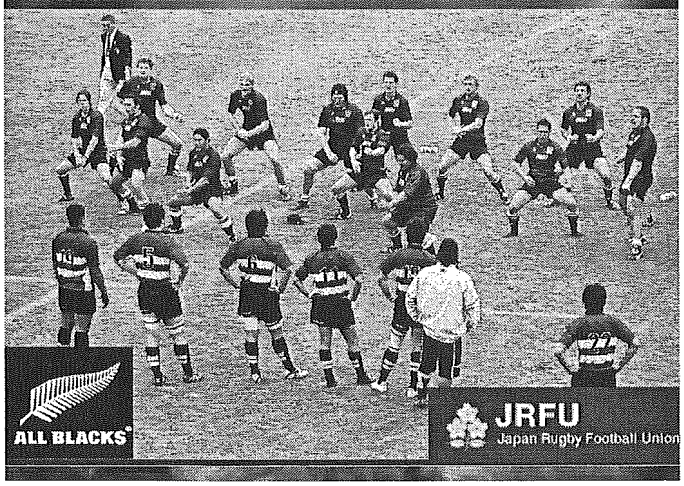
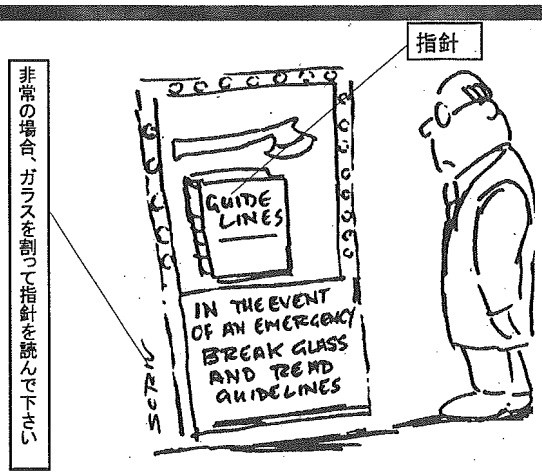


New Zealand and Japan

- Island nations bordering the Pacific Ocean
- Started developing evidence-based guidelines in 1990s
- MINDS and NZGG independent from Government
- Guidelines covering similar topics:
  - Cardiovascular diseases, stroke, low back pain, prostate cancer, femur fracture, breast cancer



Outline

- Guideline development in New Zealand
  - Development processes
  - Implementation processes
  - Designing tools to support the guidelines
  - Redesigning systems and process
- Guidelines International Network

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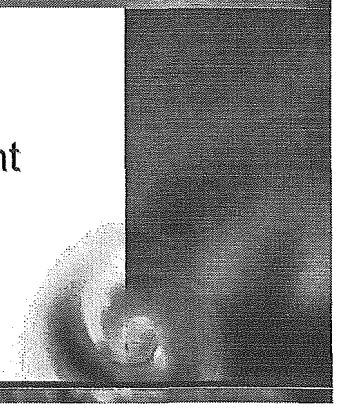
Guideline Development Processes



NZGG Promotes Culture Change

Improving outcomes for consumers by:

- reducing the gap between optimum best practice based on evidence – and current practice
- using therapies known to be effective
- providing up-to-date information about options and outcomes for clinicians and consumers and
- identifying effective care!

Guideline Development Principles

1. Guidelines focus on consumer outcomes
2. Link best evidence and strength of recommendations
3. Synthesis of evidence strongest available
4. Team of multidisciplinary professionals and consumers
5. Guidelines flexible and adaptable for local conditions

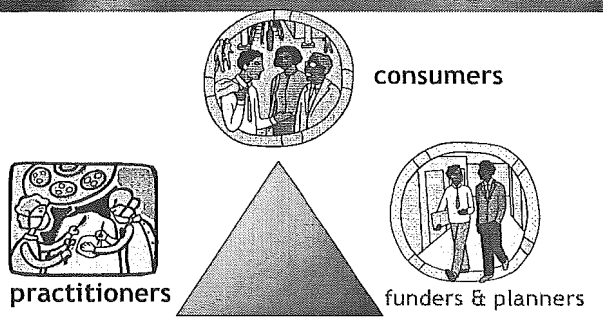
Guideline Development Principles

6. Guidelines consider resource constraints
7. Guideline development includes dissemination and implementation plans
8. The usefulness & impact of guidelines should be evaluated
9. Guidelines should be revised regularly

Essential Steps

- Identifying evidence - practice gaps
- Scoping and questions
- Literature searching, selection and critical appraisal
- Develop evidence tables
- Form clear action focused recommendations
- Consultation with stakeholders to get buy-in

EBP and Guidelines



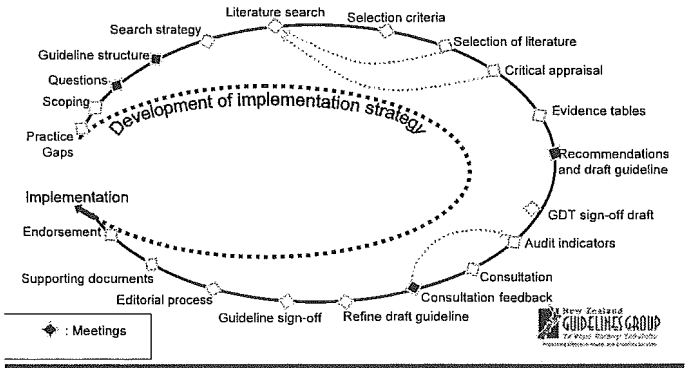
Guideline Development Team

- Balanced and representative
- Nominees from:
  - –professional colleges
  - –stakeholder organisations
  - –consumers
  - –Maori and Pacific peoples
- Geographic representation

Editorial Independence

- All funding sources for guidelines are made explicit
- All participants in the process declare competing interests
- NZGG retains copyright

Guideline development process*



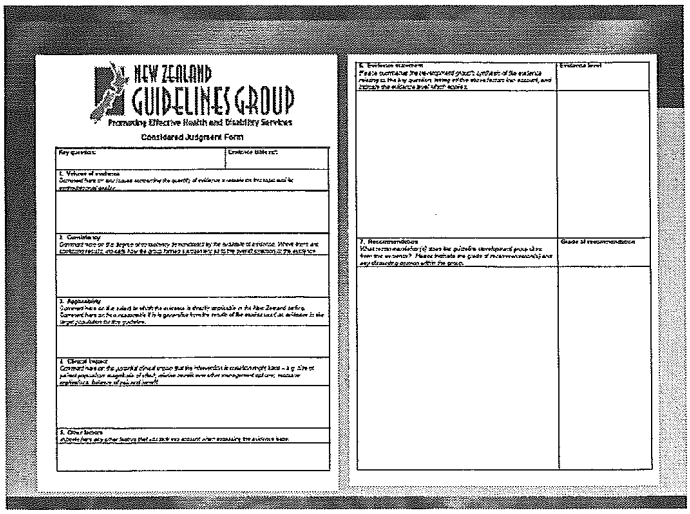
* Based on a CBO model

Evidence Trumps Opinion

Is the Judgment Considered?

Does the evidence apply to NZ conditions?

- Volume of evidence
- Consistency of message
- Applicable to NZ (cost, availability, cultural suitability)
- Clinical impact (will it lead to improvements?)



GRADING OF RECOMMENDATIONS

RECOMMENDATIONS

The recommendation is supported by good evidence (where there is a number of studies that are valid, consistent, applicable and clinically relevant).	A
The recommendation is supported by fair evidence (based on studies that are valid, but there are some concerns about the volume, consistency, applicability and clinical relevance of the evidence that may cause some uncertainty but are not likely to be overturned by other evidence).	B
The recommendation is supported by international expert opinion.	C
No recommendation can be made because the evidence is insufficient (either evidence is lacking, of poor quality, conflicting or the balance of benefits and harms cannot be determined).	I

Grade indicates the strength of the supporting evidence rather than the importance of the recommendations.

GOOD PRACTICE POINT

Where no evidence is available, best practice recommendations are made based on the experience of the Guideline Development Team.	✓

Decision Aids NOT Decisions

STATEMENT OF INTENT

Evidence-based best practice guidelines are produced to help health practitioners and consumers make decisions about health care in specific clinical circumstances. Research has shown that if properly developed, communicated and implemented, guidelines can improve care. The advice on caesarean section given in this guideline is based on epidemiological and other research evidence, supplemented where necessary by the consensus opinion of the expert development team based on their own experience.

While guidelines represent a statement of best practice based on the latest available evidence (at the time of publishing), they are not intended to replace the health practitioner's judgment in each individual case.

Where guidelines are modified for local circumstances, significant departures from the national guidelines should be fully documented and the reasons for the differences explicitly detailed.

Implementation

1. **Awareness campaign**
2. **Education programme**
3. **Dissemination programme**
4. **Implementation programme**
5. **Evaluation programme**

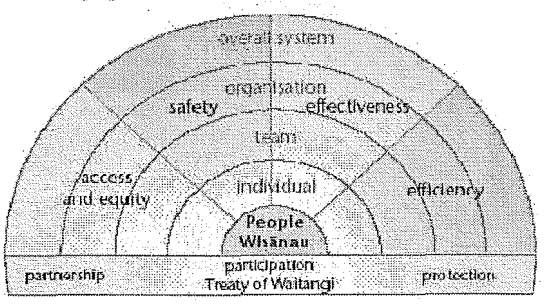
NZGG's Implementation Plan

- **Identify key themes to promote**
- **Identify the range of audiences – and find out how they want to learn about the messages**
  - **Primary care practitioners**
  - **Allied health practitioners**
  - **Policy makers and funders**
  - **Other businesses eg gymnasiums,**
  - **Pharmaceutical companies, publishing houses**
  - **Specialists**
  - **Consumers and the media**
  - **Software vendors**

SWOT Analysis

- Barriers to implementation
- Workforce requirements
- Cost implications
- Consider views of each audiences
- Identify incentives that could encourage uptake of the guideline

Quality dimensions for the New Zealand health and disability system



Improving Quality, Ministry of Health, NZ, 2003

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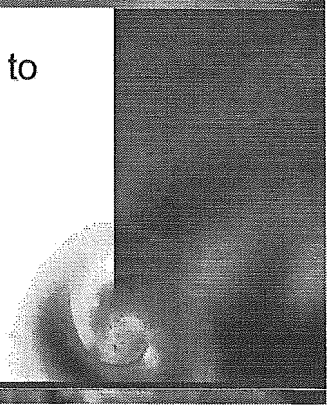
Designing Tools to Support the Guidelines



Individual Needs

- Trusted reliable, evidence-based information
- Understandable information on risks, benefits and options
- Formats that are clear and concise

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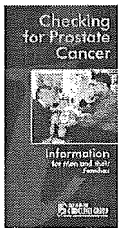
Consumer Resources



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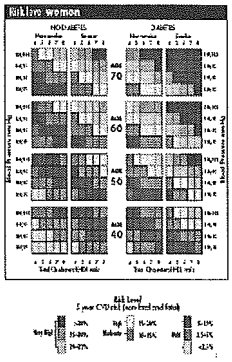
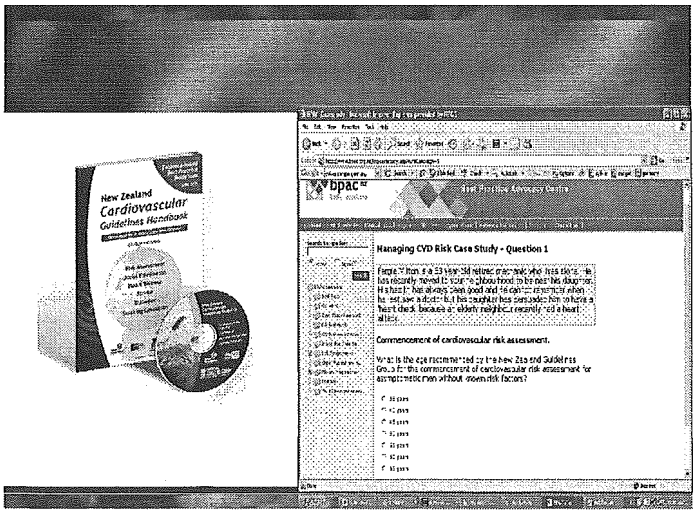
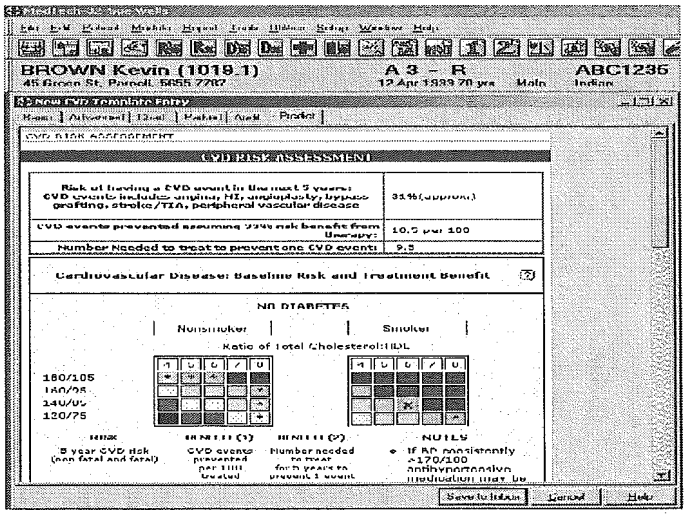
Risk Information



Your doctor, nurse or health professional will assess what level of risk you have, which will be shown as a percentage. For example, if your risk is high, e.g. 20%, and there were 100 people like you (without treatment), then approximately 20 of these people would have a heart attack or stroke in the next five years.





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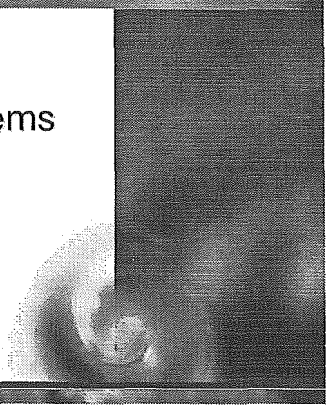
Redesigning Systems and Processes



Team Changes

Self Harm and Suicide Prevention Project

- Improve consumer experience when using emergency department, Maori and mental health services
- Improve service co-ordination and collaboration
- Give clinicians skills that they can transfer to other quality improvement initiatives
- Create and sustain a community of leaders who can implement evidence based change in clinical practice.

Making It Relevant

- National targets derived from the guidelines
- Local objectives to meet national targets
- Map consumer experiences to identify system blocks
- Plan-Do-Study-Act Cycle
- Maori Advisory Group will provide cultural oversight

Draft National Targets

Access

- **100% of people attending EDs with self harm or suicidality should be seen within 1 hour by a clinician skilled in conducting mental health and risk assessments.**

Assessment

- **100% of people presenting (to any of the services) will have a documented assessment that incorporates and assessment of psychosocial stressors, a cultural assessment, a screen for mental illness and subsequent risk assessment**

Discharge

- **Whenever a person is discharged from any of the services, they and their whanau/ significant others should be provided with a written copy of their discharge plan. A copy will be sent to all others involved in their care.**

NZGG Support for DHBs

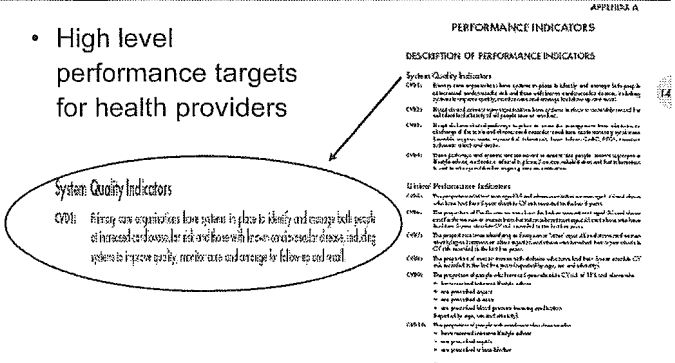
- Mentoring/ project supervision/evidence dissemination/ relationships
- Two day workshop for participants
- Monthly teleconferences
- Website for collecting stats, sharing information
- Visits by project staff to DHBs

System Changes

- Ministry of Health contracts with District Health Boards (DHBs) to implement guidelines
- District Health Boards set payments for Primary Health Care Organisations (PHOs) to adopt guideline recommendations

Performance Indicators

- High level performance targets for health providers



System Quality Indicators

CVD1: Primary care organisations have systems in place to identify and manage both people at increased cardiovascular risk and those with known cardiovascular disease, including systems to improve quality, monitor care and manage by follow-up and recall

Policy and Funding Issues

- Get policy agencies involved early
- Provide opportunities to comment
- Actively discuss the implications of the recommendations
- Assess the costs and implications of the recommendations (eg screening issues, recommendations for new drugs)

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Promoting Effective Health and Disability Services

Guidelines International Network

www.g-i-n.net