

Evidence-based Medicine: The Key to Guidelines, Disease and Care Management Programmes

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Abstract

Introduction: Evidence-based medicine (EBM) is based on the concept of applying best practice to the diagnosis or treatment of a single patient or clinical question, one patient at one time. Although this is useful as a practitioner seeing patients one at a time, it is limited in its application to populations or to single patients with multiple diseases. I will review how to apply EBM to the structure and implementation of population-based care management programmes. **Methods:** A review of the existing literature on the topic was undertaken in preparation for the First National Disease Management Conference—"Achieving seamless quality care across the continuum"—held between May 25 and 26, 2001. This material has been combined with experience and evidence of the author. **Results:** EBM and practice form the basis of the development of evidence-based guidelines that help lay the path for populations of patients with specific conditions. Care and disease management are the programmes that have been developed to implement evidence-based guidelines and best practice and to produce optimal outcomes in populations with chronic conditions, either single or multiple. Examples are presented to further the understanding of the reader. **Conclusion:** To optimally improve the health of a population, chronic collaborative care programmes must be built and implemented that utilise best practice as defined by evidence in the literature.

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Background

Health care in America and the rest of the industrialised world continues to reinvent itself at an ever-accelerating rate. The societal pressures for high quality, high value care that produces measurable improvement in quality processes and outcomes is increasing from the government and private sectors. The expectation is growing for coordinated, collaborative care across the continuum that is patient-centric and evidence-based.¹ This must all be based, when available, on evidence for efficacy, effectiveness and efficiency in the literature. Care management includes not only disease management but also other prospective health care programmes, such as case and demand management, that may be more limited in scope than classic disease management.

The rationale behind a disease management programme must be based on data and evidence concerning the outcomes of treating that condition and the degree of local variation in practice that may exist. A programme can be created because of a health problem in the population that must be addressed, or because current diagnosis and treatment of an

entity has a high measure of variation and/or cost to the system. Thus, the expected return on investment is part of the mission of the programme and helps to focus the system on defining the goals. Once this is agreed upon, a development team must be created to evaluate the epidemiology of the problem and research the best practice to address the problem that exists in the literature. This includes review of existing evidence and external guidelines that have been developed in the public, private or academic sector. Once this work has been done, a programme can be designed based upon the optimum processes that the system can provide. It is important to identify major barriers at this point as the system is analysed using classic process improvement tools.

The key to understanding the importance of disease management is understanding the complexity of the practice setting and balancing the needs of the practitioner, patient and health care system. Disease management is based on the need for guidelines to codify the best practice and, when possible, care is based on the best evidence for all customers. Development of guidelines takes a team effort

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and compromises between the developers based on the interpretations of the evidence and the self-interest of the parties involved. That, however, is only the beginning. The guidelines must be distilled into usable tools that cover the continuum, from prevention to long-term maintenance, and must be used by all members of the health care team, including the patient.

Introduction

“The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research”.² EBM is based on the concept of applying best practice to the diagnosis and treatment of a single patient or clinical question at one time. This is useful to a practitioner seeing patients one at a time; however, it is limited in its application to populations or to single patients with multiple conditions. The practice of EBM takes a great deal of discipline and most practitioners, who have learned the techniques in their training, have not been willing to take the time to use the tools and principles in their practice. It is, however, key to the understanding of how to produce clinically useful guidelines and to dissemination of new knowledge in a complex adaptive organisation.

Care management programmes encompass a spectrum of initiatives to improve the care of populations and individuals. They range from retrospective to prospective activities, and from reactive to proactive interventions. It is within these programmes that EBM and guidelines have their most useful applications, as the basis for initiatives to re-engineer health care. These programmes are described as:

Utilisation management (UM) is the evaluation of an individual case or group of cases after the care has been delivered (i.e., retrospective review) to determine the medical necessity and appropriateness of care. This review is usually done for reasons of approval or denial of payment for services rendered, for comparing patterns of care to an external benchmark or evidence, or for inter-individual or group comparisons. Evidence-based practice guidelines that recommend appropriate care for the given situation are applied retrospectively. UM may also be prospective, e.g., pre-certification/pre-authorisation processes.

Case management is designed to plan and implement a course of care for patients with complex or intensive needs over an extended period of time. Case management is used both during acute episodes of care and for patients with chronic conditions. Physicians work collaboratively with case managers, usually nurses, to define a treatment plan, secure services, monitor health status, and educate the patient and family. Within case management one can use evidence-based guidelines both prospectively when assessing needs and planning services, and retrospectively

to evaluate the care delivered.

Demand management refers to programmes and processes targeted at consumers and patients that are designed to improve their health, promote self-monitoring of conditions and symptoms, and encourage appropriate use of and access to medical services. One component of demand management is the provision of information and the best evidence to patients in real time to address their questions and needs. This information can be in the form of guidelines that supplement other information given to the patient during or in-between appointments. By educating the patient, the guidelines help make the interaction with the practitioner more meaningful.

Disease management is defined as a multi-disciplinary, continuum-based approach to health care delivery that:

- proactively identifies populations with or at risk for established medical conditions;
- supports the physician-patient relationship and plan of care;
- emphasises prevention of exacerbations and complications utilising cost-effective evidence-based practice guidelines and patient empowerment strategies such as self-management;
- continuously evaluates clinical, humanistic and economic outcomes with the goal of improving overall health.

Disease management programmes should contain the following components:

- population identification process;
- evidence-based practice guidelines;
- collaborative practice model to include physician and support-service providers;
- risk identification and matching of interventions with need;
- patient self-management education (may include primary prevention, behaviour modification programmes and compliance/surveillance);
- process and outcomes measurement, evaluation, and management;
- routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers and practice profiling);
- appropriate use of information technology (may include specialised software, data registries, automated decision support tools and call-back systems).³

This must all be based, when available, on the best evidence in the literature and evidence-based guidelines. I will present in this monograph, how I have understood and used these concepts to explain the principles of disease management and create platforms and implement programmes in complex adaptive organisations.

Methods

This article reflects the experience of the author and is a synthesis of previous experience and a use of the literature to describe the current understanding of the field. Much of the material is derived from presentations for the National Health Group in Singapore during the First National Disease Management Conference—“Achieving seamless quality care across the continuum”—held between May 25 and 26, 2001.

Discussion

“The purpose of the health care system is to continually reduce burden of illness, injury and disability, and to improve the health and functioning of the people of the United States”.⁴ This definition does not describe the present structure and functioning of health care systems in the United States or any other country at present. The recent Institute of Medicine reports clearly define the deficiencies and describe templates that will produce high quality health care for the future. Components of this redesign include an infrastructure for evidence-based practice and patient centredness.

Why are we currently in this “crisis” and why are there so many conflicting tensions for change? Health care in most cultures and countries is a transaction between a patient with an acute problem and a provider with a store of knowledge of interventions that, if accessed and used, would either improve or resolve the problem. It is the same scenario if we are describing an interaction of a patient with a physician, shaman, pharmacist or herbalist. This model was adequate as long as there was a limited number of interventions and neither party in the transaction insisted on prospectively reviewing the evidence that the treatment was efficacious.

Industrialised nations, such as Singapore, have entered a phase of rapid addition of new procedures, devices and pharmaceuticals that are being introduced into the practice of medicine with little or no control of utilisation. This leads to increasing consumption of resources without accountability and rapid inflation. When researchers look at local variation in processes and outcomes in the United States, we find what John Wennberg, MD, MPH has described as “Geography is destiny with health care”. Instead of the evidence determining a diagnostic or treatment course, the amount and type of care is dependent upon two factors:

- Capacity of the local health care system determines how much care is consumed;
- Practice styles of local physicians determine what kind of care is utilised.

Medical science provides clear guidelines about the need to hospitalise patients with certain conditions. Hip fractures and colorectal cancers are almost always hospitalised and utilisation rates of these conditions are not influenced by

physician practice style or per capita supply of hospital beds. Physicians’ decisions are also influenced by a largely invisible factor: the capacity of the acute care hospital environment.⁵ If we accept that the above factors influence the behaviour of physicians, then how do we change their behaviour in the direction that society would like? One of the most important tools is to implement evidence-based practice. This is defined as “integrating individual clinical expertise with the best available external clinical evidence from systematic research”.² It means appealing to physicians to use scientific principle vs. anecdote. I will illustrate in the following three examples on how to use “evidence” to create effective care and disease management programmes.

This point can be most simply illustrated by the example of the release of a new randomised controlled clinical trial.⁶ This study demonstrated that the introduction of interferon beta-1a into the initial therapy of multiple sclerosis could improve patient outcomes. Interferon is an expensive drug to use; hence, cost-effectiveness as well as clinical efficacy must be proven in order to incorporate this treatment into the practice of those physicians who treat multiple sclerosis. The study is powerful in several ways:

- 1) it is a randomised controlled clinical trial, so it is Grade I evidence, and
- 2) the trial not only followed the physiological measure of cerebral lesions, but the clinical outcomes of the number of clinical events and progression of disability.

These are expressed as: Rate in Placebo = 50% as compared to the Rate in Interferon = 35%. This gives an Absolute Risk Reduction (ARR) = $0.50 - 0.35 = 0.15$, so the Number Needed to Treat (NNT) = $1/0.15 = 6.6$, meaning that you need to treat 7 patients for 3 years to have one success. The only reported significant side effect was “flu-like symptoms”, so the Number Need to Harm (NNH)(flu-like) = $1/0.54 - 0.26 = 1/0.26 = 3.8$, so you need to treat 4 patients for 6 months to get one problem. These are very significant results and, with the decrease in the need to pay for physical therapy and rehabilitation, at least two local health plans in Western New York have been reimbursing within the limits of their contracts for treatment (Personal communications—Independent Health Association, Inc. and HealthNow New York Inc.). One disease management company that specialises in rare diseases has also considered recommending this treatment early on in its algorithms (Personal communication—Accordant Health Services Inc.). This is an example of evidence for simple change in a care management protocol for a rare disease with few other options.

Let us look at what happens with a more complex disease. One of the toughest groups to manage are paediatric asthma patients from lower socio-economic urban areas. Several studies have shown success in managed care

populations using the following tools:

- Nationally-recognised, evidence-based guidelines for providers, patients and families;
- Paediatric asthma experts, clinics, educators and case managers to work with patients, families and primary care physicians;
- Monitoring of medication refills and usage and reminders from a call centre;
- Measurement and feedback of outcomes;
- Disease management programmes, either internal or supported by pharmaceutical companies.

This success has not generally been achieved in Medicaid and inner city populations. However, in a recent randomised controlled trial,⁷ researchers achieved success and illustrated how to translate evidence into tools in a disease management programme to change patient, family and provider behaviours and improve outcomes. They relied on a combination of tools and concepts that had been successful in other trials and added an “asthma counsellor” to track and work with patients and families. The treatments are evidence-based and rely on a difficult multi-drug, daily management plan. Despite the good evidence of efficacy, even intact families with good coping skills have problems dealing with complex regimens without some type of support. This approach supports the physician plan and the physician-patient relationship. It empowers the family to cope with the condition and treatment, an aspect that we, as physicians, are frequently unable to do on our own.

The training of the family by the counsellor in the evidence-based guidelines involved getting at least one caregiver in the family to a centralised formal training course. There are usually many barriers that need a facilitator to overcome. The counsellors then interact with the family to develop individualised treatment plans for that child and family and then work to overcome all the barriers to implementation. The counsellors are able to access community resources and act as a conduit between the patient family unit, the primary care doctor and the asthma specialist supervising the programme. This intervention significantly boosted symptom-free days and decrease hospital utilisation. The patients with the most severe problems benefited the most. Thus, case management in combination with evidence-based guidelines and patient education has produced a successful model of a paediatric asthma disease management programme.

The third example illustrates the incorporation of multiple tracts of evidence for treatment of a chronic condition of high prevalence, diabetes mellitus, with multiple comorbidities that overlap several other chronic conditions. The guidelines must be incorporated into a model of chronic collaborative care using evidence-based guidelines to establish “Planned Care Management” utilising:

- Practice re-design
- Prevention and self-management education support
- Expert systems
- Information systems⁸

The American Diabetes Association (ADA) has published “Standards of Care” in a supplement to *Diabetes Care* every January for over 10 years.⁹ The standards are evidence-based, well-referenced and present an outline for the care of the diabetic patient that, if delivered, could prevent or delay most complications. The standards are, in reality, external, best practice benchmarks that can be used to help drive a change in systems.

In 1993 at Lovelace Health Systems, we had discovered, as we analysed our first set of HEDIS (Health Plan Employer Data and Information Set) measures, that despite having an ADA-certified diabetes education and management programme, our own system was producing process and outcomes levels that were well below the standards. We determined that this was due to multiple barriers:

System:

- No infrastructure to care for patients with chronic disease
- Lack of effective tracking systems
- Inadequate information systems
- Difficulties using available data, e.g., claims
- Inadequate feedback to providers
- Perception of limited benefit in diabetes
- Up front costs of diabetes care supplies, education and team management
- Positive outcomes not always immediately seen
- Most related cost savings are long term
- Revolving door health plans
- “It’s going to be somebody else’s problem”

Physician Level:

- Scepticism about patient willingness to change
- Keeping current with latest screening recommendations, lab values and pharmaceuticals
- Typical office visit is 10 to 15 minutes
- Limited access to certified diabetes educators and endocrinologists
- No useful feedback about their patients

Patient Level:

- Denial or fear
- Lack of knowledge
- Lack of motivation
- Economic disincentives
- Inconvenient access

To be able to implement a chronic collaborative programme, we had to create a system to overcome all these

barriers. To do this, we created our diabetes disease management programme in order to change the behaviour of the system. To implement evidence-based guidelines, we had to change the system design to deliver superior diabetes care in the most cost efficient manner with the ultimate goal to keep diabetes patients healthy and reduce burden of complications. Some of the changes included:

- *Practice re-design*: The diabetes education programme was centred in a specialty clinic next to the Endocrinology department and remote from most primary care providers (PCPs). In order to improve patient access and communication with the PCPs, clinics were held in several primary care sites. This improved the number of patients seen by the PCPs and gave the educators an opportunity to work on site with the PCPs and reinforce the intent and compliance with the evidence-based guidelines.
- *Prevention and self-management education support*: We continued to evolve the diabetes education programme and added functionality to promote patient-centred behaviour. More small group classes that were designed to promote peer-to-peer learning were established.
- *Expert systems*: This included new and unique patient education classes and individual sessions, the creation of a wallet-sized patient care card so patients could track their own process and outcomes measures, and individual goals and keep a personal record of needed exams. We initiated mailings to patients, created educational brochures and handouts and used the Health Plan newsletter for screening reminders (eye exam, lab tests) and self-care tips. Not only did the system need to handle diabetes well, but also lipid disorders, hypertension, obesity, nephropathy and macrovascular disorders
- *Information systems*: We were able to build on top of a primitive hospital information system a platform to push the evidence-based guidelines out to the providers in several ways. First, we created an electronic flow sheet that tracked the performance and results of surveillance data according to the guidelines. This included: HbA1c, lipids, urinary microalbumin, retinal examinations, podiatry visits and diabetes educational visits. We attached bullet point, formatted guidelines to this so that when the flowsheet was accessed, the next step would be pushed to the provider and patient.

Implementation of this system promoted improved diabetes care throughout the system by providing the tools to implement evidence-based guidelines and practice and measurable improvement in process and outcomes measures.¹⁰

These 3 examples illustrate the importance of evidence-based practice and the translation of evidence based practice into disease and care management programmes. As stated

in the Institute of Medicine report, this redesign should include programmes addressing collaborative care of 15 conditions on a national scale within the next 5 years.¹¹

Future Developments of Evidence-based Guidelines and Clinical Practice

Looking forward, I expect these trends and developments to occur:

- The development and implementation of care management programmes using evidence-based guidelines will become increasingly important as governments, health plans and delivery systems strive to improve the quality, continuity and coordination of care, as well as patients' satisfaction with processes and outcomes.
- Factors reinforcing the need for care management programmes using evidence-based guidelines as a fundamental component of health care systems will include emphasis on primary prevention, focus on management of high-risk populations, ageing of the population and consumer expectations for outstanding care and service.
- Sophisticated care management and collaborative care models will become more common, integrating non-physician care managers, greater use of information systems, telemedicine and the Internet to coordinate and monitor care and share information among all the involved parties. New technologies will address the systems barriers to compliance by making decision support tools available to the physician at the point of care.
- Delivery systems, physician organisations and selected practices will continue to develop and implement their own care management programmes using evidence-based guidelines. As information technology improves, it will be increasingly used to develop tools to implement guidelines and measure and promote adherence.
- As governments, payers and health plans offer incentive payments for high-quality management of defined conditions, practitioners will be increasingly involved in the implementation of guidelines and be held accountable for the outcome results.
- Care management programmes using evidence-based guidelines are a logical evolutionary development in health care and clinical practice. They are tools to help clinicians, in partnership with patients, provide the highest quality and most cost-effective care.
- Guidelines are rules-based. Tools derived from guidelines are the key to implementation and adherence.
- There needs to be a societal commitment to change the

system, especially at the practice level, to participate in and adhere to recommendations derived from guidelines. This involves the active construction of tools for implementation.

- Care management is the logical, most important extension of guidelines for physician practices, delivery systems, and health plans, especially as the focus moves to primary and secondary prevention, continuity and integration of care, management of high-risk populations, patient safety, and patient empowerment.
- Emerging elements of information technology (IT) can support care management programmes using evidence-based guideline development, implementation and adherence. IT can also enable clinicians to access guidelines and other decision support tools at the point of care. This will help establish links between adherence to guidelines and financial incentives.

Conclusion

EBM is an approach to crafting the treatment of a patient that is the key to developing an evidence-based practice. To apply EBM to a system or a specific population with a chronic condition, evidence-based guidelines must be constructed. Implementation of evidence-based practice and guidelines involves constructing tools, defining populations and building care and disease management programmes to optimise the care of patients and populations with chronic conditions. We, as society's representatives, will then be able to decrease small area variation in practice and place the patient at the centre of the health care system.

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