PART I

Principles of Implementation of Change
CHAPTER 1

Implementation of change in healthcare: a complex problem

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Summary

- Many patients do not receive optimal care; improvements in clinical practice are required to bring this about.
- Different approaches to the implementation of change in patient care can be observed, each based on different assumptions and theories of human and organizational behavior.
- Combination of top-down and bottom-up approaches is often needed to achieve real and sustainable changes in practice.

In September 2005, details about the mortality rates at the Cardiac Surgery department of the Radboud University Nijmegen Medical Center got into the newspapers. The post-surgery mortality rate in 2004 was 6.7%, compared to 2.7% in other heart centers in the Netherlands. This situation initiated a process which led to major improvements in clinical practice within a few years. The Board of Directors initially denied the problem, stating that the high mortality rates were caused by case mix. However, after the situation had been intensively analyzed, by both an internal committee and an external committee (appointed by the Health Care Inspectorate), the conclusion was reached that in fact these high mortality rates reflected a serious problem. The high mortality and complication rates could not be attributed to more seriously ill patients (in fact, the situation was quite the opposite). Instead it was discovered that staff did not work according to recent evidence and protocols; there was little or no cooperation between the disciplines involved (for example, everyone used his/her own patient record); departments did not collaborate with each other; there were conflicts among cardiac surgeons; the management of the department had lost control of the situation; and little clinical efforts was expanded in the areas of quality improvement. The Board of Directors of the hospital was aware of the problem, but left it to the physicians to solve it among themselves. For a long time, the Inspectorate relied on the department’s explanations. These findings led the Inspectorate to close the department. The Board of Directors was dismissed. The management of the medical staff and the head of the department resigned. Meanwhile, many patients looked for care elsewhere, resulting in a great many empty beds. This initiated a reorganization of the Radboud University Nijmegen Medical Center in general and the cardiac surgery department in particular. The reorganization led to operations being restarted after six months. The department’s mortality and complication rates are now far below the national average (around

Box 1.1: Unsafe cardiac surgery: the “Radboud Story”

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The number of new insights, procedures, programs, and techniques that have become available as a result of careful development and/or scientific research is enormous. It is estimated that around 2 million articles a year are published in medical journals (Mulrow 1994). The number of well-organized trials added to Medline, a large database of journals in the field of medicine, is gigantic. Subsets of this database – systematic literature analyses of clinical research studies or that portion of the literature capturing clinical guidelines – are growing at significant rates.

Knowledge about optimal patient care increasingly becomes obsolete, affected by both scientific and social developments. A great deal of knowledge that one absorbs over the years of training to become a doctor, nurse or paramedic is obsolete by the time training is completed. This is an old finding, as described in Box 1.2, but it reflects a new need – the ability to scan, absorb, and use the medical literature, described in subsequent chapters (Candy 2000).

1). (CORRAD 2011) The question is: what was the real cause of this change? Several hypotheses can be formulated, and these should be investigated in more detail on their validity.

- **Transparency:** publicizing the data and validating them provided both the public at large and the medical center with an insight into the fact that a real problem did exist. Good objective data on performance can contribute to the sense of urgency that something really needs to be done. This information prompted the Inspectorate as well as the patients to take measures.
- **Inspection and accountability:** the decision of the Inspectorate to close the center and to demand radical changes put the organization under great pressure to implement improvements in a quick and thorough way.
- **Leadership:** the new management of the department, the medical staff and the medical center, made high quality and patient safety into an absolute priority and supervised the implementation of these measures, including, among other actions, a revised and more intensive internal audit method.
- **Organization of care processes:** the surgical process was redesigned with the help of all disciplines involved, daily consultation on the patients as well as a joint medical file were introduced, and cooperation with the aim of a safer surgical process became a core objective.
- **Competency and motivation of professionals:** less-than-competent or dysfunctional surgeons were suspended, new surgeons who were prepared to work in the new system were appointed and competencies were brought up to the required standard.

These variables appear to have worked successfully in the case presented above, especially when they act in concert to achieve the complex change needed at Radboud. However, they represent hypotheses which need to be tested in more detail in practice or in research. This book presents the available scientific knowledge in this field.

1.1. Introduction

The number of new insights, procedures, programs, and techniques that have become available as a result of careful development and/or scientific research is enormous. It is estimated that around 2 million articles a year are published in medical journals (Mulrow 1994). The number of well-organized trials added to Medline, a large database of journals in the field of medicine, is gigantic. Subsets of this database – systematic literature analyses of clinical research studies or that portion of the literature capturing clinical guidelines – are growing at significant rates.

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**Box 1.2: Development of knowledge, a not-so-recent example**

In 1348, King Philip VI of France asked the medical faculty of the University of Paris for a scientific explanation of the plague epidemic, known as the Black Death, which killed about a third of the population of Europe. After extensive research, the Sorbonne came up with the cause – a threefold conjunction of Saturn, Jupiter, and Mars in the fortieth grade of Aquarius. For a long time, this was generally accepted as being the definitive explanation in both Europe and the Arab world (Achterhuis 1998).

What will we make of our explanations of the most important diseases of our time and the effectiveness of certain treatments 100 years from now?

The store of new knowledge about good patient care is also growing at an ever-increasing pace, but the percentage of valuable new insights subsequently introduced into routine patient care is considerably lower. Taken at face value, this fact would imply that investing time and means in clinical research and clinical guidelines would seem to be a useless exercise. This was the case in the past; it
may still be the case today. Although Semmelweis had demonstrated the importance of antiseptics in the 19th century, many surgeons operating after 1900 still used their bare hands, with adverse consequences. Even today, many institutions pay too little attention to washing and disinfecting hands before and after medical or nursing interventions, with huge consequences for patients and healthcare costs (Teare et al. 2001; Bolon 2011).

### 1.2. The implementation problem

The adoption of new ideas in a more modern information age, with new media and tools to transfer knowledge, is probably taking place faster than it did in the past. Nevertheless, clinicians, researchers, and policy makers have noticed that it takes a long time before research results or insights relating to effective, efficient, safe and patient-friendly care find their way into daily practice. In many cases healthcare professionals only learn and adopt new information gradually, which is understandable considering the overabundance. Almost two decades ago it was estimated that the average doctor would have to read about 19 articles a day to keep pace with the literature. However, even enthusiastic academics only spend 2 hours per week, at the most, going through recent articles (Haines 1996). Even if clinicians are informed about new insights on optimal patient care, no changes necessarily take place within their daily routines. The scientific literature is replete with examples from which it would appear that patients are not given the care that, according to recent scientific or professional insights, is desirable. A representative analysis of clinical care given to almost seven thousand patients in the USA showed that on average less than 60% of the patients received the care they should receive, based on best evidence. (McGlynn et al. 2003; Asch et al. 2006) In primary care in the Netherlands, reliable data on the implementation of guidelines, developed by the Dutch College of General Practitioners show that on average performance is better than in the USA, although there is still room for improvement (NHG, Box 1.3 Braspernning et al. 2004).

### Box 1.3: Adherence to guidelines in primary care in the Netherlands

In a National Study of Primary Care, 104 primary care practices were studied to determine their adherence to guidelines developed by the Dutch College of General Practitioners (NHG). In total, data was compiled for 58 indicators. Although the average overall score for the indicators was 74%, wide variations existed between clinical problems, the nature of the performance (for example the score for prescription of medication was 62% and for referral 89%) and among primary care practices.

In what follows you will find some data from studies, which will give you an idea of the nature and the extent of the implementation problem in specific fields of healthcare.

### Effective care

There are many examples, world-wide of the need for clinical improvement. In the United States, for example, the overall acute myocardial infarction 30-day mortality rates remain high, having only declined from 18.8% in 1995 to 15.8% in 2006 (Krumholz et al. 2009), while Canadian rates have decreased from 13.5% in 1995 to 10.6% in 2003 (Johansen et al. 2010). While demonstrating significant reductions, a portion of these deaths remains preventable. In 2001 11% of patients in the Netherlands with an acute myocardial infarct died within 30 days, in 2005 more than 8%, slightly below the OECD average (10%). The percentages for cerebral infarction were 16% in 2001 and 9% in 2005, also well under the OECD average (10%). The 5-year survival rates for various types of cancer are better in countries such as Finland, Norway, and Switzerland than in the Netherlands. The 5-year survival rate for breast cancer was slightly over 83% in the period 2000–5; for intestinal cancer this was 57% (Westert et al. 2008). Finally, in 2007, the breast cancer death rate in the USA was 22.9% (AHRQ 2010).

Improvements are also possible in the treatment of the chronically ill. For example, a study among diabetes patients at outpatient clinics of internal medicine showed that only 23% of the patients
managed to have the target value of HbA1c. The average score for a set of process indicators was 64% (Dijkstra et al. 2004). In this study, care and care outcomes improved considerably when the clinic provided structured multidisciplinary care and (specialized) nurses. Similarly, in 2007, a US study found that only 34% of hypertensive patients received adequate treatment to maintain the recommended blood pressure (Ardery et al. 2007).

**Efficient care**

While it is true that best evidence care is occasionally not offered to patients, it is frequently the reverse that holds true: unnecessary, expensive, and out-of-date care is also offered or provided. These inefficient clinical actions have considerable consequences in terms of personal and societal costs. Bodenheimer (1999) estimated that in the USA between 8% and 86% of operations are unnecessary. Confirming the presence, if not the actual percentage of surgical overuse, Null et al. (2005) indicate that 7.5 millions unnecessary surgical procedures are undertaken yearly in the US, in a country which sees approximately 53.3 million procedures annually (Cullen et al. 2009). In about 20% of their decisions, physicians in the Netherlands made unnecessary actions (Braspenning et al. 2004). The types of action concerned were inappropriately prescribing antibiotics for acute ear infections (30%), referral to a physiotherapist for acute back pain (20%), not prescribing the first-choice medicine for stomach complaints (25%), or unnecessary prostate-specific antigen (PSA) testing for men suffering from micturition problems (71%).

**Safe care**

Patients may be unnecessarily harmed by such suboptimal or inefficient care processes, not to mention the frustrations or costs that are incurred. Figures from the USA reveal a high number of deaths (45–99,000 deaths per year) as a result of poor practice and medical (mis)management (AHRQ 2010). Studies have been performed in various countries investigating adverse events for patients in hospitals. A systematic analysis of the results of those studies (employing an analysis of 75,000 files) showed an average percentage of 9.2% of patients suffering from adverse events, of which more than 40% were said to be preventable (De Vries et al. 2008). In the Netherlands, 8,000 patient files in 21 hospitals were analyzed for adverse events, showing a percentage of 5.7% of patients suffering from adverse events (Zegers et al. 2009). Every year 42,000 patients die in Dutch hospitals; of which an estimated 4% were preventable – an alarming 1,735 deaths per year. The HARM study indicated that there are 40,000 hospital admissions every year through medication errors in ambulatory patients in the Netherlands (Van den Bemt 2002); 6.7% of patients contracted an infection in hospital in 2009 (PREZIES data 2009). The scope of this problem is global. For example, 7.5% of Canadian patients contract a nosocomial infection (Baker et al. 2004); between 3% and 20% of US patients suffer some form of hospital-related adverse event (Institute of Medicine 2000). Similar results are found in Australia and New Zealand (Wilson et al. 1995; Davis et al. 2002).

One important factor in this is insufficient hand hygiene. Although clear evidence exists in this area, stipulating when hands need to be cleaned, compliance – most notably by physicians – is known to be poor. A study of 47 wards in three hospitals, in which nursing performance was closely observed (3,500 observations) showed an average rate of adherence per hospital to the infection prevention guidelines of 37%, 33%, and 19% (Brink-Huis et al. 2010). In the USA, a score of 48% compliance in hospitals was found (Pittett et al. 1999). Needless to say, there is a lot of room for improvement.

There is also room for improvement to avoid other aspects of unsafe care, for example patient falls and nutrition. Every year the University of Maastricht measures the prevalence of decubitus ulcers, patient falls and malnutrition in a large number of institutes in the Netherlands. The percentage of patients suffering from poor nutrition was 26% each in general hospitals and in nursing homes and 19% in home care (Halfens et al. 2008). Fourteen percent of patients suffered a fall in the past 30 days in general hospitals, injuring more than half of them. Nursing homes and home care
showed a lower percentage: 10% and 11%. Similar figures can be found in almost all developed countries. In 2004, 11% of nursing home residents in the USA had pressure ulcers (Park-Lee and Caffrey 2009). The Australian Institute of Health and Welfare (2011) reported that in 2009 and 2010 there were 2.4 falls per 1000 separations.

**Efficient and timely care**

Efficient and timely care is also well-organized care – patients are cared for quickly with little time lost or energy spent on unnecessary treatments or other aspects of care. Wait times and times for diagnosis or treatment are important indicators of efficient care (Box 1.4, Schouten et al. 2010). For instance, a study by El Sharouni et al. (2003) about wait time outcomes for radiotherapy for cancer patients showed that the average waiting time was 80 days in the Netherlands. This resulted in 41% of the patients who went from having a possibly curable illness to having a possibly incurable illness.

**Patient-centered care**

Patient centeredness is about the delivery of treatments and information based on best evidence, in a manner which involves the patient in decision making, and puts him or her center stage when dealing with his or her problems. In a study in 10 European countries, 17,400 patients from primary care were asked for their experiences of care, using a validated questionnaire (EUROPEP, Grol et al. 2000). Scores were collated in on two dimensions: communication and information from the physician, and organization of care. On average, patients were very positive about their primary care physician: 87% (varying between 80% and 93% between countries) was positive or very positive about treatment, communication, and information, as well as the amount of time which had been reserved for the patient. They were slightly less satisfied with the organization of care: 80% of the patients held positive views, although this percentage varied between 68% and 91% across countries (Engels et al. 2006). Most notably, countries with a system in which practices compete with each other for patients (for instance Belgium and Switzerland) received positive scores.

**Variation in the provision of care**

Studies often point to an enormous variation in performance; in some regions or hospitals, chances are much higher that a patient will undergo surgery for back trouble, or removal of the uterus, or surgical reduction of the prostate than in other regions or hospitals. While much care is given based on best evidence, it is clear that a considerable number of patients do not receive the recommended care, or, worse, receive unnecessary or possibly even damaging care. A survey of 276 patients suffering from lung cancer in hospitals in the east of the Netherlands measured the organizational quality of care on the basis of carefully constructed indicators (using scientific literature, guidelines, expert panels, and patient panels). Considerable variation was noted in patient throughput among the participating hospitals. For example, regarding finalizing the diagnosis within the recommended 21 days, the scores among hospitals varied between 58% and 73%. Regarding the start of the therapy

<table>
<thead>
<tr>
<th>Box 1.4: Organization of care for patients suffering from breast cancer</th>
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<tbody>
<tr>
<td><strong>Quick diagnosis and treatment of breast cancer can prevent aggravation of the situation.</strong> Schouten et al. (2010) mapped the times to treatment of 1,600 breast cancer patients, who were treated by 20 different teams:</td>
</tr>
<tr>
<td><strong>Average</strong></td>
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<tr>
<td>---</td>
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<tr>
<td>Admission time for the first appointment (advice max. 5 days)</td>
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<tr>
<td>Time between first outpatient visit and diagnosis (advice max. 1 day)</td>
</tr>
<tr>
<td>Time between diagnosis and operation (advice max. 21 days)</td>
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</tbody>
</table>

Apart from the fact that diagnoses can be made much quicker in a lot of places, the huge variety among institutions is remarkable. Also, a lot can be gained by multidisciplinary deliberation of patients (average 25%) and preoperative counseling of patients (average 55%).
as recommended (within 35 days after the first visit), scores varied between 38% and 66% (Ouwens et al. 2007).

Variation is also found between healthcare systems in different countries. In 2008, a survey among nearly 10,000 chronically ill patients in eight countries showed that the percentage of diabetic patients that received recommended care (including frequency of HbA1c measurement, examination of feet and fundi, and blood pressure measurement) varied between an average 35% in France and up to 60–65% in England and the Netherlands (Schoen et al. 2009). Likewise, the percentages of adults in the USA who had received an HbA1c measurement, retinal eye examination, and foot examination in the past year were 79.4%, 66.7%, and 64.6% respectively. (Coffey et al. 2004)

1.3. Various approaches to the implementation of improvements in patient care

Partly on the basis of the figures presented above, there is a high level of agreement between all parties involved in healthcare that care given could be improved in a number of ways – offering more effective, more efficient, safer, and more patient-centered care. However, when it comes to how this can be achieved, opinions differ.

Various parties and disciplines propose a variety of approaches (Grol 1997, 1999). Health professionals are often inclined to take improvements into their own hands and to promote continuing professional development and achieve consensus for and among themselves. Epidemiologists more frequently classify, rate, and catalogue scientific developments within a field, making this information available to professionals through systematic reviews or clinical guidelines. Healthcare researchers, often working on behalf of the government or formulating policy, map out health system and professional performance, indicating variations between care providers, institutions, and regions. Quality of care is measured with the help of “performance indicators”; this information is then channeled back to care providers as feedback or “mirrored information” and increasingly made public. Experts from the world of organization and management study how care processes can be optimized and how organizational conditions for optimal care can be created. Patient representatives, ethicists, and lawyers argue for the central role of patients, defending their right to better information provision and a more influential role in decisions about their illness. Insurers and governments, frequently assisted by health economists, are accountable for improving the overall quality of care, while at the same time controlling its costs. This is often done by selectively budgeting, financial incentives, or regulations and by making rules for tariffs and volume.

Thus, in the daily practice of optimizing patient care, different parties are inclined to opt for different strategies to improve care. A pressing question is which strategy is the most effective? We need a better understanding of these strategies in order for us to choose the right method, for the right setting, at the right time. This book intends to provide assistance in this process.

These different approaches or strategies are an expression of the different assumptions that concern the effective implementation of improvements in patient care – i.e., different beliefs concerning changing human behavior and the functioning of groups and organizations. Research in the field of quality improvement and implementation needs to focus on the validity of these kind of assumptions and to test the value of the various hypotheses for an effective change of the care provision (see cardiac surgery example in Box 1.1).

A number of approaches to the improvement of clinical practice are described below, highlighting the assumptions on which they are based (Grol 1997) (Table 1.1):

- The cognitive approach regards professionals (and patients) as people who make decisions on the basis of considering and weighing rational arguments. If care providers do not adopt a particular working practice, it is because they lack sufficient or convincing information about its effectiveness. Therefore, in this approach, the most important strategy is to provide them with this information in
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The form of summaries of scientific literature and evidence-based guidelines that can bear the scrutiny of criticism, as well as in the form of computerized decision support in clinical practice.

- **The motivational approach** is based on the assumption that change is mainly created by internal motivation to achieve optimal competence and performance of care providers (and patients). Strategies to improve clinical practice therefore emphasize intrinsic motivation, for instance by basing them on experiences and problems that professionals are faced with in their daily work or which are experienced by patients. “Problem-based learning” and “bottom-up” methods fit in well with this approach.
- **The management approach** is directed less towards influencing individuals and more to creating the organizational conditions essential for change; here the assumption is that poor quality care is a “systems problem.” Changing the system, redesigning the care processes, or changing roles and tasks, improving the internal culture, and continuously monitoring and improving care are increasingly considered as reasonable methods required to optimize patient care. Examples of this approach are quality and safety management.
- **Control and compulsion** best describe the final set of measures, based on the power of external pressure, control, and compulsion to change people’s performance. Many people do their utmost to avoid negative consequences of their actions and are sensitive to what happens to them in terms of earnings or privileges. Legislation and issuing rules, relicensing, recertification and compulsory accreditation, budgeting and contracts, and complaints procedures and disciplinary jurisdiction fit this type of approach to implementing improved care.
  
  Obviously, there are other approaches, a large number of which are described in this book. Each of these is based on various hypotheses and theories about behavioral change. Some theories emphasize changing the behavior of the individual professional; others are more directed at organizational and material contexts and processes. Some assume that change must come about from inside an individual, e.g., from an inner need or motivation, whereas others assume that external influence or pressure from above produces the optimal result. Likewise, some theories put the emphasis on self-regulation and personal responsibility for those who have to change, whereas others take a critical stance and assume that this approach rarely leads to the desired result.
Many terms for realizing improvements in practice are used internationally, such as innovation, implementation, dissemination, diffusion, adoption, knowledge transfer, education, quality improvement, and care modernization. A survey in nine countries among organizations providing grants on terms which were used for “implementation of knowledge in the policy and practice of care” showed a range of different terms, each with its own definition (Box 1.5; Tetroe et al. 2008).

The definitions of the terms most used also vary widely. In Canada, for example, terms such as “knowledge translation” and “knowledge transfer” are frequently employed to indicate the adoption of knowledge into policy and practice. Further, the term “knowledge exchange” is enjoying increasing popularity; it represents the two-way traffic between researchers and professionals in the field of practice and policy. In Europe and the USA, the term “implementation” is in widespread use, although other terms are also employed. The diversity in terms reflects the variation in thinking in scientific circles and in the policies that cover this

In Chapter 2, we provide an overview of theories in the field of change in healthcare, useful when designing and evaluating implementation strategies. The problem is that, as far as optimizing quality and safety of patient care is concerned, there is no convincing evidence that any one of the described approaches is more effective than another in any particular situation; the evidence for some approaches is limited or lacking. For this reason, the focus of this book is not on one specific approach, but on an integration of different approaches within a practically applicable implementation model or framework (see Chapter 3).

### 1.4. What is implementation?

Implementation can be described as “a planned process and systematic introduction of innovations and/or changes of proven value; the aim being that these are given a structural place in professional practice, in the functioning of organizations or in the health care structure” (ZON 1997).

<table>
<thead>
<tr>
<th>Approach</th>
<th>Focus</th>
<th>Selected strategies</th>
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<tbody>
<tr>
<td>Cognitive</td>
<td>Rational decision making</td>
<td>Evidence-based medicine and guidelines</td>
</tr>
<tr>
<td>Motivational</td>
<td>Intrinsic motivation of professionals</td>
<td>Problem-based learning</td>
</tr>
<tr>
<td>Marketing</td>
<td>Attractive product adjusted to needs of target group (segments)</td>
<td>Needs analysis</td>
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<td></td>
<td></td>
<td>Local adaptation</td>
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<td></td>
<td></td>
<td>Various distribution channels</td>
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<tr>
<td>Reinforcement</td>
<td>Conditioning and confirmation</td>
<td>Feedback, reminders</td>
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<td></td>
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<td>Economic incentives</td>
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<td>Social interaction</td>
<td>Influence by important others, role models</td>
<td>Peer review</td>
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<td></td>
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<td>Outreach visits</td>
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<td>Opinion leaders</td>
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<td>Management</td>
<td>Structural and organizational conditions</td>
<td>Redesign care processes</td>
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<td></td>
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<td>TQM/CQI</td>
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<tr>
<td>Control and compulsion</td>
<td>External motivation, avoiding negative consequences</td>
<td>Legislation and regulations</td>
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<td></td>
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<td>Inspection, performance indicators</td>
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<td>Financial sanctions</td>
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<td>Disciplinary measures, complaints</td>
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Box 1.5: Terms in international literature for “knowledge translation” or implementation

<table>
<thead>
<tr>
<th>Applied health research</th>
<th>Knowledge communication</th>
<th>Research into practice</th>
</tr>
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<tbody>
<tr>
<td>Capacity building</td>
<td>Knowledge cycle</td>
<td>Research mediation</td>
</tr>
<tr>
<td>Competing, cooperation</td>
<td>Knowledge exchange</td>
<td>Research transfer</td>
</tr>
<tr>
<td>Diffusion</td>
<td>Knowledge management</td>
<td>Research translation</td>
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<tr>
<td>Dissemination</td>
<td>Knowledge mobilization</td>
<td>Science communication</td>
</tr>
<tr>
<td>Exploitation</td>
<td>Knowledge transfer</td>
<td>Teaching</td>
</tr>
<tr>
<td>Getting knowledge into practice</td>
<td>Knowledge translation</td>
<td>The third mission</td>
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<tr>
<td>Impact</td>
<td>Linkage and exchange</td>
<td>Translation</td>
</tr>
<tr>
<td>Implementation</td>
<td>Popularization of research</td>
<td>Translational research</td>
</tr>
<tr>
<td></td>
<td>Knowledge cycle</td>
<td>Transmission</td>
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</tbody>
</table>

Box 1.6: Definitions related to “implementation”

<table>
<thead>
<tr>
<th>Diffusion</th>
<th>Spreading information and natural adoption by the target group of guidelines and innovations.</th>
</tr>
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<tbody>
<tr>
<td>Dissemination</td>
<td>Communication of information to care providers to increase their knowledge and skills; more active than diffusion; directed at a specific target group.</td>
</tr>
<tr>
<td>Adoption</td>
<td>Positive attitude and decision to change personal routine.</td>
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<tr>
<td>Implementation</td>
<td>Introduction of an innovation in the daily routine; this demands effective communication strategies and removal of barriers to change by using educational and policy techniques that are effective in practice.</td>
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</table>

subject. Another term, “care innovation,” seems to be used mainly for organizational changes and changes such as those in the care for the chronically ill or in mental healthcare. Individual professional workers in the field are more inclined to speak about “continuing education,” “continuing professional development,” or “quality improvement,” whereas clinical researchers, when they refer to implementation, frame this concept mainly in terms of the dissemination of their research results or knowledge transfer. Davis and Tailor-Vaisey (1997) aimed to provide definitions for some terms (Box 1.6).

In this book, we adhere to the long-standing definition of implementation by ZON, given at the beginning of this section. Still relevant, it recognizes several important elements (Hulscher et al. 2000).

- **Planned process and systematic introduction:** introduction of the improvement in clinical practice is well planned, and the strategies to achieve change are based on an analysis of the problems, the target group and the setting. These types of strategies may be directed at care providers, the patient-client, and/or organizational, or structural aspects of care. While simple dissemination of knowledge on better care provision may result in an increase in knowledge or an attitude change, on its own, it is unusual for this to lead to changes in behavior in practice. Effective implementation therefore demands a planned process, in which it is essential that effective dissemination, transfer of knowledge to practice, and attitude change take place prior to the promotion of the actual implementation of the innovation. In most cases, an iterative or incremental approach will be preferable, in which on the basis of experience gained the next step will be taken and the method of implementation is adjusted and improved. “Systematic” does not mean that, prior to the introduction, a definitive plan is made from which there is no deviation possible.

- **Innovations and/or improvements (of proven value):** this element concerns the introduction of innovations, procedures, or organizational processes that
are new, better or different from those accepted or employed in a specific setting. These may be new therapies or diagnostic procedures that have proved their worth in well-designed clinical trials. This may also be a guideline based on a systematic review of the scientific literature, a new procedure to prevent medication errors, a “time-out” or checklist procedure in surgery. The innovation can also include a new form of management of the care for patients with diabetes or heart failure that has been found to work well and that leads to the desired end. The innovation need not be fully or completely developed; in fact, the optimal time to adjust and tailor an innovation to suit the specific circumstances experienced in practice is during the implementation process.

- **Giving it a structural place**: implementation should lead to sustainable change. However, in practice, there is often a relapse, particularly when support is withdrawn after a project has finished.

- **(Professional) practice, the functioning of organization(s) or the structure of healthcare**: changes can take place at different levels. This book on implementation assumes that changes in the organization or structure of the care provided are bound to have consequences for the patient and the primary care process. The changes are usually aimed at improved effectiveness or efficiency or at making the care more patient-centered, with direct effects for patients. Implementation considers organizational and structural changes from this perspective.

Broadly speaking, two contrasting approaches to the implementation of knowledge or improved procedures can be distinguished (Hulscher et al. 2000; Wensing et al. 2000): the “rational model” and the “participation model” (Kitson et al. 1998; Van Woerkom 1998). In implementation practice one usually recognizes elements from both. When using the term rational model, one might think of the “health technology cycle” or the “innovation cycle” (ZON 1997), which work as follows. After the primary research and synthesis of the research findings have taken place, dissemination and implementation follow. There is a clear starting point, and steering takes place externally and, for the most part, from above. The starting point is the availability of new evidence, insights or procedures that are considered to be worth introducing. Hopefully, through dissemination, increasing numbers of target group members will adopt them. Critics of this model suggest that little attention is paid to the diversity of needs in the target group and that the model makes little use of the unique knowledge and experience present within that group.

In contrast, the participation model (Van Woerkom 1998; Table 1.2) uses the needs and experiences from practice as its departure point. The exact starting point for the change is often difficult to determine. It takes place incrementally, step by step and in some cases there may not be a strongly felt prior need to implement a concrete innovation or working method. Communication and feedback between people in daily practice determine whether the change will or will not be achieved. The phases of development, testing, dissemination and introduction of an innovation intertwine. A criticism leveled at this model is that it does not always introduce an optimal or evidence-based routine and that it pays inadequate attention to the structural factors that influence its introduction. The model actually describes how change is often brought about in practice, but offers few leads for a planned approach to implementation.

<table>
<thead>
<tr>
<th>Rational approach</th>
<th>Participation approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steered from external party</td>
<td>Steered from practice</td>
</tr>
<tr>
<td>Linear implementation</td>
<td>Incremental implementation</td>
</tr>
<tr>
<td>Clear start to implementation</td>
<td>Unclear start</td>
</tr>
<tr>
<td>Driven by supply of technology</td>
<td>Driven by need for technology</td>
</tr>
<tr>
<td>Often positive about innovation</td>
<td>Neutral about innovation</td>
</tr>
<tr>
<td>No attention paid to diversity of needs in practice</td>
<td>No attention paid to influence of macro-processes, chance that suboptimal technology is implemented</td>
</tr>
</tbody>
</table>

Table 1.2 Approaches to implementation (Van Woerkom 1998)
Important elements from both approaches will be used and combined in this book.

In contrast to this either/or approach, optimization of patient care may be seen as a two-way flow between practice and science (Health Council of the Netherlands 2000). Inspiration for improvement of care comes from practice, the problems noted there, developments experienced in the work place, and from research on optimal care provision.

An approach that fits in well with this construct is knowledge brokering (Lomas 2007). Knowledge brokering encompasses all activities that put decision makers (physicians, policy makers, etc.) in contact with researchers and improve their communication with each other, leading to a better understanding of each other’s targets and professional cultures, influencing each other’s work, creating new forms of cooperation and stimulating the use of research data in decision making. The basis for this construct is that researchers, policy makers, and physicians do not always understand each other very well, necessitating the need for a two-way flow in order to reduce mutual distrust (Innvaer et al. 2002). Effective knowledge exchange depends on personal networks, whereby mutual communication in the network serves as the engine that gets the implementation going (Greenhalgh et al. 2004). To be more specific, this means that there is a need for well-trained intermediaries between researchers and policy makers and people from the practice of healthcare (Lomas 2007).

**1.5. Which improvements are advisable?**

A change in patient care does not necessarily have to mean an improvement. The premise of this book is that there are desirable or necessary improvements in patient care. These improvements may involve evidence-based insights, procedures, techniques, or guidelines for good care practice. Alternatively, they may concern problems observed in routine practice that demand a solution, or good experiences using a certain care process or pathway (“best practice”) that could be implemented on a wider scale.

**New insights, methods, and collaborations**

Many insights about optimal care derive from research carried out into the efficacy and efficiency of certain routines in clinical, preventative or care practice. EBM, the evidence-based medicine movement is oriented towards helping care providers, patients and policy makers make decisions on how to act when faced with health problems by basing their decisions, wherever possible, on the best scientific evidence (Sackett et al. 1997). With this in mind, international work groups, within the framework of the Cochrane Collaboration (http://www.cochrane.org/), painstakingly summarize scientific insights within a specific area. Once located, the studies and the systematic analyses of the literature are added to a large database, the Cochrane Library. In terms of ambition, this world-wide activity has already been compared to the Human Genome Project, in which all human genes are being mapped. The initial idea was that clinicians would consult these databases regularly when solving problems in the healthcare setting, reflecting a critical attitude towards using the scientific literature. Research has shown, however, that while clinicians are eager to find support for their decisions, they find it difficult to consult databases such as these (McColl et al. 1998; Tomlin et al. 1999; Guyatt et al. 2000). New methods to make access to literature easier, for instance via the Internet, on personal digital devices, or by integrating them into the electronic health records, are therefore developed and applied to an increasing extent (Haynes 2006).

Compiling scientific evidence in the form of clinical practice guidelines is one such useful method. Guidelines are a potentially important resource for introducing insights into the best forms of patient care in an easily accessible form and for these being adopted. However, before this can be achieved, they have to meet certain requirements. At the moment, guidelines for good care are being formulated all over the world by a wide range of parties, including governments, insurers, professionals and patients’ organizations. Internationally, evidence-based tables and guidelines are exchanged in and supported by the Guidelines International Network (GIN) (www.g-i-n.net). Guidelines from a variety
of sources have different aims and development methods, and therefore their quality varies. In the past, they were often based on the consensus view of experts; gradually, guideline development has become more systematic, incorporating recent scientific insights into their development methods. On the one hand, guidelines form an important resource with which to implement new, valuable insights and they are thus an important intermediate step in the process of implementation of scientific knowledge. On the other hand, effective implementation strategies are needed to ensure that guidelines find their way into daily practice. For this reason, one chapter in this book deals explicitly with the development of guidelines that can be implemented.

Problems in care and “best practices”
Many innovations in healthcare practice are not the direct results of the introduction of scientific findings or evidence-based guidelines. In many cases, the driving force behind the desired improvement in care (which may or may not be based on factual information about variations in care provision) is that existing practice does not lead to the intended result, that mistakes are being made, that patients are not satisfied, or that working methods are inefficient or unsafe. This realization then can become the point of departure for a structured approach to realize improvements, using experiences and best practices from other places. This book will present these kinds of approaches.

No matter how carefully the search for, and analysis of, the medical literature is carried out, there is good scientific evidence for only a small minority of current clinical actions and decisions. Thus, there is a large grey area in which the experiences and preferences of those involved play a far more important role than any guidelines in determining what constitutes good care (Naylor 1995). However, even if scientific research has been carried out, translating this into useful recommendations adopted in everyday practice can prove difficult. A great deal of research and a large number of guidelines are based in decisions and concrete actions carried out by individual professionals. In daily practice, however, the reality is just as likely to involve longer running, complex care processes that include multiple care providers – doctors, paramedics and nurses – for which the approach consists of a logical series of linked interventions or actions (Grol and van Weel 2009; Grol 2010). For example, a patient who suffers a stroke should optimally be sent directly to a stroke unit, and after having received the proper treatment there, rapidly be moved to second-stage care, including (depending on the degree of disability) a rehabilitation center. Good team work, clearly defined tasks, exchange of information and logistics, supported by so-called “clinical pathways” or “disease management systems” work better here than guidelines for separate procedures carried out by individuals on their own. Seeing care provision as processes and chains of actions and the need to analyze and improve these processes and chains in their entirety takes pride of place in the “total quality management” approach (Berwick 1998; Schellekens 2000), as well as in models of integrated care, disease management (exemplifying best practices in primary care), or “the medical home” (Gabbay et al. 2011).

1.6. A systematic approach to “sustainable change”
The implementation of new routines and improvements in patient care could therefore be actuated by both new scientific insights and the fact that care does not function well. The subsequent actions should lead to a change, which will in turn become part of the normal provision of care and the routines of practice. This often appears very difficult. Studies show that the outcomes of many implementation and improvement projects are rather small and ebb away quickly.

Summarizing the state of the art regarding implementation at this moment, one conclusion could be that different innovations and proposals for changes in patient care demand different implementation strategies (Grol and Grimshaw 2003; Grimshaw et al. 2004). There is no such thing as one best practice for all innovations in all settings. Different target groups and situations create varying
implementation problems. A good diagnostic analysis of the target group and the setting is needed, in turn directing a well-structured implementation plan. In most cases, this means using a variety of improvement strategies to be applied in a certain order. Throughout the process, continuous evaluations check whether the change is under way and the target is reached. Ideally, the complete process is well prepared and organized: most experts in the field of implementation agree on the necessity of a systematic approach of implementation of improvements in patient care. From time to time, there is a breakthrough, whereby with little effort or means, important improvements are made in a short period of time. In most cases, however, the implementation strategy needs to plan for changes in a step-by-step process, thereby ensuring that all conditions for change have been realized. In Chapter 3, we present a model for a systematic approach of implementation, based on existing models, the so-called “Implementation of Change Model” (see Figure 3.1).

References

Implementation of change in healthcare: a complex problem


