Standardization and Individualization in Care for the Elderly: Proactive Behavior Through Individualized Standardization

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Abstract: There are two mega-trends in society as well as in the health care system: standardization and individualization. Our hypothesis is that these trends are not fully compatible. They are the reason for many conflicts in health care and in the care of the elderly. On the one hand, evidence-based standards of care can help to enhance disability-free life expectancy. On the other hand, these standards constrain the choice of the patient and, thus, their potential proactive behavior. We show examples of these trends and the potential conflict lines between them. We suggest “individualized standardization of care” as a possible solution to the underlying conflict. The hypothesis is that this combination of both trends helps the older patient to live a proactive life on the basis of evidence-based medicine and health care principles. This combination probably enhances disability-free life expectancy.

Keywords: Standardization, individualization, proactive behavior, care, elderly, shared decision making, guideline.

We argue from a sociological perspective that standardization and individualization are two parallel trends in society as well as in the health care system: There is a trend to standardize care and there is a trend to individualize care. Our hypothesis is that these trends are not fully compatible. They are the reason for many conflicts in health care and in the care of the elderly. On the one hand, evidence-based standards of care can help to enhance disability-free life expectancy. On the other hand, these standards constrain the choice of the patient and, thus, their potential proactive behavior. We show examples of these trends and the potential conflict lines between them. We suggest “individualized standardization of care” as a possible solution to the underlying conflict. The hypothesis is that this combination of both trends helps the older patient to live a proactive life on the basis of evidence-based medicine and health care. This could be a good basis for enhancing disability-free life expectancy.

1. STANDARDIZATION OF CARE

The history of industrialization is a history of standardization. We are living in a standardized society [1]. Standardization “prescribes or limits behavior and procedures” [2]. This long-lasting trend leads to standardized production and work [3]. Our hypothesis is that this trend also exists in the health care system. We are in the midst of a process called “industrialization of medicine”. The technological core of this is the three-phase process of formalization (phase 1), standardization (phase 2) and automation (phase 3). We are now in phase 2. There are two examples of “standardization of care”: (1) guidelines and (2) disease management programs.

Evidence-Based Clinical Guidelines

Over two decades professional actors in the health system have developed clinical guidelines. Guidelines are systematically developed statements about appropriate health care [4]. The aim is to base these guidelines on best available evidence. Evidence-based medicine means “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” [5]. Many of the guidelines, however, are still not evidence based [6]. Guidelines tell physicians and nurses how to practice medicine and health care. They produce a standardization of medical care [7] and they “shift the knowledge base in the health care field through standardization” [4]. Guidelines promise not only to reduce costs, but also to ensure process quality and to diminish variations in diagnosis and treatment.

A high process quality is attained when the process of care is organized and structured according to the results of scientific evidence. The hypothesis is that there is a causal relationship between the evidence-based process, written down in the clinical guideline, and the relevant outcome. From a sociological point of view, evidence-based medicine formalizes the knowledge (phase 1 in the industrialization process) and is the prerequisite for standardization (phase 2). Guidelines transform this formalized knowledge into practice through standardization.

One aim of guidelines is to reduce treatment variations through standardization of behavior [4]. The argument is that if there is only one best evidence-based way of treatment, there should be no unwarranted variation from this standard. Unwarranted variation would mean deviance from the right way. Studies show, however, that the effect of guidelines on
practitioner knowledge [8] and treatment variation between practitioners [4] is limited. To counteract this phenomenon professional groups and/or the government try to establish norms of guideline adherence (e.g. 90% guideline adherence).

Disease Management Programs

Governments and health insurance companies are increasingly trying to structure and control the medical process through managed care. A central component of managed care is disease management. Disease management can be defined “as an intervention to manage or prevent a chronic condition by using a systematic approach to care (i.e. evidence-based practice guidelines) and potentially employing multiple treatment modalities” [9]. The main characteristics of disease management are: systematic approach, comprehensive and integrative care, care of a chronic condition and multidisciplinary care [10]. According to this definition, disease management programs do not necessarily have to be evidence-based and they are mainly for chronic conditions. There are several studies showing that disease management could be an effective way to manage care [9, 11, 12].

Standardization of the Care of the Elderly

Evidence-based guidelines and disease management are also part of the care of the elderly. Disease management programs for heart failure, depression, dementia and diabetes have been established [10, 12-15]. The effectiveness of these programs, however, is not clear at all: studies show conflicting results [10, 13, 14, 16]. There are a lot of measures which could contribute to a more standardized approach in caring for older patients like standardization of the geriatric assessment [17], the formalization of the transition of care through hospital discharge checklists [18] and the management of hypertension in the elderly by use of medical computers to improve identification and follow-up of hypertensive people [19].

2. INDIVIDUALIZATION OF CARE

We are living in an individualized society [20]. Individual choice, individual risk, individual responsibility and personal uncertainty are characteristics of this society [21]. This is the outcome of the cultural process called individualization. For some sociologists individualization is the result of a process of de-standardization [22]. Our hypothesis is that there is in medicine too a strong tendency towards individualization. Responsibility for one’s own health, self-management and proactive health behavior [23] are prominent examples of this. Of special importance are the phenomena of shared decision-making, case management and personalized medicine.

Shared Decision-Making

Shared decision-making is a special form of decision-making which differs from the paternalistic style in giving the patient more autonomy in the process of treatment decision-making, helping him/her to be proactive within decision processes [24, 25]. Shared decision making (SDM) is defined as “the process of interacting with patients in arriving at informed values-based choices when options have features that patients value differently” [26]. There are now a lot of patient decision aids (PtDAs) or Patient Decision Support Technologies (PDSTs) available. These mostly evidence-based tools are designed to facilitate SDM [26]. SDM is especially interesting in situations where there are no clear medical answers. This is the case if the benefit/harm ratio is scientifically uncertain or “sensitive to the value patients place on benefits versus harms” [26]. The physician communicates individualized information on options, possible outcomes of options and probabilities to the patient and the patient communicates his/her preferences and personal values. On this basis an agreement on the best decision can be reached.

SDM could also be a solution for the care of the elderly. They are often confronted with a lot of medical, functional and social problems and they are often faced with multimorbidity. Hence, their decision situation is often rather complex. An additional problem is that physicians and older patients sometimes differ in their preferences and perceptions of care [27]. PDSTs could be helpful for elderly patients to express their preferences and perceptions. Decision aids designed especially for older patients are, however, rare [27]. A qualitative study showed that older patients can use decision aids as a reminder and a reference. Decision aids help the patient to express his/her concerns. They facilitate concordance between both parties, motivate the patient, improves his/her education and – a step towards individualization – customize care [27].

SDM transforms a paternalistic relationship into a partnership. The goal is a symmetrical communication between both parties which places the patient in a more proactive role: “The aim is to empower patients to express their values and preferences, to ask questions and to participate actively in decisions about their health care” [28]. Compared with the paternalistic, asymmetrical style SDM offers the patient more autonomy, but also more responsibility with regard to health.

Case Management

The inadequate coordination and integration of the process of care is a central problem of the health care system. The care of older patients in particular requires coordinated and individualized care. This is the aim of case management. Case management “is concerned with an optimisation of multidisciplinary treatment for complex patients and on the integral care needs of the individual patient without focusing on only one specific illness or population (as in disease management)” [29]. From this perspective case management is an individualistic approach in health care.

Case management has been seen as a tool for organizing the care of older patients with more complex health problems. There are case management programs for older people in the community setting [30, 31] prevention issues [32, 33], diabetes care [34] and health maintenance organizations [35]. Studies show heterogeneous results with regard to the effectiveness of case management. Case management, however, fosters self-efficacy [34]. It promotes the self-esteem and the control beliefs of older people and could strengthen their autonomy. All in all, case management is an example of the trend towards individualization of care.

Personalized Medicine

In a narrow sense, personalized medicine means “that medical care can be tailored to the genomic and molecular
profile of the individual” [36]. In this narrow sense personalized medicine equals pharmacogenomics [37, 38]. The targets of these therapies are, for example, BRCA1/2, estrogen receptor and HER2 in the case of breast cancer [36]. In a broader sense, personalized medicine encompasses “individualized access to the entire course of treatment, thereby optimizing the treatment of the individual” [37]. Out of this broader perspective, the future of personalized medicine will offer, in addition to pharmacogenomic approaches, individualized indications, individual choices of drugs, individual adaptation of drug administration, individualized dosage adapted through daily experience, individualized information, individual therapeutic monitoring and individual daily reinforcement [37]. Personalized medicine enables patients to be more proactive. Proactive managed care means screening, early treatment, prevention, the use of information technology, electronic medical records and decision-making tools [36].

There are several possibilities to personalize health care for the elderly without using pharmacogenomics. One possibility is to use the internet to tailor health and training advice. The tool for this is tailored webpages [39]. Another possibility is to use a systematic algorithm. The interventions chosen by the experts on the basis of this algorithm are tailored to the needs of older people. The aim of these interventions is to fulfill these needs “in a manner that matched the person’s cognitive, physical, and sensory abilities, and their lifelong habits and roles” [40].

3. STANDARDIZATION: A BARRIER TO AUTONOMY AND PROACTIVE BEHAVIOR

Our hypothesis is that there are potential conflicts between standardization and individualization of care. The core of standardization is de-individualization. Standardization diminishes the autonomy and proactive behavior of the elderly patient. We want to show that there are several lines of conflict between these two principles.

Evidence-Based Medicine vs. Shared Decision-Making

At the beginning of evidence-based medicine (EBM), participation in decision-making was ignored – “it was all about research evidence” [28]. In the second phase of the EBM-movement (the mid-1990s), the proponents of EBM took patients’ preferences into account and “presented the importance of integrating both evidence and patient’s choices and preferences” [28]. The potential conflict between research evidence and patient preference has to be solved by the physician alone. S/he has to be trained not to use evidence-based medicine as a “cookbook” but to individualize the treatment of the patient according to the risk profile, values and preferences of the patient: “This means taking data from a population in a trial and applying the results for both the benefits and the side effects to an individual patient who may be a different age or have a different degree of risk compared to the people in the trial” [28]. The problem is that physicians are not trained this way. Hence, the danger is that physicians use EBM as a cookbook without adapting it to the individual patient’s preferences. This could be the cause of the first conflict. The second conflict occurs when patients’ values and preferences are not compatible with EBM, as in the case of religious beliefs (e.g. Jehovah’s Witnesses and blood transfusion). In this case, it is difficult to find an adequate solution to the problem.

Guidelines vs. Shared Decision-Making

The aim of guidelines is to produce more consistent practice behavior patterns and to reduce unwarranted variation. This is reached by standardization and rigidity. This may come “at the expense of reducing individualised care for patients with special needs” [41]. If guidelines are inflexible they can harm patients by not leaving sufficient room for physicians to tailor medical care to the personal situation, preferences and medical history of the patient. This is especially true for older patients. The general problem of guidelines is: “What is best for patients overall, as recommended in guidelines, may be inappropriate for individuals” [41]. Normal guidelines are not able to integrate patients’ values and preferences, and therefore they are “rarely that flexible” [28].

Hence, there is a structural conflict between guidelines and shared decision-making. Guidelines restrict patients’ choices. The room for proactive behavior is therefore limited. This is also a problem in the case of informed decision-making, where the physician delivers information and the patient decides about the treatment in a proactive way on his/her own. The structural conflict between guidelines and patient involvement in decision-making is weaker if the older patient is a “normal” patient with whom the guideline fits best. It is stronger, if the older patient has very special preferences.

Proactive Behavior vs. Norms of Guideline Compliance

Every social system regulates the behavior of its members by installing norms of behavior. It guarantees the compliance with the norm by negative sanctions if there is deviant behavior, and by positive sanctions if there is compliance with the norm [42]. The norm could be formal or informal. Formal norms of care are, for example, written down in medical guidelines. Informal norms are written down in widely acknowledged EBM reviews (e.g. Cochrane Library). Our hypothesis is that there is a potential strong conflict between norms of guideline compliance and proactive behavior of the older patient. We distinguish individual and collective norms of care. The collective norms of care can be separated into two categories: group norms (e.g. norms for cardiologists) and institutional norms (e.g. norms for a breast care center). Individual and group norms of care are mostly norms of guideline compliance. Institutional norms of care often have the form of criteria (e.g. certification criteria). Individual norms of guideline compliance are met by a certain physician if the proportion of treatment decisions that comply with guidelines is above a certain cut-off point agreed upon (e.g. 85%). Collective norms of guideline compliance are met by a group of physicians if the proportion of treatment decisions in this group that comply with guidelines is above a certain concerted cut-off point (e.g. 80%). An institutional norm of care is met by a care organization if the proportion of treatment decisions that comply with certain criteria (e.g. breast care center certification criteria) is above a cut-off point. Even if these norms are not sanctioned, positively or negatively, they have a strong impact on the behavior of the physicians. The reason is that the cut-off point could be used as an objective which has to be reached (e.g.
management by objectives). In this situation it is difficult for the physician to accommodate the patient's values and preferences and their proactive behavior. If s/he gives too much discretion to many patients it is difficult to reach the objectives s/he agreed upon. Therefore, there is quite a strong potential conflict between patient autonomy and norms of care.

Proactive Behavior and Sanctioned Norms of Care

Norms of care give orientation to the individual physician or the acting hospitals. If non-compliance with these norms is negatively sanctioned (e.g. no pay for non-performance; refusal of recertification) or compliance is positively sanctioned (e.g. incentives; bonuses), the power of the norms of care is even greater. If individual norms of care are not met by the physician he or she could be negatively sanctioned by managed care organizations for non-compliance. If s/he fulfills the norm s/he could be positively sanctioned by receiving incentives (pay-for-performance). There is a growing tendency of governments and health insurance companies to give physicians incentives if they reach certain practice targets. Best examples of this are the pay-for-performance programs. All these forms of sanctioned norms of care have the aim of improving quality of care, but this aim conflicts with patients’ autonomy and proactive behavior. Sanctioned norms of care are not compatible with patients’ rights to make choices on their own, if these choices endanger the fulfillment of these norms of care [28].

4. AN EXAMPLE: MORE MASTECTOMIES – PATIENTS’ CHOICE?

According to the 1990 National Institutes of Health Consensus Development Panel breast-conserving surgery (BCS) is the preferred method of primary surgical therapy for women with early-stage breast cancer [43]. Before this, mastectomy was the standard of care in the United States. The rates of local recurrence after BCS are today – owing to medical progress - similar to the rates after mastectomy. Surprisingly, however, despite the good outcomes of breast conserving therapy (BCT), the “use of mastectomy in the United States seems to be increasing” [44]. Some researchers have raised concerns about an “excessive use of mastectomy for patients with breast cancer” [45]. There are several possible reasons for the rise in the mastectomy rates, such as increased use of breast magnetic resonance imaging [45, 46].

One intensively discussed possibility is that the proactive patient him/herself plays a major role in the rise of mastectomy rates. In the eyes of some researchers, “patients are pushing their surgeons for mastectomy, even bilateral mastectomy, despite being told that such treatment will not improve prognosis” [44]. Katz and colleagues showed that if the surgeon was the primary decision-maker, the mastectomy rate was 5.3%; if both patient and surgeon shared the decision, the rate was 16.8% and if the patient was the only decision-maker, the mastectomy-rate was 27% [47]. More involvement of the patient in breast surgery decisions seems to lead to higher rates of mastectomy [45]. Often, surgeons give women the chance to decide on this, without favoring one special procedure. In this case, “one-third of patients appear to choose mastectomy as initial treatment when not given a specific recommendation for BSC or mastectomy by their surgeon” [45]. One reason for this is that women who opt for mastectomy have the “desire to be safe” [44]. Women may prefer mastectomy “for peace of mind” and “to avoid radiation”. There are concerns “about disease recurrence, and inconvenience and fears of radiation” [45].

The important point in the discussion about “overtreatment” of mastectomy is that the proponents of this hypothesis did not really accept patient autonomy and proactive behavior. The inherent argument is that the fears of the patients and their need for convenience are not justified. Hence, there is a “needless increase in mastectomy rates” [44]. As a consequence, the proponents demand more patient (re-)education to overcome these irrational fears [44]. This argumentation shows that there could be a basic conflict between standards of care and the autonomy and proactive behavior of the patient. The medical experts accept patient autonomy as long as it leads to the “right” decision. If proactive behavior leads to the wrong decision, it becomes a problem of irrationality which should be treated by measures of education.

The problem becomes greater if rates of BCS are used by hospitals, health insurance companies or government as a quality indicator. This is the case in some hospitals in the United States [45] and in a systematic way in the breast care centers in Germany [48]. Standards of care are, in these cases, formal norms of care with a high potential for negative sanctions. If the US hospitals which use BCS rates as a marketing instrument realize an increase in mastectomy rates, they have to work against this increase because it demonstrates, in their view, a decline in the quality of care. The breast care centers in Germany have to fulfill different quality norms to become certified as breast care centers. One of these quality norms is a BCS rate of more than 50% in early-stage breast cancer (pT1) at the first certification and 70% three years later [48]. If this and other criteria are not met, the (re-)certification is jeopardized. The danger is that in these cases the pressure to fulfill the necessary BCS rate is so great that patients’ preferences and proactive strategies have to be neglected.

5. INDIVIDUALIZED STANDARDIZATION: A SOLUTION FOR MORE PROACTIVE BEHAVIOR

What is the solution for the potential conflict between standardization and individualization of care? We propose the strategy of “individualized standardization” as a strategy for supporting proactive behavior of the older patient. Individualized standardization of care is defined as the imposition of standards, regulations or norms which are tailored to the genes, body condition, culture, social environment, values, needs and preferences of the individual patient.

Individualized standardization of care has two meanings. One is the process of establishing an individualized standard. The other is the process of complying with an individualized standard. Individualized standards of care can be defined as norms of deciding, behaving and interacting in health care which are tailored to the biological, psychological, social and cultural conditions of the patient. Biological conditions are body structures and functions like genes and morbidity. Psychological conditions are the mental structure and processes of the individual like personal values, preferences, needs, internalized norms, attitudes, mental states (e.g. depression) and ways of thinking. Social conditions are social structures and processes like social status, roles, networks and interaction as well as cohesion, norms, lay theories and expecta-
tions of family, friends, colleagues and self-help groups. By cultural condition, we mean collective values, knowledge, symbols and central beliefs about the world and life. How can the aim of individualized standardization be realized?

There are at least five strategies available: (1) “evidence-based menu” strategy; (2) “subgroup” strategy; (3) “individualized treatment” strategy; (4) “be careful with sanctions” strategy; and (5) “warranted variation” strategy.

i. “Evidence-Based Menu” Strategy

An evidence-based menu strategy is given if the physicians offer the patient a menu of options of all possible evidence-based diagnostics or therapies. It includes not only the grade A or level I recommendations, but all recommendations from grade A to grade D (or level I to level III). It also includes expert opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. The menu approach excludes diagnostic and therapeutic measures for which there is no evidence at all. On the basis of this menu the patient should decide which measure fits best with his or her cultural, social, psychological and biological conditions. The physician has to respect this, even if the patient chooses a grade D or level III option. This strategy gives room for proactive behavior of the elderly.

ii. “Subgroup” Strategy

The subgroup strategy could be defined as a standardization that is semi-tailored to the biological, psychological, social and cultural conditions of a typical patient group. Semi-tailored means that the physician categorizes the patient and puts him/her into a certain subgroup (e.g. HER2-positive women with a low social status). The task for the physician is then to search for the therapy with the best available evidence in this subgroup. This strategy is a highly demanding strategy for medical science because it requires for each subgroup of patients separate studies, separate Cochrane reviews and separate guidelines. This kind of strategy is already practiced in practice but, given the number of guidelines needed to cover all possible subgroups, we are just at the beginning of the subgroup strategy. This “subgroup” strategy does not leave much room for proactive behavior.

iii. “Individualized Treatment” Strategy

The individualized treatment strategy was originally proposed by the proponents of evidence-based medicine [5, 28]. This strategy can be defined as “integrating individual clinical expertise with the best available external clinical evidence from systematic research” [5]. It merges evidence with patient preference. As Barratt argues, this ideal aim could only be reached by intensive training. For her it is “really important (...) that future doctors are trained to individualise treatment to patients – because that is necessary for doing a good job of both EBM and SDM”. And she adds: “we should not have a view that good practice REQUIRES doctors – and patients – to follow or comply with guidelines” [28]. This strategy is quite good for proactive older patients because the physician has to search for evidence-based solutions which fit the proactive lifestyle, behavior and needs of the elderly.

iv. “Be Careful with Sanctions” Strategy

For patients’ autonomy it is especially dangerous to sanction the fulfillment or non-fulfillment of standards of care as is the case with pay for performance, quality management (external quality assurance) or third party certification of hospitals. The standard of care could be formal or informal and the sanctions could also be formal or informal. The combination of informal standards and informal sanctions is less dangerous for patient autonomy because it leaves a lot of room for the choice of the patient. The combination of formal standards with formal sanctions leaves less room for the decision of the patient. Physicians have to follow standards of care – regardless of the patients’ preferences – if there are formal sanctions in the case of non-fulfillment of the standard. Therefore, if we want to support the proactive behavior of the elderly patient we should be careful about establishing sanctions around standards of care, which are not individualized.

v. “Warranted Variation” Strategy

Another already practiced way of merging individualization and standardization is to define margins of deviance from the standard of care. They should be wide enough to allow a certain amount of proactive behavior and autonomy of the patient within the given spectrum. It is useful to distinguish between individual and collective margins of deviance. The individual ones are for the concrete physician and the collective ones for a group of physicians or a group of hospitals. Collective margins are probably better for supporting proactive behavior of the patient because they allow room for flexible solutions on the collective level as well on the individual level.

These five strategies could be combined. One good combination is to connect the subgroup strategy with the individualized treatment strategy. In this case, the physician tries to find out in which subgroup the patient fits best according to his/her biological, psychological, social and cultural conditions. Then s/he has to look after the evidence-based therapies for this subgroup once they are identified, s/he has to individualize treatment to patients, merging EBM and SDM. Another possibility would be to present the possible therapies for this subgroup in a menu (“menu strategy”). The patient has to decide then between the options in the menu. The physician has, in this case, the role of an adviser.

6. SUMMARY

The article has shown that some phenomena like shared decision-making and guidelines could be regarded as part of a bigger picture: that of modern trends in society. The modernization of society is characterized by the two conflicting trends of standardization and individualization. These trends are also present in modern medicine and in geriatric medicine. Guidelines, disease management programs and managed care reflect the standardization trend in medicine. Shared decision-making, case management and personalized medicine are examples of the trend towards individualization in medicine. These trends are only partially compatible. If the standardization is evidence-based it could be – on the one hand – a means of enhancing disability-free life expectancy. On the other hand, standardization is a potential barrier to more proactive behavior and greater patient autonomy.
constrains the choices of the patient. The example of increased mastectomy rates showed us how more patient autonomy and proactive behavior could cause a conflict with standards of care. We presented the strategy of individualized standardization as a solution to the potential conflict between individualization and standardization of care.

Our conclusion is: if we want greater patient autonomy and more proactive behavior of the older patients, we have to be wary of inflexible guidelines and narrow standards of care. If the fulfillment of these standards is gratified (positive sanctions) and the non-fulfillment penalized (negative sanctions), patient autonomy and proactive behavior are even more in danger.

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