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Executive Summary of
APS-Whitebook on Patient Safety

Safety in healthcare: new viewpoints & concerted actions

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Presentation of the institutions

Aktionsbündnis Patientensicherheit e. V. (APS) / German Coalition for Patient Safety

The German Coalition for Patient Safety (Aktionsbündnis Patientensicherheit, APS) is a private noncommercial organization with over 700 individual and institutional members in Germany. We bring together all kinds of stakeholders interested in and committed to increasing patient safety. Although our main focus is improving the situation in hospitals we target all aspects of patient safety such as safe medication and medical technology or health apps and even curricula for training healthcare professionals. In order to do that we establish workgroups in which we develop recommendations for healthcare professionals and information leaflets for patients and distribute them free of charge. We also engage in the legislative process to include patient safety issues in lawmaking and organize congresses and events like the International Patient Safety Day (every year at September 17th) to spread consciousness about patient safety.

Verband der Ersatzkassen e. V. (vdek)

The association „Verband der Ersatzkassen e. V." (vdek) represents the interests of six German statutory health insurance funds and also acts as their service provider. The six funds insure almost 28 Million people throughout Germany. These funds are:

- Techniker Krankenkasse (TK)
- BARMER
- DAK-Gesundheit
- KKH Kaufmännische Krankenkasse
- hkk – Handelskrankenkasse
- HEK – Hanseatische Krankenkasse

The vdek was founded in Eisenach on May 20, 1912 under the original name of „Verband kaufmännischer eingeschriebener Hilfskassen (Ersatzkassen)". Until the year 2009, the association operated under the name „Verband der Angestellten-Krankenkassen e. V." (VdAK).

Today the vdek has more than 270 employees at its headquarters in Berlin. In addition, the vdek has 15 regional offices in the federal states with about 340 employees and more than 30 employees based in the regional care support centers.

Executive Summary

1. Introduction

The *White Paper on Patient Safety* reflects developments in the discussion between October 2017 and April 2018 and is comprised of seven chapters.

- Chapter 1: *To Err is Human* and its consequences
- Chapter 2: Conceptualizing patient safety – revisited
- Chapter 3: Methods of reporting data and the epidemiology of adverse events
- Chapter 4: The costs of inadequate patient safety and cost effectivity of quality improvement measures
- Chapter 5: Action plan and priority issues
- Chapter 6: Patient safety in the context of the most important developments in health policy
- Chapter 7: An updated agenda for patient safety in the German health care system

This *White Paper* takes the perspective that although advances have been made in the field of patient safety, in Germany as well as in other countries previous achievements remain well below the desired level. Instead of merely appealing for an increase in efforts, the *White Paper* analyses the possible causes for this slow pace of development. One of the most important developments, and to a certain extent maybe even the prerequisite for the start of the "patient safety movement" twenty years ago (cf. Ch. 1.2.1), was to shift responsibility to the "system" while moving away from blaming the individuals within it. However, the questions of how this "system", meaning specific organizations and the health care systems they operate in, can be steered towards improving patient safety and which specific challenges can be expected, are only now beginning to receive attention. The *White Paper* analyses this situation and proceeds from there to develop an expanded definition of patient safety as well as a theoretical conceptualization that can be used as a benchmark for questions concerning data reporting methods and the development of interventions to improve patient safety. In this context the *White Paper* makes completely clear that analysis alone is insufficient; it is necessary to develop credible alternatives, effective strategies and interventions that will verifiably and sustainably lead to quality improvements in patient safety. This pathway, having withstood extensive testing in an international context, leads to a new type of intervention known as complex multicomponent intervention (cf. Ch. 5.7, Berwick 2008, 2015, Guise et al. 2014A,B).

This executive summary roughly corresponds to the structure of the *White Paper* and is divided into the following sections:

- Introduction
- Definition and concept
- Epidemiology of (preventable) adverse events
- Data reporting methods
- Reinforcing throughput, the role of the actors involved
- Technology and digitalization
- The new intervention standard: complex multicomponent intervention (CMCI)
- The costs of inadequate patient safety and cost effectivity of patient safety improvement measures
- New orientation: six questions and two paradoxes
- Patient safety in the context of the most important developments in health policy
- An updated agenda for patient safety

2. Definition and concept

The introductory chapter (Ch. 1) takes a historical perspective and yields the somewhat irritating finding that when public discussions of patient safety began (in the USA with the publication of *To Err is Human* in 1999, in Germany with the founding of the Coalition for Patient Safety [Aktionsbündnis Patientensicherheit e. V.] in 2005), in both countries the full extent of the facts was already known. Thus, it was not a lack of knowledge, but rather an absence of the necessary framework for discussion that stifled conversations about patient safety until the issue came to be addressed less as a force of nature and increasingly as a context-based construct marked by the conditions in its environment.

Proceeding from this fundamental insight, the *White Paper* derives a **presentation of the problem** comprising four initial (later expanded to six) unanswered questions and two paradoxes. It is postulated that these questions and paradoxes hinder the further conceptual development of patient safety and thus inhibit progress. The six questions are:

1. Why is it that, in spite of intense efforts, the demonstrable successes are still not sufficiently convincing? Is this due to inadequate conceptualization, inaccurate measurements, excessively high expectations or barriers posed by unfavourable environmental conditions?
2. While there is a consensus on the extent of the problem, how can patient safety be measured more accurately so that suggested safety improvements can be evaluated better? What are possible explanations for the observation that highly plausible procedures for improving patient safety that have proved effective in controlled trails continue to fail in

reality or fail to achieve the expected effects? Could these findings be related to a lack of "everyday efficacy" or perhaps (also) inadequate methods for reporting data?

3. Why has patient safety still not been accorded sufficient priority status considering the extent of the problem, especially when compared to other social goals?
4. Why is it that, as discussions on patient safety are proliferating, so little action is being taken to address the issue? Is it because the term patient safety in its current vagueness invites misuse, e.g. because of its categorical character?
5. How can events occurring "out of the blue" be explained and integrated into a concept (emergence phenomenon)?
6. Why is it that individual interventions that form part of a bundle intervention only show weak effects when evaluated individually?

In addition to these open questions there are two paradoxes that cannot be resolved using current approaches, namely

- the **system-accountability paradox**: how can the contradiction between individual accountability and system accountability be resolved? and
- the **linearity-muddling through paradox**: should it always be assumed that standardization measures (e.g. technical measures), which are often favoured, are superior to the muddling through strategies of the frontline experts, or are decentralized approaches with a low level of standardization better?

Given this background, the first focal point of this *White Paper* is to **develop a new conceptualization** of the term patient safety that, in spite of the normative directive of *primum nil nocere*, was never far from a tautology. Patient safety is assumed to be given "if nothing happens", therefore patient safety is deemed identical to the absence of adverse events (AE). Such a "linear" understanding certainly has its merits in certain situations but in other situations (how safe is a health service provider without AE?) it quickly demonstrates its limitations.

This leads directly to the second focal point of the *White Paper*: why is it so difficult to **"realize" patient safety**? The discussion commenced with great dynamism – the elimination of individual responsibility (James Reason's (2000) person approach) came with the promise of relief and new modes of action for professionals, since responsibility was now attributed to the system (system approach). The system, organizations, remuneration systems, culture, leadership, accountability – those were the main parameters for successfully addressing the issue. Additionally, neighbouring social areas, especially the aviation industry, became significant sources of encouragement.

However, this optimism soon dissipated and the reasons for this stifling of courage are only partially known. The systemic factors were harder to influence than anticipated. The specifics of the health care system were not considered sufficiently. Of course, there was a considerable and unquestionable need for action but the organizations turned out to be slow-moving and at the level of the system everything was debated to death between the different professional associations. While it was duly noted that responsibility was to be located in the system and in organizations, the difficulty in developing these further was underestimated. A further hindrance is that up to this day, there is neither a comprehensive organizational theory (applicable to the German system) concerning the facilities for health care provision nor a comprehensive body of theory that could describe the functioning of "the system". Of course, research on these topics is proliferating (health services research is booming). However, most studies only address single questions or produce volumes of data without attempting to build conceptualizations or models that would give meaning to these numbers.

Given this research context, the *White Paper* casts a wide net. The starting point is a thorough analysis of the different **scientific-professional approaches** to the issue of patient safety. Six different "schools" are presented in detail and it is astonishing to see how extensively these approaches diverge. Ultimately it is the same as in real life: in some situations a simple, linear process model suffices; in other situations, especially if adverse events with catastrophic impacts appear out of the blue, it is necessary to dig deep into the toolbox of systems and complexity theory. Cognitive science approaches appear to be especially relevant because they provide detailed analyses of how the experts and teams on the frontline, who are not just simply working with, but also tackling uncertainty on a daily basis, cope with making and rectifying errors, enduring uncertainty and the fact that in some cases, there will be nothing more that they can do. The resulting action model (cf. Section 2.4.-5) was already introduced into the discussion fifty years ago in relation to the interaction between human/operator and information technology (IT).

Info-Box 1

The "Six Schools"

1. The patient-oriented approach
2. The value-based understanding
3. The process-oriented approach
4. Cognition and human factors
5. The organizational approach
6. Systems and complexity theory

The most significant criterion of differentiation between these six explanatory models is the level of **complexity reduction**. This is an important issue because the epidemiological terminology employed in studies on the frequency of adverse events still employs "linear" nomenclature. From this perspective, a process is understood to be constituted by "preventable adverse event = AE + error" (cf. the Info-Box 2). It is important to emphasize that the level of complexity reduction needs to be adapted to the particular task at hand. In the case of epidemiology (determining the *status quo*), the linear conceptualization is adequate. Five levels can be distinguished for specific assessments of linearity and complexity (cf. also Tab. 3). These are:

- the level of "simple communication", where the linear model is completely sufficient (e.g. the concept of the error chain, simple epidemiological investigations);
- the level of "extended event epidemiology" and monitoring: it is necessary to include the measurement context and the effect of the data reporting method (perhaps in line with a simple theoretical model) to varying extents and a discussion of the key statistical requirements (e.g. working with indicators) is essential;
- the level of a "targeted quality improvement intervention" and its evaluation: a complex procedure involving piloting, model assumptions and formative qualitative elements is indispensable, since this is the decisive level where the credibility of the whole concept is under scrutiny;
- the level of risk "management": implementation within the organization requires the use of managerial instruments inspired by systems theory; and
- the level of "political discourse": this requires attention to the types and characteristics of contexts and interventions that should be considered from a political perspective in order to promote improvements to patient safety.

Info-Box 2

The "linear" terminology – still relevant for epidemiological inquiries (extract, cf. Ch. 3.2; for sources cf. Ch. 3):

- **Patient safety** Absence of adverse events
- **Adverse events** An unintended negative effect caused by the treatment and not the pre-existing condition
- **Error** Not achieving a planned treatment goal or implementing an erroneous plan
- **Preventable AE** An adverse event caused by an error
- **Near miss** An error that does not lead to an adverse event
- **Negligent adverse event** A preventable adverse event that fulfils the criteria for negligence (epidemiological definition)

In order to broadly structure this discussion, recourse is made to the **throughput model** in its revised form (Schrappe and Pfaff 2016, Schrappe and Pfaff 2017A). As the name suggests, during the *throughput* phase *input* is transformed into *output* (e.g. safety behaviour), thus achieving the *outcome* (the safety of the patient realized during treatment) (for more details see Ch. 2.2.2.). On this basis, a preliminary multimodal concept is developed that structures Chapter 2 as follows:

1. **Object and correlate**: What traditionally constitutes patient safety and what are the limitations of this approach (Ch. 2.2.)?
2. **Context and goal orientation**: Which contextual conditions need to be considered, which goals should be prioritized and how should goals be systematized (Ch. 2.3.)?
3. **Approach and conceptualization**: Which perspectives exist, what are their strengths and weaknesses and can different applications be identified for individual perspectives (Ch. 2.4.)?
4. **Perspectives for improving quality and innovation competence**: Which fundamental options for improving patient safety exist and what are the preconditions for their realization, in other words, what is the potential for innovation (Ch. 2.5.)?

Particular attention is paid to the possible courses of action at the organizational and system levels. It is often tacitly expected that instructions for the "system" will emerge by themselves from errors and adverse events, thus the view that "every error is a treasure". Consequently, it is usually assumed that, if management takes the correct approach, safety can be "manufactured", or produced in practice and legislators only have to enact strict regulations for all problems to be solved.

This is not (quite) the case. Of course, management and leadership (cf. Ch. 5.4.5.) as well as political accountability are of paramount importance, but the obstacles should not be underestimated. Thus, the main section of Chapter 2 is devoted to their analysis and representation. The concepts of **complexity and complex systems** derived from systems theory play a vital role in health services provision with respect to how errors or harm arise and how they can be prevented. The multitude of actors, of tasks, of interferences, the frequency and intensity of communication, the interaction between humans and machines, and the many external factors do not permit any other conclusion. The definitive relevance of the concept of complexity becomes particularly apparent in its application to the dominant organizational structure in health care systems, namely the **expert organization.** This organizational form is characterized by high levels of autonomy among members who themselves have their own client relations, supervise training and tend to demonstrate an aversion towards any form of management. Both complex systems and expert organizations tend towards self-organization, they are

innovative in the area of product innovation (resistant towards externally-initiated processual and structural innovations) and exhibit a high tolerance for uncertainty and ambiguity (due to these overlaps, the term complex professional system bureaucracy is used, cf. Ch. 5.5.5.). These characteristics lead to the three central analytical statements in the *White Paper* that are important in assessing the capacity for action (cf. Ch. 5.8., Section 5.8.-1.). These are:

- **Intrinsic uncertainty**: With its pronounced autonomy, high level of standardization and its own "client" relationships the expert organization is characterized by a wide-reaching tolerance for uncertainty so that adverse events and external inputs are not perceived as mandates for action. Furthermore, the rejection of management structures means that organization-specific solutions can easily be ignored.
- **Innovation paradox**: The high degree of willingness to innovate in expert organizations and complex systems primarily applies to product innovation in therapeutic and technical fields. In contrast, processual and structural innovations are rejected, especially if they originate from outside the organization.
- **Persistence of non-personal adherence to rules**: In addition to Reason's (2000) person–system dichotomy, the level of "rules" also requires consideration. The rules in question are the result of the pronounced standardization of approaches learned during the long training period, regulated by professional bodies, that health care professionals undergo (situations are processed in a standardized fashion, so-called pigeon holing). This person-and-rules approach dominates the decentralized level of action and ensures that the rules remain intact under any circumstances, even when adverse events occur or the individuals concerned are no longer present. Individuals are not sanctioned for harm they may have caused, but rather for not applying the rules correctly.

Four conclusions can thus be drawn for the conceptualization, planning and implementation of initiatives to improve patient safety:

1. It is not realistic to assume that initiatives to improve patient safety will primarily be met with acceptance in the organizations and structures of the health care sector. The assumption that safety can simply be produced within the health care sector at the level of organizations and structures cannot be upheld. Conversely, one must accept that these organizations come with certain intrinsic characteristics that imply a high tolerance for uncertainty as well as a low level of pressure to take action. In addition to the above mentioned factors of intrinsic uncertainty, the innovation paradox and the adherence to rules, obstacles in organizational learning are also to be considered, for instance those caused by the separation of accountability from tasks or by a lacking or dysfunctional feedback etc. (for more details see Ch. 2.4.6.5.).

2. Therefore, safety across organizations and the system can only be achieved by changing the "foundations" of their existing configuration. This challenge is one of the most important arguments for including the highest level of leadership and supervision in any plans for action, because this is where change must originate.
3. Paradoxical effects should not be viewed as the exception, but as the rule (cf. the chapter on digitalization). The assumption that paradoxical developments can be recognized early and then decelerated cannot be upheld. The danger of paradoxical effects needs to be included in planning and expectations more definitively and extensively than it has been in the past (cf. the concept of complex multicomponent interventions (CMCI), Ch. 5.7.).
4. Emergence, which is a key characteristic of complex systems, needs to play a more central role in the future (cf. Ch. 2.4.7.5.). Not only can minor incidents have large effects ("high sensitivity to initial conditions"), but complex systems are also capable of forming completely new, apparently paradoxical and unpredictable results. These also include unexpected ("paradoxical") reactions to desired changes. An idea of the existence of possible attractors can be helpful to determine which interventions have good chances of succeeding and which are more likely to fail (cf. Ch. 2.4.7.6.).

Info-Box 3

Theoretical foundation of the analysis

Patient safety is not merely "manufactured"; rather, it is just as much a constitutive quality of "systems". As expert organizations and, at the same time, complex systems, health services providers exhibit high levels of autonomy among members, spontaneity in their development and a high tolerance for ambiguity and uncertainty. Standardization (rules) in the expert organization (so-called pigeon holing) leads to a pronounced tolerance for uncertainty (intrinsic uncertainty). The systems in question are highly innovative, but not in regard to externally-motivated processual and structural innovations (innovation paradox). Reason's dichotomy of the person and system approaches should therefore be extended to include the decentralized implementation of rules that steer members' behaviour and also persist in the case of adverse events (persistence of non-personal adherence to rules). This combination of tolerance for uncertainty, resistance to innovation from external sources and adherence to rules explains the inadequate, high stability or resistance to change. Effective interventions need to be able to, first of all, establish a perception of uncertainty, then to stimulate a capacity for change and they especially need to be able to function at the level of rules.

The ensuing conceptualization of patient safety (cf. Ch. 2.6.) assumes that risks (input), safety behaviour (output) and the final level of safety achieved as the outcome do occupy key positions, but are, on their own, not sufficient to comprise a comprehensive definition (e.g. the problem of preventability, i.e. narrowly prevented AE cannot be considered). Therefore, throughput (the transformation of the input factors into the output) plays a decisive role in understanding patient safety. Parts of the throughput are "contributed" by the actors involved and are therefore very difficult to access from outside. Patient safety continues to imply the capacity for individuals, teams, organizations and the system to actively implement the innovations that are desperately needed to achieve safety improvements. This capacity for innovation is characterized by the relevant conditions that in turn limit or alter the potential for innovation (e.g. the different perspectives of the various professions, organizational obstacles, economic incentives). The most effective means for mobilizing these capacities originate in the planning, introduction and implementation of complex interventions that, together with contextual factors ("dual complexity") increase safety (complex multicomponent interventions).

Consequently, patient safety does not merely consist of a different way of thinking, a different philosophy, a different way of acting or the following of a different set of rules. While these factors partially do capture the concept, **at its essence, patient safety constitutes a characteristic** and also the **capacity for action** ("providing" or "realizing" safety). Patient safety is:

1. a state of affairs (in the sense of traditional definitions),
2. a characteristic (primarily anchored in organizations and within the health care system) and
3. a capacity to actively take action with the aim of realizing safety (innovation competencies)

These three elements of patient safety as "a state of affairs", "a characteristic" and "innovation competencies" map out the dimensions that are discussed and worked through on the basis of the throughput model in the *White Paper*. As a state of affairs, safety is primarily conceptualized as an outcome, making it sensible in this context to "count" adverse events using clinical-epidemiological parameters so that one may know where one stands. However, the "characteristic" chapter is significantly more interesting. It concerns itself with the "machine room" of the throughput, asking questions such as how organizations and the system deal with safety and harm, how learning takes place or how the multiplicity of actors involved yields an output. And finally, we have the dimension of (goal-oriented) action, which, under the heading of innovation competencies, allows us to handle the dual complexity of intervention and context such that positive changes can be implemented for a sustainable improvement of patient safety.

These starting points allow for a more comprehensive definition of patient safety:

Info-Box 4

Definition: Patient safety

Patient safety is the degree to which, from the patients' perspective, the actors involved in professional groups, teams, organizations, associations and the health care system

1. demonstrate a state of affairs in which adverse events are rare, safety behaviours are encouraged and risks are successfully managed,
2. demonstrate, as a characteristic, a commitment to safety as a goal worth pursuing and a willingness to implement realistic measures for quality improvement, and
3. demonstrate the capacity to mobilize their innovation competencies in order to realize patient safety.

This definition is relatively easy to operationalize. As demonstrated above, the following categories can be defined:

- the state of affairs dimension relates to classical approaches to the definition of patient safety (e.g. frequency of adverse events),
- the characteristic dimension relates to the, primarily organizational, capacity to cope with uncertainty productively, and finally
- the innovation competencies dimension relates to the capacity for change.

Several significant contradictions and starting points become apparent when the six dimensions of input of the first order from the throughput model (individuals, professional groups, teams, organization, associations and the system) are associated with the three dimensions of state of affairs, characteristic and innovation.

- The **significance of the team dimension**: while teams work to prevent errors and harm on a daily basis and the professions represented within them require a high degree of intrinsic motivation, organizations as a whole tend to be limited by their structure (expert organizations).
- **Individuals and professional groups**: a similar contradiction can be found between the individual and the professional group dimensions. While individuals may be highly intrinsically motivated to prioritize patient safety highly (due to their everyday experiences), professional groups, in their official positions, do not prioritize patient safety sufficiently in relation to the scale of the problem.

- **Political and corporatist system dimension**: contradictions also emerge between the dimensions of the political system and that of self-administration in associations (even though these two dimensions together form the "system"). On a political level, patient safety is prioritized because patients are of interest as voters, while the professional associations, on the whole, are primarily focused on their own interests.

3. Epidemiology of (preventable) adverse events

Quantitative findings on patient safety are not just valuable for determining the current situation; rather, they are vital as the foundation for any approach to improvement. However, the methods for reporting data employed by the large national studies almost exclusively rest on a linear understanding of patient safety, which conceptualizes safety as an end result (outcome) of a completed process, such that we are confronting a "dissociation between conceptualization and data reporting methods". Thus, mortality and frequency of complications are measured, but the elements of the definition given in Ch. 2.6.2 in relation to the characteristics of the actors involved and their innovation competencies are barely mentioned. However, since methods for measuring and reporting data that focus on end result are still widely used and have been proven appropriate for *status quo* approaches, the linear terminology (see above) will be recapitulated once more in Ch. 3.2. Furthermore, a differentiated discussion of the terms accountability and preventability will be presented in Ch. 3.5, and Ch. 3.6 will provide the latest data on the litigation gap (the difference between the data drawn from legal/actuarial sources and those drawn from epidemiological sources).

In the final section of Ch. 3, an overview of the latest international **studies on epidemiology** and (as far as availability permits) those conducted in Germany will be provided. While we cannot achieve the same standard as in the Systematic Reviews conducted by the APS in 2006/2008 (Lessing et al. 2010), the validity of the studies available today is significantly better than 10 years ago. For instance, serial investigations (e.g. from the Netherlands) are now available, as well as results from intervention studies that may lack information on preventability, but do provide highly reliable findings on the scale of the most significant adverse events. In summary, epidemiological findings can be categorized as follows:

- six studies, based on the HMPS design, are available on (preventable) adverse events (at least 1 AE for between 5.7 and 12.3% of patients in hospitals, preventability of AE lies between 20 and 70%) (see Table 15),
- additionally, five studies were conducted using the Global Trigger Tool (at least 1 AE for between 13.5 and 33.2% of patients in hospitals, preventability of AE lies between 44 and 63%) (Table 16), and
- four Systematic Reviews (AE between 5.7 and 14.4%).

The question of **preventable mortality** is examined with particular attention to detail in this *White Paper*. It is not easy to capture this problem epidemiologically, since it is necessary to document a treatment-related cause (accountability) on the one hand, and to document preventability (caused by an error) on the other hand. Two large studies capture this value, which, according to a Swedish study based on the HMPS design, lies at 0.25% of all hospital patients (Soop et al. 2009), while according to a US study, it lies at 0.4% (Landrigan et al. 2010). In a third study (Classen et al. 2011), AE are equated with preventable AE and a mortality of 1% of all hospital patients is reported.

In an attempt to move closer to capturing preventable mortality, researchers persist in reporting deaths associated with adverse events. However, this measure is not identical to preventable mortality, given that preventability (relation to error) is not being assessed:

- the HMPS-analogous studies posit mortality associated with AE at rates between 6.7% and 10% (see Table 15),
- the GTT studies suggest a lower rate of 1.5% (DHHS 2010) or 2% (Classen et al. 2011) (see Table 16), and
- the Systematic Reviews present values of 3.6% and 7.4% (see Table 17; the compilation of studies by James (2003) is not taken into consideration here).

The question of applicability to the German context remains. Results remain constant by country across the entire body of international studies and there is no reason to question the applicability of findings from the Netherlands or Sweden to the German context. For modelling purposes, the German studies on mortality from nosocomial infections are compared with the international studies, yielding no differences to speak of.

The results can thus be summarized succinctly; in Germany, the following is to be expected:

- AE: between 5% and 10%
- PAE: between 2% and 4%
- negligent adverse events in 1% of cases, and
- preventable mortality of 0.1%

Subsequently, there is nothing to add to the Systematic Reviews from 2006/2008. The numbers used were already conservative estimates at the time and still do not overestimate the situation today. The figure of 0.1% for preventable mortality cases given by the German Aktionsbündnis Patientensicherheit is reliable and corresponds to roughly 20,000 cases of preventable mortality from a hospital patient population of roughly 20 million, such that with 420,000 hospital deaths, roughly every 20th case in Germany can be classified as preventable (caused by an error). Preventable (caused by an error) adverse events are experienced by between 400,000 and 800,000 hospital patients per year.

4. Data reporting methods

Chapter 3 focuses less on epidemiology than on the differential discussion and presentation of the relevant methods used to report data. Beginning with the goal orientation, the definition of research interests (e.g. scientific approach), the choice of measurement instruments (e.g. surveys) and lastly the data sources, in Ch. 3.3 and, building on that, in Ch. 5.3, a standardized procedure will be outlined with reference to six principles for reporting data on the frequency of AE and PAE.

The goal orientation constitutes the basis of each measurement procedure and is operationalized in three dimensions (Ch. 2.3.3.): the perspective taken (e.g. service provider perspective, patient perspective), the structural dimension (how the topic of interest relates to the most urgent structural developments within the system) and the dimension of needs (whether the relevant morbidity is addressed etc.). These three dimensions allow for a prioritization and subsequently the communication of different research questions (required in line with context specificity).

The **discussion of research interests** (cf. Ch. 3.3.3.) illuminates key aspects of the approach taken towards the research question. A major peculiarity associated with the issue of patient safety lies not just in its acknowledgement of the significance of **generative procedures** such as CIRS (for the elimination of double blind spots, or unknown unknowns), but also the inherent importance ascribed to the **clinical-epidemiological perspective**. The majority of epidemiological studies on the frequency of AE take this perspective, which focuses on describing the *status quo* and quantifying the problem. The research areas of infectious disease and hospital hygiene have a head start of several decades in working with this perspective such that inspiration can be gleaned, for instance in establishing clinical-epidemiological case definitions. However, these case definitions (particularly in Germany) are not distinguished from **patient safety indicators**, which in turn have the function of including larger areas of service provision in monitoring procedures (traffic light function). Thus, most parameters used as patient safety *indicators* (PSI) in Germany (and occasionally also in international contexts), are not indicators in the intended meaning of the term, but are actually case definitions. The consequences are significant, since the statistical requirements for each diverge clearly: clinical-epidemiological case definitions are characterized by a balanced sensitivity and specificity; while indicators for monitoring purposes are characterized by high sensitivity at the cost of lower demands on specificity (false-positive results are recognized during the obligatory follow-up examination). However, most PSI sets, and this will be presented in greater detail in Ch. 3.3, only contain clinical-epidemiological case definitions which "count" outcomes (which can also be important), but do not have a monitoring function for the health services sectors (especially because they lack sensitivity). The fourth

step in the procedure involves the demarcation of any remaining **scientific questions** that could, for instance, aid the evaluation of safety improvement measures. This requires elaborate settings with a focus on the complicated interaction between observation, complex interventions and the active context.

The focus of the research interest can be traced back to the conceptualization of patient safety employed. If patient safety is understood simply as "the absence of adverse events" (cf. IOM 1999), meaning that one is primarily interested in end results, then a quantification by means of case definitions should suffice. If, however, one conceptualizes patient safety in line with the definition in Ch. 2.6.2. as not merely a state of affairs (no adverse events), but rather as the characteristic of organizations and the system to cope with uncertainty and also as the competencies needed to implement innovation, one must look beyond the end results. Data reporting methods and conceptualizations of patient safety are inextricably linked.

Having determined the goal orientation and the definition of research interests, the third element is the **choice of measuring instruments**. Researchers have a variety of methods to choose from, including direct observation, surveys, trigger-based instruments (the classic *Harvard Medical Practice Study* (HMPS) design, the *Global Trigger Tool* (GTT), the *Medicare Patient Safety Monitoring System* (MPSMS)) and *big data* analysis. The MPSMS is one of the more advanced instruments, given that it links administrative data with an external, stringently standardized chart review. Additionally, other instruments have been reported to link the chart review with employee surveys.

Subsequently, a **data source** has to be selected. Routine or billing data, which are frequently used, take centre stage in this research context. While these data sources have their strengths in terms of capturing rare, financially relevant events (e.g. retained foreign bodies), they demonstrate deficits in relation to more common events, such as nosocomial infections, that may be highly relevant to patients, but that do not affect the billing process. The resulting problem of sensitivity has been documented in numerous international as well as German studies, but the continued use of billing data in Germany continues to be justified with reference to the effort involved in using alternative sources. Thus, "PSI sets" based on billing data are problematic in two ways: firstly, they are not valid because they have neither been validated in relation to a monitoring function nor are they calibrated with reference to relevant aspects of patient safety. Secondly, they are not reliable, because they do not comprehensively capture events (and thus they certainly cannot be valid either).

This four-step procedure (goal orientation, research interests, instruments for measuring and reporting data, data source) runs counter to the ubiquitous practice of first looking at existing data sources ("what do we have already?"),

subsequently extrapolating a methodology and lastly formulating the research questions to be answered. This assertion is, to a large extent, "political" because an approach oriented towards the available data and methods has two consequences:

- numerous, if not the most relevant, questions are excluded from the outset, and
- the investigations lead to predictably negative finding when, for instance, irrelevant data sources or invalid measurement instruments are used.

International experience paints a clear picture showing that the future of patient safety research lies in **mixed methods** involving analyses of patient records being linked with (critical) analyses of billing data with increasing recourse to patient-reported outcomes. Considering the criteria outlined above, the previously mentioned *Medicare Patient Safety Monitoring System* (MPSMS) devised by the *Centers of Medicare and Medicaid Services* (CMS) in the USA is currently the most attractive concept and it is recommended that an adapted form be piloted and implemented in Germany.

Based on this analysis, a data reporting concept will be presented in Ch. 5.3.8. that encompasses six principles (see Info-Box 5).

Principle 1: A goal-oriented and standardized procedure

The reporting of data related to patient safety should generally proceed in a problem- and goal-oriented manner with reference to a standardized procedure that starts with predefined questions, stays true to research interests, choses measuring instruments and, finally, identifies this data source.

Principle 2: Advance development of clinical-epidemiological frequency data

The clinical-epidemiological research interest provides the central access route to the issue of patient safety and is in accordance with the reporting of adverse events and their subgroups, but can also encompass process parameters that may provide information on the throughput. This approach is to be distinguished in no uncertain terms from the monitoring approach by means of indicators. The objective lies in the reporting of the current state of affairs. A quality improvement approach may be taken, but is not obligatory. Conservative medicine, care, and errors of omission are priority areas where reporting must be developed further, and endeavours should be adapted to the specific health services sectors and specific problems in health services provision in accordance with the relevant goals. There is an urgent need for further developing the measuring instruments used in Germany so as to improve their explanatory power. Of central concern in this regard are direct observation, qualitative methods, external chart review procedures, trigger-based proce-

dures and various combinations of these as well as the assessment of sentinel events using billing data and/or compulsory reporting, and the integration of methods for capturing unstructured data (e.g. *Quality and Safety Review System,* cf. Ch. 3.3.3.3.3)

Info-Box 5

Methods of reporting data in patient safety research: Principles

Principle 1: A goal-oriented and standardized procedure
Principle 2: Advance development of clinical-epidemiological frequency data
Principle 3: Use indicators for monitoring and to depict the provision of patient safety
Principle 4: Learning from unknown unknowns demonstrates responsibility
Principle 5: Keep in mind the standards for the evaluation of interventions!
Principle 6: Favour process parameters in steering functions

The previously limited focus of the clinical-epidemiological perspective on outcome data therefore needs to be overcome, since they are not a valid measure for the extent of (realized) patient safety. While it is possible to try to improve validity by means of risk adjustment models, risk adjustment can never be exhaustive and is hence always subject to manipulation. Furthermore, it should also be considered that only a small proportion of the outcomes can be attributed to the treatment process and can thus be viewed as preventable (in relation to the occurrence of an error) (cf. Fig. 33). As presented in the relevant sections on organizational learning (Ch. 2.4.6.3.-5.), this proportion of outcomes, which is relevant for feedback, lies significantly below the spontaneous variance associated with clinical procedures or environmental effects. Thus, it is neither possible for professionals on the frontline to recognize this proportion of outcomes nor to use it to learn from (consequently, these data need to be processed specifically for this purpose, see challenges for the "innovators" in Ch. 5.4.4.).

Consequently, outcome-adjacent parameters that contain safety-relevant information (mortality, rate of complications etc.) must be reported extensively, but these data should not be used as a "yard stick for safety"; rather, they should be employed to clarify the *status quo* and to initiate retrospective analyses (e.g. peer reviews). This statement should be emphasized clearly, given that it is initially counterintuitive (high mortality "*is*" the absence of safety, or so runs the primary assumption). The use of these data for *ex post* analysis is obligatory, but this can largely be carried out anonymously, and above all they should not be used to steer any projects to prevent disruptive effects.

Principle 3: Use indicators for monitoring and to depict the provision of patient safety

Currently, patient safety indicators (PSI) almost exclusively consist of outcomes (complications), which actually should be regarded as adverse events (AE) rather than indicators. Instead, new PSIs need to be developed that are related to the process of realizing patient safety and can be applied to monitoring different areas of health care provision. A central role is played by parameters that are based on patient self-reports (information, coordination), that take a regional perspective emphasizing integration and that are oriented towards needs (e.g. chronic multimorbidity). Five indicator sets are suggested for further development:

- patient safety from the patient perspective
- patient safety and benefits
- patient safety on a population level
- safety competencies, and
- organizational learning.

Billing data should only be used in combination with direct observation, chart reviews and trigger instruments.

Principle 4: Learning from unknown unknowns demonstrates responsibility

Generative procedures such as CIRS and morbidity mortality conferences constitute the most important instruments for integrating near misses and risks into conscious awareness and the subsequent extrapolation of learning steps (learning culture) in organizations and other systems. The reporting of incidents, however, is not sufficient in itself; the reports have to be acted upon and consequences must follow. Participation in these programmes is generally voluntary, but it is not facultative in most organizations or among their members. These instruments and the information to be gained from them are of utmost importance and ought to be part of the "rule book" of any structure in the health services sector, since the health care system (like any other high-risk sector) cannot ensure safe service provision without this information.

Principle 5: Keep in mind the standards for the evaluation of interventions!

In the international field of patient safety, complex multicomponent interventions (CMCIs) (cf. Ch. 5.7.) are the most successful type of intervention. In exceptional cases, evaluations can be carried out from a clinical-epidemiological perspective, but the scientific pathway is employed most of the time (cf. Fig. 24). This pathway is based on a stepwise model of the expected mutual interdependencies of the complex intervention, the complex (active) context, the subject of the investigation and the observation itself. The preliminary results of the evaluation already influence the intervention and the con-

text during data collection. These interdependencies need to be taken into consideration during the interpretation of results and will thus shape the expectations harboured for the investigation, since the effect of a CMCI can be greater (or smaller) than the sum of the effects of the individual interventions. Qualitative and quantitative methods should be combined and since the results of an investigation cannot always successfully be applied in another context, the research environment must be carefully documented during the reporting phase. Paying heed to methodological standards constitutes a significant step towards popularizing the notion of patient safety, since any meaningful feedback on previous accomplishments cannot otherwise occur.

Principle 6: Favour process parameters in steering functions

In most areas of society, one does not merely wait for an outcome; rather process parameters are employed to steer in the direction assumed to be associated with the outcome (e.g. speed limits for traffic regulation). In most cases, this type of procedure eliminates both the need for risk adjustment as well as the gaming option as a potential influence on risk adjustment models (e.g. the increase in comorbidity due to secondary diagnoses). However, the primary advantage is preventing the bad apple syndrome and the facilitation of an early intervention into realizing patient safety. Taking the perspective of clinical-epidemiological case definitions, process parameters with a steering function can be defined in the same way as indicators that are used for the purpose of monitoring.

These six principles provide an important foundation and prerequisite for the further development of patient safety. A new conceptualization is only be possible if a credible and differentiated concept for the measurement of parameters in the area of patient safety is advanced. Furthermore, only under these conditions is a deeper engagement with new types of interventions (e.g. complex multicomponent interventions, cf. Ch. 5.7.) meaningful, since one of the key elements of these complex interventions is swift data feedback.

5. Reinforcing throughput, the role of the actors involved

Improvement science distinguishes between five models of behaviour change. Interventions with the aim of improving patient safety generally limit themselves to the simplest forms (learning theory models), with social roles rarely receiving any attention (e.g. "learning to talk about errors"). Future discussions of initiatives for change must engage more comprehensively with the question of which theoretical foundations or models will form the basis of behaviour change. It is obvious that the focus will lie in (a) a combination of several models and (b) the use of higher-level models (organizational learning as well as concepts from behavioural engineering and context-based concepts).

As part of this strategy, patients, frontline experts and teams will all play a highly significant role, especially in relation to organizations, professional groups and policymakers.

Info-Box 6

Improvement science: Five models for behaviour change

- Learning theory concepts
- Concepts of social perception
- Concepts of organizational change
- Behavioural engineering
- Context-based concepts

cf. Grol and Grimshaw 2003, Shojania and Grimshaw 2005, Schrappe 2015 p. 252 ff, Schrappe and Pfaff 2017A, p. 45f

- For the above mentioned "higher-level" models of behaviour change, context, which is largely constituted by patients and the public, is of paramount importance. Therefore, the relevance and visibility of the **patient perspective** will take precedence within our fundamental understanding of patient safety, with regard to goal orientation, in the reporting of data on patient safety (surveys, indicators, generative procedures) as well as in the future development of measures for improving safety. This applies in particular to chronic illness from a regional or population perspective. The general political framework also needs to be taken into consideration (primacy of insured individuals and patients, danger of "medical cooling", loss of accountability through algorithmic steering).

Info-Box 7

The patient perspective takes precedence! (cf. Ch. 5.2.2.)

A patient-oriented approach is the foundation of a modern conceptualization of patient safety (Ch. 2.4.8.) and therefore lies at the core of the updated definition of the term (cf. Ch. 2.6.2.). As is becoming increasingly accepted in health policy discussions, one of the most important criteria in competitive debates regarding goals in the field of patient safety should be the extent to which the patient perspective is being represented (in comparison with, for example, the perspective of service providers). Instruments for surveys intended to gauge the patient perspective are available. Patient reports can be used as clinical-epidemiological data to describe the current state of affairs and they can function as indicators with the capacity to predict levels of safety or incidence of AE (though this requires validation). Additionally, this type of data

can be used in generative procedures (e.g. reports from patient advocates). Furthermore, it is important to take a critical stance and regularly question whether the patient perspective is really being represented or whether it is merely being used as a pretext.

- **Adopting the benefit perspective for a differentiated assessment of safety problems:** Patient safety problems are not independent from the benefits of the measures they result from (cf. Ch. 5.2.2.2.). The benefit perspective is, alongside the patient perspective, one of the most important vantage points to be taken into consideration during goal definition following the perspective dimensions (cf. Ch. 2.3.3.). In four cases, this is of particular significance:
  - Unsafe methods should also be classified according to their benefits: addressing unsafe methods without benefits should take priority over addressing unsafe methods with a given benefit.
  - Errors of omission are common, but in order to identify a PAE, an analysis is required of whether the omission resulted in the benefits of a measure not being realized (AE caused by treatment are not possible in this case).
  - Measures taken without benefits (overuse) are adverse events in themselves (lack of indication), not to mention complications and the consequences of false-positive results.
  - Diagnostic errors can be conceptualized as PAE insofar as patients cannot realize the benefit of the correct diagnosis and/or insofar as they suffer complications resulting from the (false) diagnosis and subsequent therapeutic measures.
- **Frontline experts** assess situations, anticipate risks, prevent adverse events and mitigate their consequences (cf. Ch. 5.4.2.). Since they work within complex systems, they are used to unpredictable events and procedures (emergence), but they should still be given the opportunity to prepare for these even more comprehensively. In other sectors, regular training programmes for safety procedures are in place, even though relevant events are significantly rarer than in the high-risk health care sector. These types of training programmes should call into question the socialized high tolerance for uncertainty ("intrinsic uncertainty"), which is particularly common amongst physicians, in order to replace it with an understanding of uncertainty as a profound problem that can also, even particularly, manifest amongst experienced professionals and can be addressed in a targeted manner (resolution of the innovation paradox). The following points are important to keep in mind with regard to training approaches for frontline experts:

  - communication of the programmes on offer and encouragement to participate are necessary to achieve reductions in intrinsic uncertainty and the innovation paradox,
  - training programmes need to be carried out with greater urgency and accountability than in other areas of life in society, given that the health care sector constitutes a high-risk field, and
  - programmes need to be offered to practitioners with all levels of professional experience with special attention being paid to experienced staff.
- The expertise of **teams**, which constitute the smallest organizational unit in health services provision and are widespread in areas requiring the completion of tasks with a functionalistic character, is of key significance for the realization of patient safety (cf. Ch. 5.4.3.). Unfortunately, there are numerous areas of health services provision in which the notion of true teamwork remains absent (e.g. normal hospital ward work; necessity of interprofessional ward teams). Team-based training programmes have been proven to aid the improvement of patient safety and should be implemented on a significantly more binding basis than is enforced presently. A precondition for the success of these types of training measures is a more team-oriented working structure throughout the entire health care sector.
- **Professional groups** are faced with a challenging task, given the health care system's lack of problem solving ability in relation to its fundamental structural problems. The term professionalism delineates a two-fold concept, assigning, on the one hand, autonomy and responsibility for questions of quality and safety to practitioners, while, on the other hand, requiring professional values such as patient-centred practice and altruism. Currently, the professions are taking a defensive stance. A new professionalism that renews and reinforces responsibility for quality and safety would resolve this situation. In Germany, the initiatives Choosing Wisely and Open Disclosure as well as the Aktionsbündnis Patientensicherheit constitute first steps in this direction.
- All institutions of the health care sector should be obligated to employ **dedicated patient safety officers and specialists** (cf. Ch. 5.4.4.), because the work that lies ahead in the field of patient safety requires the establishment of an independent professional group, as has been the case in the field of hospital hygiene. The independence of the members of this professional group ought to be ensured according to the template offered by the position of data protection officer. The efficacy of the previously preferred approach, which was primarily voluntary and relied on spontaneous developments for problem solving, has shown itself to be an illusion.
- Active accountability and role-model behaviour within the **leadership** is a decisive, empirically supported criterion for a successful engage-

ment with patient safety (cf. Ch. 5.4.5.). The international literature contains numerous urgent recommendations for executive committees that can be applied to Germany and can, if necessary, be codified in law. These recommendations revolve around the aim of making the leadership's commitment to patient safety more visible within the organization and easier to control for regulatory bodies (executive walkarounds, annual internal and external reporting, the verifiable integration of patient safety into strategy formation, the selection of a personally accountable Chief Patient Safety Officer (CPSO) as an executive board member, selection of a personally accountable member of the governing board, the formation of a relevant working group within the governing board, verifiable engagement with individual, harmed patients etc.). The predictable criticism of excessive regulation needs to be challenged with recourse to the urgency of the issue.

- The term **accountability** has traditionally been used to describe the responsibility of health professionals, organizations, and the system towards their patients, especially when errors or adverse events have taken place. The so-called accountability-system paradox thoroughly examines the tensions between individual accountability and system accountability that can only be resolved by achieving a shared accountability for realizing patient safety. The most current facet of this tension relates to digitalization. The increasing significance of algorithms and artificial intelligence feeds the potential for a dangerous shift of accountability for treatment and errors away from individuals and organizations towards the hidden realm of a "self-learning" system of algorithms. In the field of patient safety especially, this would result in an alarming lack of rights for patients.
- **Reporting on cultures of patient safety** opens up an important vantage point on the throughput phase during the realization of patient safety. It is advisable to compile reporting data in a targeted manner, to plan data collection alongside other procedures (in the sense of a complex multicomponent intervention, CMCI) and to base these on a framework for estimating the effects of external factors. Significantly more methodological work is required to account for the cultural and hierarchical heterogeneity of expert organizations and physicians as a professional group. A survey on cultures of patient safety would constitute an intensive intervention with the capacity to alter the context in which it is carried out. It would be sensible to combine quantitative and qualitative instruments.
- **Incentives and leadership**: incentive systems may be able to increase patient safety, since realizing patient safety, as conceptualized in the definition given in Ch. 2.6.2., can be understood from the vantage point of information asymmetry. With recourse to principal-agent theory, it seems sensible to employ indirect (immaterial) as well as direct (mate-

rial) incentives in both the institutional field and on a system level in order to come closer to achieving the key objective of improved patient safety. For instance, indirect incentives may include public reporting, while direct incentives may be pay for performance (P4P). The efficacy of both measures is highly dependent on the details of their implementation. Thus, in most areas of society, one does not merely wait for an outcome; rather process parameters are employed to steer in the direction assumed to be associated with the outcome (e.g. speed limits for traffic regulation). In most cases, this type of procedure eliminates both the need for risk adjustment as well as the gaming option as a potential influence on risk adjustment models (e.g. the increase in comorbidity due to secondary diagnoses). However, the primary advantage is preventing the bad apple syndrome and the facilitation of an early intervention into realizing patient safety. Taking the perspective of clinical-epidemiological case definitions, process parameters with a steering function can be defined in the same way as indicators that are used for the purpose of monitoring.

- In the **organizations**, leadership and feedback are of paramount importance, even though the health services sector is subject to significant limitations. Relevant external conditions must be taken into consideration. Regular engagement and accepting individual accountability on the part of governing and executive committees as well as working with the measurements yielded by various sets of indicators and other data sources should receive the highest priority. High priority should still be accorded to internal structural decisions that facilitate optimal cooperation on the issue of safety, visible leadership initiatives and the hiring of an independent patient safety officer as well as training programmes for frontline staff or teams.
- The level of the **associations** is of great importance to the "holistic context". In accordance with the concept of governance, bodies for self-government within the health professions cooperate in the Federal Joint Committee. Blockades within these bodies have an extremely negative influence on the issue of patient safety that goes far beyond any single measures; rather, such blockades harm the context required for the establishment of sustainable changes to behaviour and procedures that are urgently required.
- While **public health policy** has ceded responsibility for numerous tasks to the level of the associations (governance), it still has to retain control over key functions such as direction pointing, the balancing of different activities, the supervision and if necessary reorientation of measures in order to ensure efficacy, and the anticipation of possible negative effects. The fundamental decisions involved in policy direction include prioritizing the patient perspective, the benefit perspective and the population perspective; the issue of monopolization; the evaluation of

ongoing interventions into the system; and the duty of quantification with recourse to methodological principles. Fundamental legal questions take on a particular significance. In this context, it is especially helpful to look at the internationally applied strategies of "no fault" (New Zealand) and "no blame" (Scandinavia), which allow for compensation and income replacement even in the absence of a verifiable error (no fault) or verifiable culpability (no blame). Ongoing debates on compensation and hardship funds could be stepped up a gear by taking note of these strategies. Simultaneously, health services research should be better supported and encouraged in devising approaches for improving patient safety as well as in assessing the economic effects of the approaches and their applicability to the German context.

6. Technology and digitalization

Technological solutions are highly attractive to everyone involved in the health services, since they imply "absolute" efficacy and raise hopes that one can avoid the labour-intensive recalibration of processes, structures and contexts. However, medical technology and health information technology (HIT) should not be conceptualized as linear-additive elements of the work and system environments, since this would, when applied to the field of patient safety, constitute a purely technical conceptualization of patient safety and would be equivalent to a step backwards given the current concepts from the fields of cognitive science or systems theory. Instead, medical technology and health information technology (HIT) should be understood as active elements in a complex environment that has been described as a sociotechnical system in the cognitive sciences, in health services research and in IT research. Thus, technical elements can be found within most complex multicomponent interventions (CMCIs), including the ones described in this *White Paper* as setting the standard for interventions to improve patient safety.

Adverse medical device events (AMDEs) are subdivided into classical medical product-related adverse events and HIT-related errors/adverse events. These can be classified further according to technical defects, safety of use, and the benefit perspective (application without proven positive or with negative benefit). HIT-related errors/adverse events are defined according to their origin as resulting from erroneous development or malfunction, deficient implementation and inappropriate interactions between technology and users or between technology and the work process. The term thus extends beyond functional disruptions of IT-instruments and also encompasses the external consequences of these disruptions as well as the consequences of usage errors. The most important application examples (e.g. computer-assisted physician order entry (CPOE) systems, electronic health records (EHR) and medical apps) illustrate the various positive and negative effects. Medical products and HIT

have the capacity to lend significant support to improving patient safety (enablers), but they are not sufficient by themselves to ensure efficacy.

In Germany, it is vitally important to invest more resources into the implementation of HIT, meaning research on sociotechnical systems in particular. Merely increasing pressure to realize and implement HIT would, based on the current state of international research, lead to failure.

7. The new intervention standard: CMCI

A credible strategy for tackling the issue of patient safety relies on the availability of functional, implementable interventions that can be employed for the purpose of improving safety. This applies to the type of intervention discussed here: the complex multicomponent intervention (CMCI), which has led to even groundbreaking success in numerous settings, especially the USA, over the past 10 years (cf. Ch. 5.7.2.). By combining interventions at various levels, complications such as nosocomial sepsis due to central venous catheters or ventilator-associated pneumonia have been reduced significantly and sustainably (see Info-Box 8). Given the complexity of entry points, CMCIs constitute a particularly appropriate type of intervention for complex systems. However, certain disadvantages are also associated with CMCIs, for instance, their pronounced context sensitivity results in lower generalizability than may be desired, paradox ("emergent") effects are a regular occurrence and individual interventions occasionally lead to disappointing results in isolated evaluations, since the holistic effect of a complex multicomponent intervention can be significantly stronger (or even weaker) than the sum of all individual interventions.

Alongside primary interventions, which should be based on evidence as far as possible, there are five further levels of intervention that can be combined into a CMCI (cf. Ch. 5.7.1., also Fig. 41):

- the technical component (generally a necessary precondition, problems with the human-machine interface need to be taken into consideration),
- the system component, e.g. changes to remuneration practices,
- the patients, whose should participate in the intervention as active partners,
- the organizational component (e.g. teams, leadership), and
- learning on the basis of valid data and by means of functional feedback procedures.

The following must also be taken into consideration:

- the relatively high degree of effort involved, in contrast to (almost always ineffective or only temporarily effective) selective individual interventions, and

- the well-known factors for increasing the chances of success, which include (cf. Dixon-Woods et al. 2011, Pronovost et al. 2016, Einahal et al. 2017):
  - clearly formulated goals without contradictions,
  - reframing of the problem as a professional project that reflects the social canon of values (culture) and strengthens intrinsic motivation,
  - horizontal networking according to normative postulates,
  - vertical accountability across all levels, including system-level measures encouraging this,
  - adequate feedback (timely, targeted) on the basis of valid data, and
  - strengthening the scientific and professional knowledge base.

CMCIs play a central role within this *White Paper*, because, alongside aspects such a leadership and team orientation, they allow for an optimistic outlook on the attainability of safety improvements despite the limiting factors (intrinsic uncertainty etc.).

Info-Box 8

Michigan Keystone Study on the prevention of central line-associated blood stream infections (CLABSIs)

The so-called Michigan Keystone Study conducted by Pronovost et al. (2006) employed a time series design based on 375,757 catheter days across 103 intensive care units and succeeded in reducing the mean rate of central line-associated blood stream infections (the nosocomial infection with the highest mortality rate) from 7.7 to 1.4/1000 catheter days. The "CLABSI-bundle" that was implemented consisted of a team-based comprehensive unit-based safety programme (CUSP) (Pronovost et al. 2005) and five additional measures (hand hygiene, use of chlorhexidine as a disinfectant, use of full-barrier precautions during insertion, localization to *vena subclavia*, regular reviews leading to earliest possible removal). The improvement was sustainable (Pronovost et al. 2010) and was validated in a retrospective, controlled evaluation (retrospective, quasi-experimental time series design, Lipitz-Snyderman et al. 2011) employing a control group of hospitals from the surrounding Midwest region (95 hospitals in Michigan vs. 364 hospitals from the surrounding region). The results were also confirmed in a cluster-randomized study outside of Michigan and were thus elevated to a higher evidence level (Marsteller et al. 2012). With 45 participating intensive care units from 35 hospitals, the rate of central line-associated blood stream infections was reduced in the intervention group from 4.48/1000 to 1.33/1000 catheter days, an effect which persisted past the conclusion of the study (after 19 months, a reduction to under 1/1000 catheter days was measured). The rates for the control group were 2.71/1000 days before and 2.16 after the intervention, but after 122 months, this group also achieved rates under 1/1000 catheter days. The Michigan study was also successfully replicated in

Spain (Palomar et al. 2013). However, in the UK and Brazil, the effects of the CLABSI-bundle could not be distinguished from the secular trend (improvement without intervention) (Bion et al. 2013, BRICNET 2016). This context sensitivity is a well-known aspect of complex multicomponent interventions and needs to be taken into account (Dixon-Woods et al. 2013).

8. The costs of inadequate patient safety and cost effectivity of patient safety improvement measures

The numerous studies on the costs incurred by adverse events should be differentiated according to the following criteria:

- the type of costs taken into consideration: direct, indirect and intangible costs;
- the type of negative events analysed: all negative events vs. treatment-related adverse events vs. error-related preventable AE;
- the type of adverse events included (e.g. inclusion of errors of omission), and also
- the perspective taken: patient, service provider or system perspective.

Only few studies have been conducted from a **patient perspective** and their results are strongly influenced by the assumptions made regarding the costs associated with one (adjusted) year of life lost. The best data-supported investigation originates from the UK. It examines six selected adverse events (which are considered preventable for the purpose of the study) affecting hospital patients and calculates an annual cost of € 650 million (corresponding results from the USA calculate between $ 73.5 and $ 98 billion). The extended hospital stay alone incurs costs of € 200 million.

In contrast, most studies focus on the **service provider perspective**. Studies on the whole range of AE can be subdivided into epidemiological studies (mostly HMPS design), studies on the basis of billing data, liability insurance data and studies on extended hospital stays. They demonstrate additional costs per case of between $5,000 and over $80,000. The value of €5,000 per case as has been specified for the German context can be viewed as an absolute minimum. The extension of the hospital stay is equivalent to roughly 6 days. Nosocomial infections lead to additional costs of between $1,500 and over $30,000 per case. Adverse pharmacological events are estimated at $3,000 per case.

Studies that take the **system perspective** calculate the annual costs of AE as lying between € 194 million (Ireland), € 355 million (Netherlands), $ 460 million (Australia), NZ$ 870 million (New Zealand), $1.1 billion (Canada), € 1.25 billion (UK) and up to $ 37.6 billion in the USA. The costs of PAE are estimated to be between € 161 million (Netherlands), $ 397 million (Canada) and $ 17 billion (USA).

If these data are applied to **Germany** and one assumes a very conservative estimate of € 5,000 per AE, then additional preventable costs of between € 2 billion and € 4 billion per annum can be expected. On the basis of a special evaluation of the APS Systematic Reviews from 2006/2008, one can expect preventable costs of between € 1 and € 2 billion per annum for extended hospital stays alone. With recourse to the well-researched "model" of nosocomial infections, calculations show that additional annual preventable costs of between € 500 million and € 1 billion can be expected. Thus, the results are relatively consistent.

The studies and the Systematic Review almost exclusively find that measures for improving patient safety are cost effective. However, this assessment depends to a large extent on certain assumptions, particularly with regard to the economic weighting of the benefits of these measures. Additionally, it is necessary to engage with high levels of heterogeneity in terms of the subjects and types of interventions, which leads to the assessment that recommendations for particular fields seem to be more appropriate than global statements.

9. New orientation: six questions and two paradoxes

The stance outlined in Ch. 2.6.1. is clear: a new orientation is impossible without a consistent conceptualization. Four questions were raised (and later two more were added) and each requires a dependable, practice-oriented answer (cf. also Ch. 2.1.):

- **Question 1**: Why are there so few demonstrable successes?
- **Question 2**: Why are there problems associated with the measurement and evaluation of interventions?
- **Question 3**: Why is the issue still not being adequately prioritized, why do problems of acceptance persist?
- **Question 4**: How is the term patient safety being misused?
- **Question 5**: How can events occurring "out of the blue" be explained and integrated into a concept (emergence phenomenon), and
- **Question 6:** Why is it that individual interventions that form part of a bundle intervention only show weak effects when evaluated individually?

In addition to these open questions there are two paradoxes that cannot be resolved using current approaches, namely

- the **system-accountability paradox**: how can the contradiction between individual accountability and system accountability be resolved? and
- the **linearity-muddling through paradox**: are the linear (e.g. technical) standardization measures always superior to the muddling through strategies of the frontline experts?

The concepts outlined in Ch. 2 and Ch. 5 as well as the discussion on data reporting methods (Ch. 3) indicate that it is possible to find answers to these questions:

1. **The lack of success demonstrated by previous measures** (question 1) may result from a choice of inadequate interventions, a lack of efficacy associated with the interventions chosen or a suboptimal implementation of interventions. All of the above mentioned reasons interact:
   - **"monochrome" single interventions** are neither able to effect change at the sharp end of a complex cognitive system (cf. Ch. 2.4.5.), nor are they capable of impacting the entire complex system of an organization or health care system, at least not in a sustainable manner. From today's perspective, one must concede in retrospect that this approach was neither productive in the field of guidelines and quality management, nor in regards to the early interventions in the area of patient safety. This assessment is not just based on the versatile range of theoretical principles available for interpreting such patterns (cf. the six "schools" outlined in Ch. 2.4.), it is also based on the broad range of concepts of change (e.g. learning theory or role-based concepts) that have previously only been acted on to a limited extent in the health services sector (cf. Ch. 5.8.4.). Currently, it is important to recognize that complex multicomponent interventions (CMCIs) have been discussed as an alternative for at least 10 years and that their efficacy has been demonstrated to an impressive extent. CMCIs are determining the current and future standards and while they cannot be mistaken for magic bullets with the capacity to solve all existing problems simultaneously, they have not yet been accorded their rightful place in the German context. The investment of resources and efforts into CMCIs is essential; patient safety officers must be trained in these methods in the present and in the future.
   - **Object:** Inadequate interventions failing to work effectively can hardly be cause for surprise. However, it seems that the material was underestimated in the wake of the initial euphoria associated with the fact that a discussion of errors was taking place at all. It is important to emphasize repeatedly that this *White Paper* on patient safety does not intend to be discouraging in its surgical dissection of the resistance and limitations present within organizations and the other actors involved. On the contrary, the main concern of this analysis is to communicate that efforts towards patient safety must continue in a manner that is even more targeted, differentiated and intense. Thus, it was not just a matter of choosing the wrong interventions; the resistance to implementation has also been difficult to overcome.

- **Challenges posed by new types of intervention**: what remains to be said on the subject of suboptimal implementation is that complex multicomponent interventions constitute a real challenge. Their implementation requires a combination of quantitative and qualitative procedures, the formulation of adequate questions, models and expectations (!) and given that the discipline of health services research is (still) relatively young in Germany, a great deal of catching up is necessary in this area. However, there is a light at the end of the tunnel:

2. Question 2 leads to the problem of **measuring and evaluating interventions**. Given certain specificities of the German context (cf. Ch. 5.3.1.), one is faced with a difficult state of affairs that will threaten any new development in this area until it is rectified. This can be briefly summarized as follows: the nomenclature and methodology developed within self-administration since the 1990s needs to be updated and outfitted with a solid empirical foundation in order to meet epidemiological requirements and rise to the international standard that is given by the scientific approach. It is not possible to evaluate on the basis of indicators, unless one is actually working with clinical-epidemiological case definitions in disguise, but even these should only be used for evaluations in exceptional cases. These issues have been discussed thoroughly in this *White Paper* and the alternatives are presented clearly. The most important three basics are summarized below once again:
   - goal orientation and questions formulated *a priori* as opposed to searches based on data availability,
   - clarification of research interests as the second step (empirical, clinical-epidemiological, monitoring, generative procedures) and only then
   - the choice of measuring instruments (e.g. surveys) and data sources follows.

   It is essential that this order of steps is adhered to. Especially when complex interventions are evaluated, it is important to realize that the evaluation itself constitutes a form of intervention (anyone who has investigated administration of antibiotics or hand disinfection in the field ought to know this). Thus, it is important for observation to gain entry into the model.
3. Question 3, which refers to the **limited acceptance and extent of priority accorded** to the issue of patient safety, also allows for several answers. The German health care system suffers from a fundamental malaise in the form of segmentation (cf. Ch. 5.5.3.) from which it is unable to free itself. Naturally, a form of self-inhibition is apparent in self-administration, which has been assigned so many responsibilities by the political sector. However, perhaps the issue of patient safety would enjoy higher priority if there were a more credible conceptualization, more

verifiable successes and more effective interventions such that a better argument could be made in its favour. This is where the overriding importance of complex multicomponent interventions comes in. As important as the figures on prevalence may be (cf. Ch. 3.6.), these alone will not be able to rectify the present situation, just as the costs incurred by adverse events seem to be insufficient in providing motivation for change (Ch. 4.5.); an effective remedy is desperately needed.

4. The **misuse of the term** patient safety (question 4) can only be curbed by means of updating the concept and methodology behind it so that conceptual confusion may be "nipped in the bud" (e.g. inclusion of errors of omission).
5. **Emergence** (question 5, cf. Ch. 2.4.7.5.) is a core characteristic of complex systems and constitutes the core challenge for any quality improvement initiative in the field of patient safety. The occurrence of adverse events "out of the blue" constitutes one of the most important aspects of public and expert discussions and plans for action. The development of an understanding of patient safety that integrates the phenomenon of emergence is desirable.
6. The **lower efficacy of individual interventions** when these are "removed from the bundle" (question 6) plays a similarly important role, since one of the characteristics of complex multicomponent interventions is that the interaction of their individual components (cf. Ch. 5.7.1.) produces additive effects (or the opposite).

If the above mentioned points are thoroughly discussed and clarified, an increase in the visibility and credibility of the concept of patient safety can be expected. A similar result can be expected in relation to the two paradoxes that weave themselves through this *White Paper* like two central threads from start to finish.

1. The **accountability-system paradox** (Ch. 5.4.6) does not relate to the frequently cited "balance" between individual accountability on the frontline (experts, teams) and the system or organization; rather, it refers to a shared responsibility for realizing patient safety that needs to be negotiated between frontline staff and the higher levels in the hierarchy (Wachter 2013). In this context, none of the actors involved can evade accountability; especially the leadership would run the risk of being cut off from peripheral sources of information and, at least with regards to the issue of patient safety, lose the cooperation of the other employees. For algorithms purporting to offer "just" solutions that maintain segmented accountability, the future looks bleak (Aveling et al. 2016).
2. The **linearity-muddling through paradox** addresses not only a previously largely ignored conflict within the field of patient safety but also

relates to one of the decisive fundamental conflicts within complexity theory. When all the rules are obscured, when the number of elements is unknown and when interactions are nonlinear (this is the view taken by "hardliners" or neo-reductionists (Richardson 2008)), it is impossible for an outsider to measure anything or identify any regularities (Cohn et al. 2013, Paley 2010, the counterposition was argued amongst others by Greenhalgh et al. (2010) and the Medical Research Council (2000, 2008), cf. Ch. 2.4.7.4.). The question of whether is it possible or even permissible to operationalize a complex system for the purpose of improving accessibility for empirical analyses or whether this would lead to a destruction of the complexity, has significant implications in practice; in the latter case, it would not be sensible to formulate linear or standardized recommendations for improving patient safety. A complex system would immediately reduce any form of checklist to absurdity. Instead, it may be better to "muddle through". Martin Marshall et al. (2010) even described this ability as a key characteristic of physicians: "every day doctors make trade-offs". Conversely, the other side fears, not entirely without foundation, the loss of any meaningful capacity for action and analytical competencies.

Presently, even "pure" complexity theorists are emphasizing that the assumptions that follow from this theory do not have any direct practical applications because they are pure mathematical models (Paley 2011). Thus, the contradiction of linearity vs. muddling through continues to elude simple black-and-white conceptualizations. This *White Paper* positions itself clearly with respect to complexity theory, because phenomena such as the emergence of adverse events cannot otherwise be described or explained ("Ophelia" effect, cf. Ch. 2.4.7.5.). On the other hand, this *White Paper* consistently advocates for the **task-specific application** of complexity theory assumptions (cf. Ch. 2.4.8.). As stated in the introduction to Ch. 2, modern health services provision may be complex, but there is no duty to really approach every single problem as a highly complex system. On the contrary, in certain situations a linear "simple" reaction may even be necessary (e.g. immediate reactions to harmful events).

Thus, the core of the matter is the degree of complexity reduction required, which is determined by adapting it to each research question formulated (cf. Bar-Yam et al. 2010). For this purpose, five levels of the problem were outlined in Ch. 2.4.8., which range from "simple communication" (linear model), over the levels of "extended event epidemiology" and monitoring (including the measurement context is usually advisable), risk management (managerial instruments inspired by systems theory), "targeted quality improvement interventions" (highly complex), all the way to the level of "political discourse" (see above).

10. Patient safety in the context of the most important developments in health policy

The newer regulations that currently apply to the field of patient safety in Germany can generally be traced back to the 2013 "Patients' Rights Act" (*Patientenrechtegesetz*), the 2014 "Financial Structuring and Quality Development Act" (*Finanzstruktur- und Qualitäts-Weiterentwicklungsgesetz*, FQWG), the 2015 "Health Services Provision Enhancement Act" (*Versorgungsstärkungsgesetz*, VSG) and the 2015 "Hospital Structuring Act" (*Krankenhausstrukturgesetz*, KHSG). Part of the "**Hospital Structuring Act**" covers revisions to Chapter 4, Section 9 of the Social Security Code Book V (*Sozialgesetzbuch* V, SGB V), including the duty for quality assurance (§§135a-c), the role of the Federal Joint Committee, FJC (*Gemeinsamer Bundesausschuss*, G-BA) in quality assurance (§§136-136d), implementation and control (§137) and the Institute for Quality Assurance and Transparenacy in the Health Services, IQTiG (*Institut für Qualitätssicherung und Transparenz im Gesundheitswesen, IQTiG*) (§§137a,b)). The key regulations can be found in §136a "Guidelines of the Federal Joint Committee for Quality Assurance in Selected Fields" and form the basis of the highly differentiated quality management guidelines passed by the Federal Joint Committee on 15th September 2016 (G-BA 2016). They contain regulations framing patient safety as the highest goal of quality management and patient orientation, they emphasize the staff perspective as well as a safety culture and also highlight several instruments (e.g. checklists, team meetings, risk management, error management and error reporting systems, hygiene management, pharmacological safety, fall prevention).

These detailed regulations on patient safety should be regarded as implicit within the broader context of the **regulatory framework**, which can be subdivided into instruments for enhancing competitiveness (e.g. public reporting, P4P), selectively contractual regulations (e.g. quality contracts according to §110a SGB V, revised version of §140a SGB V), instruments for planning health services provision as well as regional structures (e.g. quality-oriented hospital planning according to §136c sections 1 and 2 SGB V) and evidence-based health care policy (e.g. the development of quality indicators by the IQTiG according to §137a SGB V).

Perspectives for further development and therefore the basis for political options for further development are given by (with waning predictive power) demographics and the aging of society, the further development of segmented structures for population-related provision structures, digitalization and globalization.

In this context, **recommendations for a framework concept** are outlined, with the (selection of the) patient perspective functioning as the foundation for a reconfiguration of the entire system. They further provide a differentia-

ted representation of benefit assessments, the population perspective, the treatment of chronic comorbidities and the data-driven development of the system.

Accordingly, **eight overarching recommendations** are formulated:

1. operationalize patient orientation,
2. include aspects of the benefit perspective into the field of patient safety,
3. develop links to the population, regional approaches and area indicators,
4. publish an annual "National Report on Patient Safety" to move in the direction of a learning health system,
5. develop indicator sets with recourse to extensive cooperation and coordination,
6. integrate external incentive systems such as public reporting or P4P,
7. draw critically on technological support in the form of health information technology (HIT), and
8. mobilize under the banner of a "patient safety offensive".

Six additional recommendations have been formulated for **institutional use**:

1. frontline experts need to receive particularly intensive support for safety behaviour in the form of compulsory training programmes,
2. training programmes as well as support for cooperative working should also be offered to teams as the smallest organizational unit in health services provision,
3. it should be made compulsory for organization to employ dedicated patient safety officers and experts,
4. active accountability and role model behaviour must be codified in regulations for leadership (e.g. verifiable integration of patient safety into strategies, the selection of a personally accountable patient safety officer (CPSO) as an executive board member),
5. accountability for adverse events must be shared between experts, frontline teams and executive committees and has to remain in place despite the implementation of algorithm- and AI-supported procedures, and
6. targeted reporting on patient safety culture needs to be implemented.

Finally, six **areas for innovation with the potential for further development** that could become subjects of collaboration between the Federal Ministry for Health and the Aktionsbündnis Patientensicherheit are identified and introduced briefly. These include innovation and patient safety, measurement methodologies, patient safety and system interventions, patient safety and regional or population-related service provision, tangible organizational implementation (e.g. leadership accountability) and, as the focal point, making complex multicomponent interventions the new standard for quality improvement initiatives in patient safety.

11. An updated agenda for patient safety

In Ch. 7, which rounds off the *White Paper*, an updated version of the Agenda for Patient Safety is presented. The agenda builds on the version formulated at the founding of the Aktionsbündnis Patientensicherheit and revised to its "round" anniversaries. The revised agenda builds on the recommendations of this *White Paper* and covers 28 topics in 5 sections, which are summarized below:

A) Principles

1. Update the context relevance and goal orientation.
2. Discuss patient safety in the context of the necessary perspectives for further developing the German health care system.
3. The Aktionsbündnis Patientensicherheit takes an open and transparent stance towards the different conceptualizations of patient safety, it considers the patient-oriented conceptualization to be the foundation and fundamentally supports an integrative, cooperative model.
4. Within its conceptualization and definition of patient safety, the Aktionsbündnis Patientensicherheit focuses on the characteristics of the actors involved and their innovation competencies.
5. The Aktionsbündnis Patientensicherheit holds the position that the time has come to place a stronger emphasis on sector-specific conditions rather than the long-held approach of adopting analogous solutions from other societal areas (e.g. aviation). This is not a call to curb current efforts, but a call to implement more targeted strategies for change in order to overcome socialization-related barriers in the health care sector. These barriers consist of the three specific aspects of intrinsic uncertainty, the innovation paradox and the persistence of non-personal adherence to rules.

B) Goal orientation

6. The Aktionsbündnis Patientensicherheit prioritizes the patient perspective above all else.
7. The Aktionsbündnis Patientensicherheit emphasizes the key role played by the benefit perspective. Problems of patient safety cannot be considered independently from the benefit inherent in the procedures they result from. This is particularly important in relation to errors of omission, treatments that can be considered as overuse and diagnostic errors.
8. In the view of the Aktionsbündnis Patientensicherheit, discussions of patient safety ought to focus more on regionality and the local population in relation to health services provision.

9. A deeper engagement with structural dimensions is required, especially with regard to the interdependence between interventions to improve patient safety and the structural characteristics and developmental deficits of the health care system.
10. The dimension of needs constitutes the traditional approach to the prioritization of issues. The current iteration of quality assurance according to §136 SGB V, which focuses heavily on acutely medical and procedural prioritization must be redeveloped in relation to patient safety.

C) Data reporting methods and the epidemiology of adverse events

11. The Aktionsbündnis Patientensicherheit views the data reporting methods used for aspects of patient safety as a key element of effective quality improvement initiatives and thus advocates for the differentiated use of measuring instruments, in particular with regards to the targeted utilization of clinical-epidemiological methods and the patient safety indicators used for monitoring.
12. The Aktionsbündnis Patientensicherheit advocates for a rethinking of the methods for measuring and reporting data currently popular in Germany in the field of quality assurance and patient safety. Change is especially urgent in four areas (primacy of problem-oriented quality improvement, choosing measuring and reporting methods in accordance with statistical requirements, correct understanding of indicators as used internationally (particularly in terms of validity) and problem-oriented procedures).

D) Realizing patient safety

13. The Aktionsbündnis Patientensicherheit visualizes further developments focusing both on the decentralized level (frontline experts, teams, regional structures for services provision) and on the central leadership level in terms of increased accountability (executive boards, governing committees, associations, politics and policy). This bipolarity of demands applies to organizations as much as to the system level.
14. The Aktionsbündnis Patientensicherheit demands a widespread, obligatory implementation of training programmes with the aim of engendering an understanding of unsafe practice and of the necessity for interventions for quality improvement (innovation). The ubiquitous acceptance of uncertainty in the health care sector ("intrinsic uncertainty") has to be called into question in these training sessions and replaced by an attitude that acknowledges uncertainty as a problem requiring targeted solutions.
15. The Aktionsbündnis Patientensicherheit demands the implementation of widespread, obligatory team training programmes with the aim of engendering an understanding of unsafe practice and of the necessi-

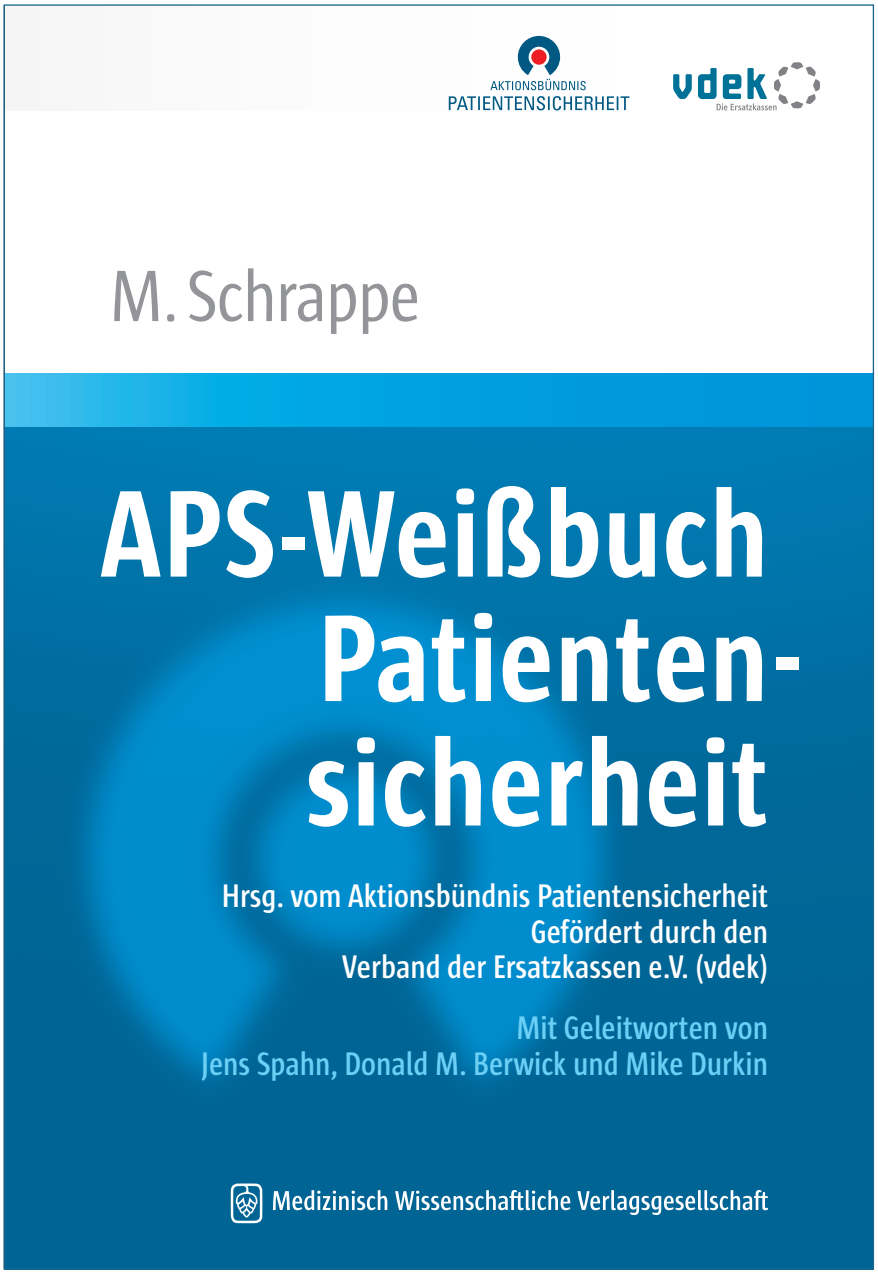
ty of interventions for quality improvement. Simultaneously, teamwork structures should be introduced into more areas of the health care sector (cf. Ch. 5.4.3.).

16. The Aktionsbündnis Patientensicherheit demands the compulsory instatement of patient safety officers and patient safety experts, analogous to those for hospital hygiene (cf. Ch. 5.4.4.).
17. The Aktionsbündnis Patientensicherheit demands legal initiatives with the aim of increasing accountability for patient safety at both the leadership and the supervisory levels.
18. The Aktionsbündnis Patientensicherheit emphasizes the significance of attributable accountability in relation to both the accountability-system paradox and the significance of algorithms in decision-making within health services provision (cf. Ch. 5.4.6.).
19. The Aktionsbündnis Patientensicherheit advocates for a stronger enforcement of the demand for patient safety codified in the command *primum nil nocere* by means of a stronger emphasis in professional committees, publications and resolutions. The Aktionsbündnis Patientensicherheit thus hopes that the professionalism within occupational groups will become the driving force of the patient safety movement.
20. The Aktionsbündnis Patientensicherheit demands enduring accountability from the associations and self-administration structures for issues of patient safety (e.g. FJC, *G-BA*).
21. The Aktionsbündnis Patientensicherheit considers the central positioning of patient safety culture to be an opportunity for the operationalization of the processes involved in the throughput of realizing patient safety. However, the instruments required for this are not yet sufficiently developed, especially in relation to the question of organizational and professional heterogeneity (cf. Ch. 5.4.7.).
22. Given the structurally disadvantaged position of prevention initiatives (benefits emerge downstream from acute situations), the Aktionsbündnis Patientensicherheit demands a thorough integration of the instruments of public reporting and pay for performance into quality improvement initiatives in patient safety.

E) Improving patient safety

23. The Aktionsbündnis Patientensicherheit advocates for the use of high-level models of behaviour change (e.g. organizational learning, context-based models) alongside simple learning theory models based on feedback procedures.
24. Consequently, the Aktionsbündnis Patientensicherheit advocates for the integration of patients as active partners into the development of quality improvement instruments.

25. The Aktionsbündnis Patientensicherheit advocates for the preferred use of appropriate process parameters for steering organizations and the system in the direction of realizing patient safety. While ex-post assessments based on outcomes are very important (for describing the status quo), their utility as steering parameters is limited by the ex-post perspective and the incentive to employ gaming strategies.
26. Technical and digital elements (health information technology, HIT) are important components of interventions for improving patient safety. The Aktionsbündnis Patientensicherheit calls for a differentiated application of these technologies underpinned by critical awareness regarding paradox effects that are recognizable even today.
27. The Aktionsbündnis Patientensicherheit emphasizes the centrality of complex multicomponent interventions (CMCI) in future quality improvement strategies. This type of intervention consists of multiple individual interventions, each of which originates from a different field (technology, integration of patients, learning, organization, system). International studies have demonstrated across several domains that CMCIs have achieved sustainable improvements to patient safety above and beyond the results of previous approaches.
28. The Aktionsbündnis Patientensicherheit demands that decision-makers in health policy carry the "Quality Offensive" from the previous legislative period into the newly commenced current legislative period in the form of a "Patient Safety Offensive" (cf. Ch. 6.4.2.).



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