Patient safety is an emerging, major health care discipline with significance accentuated in the influential Institute of Medicine (IOM) reports in the United States “To Err is Human” [1] and “Crossing the Quality Chasm” [2]. These reports highlighted the danger and prevalence of medical errors and preventable adverse events, explained the three main sources of system-related, human factors-related and cognitive-related errors, and recommended the use of information and decision support technologies to help alleviate the problem. A number of studies and reports from all over the world with similar findings have since followed, culminating in the 55th World Health Assembly Resolution on Patient Safety [3] and the 58th World Health Assembly Resolution on eHealth [4]. These efforts initiated a global mandate to improve patient safety in health care; one of the critical strategies identified is to adopt and apply effective and efficient information technology (IT) solutions and clinical decision support technologies [5].

A number of advanced knowledge representation and decision support techniques in general use today were first introduced or demonstrated in clinical decision support settings, e.g., rule-based systems [6], model-based systems [7], Bayesian networks [8], etc. With the exception of some established health information systems and various information management and communication frameworks applied in specific clinical tasks and settings, however, widespread adoption of clinical decision support systems that can assist clinicians in complex decision situations has seen limited success. Many factors have prevented the general adoption of clinical decision support technologies; different technological, cognitive, behavioral, and organizational barriers have often been cited [9].

Experiences gained and lessons learned in the past have helped identify a set of desiderata for successful, modern clinical decision support systems: patient-centric functionalities, evidence-based recommendations, easy-to-use interfaces, standardized terminologies and languages, collaborative development and application settings, easy development, maintenance and dissemination processes, and close integration with clinical workflow. These features would facilitate the right information to be delivered to the right person (or decision maker) at the right time and at the right place; the ultimate objective is to have clinical decision support transparently, seamlessly, and unobtrusively integrated into and enable effective and efficient patient care [10].

New approaches to improve patient safety through IT solutions and decision support systems call for: 1) advanced pattern recognition and risk management methodologies to better diagnose diseases and predict outcomes; 2) patient-specific, evidence-based computerized clinical practice guidelines (CPGs) to reduce variation in care practices, lower costs, and improve care outcomes; and 3) practical planning and decision making techniques for developing and integrating intervention recommendation and execution into the clinical workflow.

This issue of Methods includes a collection of three articles on the theory and practice of representing and reasoning with complex diseases, clinical tasks, and de-
cision logics in diagnostic systems and computerized CPGs. This topic complements the topic of process modeling in the development of clinical information systems to appear in the next issue [11]. Together, these two collections include editorial, survey, and original research articles that contribute toward the overall theme of concept representation and process modeling in decision support to improve patient safety.

In recent years, the concerns on patient safety and the quest to reduce medical errors have led to growing interest in and active development and application of evidence-based CPGs. CPGs, as defined by IOM, refer to systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances [12]. Computerized CPGs integrate guideline models into the clinical workflow to enhance the advantages of guidelines by supporting timely decision making.

Latoszek-Berendsen et al. [13] presented a comprehensive literature survey on the theory and practice of both general and computerized CPGs. While there are a number of systematic review articles on computerized guideline models, this survey focuses on guideline characteristics, development and implementation, and dissemination. The authors examined the motivation and objective of developing computerized CPGs, identified the characteristics of high-quality guidelines and the relevant evaluation methods and appraisal systems, and surveyed methods for guideline formalization, computerization, and implementation. They showed how CPGs affect the care processes and patient outcomes, and discussed the reasons for low CPG acceptance. The authors concluded that successful implementation of computerized CPGs can be facilitated by adopting standardized terminologies and interfaces, integrating with the patient’s electronic medical record (EMR), providing evidence-based, personalized recommendations, setting up dissemination model for easy updating of guidelines, and establishing appropriate evaluation methods to assess quality of the guidelines and individual recommendations. Due to cost concerns, sharing of CPGs is also important for guideline development, implementation, and dissemination.

While the actual impact of CPGs on the clinical workflow and patient outcome is still inconclusive and sometimes controversial, there is unquestionable urgency and irreversible trend in using information, communication, and decision support technologies to help improve patient safety. The thought process of carefully specifying concept and task models of guideline care, and the formal nature of the computerized version support formal verification; these practices should lead to fewer inconsistencies and omissions in the health care processes.

The insights gained from this study have highlighted some of the main medical informatics challenges in supporting effective guideline-based care. One major challenge is in effective concept representation that would allow accurate description and efficient application of the guideline models. Another important challenge is in minimizing the effort in specifying the guideline models, thereby facilitating development, dissemination, implementation, and adoption of the guidelines.

Dominguez et al. [14] introduced an engineering approach using common tools and systems to automatically generate guideline-based decision support systems (DSSs) and store the relevant application data for traceability. The approach combines model-driven development techniques with database schema mappings for metadata management to generate guideline-based persistent components in the DDSs. Standard statecharts in the Unified Modeling Language (UML), a general purpose system development process modeling language, are used to capture the dynamics of the guidelines, and to generate the guideline-dependent components. The application data, stored in bitemporal databases, can reconstruct what the users of the database actually could have known from available information, thereby supporting both research and legal queries. The only manual activity, but perhaps also the most challenging part in the system generation process, is in specifying the medical knowledge and guideline logic in the UML statecharts. Using existing computer-assisted software engineering (CASE) tools, the system is implemented and validated as an Eclipse plug-in.

The authors attributed their approach to “guideline compilation”, in the software engineering vocabulary, in contrast with the “guideline interpretation” approach adopted by most specialized guideline modeling languages, such as GLIF, PROforma, Asbru, etc. Commonly used in existing guideline-based DSSs, the guideline languages are formal representations with specific domain ontology. Together with the targeted parsers in the guideline execution engines, they are often connected with EMR data to ease storage, updating, and application of the guidelines. Such specialized guideline languages and frameworks, however, could incur overhead in understanding and mastering the rules and formats involved in the modeling process, and inadvertently lead to errors and inconsistencies in the resulting guideline models. In this work, mainstream tools and systems are put together instead to support complex domain-specific tasks. This approach is an alternate attempt to ease guideline development and maintenance, aiming for rapid system construction and wide acceptance. While a different set of challenges in transforming and mapping domain-specific knowledge into the generic formats may exist, the proposed approach showed promise in its adaptability and generality, and hence could potentially facilitate adoption, compliance, and quality assessment and monitoring in guideline-based decision support.

Research and development in both paper-based and computerized CPGs focuses on interpretation and representation of the medical concepts, clinical tasks, and decision logics involved. This emphasis is to be contrasted with the process modeling perspective, which also addresses whole system development methodologies, including requirement elicitation and user acceptance. Moreover, the definitions of the concepts, tasks, and logics in current guideline-based and other clinical decision support systems are often pre-determined, and represented in generally accepted or simplified conceptual models and data structures as, for example, disease-symptom pairs or clusters, production rules, frames, networks, etc. With the rapid ad-
vancement of medical knowledge and increasing availability of patient data and care information, new opportunities arise for closer examination and understanding of the complex disease dynamics. More accurate representation of the underlying disease model would facilitate both diagnosis and treatment to improve patient safety.

Bhavnani et al. [15] combined exploratory network analysis with quantitative data reduction techniques to identify co-occurrence of multiple symptoms in cancer patients. They proposed using network visualization to discover data structure before applying data reduction methods with appropriate biases to quantitatively analyze data. As most cancer patients exhibit multiple symptoms as their condition worsens, understanding how symptoms co-occur would lead to better cancer care management and improve patient outcome and quality of life. Unlike direct data reduction methods, the proposed approach does not assume a priori structures such as hierarchies or clusters in the data.

Network analysis allows identification of multiple structures – hierarchical, disjoint, overlapping, and nested structures. Insights gained can be used to apply or further develop new quantitative measures to analyze and validate the results; these include measurement using network modularity and hierarchical clustering, and degrees of symptom overlap and co-occurrence.

With the new data analysis approach, the authors found that cancer symptoms often co-appear in nested structures, with various degrees of overlapping in different patients. This is in contrast to the common belief of symptoms occurring in clusters in many diagnostic systems. This work demonstrated the power of combining exploratory network analysis and statistically sound quantitative methods to identify or discover complex patterns in multivariate problems in medicine. This work also contributed to the formal evaluation of degrees of overlapping in nested structures and its use in symptom assessment and management in diagnosis.

One of the emerging trends in managing complex diseases is to regard diagnosis as efficiently managing and resolving uncertainty to safeguard patients from misdiagnosis or diagnostic errors [16]. Computerized decision support would help both in improving diagnostic reasoning and training clinicians to be effective and evidence-based diagnostic thinkers. There is a need to better understand and model the complex etiology, manifestation, and progression of diseases, with and without interventions. There is also a need to accurately transform or map what we know or understand about medical knowledge and decision logic into computer-interpretable programs for actionable recommendations. The three articles illustrated some current trends toward effective and efficient concept representation in decision support. One other important aspect, which is not reflected in this collection of articles, is on integrating and learning from multimodal information, including expert opinions based on cognitive understanding and experience, offline and patient-specific structured and image data, and physiological signals, to build and update predictive models for diagnosis, pattern recognition, treatment planning, and guideline generation. Together with effective concept representation and process modeling, advancement in this direction would allow clinical decision support systems to deal with change efficiently, and facilitate their development, maintenance, implementation, and adoption to improve patient safety.

References