

# ERASMUS+ KA2 Strategic Partnership 2017-1-FI01-KA203-034721 HELP – Healthcare Logistics Education and Learning Pathway



# PhD module: Pre-assignment





# ERASMUS+ KA2 Strategic Partnership 2017-1-FI01-KA203-034721 HELP – Healthcare Logistics Education and Learning Pathway



## Typical logistic problems in healthcare illustrated

#### Presentation







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#### Compulsory reading (included in this package)

For logistics: Volland (2017)

For risk mgmt.: ECRI (2019)

For care pathways: Lodewijckx (2012), Deneckere (2012)

For "future outlook": Deloitte (2017)

#### Recommended reading (students pick the materials in the areas new to them)

Griffin, D.J., 2012. Hospitals: What they are and how they work, 4th ed, Jones & Barlett Learning.

Graban, M., 2016. Lean Hospitals, CRC Press.

Denton, B., 2013. Handbook of Healthcare Operations Management: Methods and Applications, Springer.

Hall, R., 2012. Handbook of Healthcare System Scheduling, Springer.

Vissers, J. and Beech, R., 2005. Health operations management: Patient flow logistics in health care, Taylor & Francis.

McLaughlin, D. and Olson, J., 2017. Healthcare operations management, 3th ed, Health Administration Press.



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#### Review

### Material logistics in hospitals: A literature review<sup>☆</sup>



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#### ABSTRACT

Hospital material management has been identified as one key cost containment lever to cope with steadily increasing healthcare costs in industrialized countries. The purpose of this work is to present the state-of-the-art of research on material logistics management in hospitals. Particular focus is given to articles that apply quantitative methods. Our contribution is threefold: First, we provide research guidance through categorizing literature and identifying major research streams. Second, we discuss applied methodologies and third, we identify future research directions. A systematic approach is undertaken in order to identify the relevant literature from 1998 to 2014. Applicable publications are categorized thematically and methodologically and future research opportunities are worked out. In total, 145 publications are identified and discussed in this work. The literature is categorized into four streams, i.e., (1) Supply and procurement, (2) Inventory management, (3) Distribution and scheduling, and (4) Holistic supply chain management. The use of optimization techniques is constantly gaining importance. The number of respective publications has continually grown and has peaked over the last three years. Optimization has been successfully applied in research streams (1), (2), and (3). Category (4) comprises a rather qualitative research field of literature dealing with supply chain management issues.

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#### 1. Introduction

In the countries of the OECD, total healthcare expenditures have grown with an average of 4% per year from 2000 to 2009 [127]. Hospitals account for 29% of total healthcare expenditures [128]. Of hospital costs, more than 30% are linked to logistics activities [122]. This makes logistics costs the second largest cost block after personnel costs [138,148]. Compared to other industries, material management and logistics have not been given high priority in hospital management research in the past. Possible reasons are the high complexity of healthcare supply chains and their merely supporting role in the foremost goal of hospital management, i.e., effective treatment of patients [13]. However, in the last fifteen to twenty years, logistics has been identified as one key lever to manage healthcare costs [164,33]. Research estimates that through efficient logistics management, around half of the logistics-related costs in hospitals can be eliminated [138].

The potential of hospital logistics optimization within the healthcare sector is considered significant both by academia and practitioners. The most obvious upside from optimizing material logistics is that cost reductions do not directly affect the quality of patient care [78]. In contrast, logistics-related activities are often performed by medical staff, taking away time from taking care of patients. In a recent survey among registered nurses in the U.S., time wasted on activities other than patient care, such as restocking supplies, was the major driver that negatively impacted nurses' time at bedside [75]. Relieving nurses from non-patient care related activities can thus improve the quality of care.

The aim of this work is to present the state-of-the-art of research on material logistics management in hospitals. In the discussion, we set a distinct focus on publications that apply quantitative methods. Respective papers are discussed in detail, e.g., by providing tables with deep-dive analyses on the applied methodologies. Our contribution is threefold: First, we provide research guidance by categorizing the literature and identifying major research streams. Second, we discuss applied methodologies and third, we identify future research directions. There exist rather general literature reviews on healthcare operations research/operations management (e.g., [42,68,141]). Also, a number of reviews exist on supply chain management (SCM) in healthcare, e.g., de Vries and Huijsman [165], who focus on the question whether or not there exist parallels between the industrial sector and healthcare services. Dobrzykowski et al. [38] thematically assess a more general scope than this work as they include operations management topics like service management, planning, and scheduling. Furthermore, they limit their review to publications from seven U.S. journals only and review a different time period (1982 to 2011). Consequently, to the best of our knowledge, there is currently no comprehensive review on material logistics in hospitals with a focus on quantitative methods. This publication fills the research gap.

The remainder of this article is structured as follows. Section 2 presents the methodology of the literature review and introduces a framework to cluster the relevant literature thematically. Section 3 provides a quantitative overview of topics, applied methodologies, and the regional coverage of assessed publications. Furthermore, an overview of all publications is provided. Sections 4–7 discuss the literature along this framework and point out future research potential. We present a conclusion and a summary of research opportunities in the final section.

#### 2. Methodology

#### 2.1. Scope

This paper reviews all relevant publications regarding the logistics activities of handling physical goods in hospitals. Physical goods comprise all items that are directly linked to the care of patients, like pharmaceuticals, medical consumables, food, laundry, sterile items, laboratory samples, waste, etc. Pharmaceuticals represent 70% to 80% of the supply costs, while medical-surgical materials account for 20% to 25% [142]. Non-patient care related products, e.g., office supplies, mail, etc., are excluded. Further, although partly included in logistics activities, flow of information is excluded. Due to its distinct characteristics, such as the irregularity of supply and the lacking comparability to the items stated above, blood products are out of scope of this review. Comprehensive reviews on SCM of blood products are available in the literature [149,15]. Considering the supply chain of goods from manufacturing to use, this review starts with the supply chain partners one step upstream from the hospital, i.e., typically the hospital-supplier interface. One exception is Section 4.4, where we shed light on the interface between drug manufacturers and wholesalers and implications for hospital purchasing. Also, reverse logistics is not in particular scope of this publication, however we refer to Srivastava [152] for designing a reverse logistics network. Logistics activities associated with outpatient treatment, like home delivery of meals or outpatient medication, are out of scope. Exemplarily, Liu et al. [104] present related work. Our restriction of scope is in line with existent literature, as hospital-internal logistics activities are the major source of competitiveness within healthcare material management [144,97]. Personnel planning and scheduling that is not directly related to logistics activities as well as bed and patient transportation are out of scope of this work.

#### 2.2. Identification of publications

In order to identify the relevant literature, a five-step approach is undertaken. First, Google Scholar and Science Direct are searched for relevant keywords, e.g., "hospital" and "logistics". Second, a forward and backward search of the most relevant publications is performed. Third, the categorization framework presented below is developed and the literature is classified accordingly. Fourth, another Google Scholar and Science Direct search applying relevant key words within the respective category is done. Fifth, a final forward and backward search within those publications concludes the search process. We limit our research to English articles published in peer-reviewed journals. Books, theses, PhD dissertations, conference articles, and working papers are neglected. A focus is set on publications after the year 1998 until yearend 2014. Of the papers published earlier, the most often cited ones are included. A review of previous work is included in Jarrett [78].

#### 2.3. Literature classification framework

The literature is thematically classified along the framework in Fig. 1. We identify four major research topics in the literature. Categories (1) to (3) comprise the supply chain that material follows before being used in hospitals. (1) Supply and procurement contains the literature regarding the purchasing of material as well as all activities related to the hospital-supplier interaction, for example outsourcing and means of supplier collaboration. Furthermore, the literature on demand forecasting is presented in this Section (2) Inventory management includes the literature on inventory policy, location planning, as well as classification schemes and practiceoriented inventory publications. Drug inventory management and drug shortages are also discussed. (3) Distribution and scheduling covers all material-linked distribution activities within and outside the hospital. In research topic (3), we focus on the actual transportation or distribution rather than the location of the goods as well as the handling of sterile medical devices. (4) Holistic supply chain management takes a holistic and mostly qualitative approach to optimize the supply chain.

All four research topics including their subtopics are presented and discussed. A focus is given to areas where quantitative methods are applied, however, for the sake of completeness and to provide insights on related research directions, the remaining research areas are also presented. The literature search yields 145 publications that are categorized along the presented framework. In case multiple categories are addressed, the publication is allocated to the most relevant category. Six methodological categories are distinguished.

Optimization (containing an operations research (OR) model), simulation/scenario analysis, empirical research, literature review, theory/conceptual (introducing or discussing new theory or concept), case study (findings from practical research projects etc.).

#### 3. Publication meta analyses

The subsequent section provides a quantitative assessment of the identified publications. Publications in this section are assessed from three perspectives: Thematically, methodically, and regionally. Thereafter, an overview is provided, and research opportunities are identified.

#### 3.1. Thematic categorization

We generally limit the scope to publications published from 1998 onwards. However, eight earlier publications are included due to their pivotal importance for the relevant literature streams. A time-wise development of publications and its thematic scope along our review framework is provided in Fig. 2. The different shadings reflect the allocation to our four main categories.

The number of publications has grown considerably over time. The increasing relevance of hospital material logistics in academia is indicated by a nearly doubled number of publications from 2009 to 2011 until 2012 to 2014. The categories with the highest growth rates over the last years are (3) Distribution and scheduling and (2) Inventory management. Both categories combined account for an increase in publications from 14 between 2009 and 2011 to 34 between 2012 and 2014. In the entire time span, the majority of publications, 66 papers, has been published in (2) Inventory management.

#### 3.2. Methodological categorization

The methodologies applied in the reviewed publications are presented in Fig. 3. In the chart, the color of the shapes indicates the quantitative nature of the applied methodologies. Over the entire time span, papers have most often been published in the field of case studies with 47 publications, and theory/conceptual with 32 publications. The category of optimization has experienced a large increase of publications from four in 2009 to 2011 to 15 in 2012 to 2014. This indicates a further evolving interest in the field of operations research on hospital materials management. The second quantitative-focused category, simulation/scenario analysis, also peaks in the last time segment, underlining the importance of quantitative research in hospital materials management.

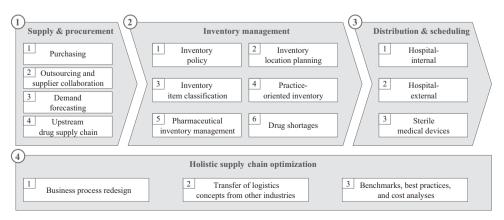


Fig. 1. Literature classification framework.

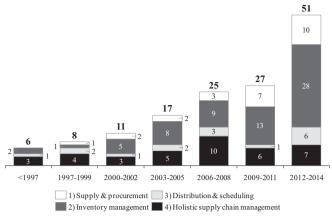


Fig. 2. Thematic categorization.

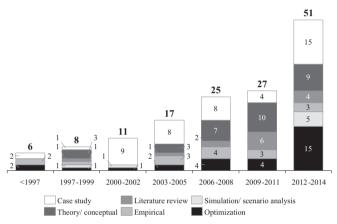


Fig. 3. Methodological categorization.

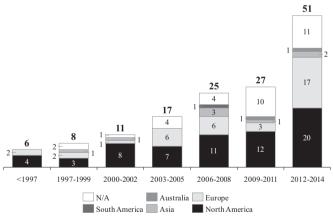


Fig. 4. Regional coverage of publications.

#### 3.3. Regional categorization

In this section, the regional scope of the assessed publications is presented. This is to be understood as the place where research relates to, e.g., where the relevant case hospital is located. However, the location of the research institution is not relevant for this overview. Fig. 4 presents the regional scope for the entire time span. N/A indicates either publications that take a global scope, e.g., literature reviews, or methodology-focused publications, or that it was simply not possible to identify which locations the publications relate to. The filling indicates the regional allocation of publications. North America and Europe are the continents with the most

publications during the entire time span with 65 articles and 37 articles respectively. Combined, this accounts for more than two thirds of total publications. Within North America, the U.S. account for 54 publications making it the country with most publications globally. Within Europe, the U.K. and the Netherlands lead with nine and six publications respectively. Due to the strongly regulated nature of national healthcare systems and their significant regional differences, it is of pivotal importance to perform research with a clear regional focus, considering specifics in national legislation. In our review, only English publications are considered, which might bring forward publications from English speaking countries and thus slightly bias the regional coverage display.

#### 3.4. Overview of publications

A thematic and methodological overview of all publications is presented in Table 1. We derive that optimization techniques are mostly applied in (2) Inventory management and (3) Distribution and scheduling. Both research areas are characterized by rather welldefined problem settings that also occur in other industries, such as manufacturing. (1) Supply and procurement also offers possibilities to apply optimization techniques, but only five publications exist in this field of research. In (4) Holistic supply chain management however, no publications exist that apply optimization techniques. Potentially, this is due to the high complexity of integrated processes and the hard to define nature of holistic supply chain problems. Instead, mostly qualitative research is applied, namely theoretical/ conceptual research or case studies. Another interesting insight is that most literature reviews are published within this field. This underlines that this publication fills a research gap as it focuses on publications applying quantitative techniques. A further evident research gap lies within the application of case studies and conceptual research in the field of (3) Distribution and scheduling.

#### 4. Literature on topic: (1) Supply and procurement

A natural approach to minimize material costs is to minimize the actual purchasing costs. Supply chain costs constitute a major part of hospitals' operating expenses. For example, U.S. hospitals spent \$27.7 bn. for drugs alone in 2009 [39]. Hospital material management literature mainly focuses on four areas. First, bundling of purchasing volumes and thus increasing purchasing power. In this stream of literature, hospital group purchasing organizations (GPOs) are chiefly discussed. Hospitals strive to increase their purchasing power against suppliers by combining their respective purchasing volumes. The second stream of literature primarily discusses hospital inventory outsourcing approaches, e.g., stockless inventory systems or vendor managed inventory (VMI), with regards to supplier integration. The third section offers an overview of demand forecasting, which is of high relevance for the hospital-supplier interface, while the last section sheds light on specifics of the upstream pharmaceutical supply chain and potential implications for hospital buyers. All four streams are presented below.

#### 4.1. Purchasing

Hospitals are mostly organized in GPOs, i.e., voluntary alliances aggregating hospitals' purchasing volumes. In the U.S., 90% to 98% of hospitals are organized in purchasing alliances [24]. GPOs help to reduce material costs in a twofold manner. First, they allow leveraging economies of scale due to purchasing volume bundling. Second, they enhance price transparency and create price ceilings through framework contracts in which price bands are agreed on [24]. A qualitative comparison of advantages and disadvantages of GPOs is provided by Rego et al. [142] and Burns and Lee [24]. In line with the remainder of

**Table 1** Overview of publications.

	(1) Supply and procurement	(2) Inventory management	(3) Distribution and scheduling	(4) Holistic supply chain management
Optimization	Hu and Schwarz [66] Iacocca [70] Rego et al. [142] Ross and Jayaraman [148] Zhao et al. [170]	Baboli et al. [9] Bijvank and Vis [21] Dellaert and van de Poel [37] Guerrero et al. [57] Kelle et al. [84] Little and Coughlan [103] Nicholson et al. [124] Priyan and Uthayakumar [140] Rosales et al. [146] Rosales et al. [147] Uthayakumar and Priyan	Augusto and Xie [7] Bailey et al. [10] Banerjea-Brodeur et al. [11] Kergosien et al. [85] Lapierre and Ruiz [98] Medaglia et al. [116] Michelon et al. [119] Ozturk et al. [130] Shih and Chang [150] Swaminathan [153] Tlahig et al. [155]	
		[157] Vila-Parrish et al. [163]	Van de Klundert et al. [90]	
Simulation/ scenario analysis	Azzi et al. [8]	Gebicki et al. [53]	Dean et al. [36]	Iannone et al. [71]
unuiysis		Pasin et al. [132]	Di Mascolo and Gouin [107]	Iannone et al. [72]
Empirical	Burns and Lee [24] Nollet and Beaulieu [125] Oumlil and Williams [129] Kumar et al. [95]	Baumer et al. [12] Beier [13] De Vries [164] Fox and Tyler [51] Hall et al. [63] Huarng [67] Kaakeh et al. [82] Lee and Shim [101] McBride et al. [112]		Kafetzidakis and Mihiotis [83] Kim and Schniederjans [89] Zheng et al. [171]
Literature review	Jack and Powers [74]	Coustasse et al. [31] Irani et al. [73] James et al. [76] Fosso Wamba et al. [49]	Beliën et al. [14]	Abukhousa et al. [2] De Souza [151] De Vries and Huijsman [165] Ford and Scanlon [48] Jarrett [77] Jun et al. [81] Mazzocato et al. [111] Young et al. [168]
Theory/concept	Cruz and Marques [32] Brennan [23] Fein [43] van Donk [40]	Almarsdóttir and Traulsen [3] Alspach [5] Danas et al. [35] Fox et al. [50] Gu et al. [56] Gupta and Huang [59] Huys and Simoens [69] Johnson [80] Le et al. [100] Lee and Özer [102] Mangan and Powers [105] Mazer-Amirshahi et al. [110] McLaughlin et al. [114] McLaughlin et al. [115] Meiller et al. [118] Phillips and Berner [134] Rider et al. [143] Vaillancourt [158] Ventola [161]		Chandra [28] Di Martinelly et al. [106] Jarrett [78] Kim et al. [87] Kollberg et al. [91] Landry and Beaulieu [96] Meijboom et al. [117] Whitson [166] Young and McClean [169]
Case study	Bendavid et al. [16] Bendavid et al. [17] Bhakoo and Chan [19] Bhakoo et al. [20] Guimarães et al. [58] Haavik [61] Matopoulos and Michailidou [108]	Abijith and Fosso Wamba [1] Beso et al. [18] Çakıcı et al. [25] Chan et al. [27] Chang et al. [29] Danas et al. [34] Fitzpatrick et al. [47]	Mühlich et al. [120]	A. Kumar et al. [94] Aptel and Pourjalali [6] Born and Marino [22] Coulson-Thomas [30] Dacosta-Claro [33] Fillingham [45] Ferretti et al. [44]
	Mustaffa and Potter [121] Rivard-Royer et al. [144]	Franklin et al. [52] Granlund and Wiktorsson		Heinbuch [64] Jayaraman et al. [79]
	Varghese et al. [159]	[54] Griffith et al. [55] Gupta et al. [60] Khurana et al. [86] Koppel et al. [92] Maviglia et al. [109]		Kriegel et al. [93] Landry and Philippe [97] McKone-Sweet et al. [113] Pan and Pokharel [131] Trägårdh and Lindberg [156]

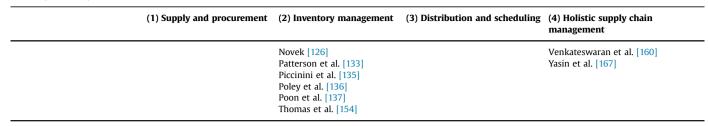


 Table 2

 Purchasing publications containing optimization models.

Publication	Problem description	Model characteristics	Objective function	Type of goods
Hu and Schwarz [66]	Role of GPOs in healthcare supply chain and cost reduction potential	Hotelling duopoly model	Minimize costs	Not specified
Rego et al. [142]	Decision support to set number of GPOs, size and composition for hospitals willing to cooperate	Metaheuristic (hybrid VNS/tabusearch)	Minimize hospitals' shared supply chain costs	Not specified
Ross and Jayaraman [148]	Purchasing strategy for bundled refurbished medical products	Mixed-integer problem solved with SA heuristic	Minimize total acquisition costs of purchasing plan	Durable items (new and refurbished)

this article, publications containing optimization models are displayed separately (see Table 2) and discussed in depth.

Rego et al. [142] present a decision support tool helping hospital purchasing managers to identify and to assess alternative GPO forms. For a defined group of hospitals willing to cooperate, the tool presents the number, size, and composition of GPOs and a financial assessment. A metaheuristic comprised of a two-module hybrid variable neighborhood search (VNS) and tabu search is applied to solve the optimization problem. The tool allows evaluating alternative cooperative purchasing strategies and is applicable for a wide range of purchasing groups. Ross and Jayaraman [148] focus on the single-hospital level. They assess how products should be bundled when placing orders at suppliers. They especially focus on bundling new products with refurbished products, which several U.S. healthcare providers have recently started to explore in order to reduce material costs. Examples for refurbished products constitute investment goods such as medical devices or electric beds, which are bundled with (new) consumable products. The authors develop a mixed-integer program (MIP) aiming to minimize the total purchasing costs. They build a heuristic based on simulated annealing (SA) to find near optimal purchasing strategies, i.e., which products to buy from which supplier and decide if to conduct a bundle or single item purchase. Potential item surplus in bundles exceeding the buyer's requirements are minimized in the objective function (apart from purchasing costs). Hu and Schwarz [66] assess the general role of GPOs in the healthcare supply chain and their impact on pricing mechanisms with a hotelling duopoly model. They find that GPOs indeed achieve lower prices for healthcare providers through increased competition between manufacturers. However, they carve out downsides of GPOs like reducing incentives for manufacturers to innovate and enhance their existing product portfolio.

Non optimization-focused publications include the following: Oumlil and Williams [129] discuss strategic purchasing alliances in the healthcare sector both in terms of organizational factors as well as personal factors. Organizational factors include, e.g., the hospitals' type and size while personal factors comprise, e.g., the education and the experience levels of purchasing managers. They find that selected demographic characteristics of purchasing managers are linked to decisions on alliances. For instance, job experience and the success of the alliance are related. Burns and Lee [24] provide an empirical

study on the utilization, services, and performance of hospital purchasing alliances from the hospital material management's point of view. The authors find that purchasing alliances achieve cost reduction by lowering product purchasing prices, especially for commodity and pharmaceutical products. They stress that alliances further reduce transaction costs as contracts are commonly negotiated. However, cost benefit realization is hindered for service products or when physicians prefer certain items. Burns and Lee [24] further present several literature streams – not necessarily related to operations management – in the field of purchasing alliances, such as pooling alliances and value-chain alliances.

Another empirical study states that purchasing groups are subject to lifecycle stages [125]. The authors identify critical characteristics influencing the development of purchasing groups. These include payers' intervention, nature of benefits, procurement strategy, nature of relationships with suppliers, structure, and resources. They further develop a lifecycle model to show the evolution of GPOs and the changing importance of these characteristics.

Regarding future research opportunities in terms of methodology, Ross and Jayaraman [148] underline the combinatorial complexity of practical problems in healthcare logistics, marketing, and purchasing. They propose the development of heuristics in order to cope with large problem instances. Generally, there seems to exist a bias in this research stream towards manufacturing industries, thus healthcare in particular provides further research opportunities [129]. Other potential research fields include the assessment of performance determinants of GPOs to facilitate comparisons across purchasing alliance characteristics, e.g., in terms of size or management. Furthermore, such research would allow to identify the potential to differentiate between GPOs [24]. Also, assessing outsourcing activities compared to GPOs seems worthwhile for future research. Past publications indicate that the attractiveness of outsourcing logistics is positively correlated to hospital size [129].

#### 4.2. Outsourcing and supplier collaboration

It is widely accepted that outsourcing logistics activities to third party providers can generate significant efficiency advantages for both parties due to economies of scale and scope, fixed cost reduction, and focus on core competencies [72,8]. There are many

general studies on logistics outsourcing, but literature concerning healthcare is rather scarce, which is in line with the overall tendency in the healthcare sector to slowly embrace new SCM practices [113]. However, outsourcing inventory decisions to healthcare providers has recently gained importance, especially in practice where outsourcing concepts are widely applied [124]. Kim et al. [88] stresses the potential of VMI in the healthcare sector. The author finds that hospitals can significantly reduce inventory stock. However, he states that supply chain integration might be hindered due to the absence of standards for information sharing and missing participation of pharmaceutical manufacturers in collaborations.

In order to assess outsourcing opportunities, scenario modeling is applied in several publications. Azzi et al. [8] consider different outsourcing options for a healthcare network in central Italy, comprising several hospitals and one centralized logistics hub. The authors both qualitatively and quantitatively evaluate three scenarios with varying outsourcing degrees: Logistics self management, partial logistics outsourcing, and total logistics outsourcing. The qualitative assessment is mainly based on an extensive literature review while the quantitative assessment of outsourcing options is performed using a system dynamics simulation. The authors state that logistics outsourcing is often the most economical option for different sets of distribution network layouts. van Donk [40] develops a tool to assess several potential supply chain designs between a hospital and its supplier of medical and non-medical gases. Nicholson et al. [124] compare inventory costs of an in-house 3-echelon distribution network vs. an outsourced 2-echelon distribution network (i.e., direct delivery to the care unit) for non-critical medical items. For a detailed analysis of this paper, see Section 5.1.

There is a large stream of literature presenting and discussing case studies without quantitative methods or simulation/scenario analyses. One example that is thematically linked to the previously discussed publication is the work by Rivard-Rover et al. [144]. They present a case study in a Canadian hospital that applies a hybrid stockless inventory management system. Hybrid means that suppliers have two options to deliver to the hospital. Either they supply goods to the hospital's central warehouse, which is the classical approach, or the suppliers pack products according to the need of the respective care unit and perform direct delivery. The authors find that the hybrid model may yield marginal benefits compared to the classical approach. They also show that different forms of packing are a significant lever for cost savings. This packaging issue is analyzed in more detail in the publication by Kumar et al. [95]. The authors empirically assess whether package design plays a significant role in the hospitals' purchasing decision making process. They find that packaging and environmentally friendly supplies do currently not play a pivotal role in purchasing decisions in the U.S. Further case studies regarding VMI concepts in the hospital surrounding are presented in Bhakoo et al. [20], Guimarães et al. [58], Matopoulos and Michailidou [108], and Mustaffa and Potter [121]. All publications provide a good overview of the overall concept as well as its application in the hospital setting. Bhakoo et al. [20] state that VMI has widely been ignored in the healthcare industry. They qualitatively assess different collaborative arrangements between hospitals and pharmaceutical suppliers, such as the "ward box", a variant of VMI where hospitals place direct orders of the items required in a specific ward and the suppliers deliver to the ward without taking the detour of a central warehouse. They remarkably find that hospital material managers were more willing to undertake collaborative arrangements along the supply chain than their suppliers. Guimarães et al. [58] present an assessment of VMI regarding its benefits, risks, barriers, and enablers. They further conduct a case study of a multi-location hospital that aims to create transparency along its value chain. Matopoulos and Michailidou [108] study the application of CMI (co-managed-inventory), a form of VMI where hospitals remain partly responsible for inventory. The authors present a case study for a Greek hospital. Mustaffa and Potter [121] assess a private hospital in Malaysia and its supplier relations and identify two issues: Urgent orders and stock availability at the wholesaler. Based on their findings, they propose the introduction of a VMI setup in order to cope with these difficulties. Bhakoo and Chan [19] summarize complexity factors around pharmaceutical healthcare supply chains. They present factors that hinder the implementation of e-business processes in the procurement area of healthcare supply chains: Lack of consistency, poor data quality, and the global nature of supply.

Comparable to VMI approaches are consignment agreements in the hospital sector, where ownership of goods remains with the suppliers until they are consumed. This approach is mostly applied for expensive items, such as implants [41]. Compared to VMI approaches, recent literature on consignment agreements is rather scarce and focuses on case studies [16,17]. The authors present an RFID-based traceability system for consignment and high value products. Compared to other systems in the market, such as RFID-enabled cabinets or smart shelves, the system is rather simple and has lower technological requirements.

One obvious future research area is the extension of the outsourcing degree from VMI, where suppliers take over responsibility for hospitals' inventories, towards just-in-time (JIT). JIT means that suppliers provide goods to point-of-use locations in hospitals without intermediate buffer inventories. The implementation of JIT concepts in hospital supply seems to be hindered, however. Identifying underlying reasons and providing ideas on how to embrace those difficulties could be an interesting future research field. For a continued discussion on the general applicability of IIT, please refer to Section 7.2. Also, as mentioned before, the availability of information across the supply chain might hinder the applicability of more integrated supply chain concepts. Identifying how to increase data transparency, while respecting intellectual property rights and legal constraints, might bear future research opportunities. Another potential research area could be the application of optimization techniques in outsourcing. So far, optimization models have not been applied in this research field. Potential questions include determining the characteristics of products that could be outsourced or defining the optimal outsourcing degree, i.e., answering which product categories are appropriate for outsourcing.

#### 4.3. Demand forecasting

One major obstacle for a better integration of hospitals and their suppliers is the unpredictable nature of hospital demand. It is argued by numerous researchers that the patient mix and the resulting demand for materials is very hard or impossible to predict [32,62,65,10,103]. However, as contracts with suppliers are occasionally building on minimum purchase quantities, accurate demand forecasting is of high relevance for hospital purchasing managers. Brennan [23] stresses the importance of regular demand forecasts based on clinical guidelines linking patient groupings' requirements with resulting materials demand. To tackle unreliable resource demand predictability, Varghese et al. [159] apply demand forecasting algorithms. Haavik [61] stresses the importance of sharing hospital demand information with suppliers, e.g., through implementing VMI software able to forecast demand and placing orders at suppliers accordingly. Danas et al. [34] cope with demand uncertainty through several point-of-use inventory locations to one large virtual inventory in an attempt to reduce demand uncertainty. For further reading, we refer to Jack and Powers [74], who provide a literature review on demand management and capacity management in healthcare services, and Narayana et al. [123], who investigate the redesign of the pharmaceuticals supply chain, not limited to hospitals. Improving forecasting mechanisms for hospital demand seems to bear worthwhile future research opportunities.

#### 4.4. Upstream drug supply chain

In this section we offer a brief overview of changes in the upstream drug supply chain, i.e., the interface between drug manufacturers and wholesalers. We specifically point out one aspect that has an impact on hospital pharmacies.

Starting in the year 2005, the payment and distribution scheme of the U.S. pharmaceutical supply chain went through a significant transition. Drug manufacturers and wholesalers changed their collaboration model from Buy-and-Hold (BNH) to Fee-for-Service (FFS) [70]. In the BNH scheme, one of the wholesalers' major revenue sources was to speculate on drug price increases. When wholesalers held high stock levels and manufacturers increased their prices, wholesalers would hand down the higher price to their buyers, namely hospitals pharmacies. Apart from high stock levels, this scheme resulted in several other disadvantages, such as big fluctuations in wholesalers' order quantities, revenue losses for drug manufacturers, as well as unstable and unpredictable wholesaler revenues [170]. In the FFS scheme however, the wholesalers agree to reduce or eliminate the afore mentioned drug investment buying in return for fees paid by drug manufacturers to hold inventory and fulfill their distribution role [70]. According to Fein [43], the FFS scheme comes with two major threats for hospitals. First, the wholesalers' discount range is reduced as they share detailed order, inventory, and shipment data with drug manufacturers. This reduces their volume buying potential and consequently their discount range. Second, as inventory levels at wholesalers are reduced, the threat of drug shortages is significantly higher in the new scheme (see Section 5.6).

In this research area, two publications might be of interest for hospital pharmacy buyers. Zhao et al. [170] investigate the design and benefits of FFS contracts and derive implications for inventory policies and their parameters for drug manufacturers and wholesalers. Iacocca et al. [70] compare the differences of the two schemes and a third payment and distribution scheme, the Direct-to-Pharmacy (DTP) agreement, where wholesalers manage drug distribution and inventory for a fee, but the manufacturers remain the owner of the drug until it reaches the point-of-use [70]. As the focus of the presented publications lies mostly on the manufacturer-wholesaler interface, we believe that future research should focus on the explicit implications for hospital buyers.

#### 5. Literature on topic: (2) Inventory management

While the management of inventory systems has been widely discussed in the industrial context, healthcare managers have traditionally paid little attention to the management of inventories [164,58,84,124,149]. However, in recent years, the management of

inventory has been identified as one key lever to realize efficiency improvements without negatively affecting the care of patients. Scholars estimate that 10% to 18% of hospitals' net revenues are spent on inventory costs [78,124]. Hospitals in the U.S. and in France hold an average amount of USD 4,000 and USD 5,720 per bed in medical supplies alone, respectively [6].

In hospitals, goods distribution is typically designed as a multiechelon inventory system. A central warehouse receives goods from suppliers. Commonly, the central warehouse is closely connected to the central pharmacy being in charge of pharmaceuticals handling and the production of perishable drugs, e.g., intravenous fluids. The central warehouse regularly delivers to the point-of-use inventories that are typically located close to patient care locations (see Fig. 5; similar figures may be found in Bijvank and Vis [21]; Rivard-Royer et al. [144]). Apart from this "traditional method", two other goods distribution systems are typically applied in practice, i.e., "semidirect delivery", where the suppliers skip the central warehouse and deliver directly to the point-of-use location. The third approach, "direct delivery", is closest to IIT meaning that the supplier takes responsibility for reacting to patient demand and refilling supplies at the point-of-use locations [6]. Scholars distinguish between the hospital-external and hospital-internal supply chain. While external supply chain integration efforts receive most of the attention from the area of SCM, the internal supply chain remains the weak spot of the entire chain [97].

Regarding the setup of hospital inventory systems, several studies argue that hospital inventory management is to some extent comparable to other industries. Thus, proven concepts can be transferred to the healthcare industry. Due to the storage space constraints at the point of delivery, i.e., the care unit, laboratory, or the operating theater, Little and Coughlan [103] argue that the respective inventories are comparable to retail. Another retail inventory management aspect that could be incorporated in the healthcare environment is the application of "actual use inventory management", meaning the use of point-of-use data in the upstream supply chain [159]. Danas et al. [35] see strong similarities with the case of spare part inventories for production machines in industrial plants. Decision makers are faced by a trade-off between the costs for production delays and the costs for safety stock. Literature on hospital inventory management is presented in the following section. The discussion starts with the most relevant field of literature, which is "inventory policy". Thereafter, publications in "inventory location planning", "inventory item classification", and "practice-oriented inventory" are discussed. Afterwards, we present specifics of and additional requirements in the management of drugs in "pharmaceutical inventory management". The chapter concludes with a section

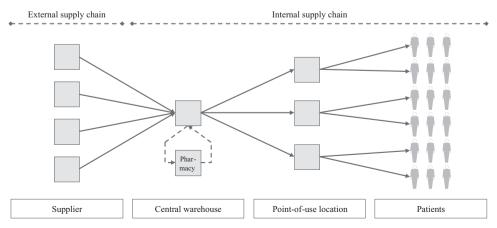


Fig. 5. Illustrative supply chain.

focusing on drug shortages and strategies on how to avoid them. Future research directions are provided at the end of each section.

#### 5.1. Inventory policy

The following section presents the literature regarding inventory policy. The most widely discussed topic is the choice of the suitable inventory policy, which comprises the definition of the inventory review cycle (periodic or continuous) and parameter setting for the reorder point, the reorder quantity, and/or the order-up-to level. All presented publications include optimization models. Aspects of hospital inventory management literature reviews may further be found in the following publications. Bijvank and Vis [21] frame their problem with a brief review of replenishment policies for hospital inventory systems, de Vries [164] gives an overall introduction into inventory management, and Rosales et al. [146,147] introduce their research with a general review of inventory models and briefly discuss related quantitative models in the hospital setting.

The section starts with an overarching discussion of the inventory review logic. Thereafter, the publications are clustered along the inventory locations that they address. It starts with "multi-echelon", followed by the "central inventory". Then, the focus shifts towards the patient, meaning the "point-of-use location". At the end of the section, future research opportunities are presented.

#### 5.1.1. Inventory review logic

As the notation in the literature varies, we introduce the following notation in order to make policies comparable: T (Review cycle time), s (reorder point), O (order quantity), S (order-up-to level), c (can-order point). An overview of the basic inventory policies is provided in Fig. 6. We distinguish between periodic review and continuous review. Periodic review comprises the (T. S) policy, which is also called "par level policy". It means that after every review cycle T, orders are triggered so that the order-up-to level S would be on stock. Continuous review comprises two basic policies. The first policy is the (s, Q) policy, where whenever inventory levels fall under reorder point s, a refill quantity of Q is triggered. The second continuous policy is the (s, S) policy, where instead of a fixed reorder quantity Q, orders are triggered so that the order-up-to level S would be on stock, as soon as storage falls below reorder point s. N/A indicates that the policy framework is not applicable. A performance comparison of periodic fixed order size replenishment policies and order-up-to policies is provided in Bijvank and Vis [21]. Regarding stock, we distinguish between safety stock being the average buffer inventory, and the cycle stock being the average inventory above the safety stock [84].

Relevant literature containing optimization models is presented in Table 3. Most publications apply a periodic inventory review policy, which is in line with historic and current practice in hospitals, especially at point-of-use inventory locations such as the wards [124]. In light of the ongoing modernization of point-of-use technologies like the introduction of advanced identification technologies as barcodes

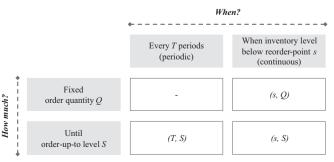


Fig. 6. General inventory policies.

or radio-frequency identification (RFID), researchers have recently started investigating new types of replenishment policies, e.g., hybrid policies [21,145,146]. Rosales et al. [146] develop such a hybrid replenishment policy. They generally perform a cost-efficient periodic review. However, in order to avoid costly stock-outs, continuous review is allowed. While PhD theses are out of scope for this review, due to its importance we refer to Rosales [145] who elaborates on technology-enabled new inventory policies for hospitals. Kelle et al. [84] study an automated ordering system, which allows for a continuous review. Uthayakumar and Priyan [157] argue that periodic inventory review policies are not applicable in practical healthcare settings due to the uncertainty of patient arrivals and resulting demand. Most of the discussed publications incorporate capacity constraints in their inventory models, as in the hospital setting, space is a limiting factor, especially at the point-of-use inventories.

When implementing the defined inventory parameters in practice, some typical obstacles exist. Inventory par levels often reflect the desired inventory levels of physicians and nurses rather than the calculated inventory levels. Thus, par levels tend to be experience- or policy-driven rather than data-driven [139]. Furthermore, it appears to be common to keep "hidden" safety stock in several locations at care units due to difficulties in policy implementation, personal judgment, and silo-structured organizations [58].

#### 5.1.2. Multi-echelon inventory

In the following publications, supplier inventories are discussed parallel to hospital inventories. Baboli et al. [9] provide a cost comparison for a joint optimization of a pharmaceutical supply chain from a retailer and hospital perspective. They take into account inventory and transportation costs and consider two cases where costs are optimized, i.e., a decentralized and a centralized case. In the decentralized case, companies independently optimize their costs, while in the centralized case, several participants of the supply chain are considered as a single organization. They focus on products with high demand and assume that demand for the respective products is deterministic. Uthayakumar and Priyan [157] take an entire value chain perspective in the case of pharmaceuticals. In their inventory model, they include production and distribution of pharmaceuticals. They develop an algorithm to find the optimal inventory lot size, lead time, and number of deliveries with minimum costs under a continuous review policy. The algorithm is based on a Lagrangian multiplier approach. In a second work, Priyan and Uthayakumar [140] extend their model to cover a fuzzystochastic environment, discrepancies between ordered quantities and actually received quantities, and lead times consisting of mutually independent components. Based on the signed distance method, the environment is defuzzied and an optimal inventory policy is determined using the same Lagrangian multiplier approach as in the first paper. Nicholson et al. [124] assess the differences between an in-house 3-echelon inventory system and an outsourced 2-echelon distribution network, where the replenishment activities are performed by an outside agent that directly delivers to the point-of-use inventory locations in the hospital. The authors develop two optimization models to minimize the holding and backorder costs and apply a heuristic to solve their problems. They find that outsourcing the distribution of non-critical items is a viable choice, enabling staff to concentrate on patient care activities.

Guerrero et al. [57] develop a methodology to find near-optimal inventory policies for multi-echelon inventory networks, i.e., one central inventory and n point-of-use inventories. They aim to minimize the total stock on hand for the entire system and employ a Markov decision process. The reorder points at both echelons are derived via a probability calculation while the optimal order-up-to level is one unit higher than the reorder point at the point-of-use inventories. The near optimal order-up-to level at the central inventory is derived from a heuristic algorithm. Their approach is

**Table 3** Inventory policy publications containing optimization models.

Publication	Problem description	Model characteristics	Objective function	Type of goods	Review logic	Replenishment policy	Capacity const.	No. of products	Invent. type
Baboli et al. [9]	Cost comparison of 2-level pharmaceutical supply chain: Decentralized vs. centralized replenishment	Heuristic	Minimize total cost	Pharmaceut.	N/A	N/A	Yes	Multi	Multi echelon
Bijvank and Vis [21]	Inventory policy (reorder points and order quantities) for point-of-use inventories	Heuristic	<ul><li>(1) Maximize service level</li><li>(2) Minimize required</li><li>capacity</li></ul>	Disposable items	Periodic	(T, S)	Yes	Multi	Point-of- use
Dellaert and van de Poel [37]	Easily applicable inventory policy for central inventory	Heuristic	Minimize ordering cost per cycle	Consumable items	Periodic	(T, s, c, S)	No	Mulri	Central inven-tory
Guerrero et al. [57]	Optimal inventory parameters for mutli-echelon inventory	Heuristic based on Mar- kov DP	Minimize stock on hand of entire system (CU and CP)	Non-critical, e.g., infusion solutions	Periodic	(T, S)	Yes	Multi	Multi echelon
Kelle et al. [84]	Easily applicable algorithm for inventory policy parameter setting in point-of-use inventory	Heuristic	(1) Minimize ordering and inventory cost (2) Minimize number of refills	Pharmaceut.	Contin.	(s, S)	Yes	Multi	Point-of- use
Little and Coughlan [103]	Optimal stock levels under hospital space constraints	Heuristic (constraint programming)	(1) Maximize minimum service levels (2) Max. average service levels	Sterile items, consumables	Periodic	(T, S)	Yes	Multi	Point-of- use
Nicholson et al. [124]	Costs and service level comparison for in-house 3-echelon inventory vs. out-sourced 2-echelon distribution network	Heuristic (greedy- algorithm)	Minimize inventory cost (holding and backorder)	Non-critical inventory items	Periodic	(T, S)	No	Single	Multi echelon
Priyan and Uthayaku- mar [140]	Extension of Uthayakumar and Priyan [157]: Fuzzyness, delivery quantity discrepancies, independent lead times	Fuzzy model defuzzied w. signed distance method	Minimize total cost	Pharmaceut.	Contin.	(s, Q)	Yes	Multi	Multi echelon
Rosales et al. [146]	Hybrid inventory policy (periodic and continuous review) and inventory parameter definition	Heuristic based on simulation	Minimize long-run aver- age cost per unit time	Pharmaceut., medi- cal supplies	Periodic, continu-ous	(T, S, s, Q)	Yes	Single	Point-of- use
Rosales et al. [147]	2-bin replenishment system: (1) Parameter optimization for periodic review (2) RFID use to enable continuous review	SMDP, linear programming	Minimize order cost and stockout cost	High volume, low cost items	Periodic, continu-ous	N/A	Yes	Multi	Point-of- use
Uthayakumar and Pri- yan [157]	Optimal inventory lot size, lead times and number of deliveries for hospital delivery	Langrangian multiplier algorithm	Minimize total cost	Pharmaceut.	Contin.	(s, Q)	Yes	Multi	Multi echelon
Vila-Parrish et al. [163]	Inventory and production policy for pharmaceuticals with 2 stages: Raw material and highly-perishable finished good	Heuristic based on Mar- kov decision process	Minimize expected inventory and production cost	Perishable pharmaceut., e.g., intrav.	Periodic	(T, S)	No	Single	Central inven-tory

especially suitable for non-critical goods, such as infusion solutions. In summary, publications cover inventory parameter setting as well as cost comparisons within and outside the hospital.

#### 5.1.3. Central inventory

Dellaert and van de Poel [37] develop a simple and easily applicable inventory control rule for the hospital's central warehouse. The new policy called "(R, s, c, S) policy" is in our notation a (T, s, c, S) policy, which is an extension of the (T, S) policy that incorporates a can-order level c. Whenever inventory levels fall below c at the review, an order up to level S can be triggered, while when inventory levels fall under s. an order must be triggered. For a periodic review with given review cycles, the inventory parameters are determined using a simple algorithm that minimizes ordering costs based on order bundling. A special case regarding the management of the central inventory is studied by Vila-Parrish et al. [163]. They discuss inpatient medication with two stages being raw materials and finished goods. This holds for example for intravenous fluids that are produced in the hospital pharmacy. All goods are perishable, but finished goods are of a more perishable nature. The authors model production and raw material ordering using a Markov decision process.

#### 5.1.4. Point-of-use location

In this section, the inventory closest to the patient, being the point-of-use location, is discussed. Bijvank and Vis [21] determine the optimal inventory policy for hospital point-of-use inventories. The authors develop two exact models: A capacity model and a service model. In the capacity model, they maximize the service level subject to capacity restrictions while in the service model the strategy is vice versa. They develop a simple heuristic inventory rule that can be easily utilized by hospital staff for the capacity model. Little and Coughlan [103] provide a constraint programming based algorithm that finds optimal inventory parameters, which are service level, delivery frequency, and order-up-to amount for a periodic inventory policy (*T*, *S*). They especially stress space restrictions and criticality of items.

The 2-bin replenishment system, a special replenishment system used in practice, applies two equally-sized bins in the care units, i.e., one bin where goods are taken from and one reserve bin. Once one bin is empty, replenishment is triggered, mostly relying on Kanban logic. This system is discussed in the following publications. Rosales et al. [147] study the 2-bin replenishment inventory system in combination with RFID tags and assess the applicability of different replenishment policies. Generally, a periodic replenishment policy is applied. Rosales et al. [147] assess two ways of optimizing the 2-bin replenishment system: Through parameter optimization for periodic review and through replenishment policy optimization shifting to a continuous replenishment policy. For parameter optimization, the periodic replenishment policy is modeled and it is demonstrated that the average costs per unit time is quasi-convex, thus allowing for a simple search to find the optimal review cycle. The policy changedriven optimization is enabled through the incorporation of RFID tags, allowing for continuous replenishment. Using a semi-Markov decision model (SMDP), the optimal replenishment policy is modeled and heuristically determined. Landry and Beaulieu [96] extensively discuss the 2-bin replenishment inventory system and assess which lean concepts it addresses.

Automated inventory systems at the point-of-use are discussed by the following two publications. Kelle et al. [84] provide the reorder point *s* and order-up-to level *S* for the point-of-use inventory of an automated ordering system in a continuous review setting. These inventory parameters are derived via a near-optimal allocation policy of safety stock and cycle stock. Parameters are derived using an iterative heuristic algorithm. Rosales et al. [146] develop a hybrid inventory policy for point-of-use hospital inventories, called "(*s*, *S*, *R*, *Q*) policy". They combine a periodic (*T*, *S*)

policy with a continuous (*s*, *Q*) policy. Consequently, in our notation this equals a (*T*, *S*, *s*, *Q*) policy. During the review cycles, reactive replenishments are allowed. This new policy is especially applicable for automated dispense machines (ADMs) at point-of-use inventory locations. The authors develop a simulation-based heuristic to determine the parameter values for the reorder points, the order-up-to level, the order quantity, and the review cycle. They find that hybrid policies may provide substantial cost benefits versus purely periodic or purely continuous reviews.

Although a multitude of publications in the field of hospital inventory policy exists, this area remains promising for future research. Potential research includes the unpredictable nature of demand in hospitals and its implications on inventory policies. A majority of the presented publications focus on goods with high turnover and predictable demand. However, demand with low volume and lumpy characteristics and its potential effects on workload and policy setting is hardly considered. This area of research is stressed by Kelle et al. [84] and Little and Coughlan [103]. Furthermore, most papers assume independence of the demand for the different goods [124,84]. Including dependencies into inventory models could be an interesting research field. Regarding the characteristics of inventory items, it could also be beneficial to incorporate expiration dates or special storage requirements such as cooling [57]. Further, the effects of substitution products on service levels in case of stock-outs could be assessed, as proposed by Bijvank and Vis [21], or the fact that emergency deliveries from other care units are possible and for many goods occur at little cost. For multi-echelon inventory settings, a further research area could be to incorporate lead times into inventory models, especially between outside suppliers and the hospital, as proposed by Nicholson et al. [124]. A detailed assessment of review cycle length at the point-of-use inventories and lead times of respective suppliers could therefore be beneficial [21]. Stressing the hospitals' need for simplicity and ease of usage could also be a potential future research area. Typically, staff dealing with logistics activities in hospitals often does not have the same technical background and knowledge as their counterparts in manufacturing industries. Consequently, the implementation of sophisticated inventory systems may be difficult in hospitals. Examples where the usage could be eased comprise simple inventory policies for largescale inventory systems (e.g., [146]) or materials handling of ADMs.

#### 5.2. Inventory location planning

Danas et al. [34] provide a publication related to inventory layout planning. The authors introduce the concept of a virtual hospital pharmacy that bundles the inventories of several hospitals in one specific geographic region to allow for a more efficient use of storage capacity. Pasin et al. [132] assess the impact of inventory pooling by using a simulation tool. They show that significant efficiency improvements are possible when centralizing inventories of several hospitals. Thomas et al. [154] assess placing an ADM in the point-of-use inventory at an operating room. The authors show that benefits can be realized through the reduction of preparation and setup time of medication. For emergency medications, the preparation and setup time could be reduced from fifteen to five minutes.

In the context of manufacturing industries, strategic planning of inventories like inventory location or layout planning is a large research area. Apart from defining inventory locations, the question where goods should be stored in a multi-echelon inventory setting has been addressed [26]. However, in the healthcare context, inventory location or layout planning is a rather untouched research field. One potential justification is that in the process of designing a hospital, planners focus on medical aspects, such as the location of operating theaters and wards. Logistics planning is often performed at a late stage, which leads to immature solutions that are not optimal from a materials management perspective

[33]. Future research opportunities could lie in the development of an integrated approach for hospital layout planning that better incorporates logistics aspects on the strategic level.

#### 5.3. Inventory item classification

One lever to efficiently manage inventory is to categorize inventory items and establish individual inventory policies for these categories. This allows for standardized treatment of items within the same category, e.g., in terms of safety stock levels, required management attention, purchasing strategies, etc. In a case study by Beier [13], 45% of U.S. hospital pharmacies were using a classification scheme to distinguish important items. Potential categorization methods include ABC analyses, meaning categorization along the items' monetary value and rate of consumption, and VED (vital, essential, and desirable) analyses, which is a classification scheme along criticality of items or combinations of the above. Khurana et al. [86] develop a combination of ABC and VED classifications in order to define the required management attention for the different item categories. A case study for a combined ABC/ VED classification is provided by Gupta et al. [60]. Danas et al. [35] transfer the MASTA logic (multi attribute spare tree analysis), a concept that has been developed in the context of industrial spare parts, to the hospital inventory case. The idea is to classify each drug item along a classification tree in order to determine its stock and inventory strategy, thus to ascertain whether the respective drug needs a safety stock within the respective clinic, hospital, or geographic region, or if it can be supplied as a IIT item. Classification is performed along four dimensions: Patient treatment criticality, supply characteristics, inventory problems, and usage rate. We further refer to Al-Qatawneh and Hafeez [4] who present a multi-criteria inventory classification based on criticality, cost, and usage value, knowing that conference proceedings are not in scope of this review (see Section 2). Gebicki et al. [53] incorporate drug characteristics into inventory policy. They achieve higher patient safety and lower overall costs compared to traditional inventory management approaches. They evaluate the performance of several inventory policies with regards to total costs and service levels using event-driven simulation. The policies differ in the levels to which they incorporate information about the drugs, such as criticality or availability, cost components, e.g., whether stock-out or waste costs are included, as well as the application of sophisticated techniques, e.g., conditional demand forecasting.

Future research potential lies in the extension of the previously presented models in order to assess correlations between drug characteristics and the applied policy versus stock-out costs and the individual cost components [53]. Inventory item classification is further required for the use of innovative inventory systems, such as virtual pharmacies.

#### 5.4. Practice-oriented inventory

Several practical case studies and empirical publications on inventory management exist. Huarng [67] assesses material management practices in Taiwan across several hospitals in an empirical study. Across the participating hospitals, purchasing strategies, inventory turnover rates, and inventory fill rates are compared across the participating hospitals, and significant performance disparities are worked out. An exploratory case study performed by de Vries [164] underlines the complexity of inventory management in hospitals. The author identifies and assesses the relevant stakeholders and their interests in the process of redesigning a hospital inventory system. Beier [13] assesses inventory policies from a U.S. data sample and identifies cost improvement potential in inventory management and the collaboration with suppliers. Poley et al. [136] present a case hospital which contains two pharmacy inventory and distribution systems, i.e., a multi-echelon system and a ready-to-use

distribution system. Both systems are systematically compared and differences in their cost structures are highlighted.

Future practical research on inventory management should be performed in order to better understand the concrete differences between industrial settings and hospitals. Furthermore, reports on past inventory projects in hospitals would be highly beneficial in order to understand the dynamics and potential obstacles in the hospital setting [164].

#### 5.5. Pharmaceutical inventory management

Pharmaceuticals impose high requirements on inventory management. According to Almarsdóttir and Traulsen [3], inventory management for pharmaceuticals differs from other medical product categories based on their specific characteristics. While hospital inventory-related publications on pharmaceuticals were already discussed in detail earlier, we refer to Kelle et al. [84]. Privan and Uthayakumar [140] and Uthayakumar and Priyan [157], who evaluate pharmaceutical supply chain specifics from the hospital's perspective. For a general introduction to hospital inventory management for pharmaceuticals, we refer to Vila-Parrish and Ivy [162]. Based on regulatory constraints, hospitals must make sure that information about the manufacturer, production lots and/or dates, as well as shipping information, etc. must be registered and known [25]. In order to fulfill these identification requirements and prevent medication errors and costly return deliveries, hospitals rely on identification means, namely barcodes and RFID. In the following section, both technologies and their application in hospitals are presented. The section concludes with a brief overview of drug handling techniques.

The use of barcodes is the today's most widespread identification technology. According to a cost-benefit analysis by Maviglia et al. [109], hospitals can achieve significant savings when applying a barcode-based identification/dispensing system instead of a manual system. In their specific case, the break-even point for the upfront investment occurred within one year after the implementation of the new system. Poon et al. [137] find that by implementing a bar code based hospital pharmacy system, the rate of dispensing errors can be significantly reduced. Pitfalls of such a system are presented by Phillips and Berner [134]. The work by Koppel et al. [92] concentrates on workarounds that are performed by medical staff when barcode medication administration systems (BCMA) are in use. Another work by Patterson et al. [133] presents a case study on implementation problems when using BCMA. The second and more technologically sophisticated identification technology is RFID. Key advantages include easier scanning and a high product visibility along the supply chain, however at a high implementation cost. A general introduction to the supply chain implications of using RFID - not limited to healthcare - is provided by Lee and Özer [102] and Irani et al. [73]. For RFID applications in the healthcare industry, we refer to Coustasse et al. [31] and Fosso Wamba et al. [49], who provide comprehensive literature reviews. The former find that despite the rising penetration of RFID in healthcare, few empirical studies exist that assess the actual potential of RFID. An exception is the work by Abijith and Fosso Wamba [1], who assess the financial impact of RFID-enabled transformation projects in the healthcare sector. Lee and Shim [101] investigate on the rationale behind introducing RFID in the healthcare industry. A highly practice-relevant work is provided by Chang et al. [29], who elaborate on where to mount RFID tags on products from a material handling perspective. Potential future use cases for the information generated through the application of RFID are presented by Meiller et al. [118] to further optimize material handling and reduce safety stock levels. A comparison of barcodes and RFID is provided by Çakici et al. [25] and Chan et al. [27]. Regarding inventory policies, Çakici et al. [25] find that continuous review is superior to periodic review whenever real-time information are available, which is the case for RFID-enabled inventories.

Regarding pharmaceuticals inventory design and drug distribution, hospitals employ either a classical ward stock system or a unit dose drug inventory and distribution system. In the classical system, inventory is held at the wards and can be divided into standardand patient-specific medication. In a unit dose system, drugs are being picked in the central pharmacy according to the patients' actual needs [135]. New material handling technologies are commonly first adopted in the central hospital pharmacy, where manual picking is replaced by ADMs. There are case studies at hand regarding their effects and learning from their implementation: In particular, the publications by Fitzpatrick et al. [47]. Franklin et al. [52], and Piccinini et al. [135] evaluate ADMs in hospital pharmacies. Major effects include a significant reduction of dispensing errors, reduced picking times, increased staff satisfaction, and better use of storage capacity [47,52]. Piccinini et al. [135] present and analyze an automated picking workstation as part of an automated pharmacy distribution center for a group of hospitals. They focus on the actual picking step and assess how to pick very diverse and complex objects available on belts or bins. Novek [126] and Granlund and Wiktorsson [54] more broadly assess the implementation and implications of automation in hospital-internal logistics. For a literature review on types and causes of dispensing errors, we refer to Beso et al. [18] and James et al. [76]. Future research should further incorporate new handling technologies that emerge in other industries with a focus on their applicability in hospitals.

#### 5.6. Drug shortages

In recent years, drug shortages have occurred more and more often, having notable implications for hospital material management in general and inventory management in particular. Historically, the problem of drug shortages has mostly been common in either niche drug segments or developing countries. However, since the early 2000s, it has been reported that several drug groups in the U.S. are insufficiently supplied – a trend which experts argue is also prevalent in Europe, while exact data to prove this is missing [51,69,100].

Most of the existent literature focuses on drug shortages in the U. S. A variety of publications assesses the causes for drug shortages and their implications to the healthcare system. Reasons for shortages include the unavailability of raw material, production ramp-downs or manufacturing difficulties, mergers and acquisitions of drug manufacturers, voluntary recalls, regulatory issues, unexpected demand, natural disasters, and labor disruptions [56,105,161]. Drug shortages have significant negative financial effects for the healthcare system as well as the quality of patient care [5,12,82]. Nowadays, pharmacists and pharmacy technicians spend an average of 8-9 hours per week on drug shortage related activities [82].

Several authors present very hands-on suggestions on how to cope with drug shortages from a hospital logistics perspective. One key factor is to take proactive action, which includes purchasing strategies as well as the implementation of concrete actions plans that ought to be developed before shortages occur. The plans include lists of substitute products and hospital organizational issues, such as to define responsibilities in case shortages occur. Introducing substitute products might have significant effects on logistics processes. For example, the IT and inventory systems must be able to cope with short-term changes of drug names etc. [110]. In inventory management, one lever to cope with drug shortages is changing the inventory policy and updating the order point and order quantities. Also, inventory sharing and pooling, as well as rationing and prioritizing policies should be considered [80]. Having transparency on upcoming or expected shortages and the actual inventory level of respective drugs helps to be able to act proactively [80].

Apart from the rather practical action plans discussed in the previous publications, there are also publications that present general guidelines on how to attune to (potential) drug shortages [50,59,114,143,158]. We also refer to a number of studies that focus on the effects of shortages for certain drug groups [55,63,112,115]. According to pharmacists, there exists a lack of information needed when managing shortages, e.g., actual inventory data throughout the hospital [82]. Consequently, one future research area could be to further enhance data transparency and the availability of up-to-date stock information.

#### 6. Literature on topic: (3) Distribution and scheduling

The subsequent section discusses hospital-internal and hospital-external distribution and scheduling topics. Due to its distinct characteristics, the logistics of sterile items is presented in a third category. Hospital-internal distribution comprises mainly routing and scheduling problems of goods within the hospital, primarily from the central warehouse location to the respective care units. External distribution relates to inter-hospital transports as well as waste management. Sterile items handling comprises both transportation tasks as well as the actual sterilization process.

#### 6.1. Hospital-internal distribution and scheduling

In the field of hospital-internal distribution and scheduling, four publications that contain optimization models are identified (see Table 4). "Classical" pharmacy delivery is scarcely addressed in the literature [7]. However, rather specific issues are discussed, such as routing and scheduling problems of combined storage/delivery material management systems, e.g., mobile medicine delivery closets. Interestingly, due to the different delivery tools and setups, standards and common practice on how to transport material in hospitals hardly exist.

Augusto and Xie [7] and Michelon et al. [119] explore delivery problems of sophisticated inventory storage and delivery systems, i.e., medicine closets and twin trolleys. Augusto and Xie [7] consider a hospital pharmacy delivery problem. In their study, pharmacy delivery is performed in a manner such that care units are equipped with mobile medicine closets. Periodically, these closets are collected and transported to the central pharmacy for inventory stock assessment and refill. The problem consists in creating a transportation and supply plan. The aim is to have a balanced workload for the two limiting human resource types, i.e., transporters and pharmacy assistants. The problem is formulated as a MIP and a near optimal schedule is determined using a standard solver. In a second step, a simulation model is applied to redesign the pharmacy delivery process in a case study. Michelon et al. [119] compare two supply distribution systems. In their research case, supplies are delivered in a twofold way: Either through so called "twin trolleys" that contain most of the regularly required supplies, which are always doubled. One trolley is in use at the point-of-use and the "twin" is located at the central inventory location. Moreover, there are "non-twin trolleys" containing non-medical items, e.g., meals or cleaning products. Each of those trolleys is assigned to a number of point-of-use locations. In their publication, Michelon et al. [119] assess whether it is beneficial to change the allocation of items to the twin or non-twin trolleys relying on a tabu search heuristic.

Linen delivery is modeled and optimized by Banerjea-Brodeur et al. [11]. Based on shortfalls that regularly make emergency deliveries to the care units necessary, the transportation system is reviewed. The authors set up a periodic vehicle routing problem (VRP) in order to optimize delivery routing, scheduling, and quantities. To solve the VRP, a tabu search heuristic is applied.

**Table 4**Hospital-internal distribution and scheduling publications containing optimization models.

Publication	Problem description	Model characteristics	Objective function	Type of goods
Augusto and Xie [7]	Transportation and supply plan for mobile medicine closets located at care units; weekly replenishment in central pharmacy	Mixed-integer linear programming, simulation	(1) Minimize number of routes (2) Minimize workload	Pharmaceut.
Banerjea-Brodeur et al. [11]	Deliver quantity and schedule of regular linen delivery from central laundry to care units	PVRP solved with tabu search heuristic	Minimize total cost	Laundry (linen)
Lapierre and Ruiz [98]	Multi-item inventory replenishment schedule under storage and manpower capacity constraints	Mixed-integer non-linear prob., meta-heuristic search	Minimize total inventory cost and minimize deviation of workload equilibrium	Not specified
Michelon et al. [119]	Comparison of mobile inventory and distribution systems with varying amount of items kept locally in care units		Minimize number of tasks that can- not be performed by respective system	Medical, bed-related, meals, etc.

Dean et al. [36] focus on scheduling pharmacists who visit care units in order to trigger medication orders. In their model, drug prescriptions are added to the patient files, which are typically mounted to the bed of the respective patient. The study demonstrates that changing the time of the day when the visit is performed affects the delay of medication arrivals.

The publication by Lapierre and Ruiz [98] assesses scheduling activities and logistics optimization. The authors state that in the context of hospital supply systems, basically two approaches exist to plan logistics activities. First, the inventory-oriented approach where in multi-echelon inventory settings, orders are placed whenever reorder points are met. In this predominant approach in the literature, the main focus lies on assuring sufficient stock levels (see Section 5). According to the authors, this approach however neglects further questions such as planning of scheduling activities and human resources. Questions to be answered include: When should employees work? How often should replenishments be performed? How often and when should supplies occur? Lapierre and Ruiz [98] propose an approach to schedule replenishments, purchasing activities, and supplier activities to avoid stock-outs and respect resource availability. The authors formulate a mixed-integer non-linear scheduling problem that balances employees' workload. They develop a tabu search meta-heuristic algorithm for solving the problem.

Scheduling and questions around goods distribution of hospitalinternal logistic activities appear to be a promising field for future research. Three potential research areas have been identified. First, the introduction of sophisticated inventory and delivery systems in hospitals raises optimization potential for associated activities. These systems include, for example, mobile medicine closets, twin trolleys, or the 2-bin replenishment system. The motivation behind their introduction derives from hospital-specifics that limit the applicability of standard solutions from other industries. Respective characteristics comprise the limited storage space at point-of-use locations or staff that is untrained in the use of logistics system. Moreover, legislative constraints in drug handling make healthcare specific solutions necessary. A respective use case is presented by Augusto and Xie [7]. The authors schedule pharmacists and transporters used when introducing mobile medicine closets. The case of twin trolleys is discussed by Michelon et al. [119] while Dean et al. [36] optimize the scheduling of pharmacists visits to wards. A topic that has been untouched so far is the 2-bin replenishment system and associated scheduling requirements. Related scheduling activities as when to refill stock and in which overall schedule has not yet been addressed. The work by Lapierre and Ruiz [98] initially covers logistics-related scheduling tasks around hospital inventories. However, many potential areas for optimization remain. Second, as the majority of the presented publications apply heuristics to solve their models, the development of exact solution procedures could further provide interesting research areas. A third promising field is the extension of existing logistics-related scheduling activities to personnel planning and shift planning. Respective questions might appear when logistics activities are transferred to non-medical support staff.

#### 6.2. Hospital-external distribution and scheduling

Hospital-external distribution and scheduling is hardly covered in the literature. In total, there exist five relevant publications including optimization models (see Table 5). They handle interhospital transports, transports between suppliers and hospitals, as well as the collection and disposal of waste. In the context of this work, only hospital-related publications are discussed.

Bailey et al. [10] investigate an alternative supply route for timecritical items to hospitals, which usually travel in conjunction with regular goods. They demonstrate that an unattended locker box can serve as an alternative delivery solution for urgent items, allowing the separation of those items from regular material flows. The authors use a hill-climbing optimization algorithm to identify the optimal size of a locker box to cover a certain service level in a typical hospital. Combined with results from staff interviews, they find that the introduction of unattended locker boxes would be beneficial in terms of speed of delivery and healthcare quality. Kergosien et al. [85] address a two-level VRP with time windows, a heterogeneous fleet, multi-depot, multi-commodity, and split deliveries. The first level addresses fleet routing for collection and delivery of pharmaceuticals and hospital consumables. The second level addresses routing employees between hospital unit buildings and sizing of warehouse employees. To solve the problem, two metaheuristic algorithms are presented, a genetic algorithm and a tabu search algorithm. Swaminathan [153] discusses the allocation and distribution of scarce drugs to 150 hospitals in California. Therefore, an optimization model is developed that is solved based on an allocation heuristic.

The collection and disposal of waste is considered a separate field of research that mainly deals with VRPs. As of its relevance to hospital logistics, publications that cover hospital waste disposal are briefly presented. For more detailed information on waste collection and waste management, we refer to the literature review by Beliën et al. [14]. Medaglia et al. [116] design a hospital waste disposal network in Columbia. They formulate the problem as a bi-objective obnoxious facility location problem (BOOFLP) that incorporates the tradeoff to find the cost-optimal facility locations and the negative effects on the population close to waste treatment facilities. They solve their model with a multi-objective evolutionary algorithm. Shih and Chang [150] develop a periodic VRP to model a routing and scheduling problem for the collection of infectious hospital waste. They develop a MIP to assign routes to particular days of the week in a second step. An overview of infectious waste management of European hospitals is provided by Mühlich et al. [120].

Three potential future research areas have been identified: First, it could be promising to assess the robustness of the presented VRPs and its modifications, e.g., through the application of discrete-event simulation as proposed by Kergosien et al. [85]. Second, referring to

**Table 5**Hospital-external distribution and scheduling publications containing optimization models.

Publication	Problem description	Model characteristics	Objective function	Type of goods
Bailey et al. [10]	Feasibility demonstration of unattended locker box delivery system; specification of locker box characteristics	Hill climbing optimization algorithm	Maximize number of orders to be stored within locker box	Urgent items
Kergosien et al. [85]	Transportation flow design between hospital units; warehouse employee dimensioning	2-VRP sol. w. meta-heuristics (generic alg. and tabu search)	Minimize the sum of delays and minimize required number of employees	Pharma-ceuticals, consumables
Medaglia et al. [116]	Optimal facility location for hospital waste treatment network	Biobjective facility loc. prob. (MIP), sol. with heuristic	Multiobjective: (1) Minimize transport. cost (2) Min. affected population	Waste
Shih and Chang [150]	Route and schedule for periodic waste collection of hospital network	PVRP and MIP to assign routes to days of week	<ul><li>(1) Minimize transportation cost</li><li>(2) Minimize daily travel mileage in a week</li></ul>	Waste
Swaminathan [153]	Decision support for allocating scarce drugs to hospitals	Multiobjective optimization model, solved with heuristic	Minimize total value of drug budget left over / maximizing total value of allo- cated drugs	Pharma-ceuticals

Section 5.2, where we identified hospital layout planning as one potential future research area, incorporating inter-hospital transportation issues into layout planning could be a promising future research field. Third, emergency deliveries within hospital networks could furthermore be assessed within this context.

#### 6.3. Sterile medical devices

The handling of sterile medical items is a distinct field of research within hospital distribution and scheduling. Fineman and Kapadia [46] were among the first to address this problem in the OR literature. For a brief introduction into sterilization logistics, see Di Mascolo and Gouin [107]. There are two kinds of sterile medical items, single-use and reusable medical items. We consider the latter because of the complexity of the repetitive sterilization process, which is omitted for single-use items. Typically, reusable sterile items such as surgical instruments are sterilized after usage in either a hospital-internal sterilization department or by external service providers.

An overview of publications in this research stream applying optimization models is presented in Table 6. The washing process itself is assessed by Ozturk et al. [130], which they claim to be the bottleneck of the sterilization process. They provide a branch and bound based heuristic in order to optimize the washing machine schedule, van de Klundert et al. [90] state that hospitals intensively attempt to outsource sterilization activities in order to save costs and free space in the central sterilization service departments (CSSDs). Outsourcing, however, comes with downsides, for example longer transportation distances and potentially lower availability. In their work, the authors formulate an optimization problem aiming for cost minimization of inventory and transportation costs as a lot sizing and transportation model, which is solved in polynomial time by dynamic programming. Further, they extend the model to a dynamic, non-deterministic setting addressing the value-added of real-time information availability, e.g., when applying RFID. Additionally, they present a bundling problem regarding the composition of medical item nets. Tlahig et al. [155] assess two different setups of sterilization services. They compare decentralized inhouse sterilization versus centralized sterilization services in a hospital network. In their model, they aim to find the general setup (centralized vs. decentralized), the optimal location, and the optimal capacity. The problem is modeled as a MIP and solved based on the addition of appropriate cuts. Di Mascolo and Gouin [107] also aim at improving sterilization services within hospitals. They assess the implications of changes in processes and the organization. Therefore, they develop a generic discrete-event simulation model, allowing the authors to represent and quantify any sterilization service in the respective health establishment in France.

Future research may focus on further assessing the performance of different sterilization services in hospitals [107], as well as different organizational setups. These include mixed forms, where some sterile items might be treated within the hospital, while others are sent to external service providers [155]. Also, the incorporation of uncertainty in scheduling the washing process seems to be a worthwhile research field [130].

#### 7. Literature on topic: (4) Holistic supply chain management

Publications regarding the management of the entire supply chain are presented in this section. They do not contain optimization models, but are qualitative or conceptual. Consequently, all presented areas offer new perspectives of incorporating and developing optimization models. We classify the publications into three categories. "Business process redesign" covers all topics associated with the assessment and redesign of logistics processes and the organization of the hospitals' logistics function. "Transfer of logistics concepts from other industries" presents publications that assess if logistics concepts that are successfully implemented in other industries, such as lean, can be transferred to hospital logistics. The final part "Benchmarks, best practices, and cost analyses" discusses practice-related publications, mostly case studies that assess logistics costs and its components, as well as cost comparisons across countries or within hospital departments. The major discussion points and most relevant conclusions are presented.

#### 7.1. Business process redesign

In this section, publications are presented that aim at improving hospital business processes. Therefore, several approaches according to the literature are shown and tools are presented. Generally, it is accepted that logistics processes in hospitals bear significant cost improvement potential. One relevant lever is to redesign logistics processes through implementing SCM practices (e.g., [61,94,138,164]).

Landry and Philippe [97] generally consider the role of logistics and show how it can service healthcare and improve the quality of care. A variety of publications focuses on reengineering the hospital-internal logistics processes, which are the major weak point in hospital logistics [22,30,79]. Chandra [28] discusses trends, issues, and solution techniques for hospital SCM and presents a generic supply chain problem modeling methodology. Kriegel et al. [93] evaluate what role external contract logistics service providers can play in the German hospital sector. Iannone et al. [72] and Zheng et al. [171] assess the potential of the supply chain integration

 Table 6

 Sterile devices publications containing optimization models.

Publication	Problem description	Model characteristics	Objective function	Type of goods
Ozturk et al. [130]	Near optimal parallel job batch definition for washing step of sterilization process for sterile medical devices	Heuristic based on branch and bound	Minimize makespan of sterilization process	Sterile medical devices
Tlahig et al. [155]	Comparison of decentralized in-house vs. central sterilization service of hospital network	MIP, solved via addition of approp. customized cuts	Minimize total cost (transportation, sterilization, resource transfer, acquisition)	Sterile medical devices
Van de Klundert et al. [90]	Sterilization cost minimization (transportation and inventory costs) for outsourcing sterilization of medical devices	Dynamic programming	Minimize total cost	Sterile medical devices

through enhanced IT integration, e.g., data and information sharing. This enables a higher visibility of inventory data and a reduction of lead times and safety stock. In order to analyze the healthcare supply chain, several tools are on hand to support the decision making process. The tools comprise process modeling techniques [106,71,94] and simulation techniques [2,81].

#### 7.2. Transfer of logistics concepts from other industries

Whether logistics concepts that have successfully been implemented in other industries, e.g., car manufacturing or retail, are transferable to the healthcare sector, is an intensively debated topic in the literature. Most publications conclude that generally, these concepts are applicable in healthcare, but there are major obstacles that need to be overcome. Young et al. [168] very broadly discuss the applicability of industrial processes to healthcare, i.e., lean thinking, theory of constraints, six sigma, and scenario simulation. They conclude that all concepts are applicable in the healthcare sector. However, they state that improvements are not to be expected immediately, but will typically need to undergo an iterative implementation process in order to be successful.

Lean thinking emerged in operations in the beginning of the 1990s, in service operations management around mid/end 1990s, and entered the healthcare sector in the early 2000s [99]. The applicability of lean thinking to healthcare, not necessarily related to material logistics, is conceptually discussed by de Souza [151], Fillingham [45], Kim et al. [87], Kollberg et al. [91], Mazzocato et al. [111], and Young and McClean [169]. These authors find that lean thinking has been applied successfully for a wide range of healthcare applications, but while lean thinking usually takes a holistic approach to problems, healthcare often remains limited to narrower applications with limited organizational reach [111]. Although there seems to be a general agreement on the potential of lean healthcare, it remains challenging to quantify the potential and assess its impact critically. Compared to other industries such as the automotive industry, healthcare lags behind regarding the implementation of lean concepts [151]. Also, a clear definition of the term value is missing in healthcare, hindering the reduction of non-value adding activities, as is standard in industry operations [169]. However, Kim et al. [87] rather optimistically conclude that in the healthcare sector, especially in hospitals, lean thinking can provide significant process improvements and thus improve the quality and efficiency of patient care. A range of publications encompasses case studies where lean concepts have been implemented in healthcare. Trägårdh and Lindberg [156] provide a study of a lean production inspired transformation project in the healthcare sector in Sweden. Landry and Beaulieu [96] present the case of a two-bin Kanban system for pointof-use inventories and discuss its implications to the inventory system. Venkateswaran et al. [160] show that through performing the 5S (sort, set to order, shine, standardize, and sustain) methodology in hospital warehouses, significant increases in inventory turnover can be achieved. 5S represents activities that are required to create a desired work environment. Varghese et al. [159] assess whether actual usage inventory management practices used in the retail industry are applicable in healthcare inventory systems. In particular, they evaluate whether ABC classification, demand characteristics classification, forecast-based demand planning, and inventory control policies are beneficial in the healthcare setting. They create a mathematical model that assesses the possibility to optimize parameters for a (*s*, Q) inventory policy, based on actual usage inventory management practices and real data. The authors conclude that by applying those concepts, cost improvements may be achieved.

The applicability of IIT to healthcare logistics is assessed in several publications. Jarrett [78] states that the healthcare industry had not implemented IIT at that time and provides examples from the literature to prove this point. Already very early, Kim and Schniederjans [89] demonstrate that JIT or stockless material management can significantly improve hospital operations. Heinbuch [64] provides a case study for the successful implementation of JIT in the hospital sector and proves that significant cost improvements are achieved. Whitson [166] even argues that materials management in the hospital's pharmacy would be an ideal candidate for implementing IIT due to its manufacturing-like operations characteristics. Jarrett [77] again underlines the general transferability of JIT concepts to the healthcare sector but claims that there exists a research gap regarding the actual implementation of JIT in healthcare. Organizational modification to support the introduction of JIT are presented by Yasin et al. [167]. Contrary to the previously presented papers, Danas et al. [34] argue that JIT can hardly be applied in healthcare due to the unpredictable nature of patient mix and the resulting product demand which is hard to forecast. Kumar et al. [95] state that one reason why the healthcare sector has been slow in embracing SCM practices compared to other industries is the danger of stock-out situations to the health of patients.

More broadly, a variety of publications assesses if SCM practices from other industries can be applied in the healthcare sector. De Vries and Huijsman [165] identify five future research areas in healthcare SCM based on a review of the literature: First, the future role of information technology. Second, the influence of different stakeholders on establishing SCM relationships within and between health service providers. Third, to understand strengths and weaknesses of management philosophies like lean/ agile manufacturing, business process management, and lean six sigma. Fourth, to define performance metrics of healthcare SCM, and fifth, to apply SCM techniques not only to logistics, but also to patient flow. Ford and Scanlon [48] discuss SCM performance measurements and supplier contracting principles including the applicability to healthcare. Meijboom et al. [117] assess the applicability of SCM practices to patient care. McKone-Sweet et al. [113] find that while the importance of SCM in healthcare is widely recognized, there is only limited research on the unique challenges of healthcare SCM. Operational, organizational, and environmental barriers that hinder the implementation of SCM in healthcare are presented.

#### 7.3. Benchmarks, best practices, and cost analyses

Several practice-related publications, mostly in the form of case studies, compare cost characteristics across hospital departments, different countries, etc. and provide benchmarks for the hospital logistics costs setup. Aptel and Pourjalali [6] compare logistics costs and differences in hospital SCM of large hospitals between France and the U.S. Pan and Pokharel [131] investigate logistics activities of hospitals in Singapore and specifically assess what kinds of activities are performed by the logistics departments. The same field of research is covered by Dacosta-Claro [33] who studies the tasks and management approaches of hospital materials managers. Ferretti et al. [44] assess implications of reorganizing hospital materials processes and organization, while Kafetzidakis and Mihiotis [83] more generally evaluate the awareness of logistics in hospitals in Greece. Potential future research could include a global benchmarking tool that allows for comparison of different logistics setups as well as knowledge transfer and transfer of lessons learnt.

#### 8. Conclusion

The healthcare sector in general and hospitals in particular face significant challenges due to steadily increasing healthcare costs. In hospitals, logistics-related costs are the second largest cost block after personnel costs. In order to reduce material-related logistics costs, healthcare academics as well as practitioners have acknowledged the potential of applying quantitative methods. These methods have already proven their potential in other industries, such as manufacturing or service industries, but need to be modified to account for healthcare specific problem settings. Moreover, the existence of several implementation difficulties is obvious due to the operational complexity of hospital logistics as well as organizational barriers. Further, staff entrusted with logistics activities in hospitals often has no logistics background, which makes implementation of sophisticated concepts difficult. Optimal solutions are overruled or tend to be policy- and experience-driven rather than data-driven.

The purpose of this paper is to present the state-of-the-art of research in hospital materials logistics with a specific focus on publications applying quantitative methods. A comprehensive literature review is conducted. Our contribution is threefold: First, we provide guidance for researchers by categorizing the literature and identifying major research streams. Second, we methodologically discuss the publications and third, we identify future research directions. Four major research fields are identified of which three, i.e., (1) Supply and procurement, (2) Inventory management, and (3) Distribution and scheduling apply optimization techniques. The remaining identified research field, (4) Holistic supply chain management, comprises a rather qualitative field of literature. In total, 145 publications are identified, categorized, and discussed thematically and methodically. The largest thematic category in terms of number of publications is (2) Inventory management (66 publications) over the entire time span, followed by (4) Holistic supply chain management (38 publications), (1) Supply and procurement (25 publications), and (3) Distribution and Scheduling (16 publications), respectively. The number of publications in the field of hospital logistics has been growing over the last years. For example, during the previous three years, the total number of publications nearly doubled compared to the years before. Apart from its relevance for academics, the results of this publication and the overview it provides should also be of interest for practitioners in hospital material management functions.

Hospital materials management is a constantly growing field of research in which further promising research opportunities exist. Opportunities are presented in detail in the respective sections. Summarizing, we identify five overarching research possibilities:

First, when integrating the four identified major research streams with applied methodologies, it becomes apparent that the field of (4) Holistic supply chain management offers further research potential with regards to the application of quantitative techniques. So far, integrated optimization across the entire supply chain has not yet been performed in the hospital logistics context. Second, answering the question on how to measure performance in hospital logistics is also a promising future research opportunity. Metrics from other industries, e.g., throughput time, are not directly applicable to hospital logistics as they do not take into account the patient care specifics. Third, future research should continue to incorporate the healthcare and hospital view into operations management and transfer established concepts from other industries into healthcare while accounting for industry specifics. Doing this, it is of pivotal importance to adjust research according to regional specifics due to the high importance of national legislation and strongly regulated nature of the healthcare industry. Fourth, it could be worthwhile to assess which enablers exist that could further push the implementation of sophisticated logistics concepts in hospitals. Potential enablers include consistent information technology systems and data standards across hospitals, clearly defined data interfaces between hospitals and their suppliers, or the introduction of uniform RFID technology. Fifth, in this context, it could be worthwhile to more specifically assess why healthcare has not yet reached the same professional level as other industries and to identify and evaluate potential implementation barriers. However, as healthcare is lacking behind regarding the implementation of quantitative tools as well as SCM practices, other more successful industries should stand as an example for future research.

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#### Review

#### Care pathways lead to better teamwork: Results of a systematic review

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#### ABSTRACT

Care pathways are often said to promote interprofessional teamwork. As no systematic review on pathway effectiveness has ever focused on how care pathways promote teamwork, the objective of this review was to study this relationship. We performed an extensive search of electronic databases and identified 26 relevant studies. In our analysis of these studies we identified 20 team indicators and found that care pathways positively affected 17 of these indicators. Most frequently positive effects were found on staff knowledge, interprofessional documentation, team communication and team relations. However, the level of evidence was rather low. We found Level II evidence for improved interprofessional documentation. We also found Level II evidence for increased workload; improved actual versus planned team size; and improved continuity of care. The studies most frequently mentioned the need for a multidisciplinary approach and educational training sessions in order for pathways to be successful. The systematic review revealed that care pathways have the potential to support interprofessional teams in enhancing teamwork. Necessary conditions are a context that supports teamwork and including appropriate active pathway components that can mediate an effect on team processes. To achieve this, each care pathway requires a clearly defined team approach customized to the individual teams' needs.

#### **Background**

In Western countries, interprofessional teamwork is perceived as being essential for the delivery of high-quality health care (Committee on Quality of Health Care in America, 2001). Reports of the Joint Commission show that 70% of medical errors are caused by lack of communication between team members (Joint Commission, 2006). A report of the World Health Organization (WHO) World Alliance for Patient Safety identified this lack of communication and coordination as the first priority for patient safety research in developed countries (Bates, Larizgoitia, Prasopa-Plaizier, & Jha, 2009). In "peer industries to health care" such as aviation and automobile manufacturing, the value of high-performance teams has long been recognized (Cohen & Bailey, 1997; Salas, DiazGranados,

Weaver, & King, 2008). A meta-analysis on team training interventions across different settings, reported that they account for approximately 20% of the variance in team performance (Salas, DiazGranados, Klein, et al., 2008; Salas, DiazGranados, Weaver, et al., 2008). A RAND report that reviewed 16 health care studies found empirical evidence supporting the relationship between teamwork and patient outcomes (Sorbero, Farley, Mattke, & Lovejoy, 2008).

Teamwork in healthcare is defined by Xyrichis and Ream (2008) as a dynamic process involving two or more health professionals with complementary backgrounds and skills, sharing common health goals and exercising concerted physical and mental effort in assessing, planning, or evaluating patient care. Traditionally, teamwork is described using systems theory with an "input-process-output" based approach (Baker, Gustafson, Beaubien, Salas, & Barach, 2005; West, Tjosvold, & Smith, 2005). This implies that effectiveness of teamwork will be defined by a complex set of interactions between team inputs, team processes and team outputs (Fig. 1). Team inputs consist of the organizational context and environment in which the team is working, the type and structure of the team, its composition and task features. Team

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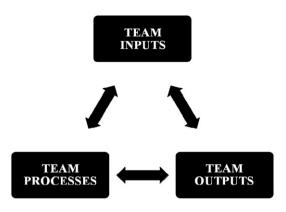


Fig. 1. Systems theory approach of teamwork.

processes include the interactions, relations, cohesion, communication, and coordination between team members. Team outputs include the actual result of the team's performance. These can be both objective (e.g. patient outcomes, efficiency) as subjective (e.g. perceived performance, well-being, job satisfaction).

Of the several types of teams described in the literature (Cohen & Bailey, 1997), our focus is on interprofessional teams involved in care processes. These teams consist of a group of clinicians and staff who have a shared clinical purpose and direct care responsibilities for a well-defined group of patients. They can be viewed as "temporary firms" that emerge and operate every time a patient with a specific condition is admitted to a hospital or other health care system (Chilingerian & Glavin, 1994). Manser (2008) refers to this type of teams as 'action teams', because of the dynamic conditions under which they have to work and their frequently changing team membership. In this temporary firm the team delivers a unique bundle of products and services, termed here as key interventions, to promote a patient's recovery. Combined together these key interventions form a specific care process. Because these teams comprise different professionals, operate in complex contexts, and are temporary and interactive in nature, communication, coordination, and control over care processes are challenging.

One intervention that can promote teamwork in health care is care pathways (Allen, Gillen, & Rixson, 2009). Care pathways are widely used quality improvement strategies for organizing and reorganizing care processes (Vanhaecht et al., 2006). Compared with other care coordination interventions, such as the chronic care model or integrated care, care pathways are most effective for standardizing low complexity and uncertainty care processes (McDonald et al., 2007). Their use supports healthcare teams in implementing evidence based key interventions and reduce clinical variations in every day practice (Panella, Marchisio, & Di, 2003). Furthermore, they are high-performing work systems that improve organizational performance by strengthening relationships and coordination among team members (Gittell, 2002; Gittell, Seidner, & Wimbush, 2010). The European Pathway Association (E-P-A) defines a care pathway as "a complex intervention for the mutual decision making and organization of care for a well-defined group of patients during a well-defined period" (Vanhaecht, Panella, Van Zelm, & Sermeus, 2010). Complex interventions are those that have been built up from a number of components that may act both independently and interdependently (Craig et al., 2008). Evaluating complex interventions requires more than just knowing whether they work. One needs to understand how and in what circumstances these interventions work by exploring the context in which they are implemented and by identifying their active components (Berwick, 2008; Pawson & Tilley, 1997). As Gittell (2002) found that the performance effects of care pathways are mediated by strong relational coordination, which is an indicator for quality and strength of communication and functional relations between team members, one of these active components might be its effect on interprofessional teamwork. Furthermore, Thomas (2011) states that quality improvement strategies as care pathways, although not always explicitly targeted, could even improve teamwork and have better results for patients than other team training interventions that focus solely on teamwork. Previous published systematic reviews on pathway effectiveness did not primarily focus on how they affect teamwork (Barbieri et al., 2009; Kwan & Sandercock, 2004; Rotter et al., 2010). Our objective was therefore to study this relationship. The following two research questions were addressed:

- (1) What is the effect of care pathways on team indicators used to study the relationship between care pathways and teamwork?
- (2) What conditions are described needed in order for care pathways to be successful?

#### Methods

Search strategy

We applied a sensitive literature search strategy to identify relevant studies. We searched three electronic databases—Medline, Embase, and Cinahl-for articles published between January 1999 and December 2009. Although teamwork is defined as a multifaceted concept, much of the literature on teamwork only focuses on individual facets of the team concept (Lemieux-Charles & McGuire. 2006). Because we wanted to study the relationship between pathways and teamwork in terms of all its facets, we used the results of an international expert panel on team indicators in care processes to identify search terms (Deneckere et al., 2011). Both Mesh and non-Mesh terms for care pathways and teamwork were combined which led to the following search strategy: ('critical pathways' OR 'clinical pathway' OR 'integrated care pathway' OR 'care map') AND ('patient care team' OR 'organizational culture' OR 'personal satisfaction' OR 'job satisfaction' OR 'leadership' OR 'interdisciplinary communication' OR 'cooperative behavior' OR 'conflict' OR 'continuity of patient care' OR 'coordination' OR 'team\*' OR 'work\*'). Limits used were 'humans', 'English', 'abstract', and 'publication in last ten years'. We also examined the reference lists of identified publications. For Medline, the search generated 2026 hits; and for Embase, the search generated 367 additional hits. For the Cinahl search, we combined the terms and the search generated 553 hits. Experts in the field, in this case the board members of the European Pathway Association (www.e-p-a.org), were asked to suggest additional publications. The entire search strategy led to 2946 publications.

#### Selection of studies

To identify pertinent studies for further analysis, we assessed all studies identified by the search based on their eligibility and quality (Appendix 1). We applied the following inclusion criteria. First, the study had to measure the relationship between care pathways and team indicators. We concluded that a study "measured carepathway—team-indicator relationships" if authors performed retro- and prospective analyses of team indicators and/or if they used surveys and qualitative interviews to explore team members' perspectives. Second, the care pathway evaluated had to meet the three operational pathway criteria of Rotter et al. (2010)—i.e., it had to be multidisciplinary, protocol- or algorithm-based, and evidence based. Third, the study implemented a 'mixed methods' approach—i.e., both effect-evaluation and exploratory-evaluation studies were

considered for inclusion (Shepherd et al., 2006). In effect-evaluation studies, the effect of care pathways on team indicators is compared before and after care pathway implementation and/or between an intervention and control population. In exploratory-evaluation studies, team indicators are measured on the basis of team members' perspectives after care pathway implementation. In these types of studies, no comparisons are performed. Fourth, the study had to report original collected data.

Using these four selection criteria, the first author evaluated the titles and abstracts, which limited our search further to 191 publications. Afterwards, he evaluated the full text of these articles for eligibility, leaving 30 publications for further in-depth analysis. To validate this selection process, a second reviewer randomly selected 10% of the 2946 publications obtained from the original searches and independently assessed these for eligibility. The level of inter-rater agreement was .90. Disagreements were resolved by consensus.

The first author subjected all studies meeting the inclusion criteria to quality appraisal based on the standardized framework outlined by the Evidence for Policy and Practice Information and Coordinating Centre (EPPI-Centre) (Shepherd et al., 2006). An overview of the process of quality appraisal can be found in Appendix 2. To validate this quality appraisal process, a second reviewer randomly selected 15 of the 30 (50%) publications and independently appraised them. There were no disagreements on whether to exclude any of the 30 publications. On the basis of critical appraisal, we excluded four studies.

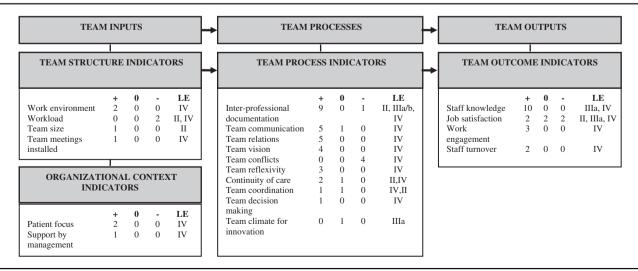
#### Results

We included 26 studies in this review. Appendix 4 contains detailed information on all the data of each included study and a full reference list. In total, we identified 20 team indicators that were used to study the relationship between care pathways and teamwork. Table 1 presents an overview of the effects we found of care pathways on the identified team indicators. In the following part we describe those effects that were most frequently found and that reached highest level of evidence. Level of evidence was based on a modified four-level evidence hierarchy (Appendix 3) (Polit & Beck, 2004).

We found that care pathways positively affected 17 and negatively affected 4 of 20 indicators. Ten publications reported that the implementation of care pathways increased staff knowledge. Using a pretest—posttest non-equivalent groups design (Level IIIa), a study measured a 5% increase in 15 of 20 items of the Palliative Care Knowledge Ouiz for Nurses four months after pathway implementation (p < 0.003). Nine publications reported that care pathways positively affected interprofessional documentation of care. Level II evidence from a cluster randomized controlled trial showed that pathways significantly reduced prescribing errors by 30% (p = 0.002). In addition, Level II evidence from a randomized controlled trial demonstrated that pathways significantly increased documentation of discharge information given to patients by 19% (CP = 89% vs. non-CP = 70%; p = 0.024). We also found Level II evidence for the indicator team size. A randomized controlled trial showed improved planned versus actual team size. In this case the absolute value of the number of planned versus actual disciplines was significantly lower in the test or CP group than in the control or non-CP group (CP = 12; non-CP = 24; p < 0.001). Improved continuity of care was found based on level II evidence. A randomized controlled trial showed that early discharge notification to general practitioners increased significantly (80% versus 45%; p < 0.001). Level II evidence indicated that the implementation of care pathways increased workload. A cluster randomized controlled trial found that the number of clinical contacts was significantly higher in a care pathway (CP) group than in a standard care or non-CP group (CP = 6; non-CP = 5.5; p = 0.04). Another study also reported higher workload based on level IV evidence. In a randomized controlled trial, pathways had no effect on job satisfaction (Level II). Similarly, using a pretest—posttest non-equivalent groups design no significant effect on job satisfaction was found (Level IIIb). However, they did find a significant positive effect on satisfaction with autonomy but a significant negative effect on satisfaction with task requirement.

We found Level IV evidence for the following conditions described needed in order for care pathways to be successful: (1) multidisciplinary team approach in care pathways; (2) educational training sessions on how to use the care pathway; (3) a case manager that coordinates the care team; (4) sufficient time and resources required to develop, implement, and follow-up the care

**Table 1**Overview of impact of care pathways on the identified team indicators.



pathway; (5) adequate management support; (6) physician involvement; and (7) cross-boundary collaboration.

#### Discussion

This is the first systematic review to explore the relationship between care pathways and teamwork. To evaluate this relationship, we adopted a multifaceted "input-process-output" approach. This approach enabled us to study the relationship between care pathways and all facets of teamwork, and therefore enhances our understanding on how and in what circumstances care pathways operate. We chose to adopt a broad perspective as we selected studies by including both effect-evaluation and exploratoryevaluations. The choice to include studies with a lower level of evidence was carefully considered. In his commentary, Berwick (2008) advocates researchers to embrace a wide range of research methodologies when evaluating complex improvement interventions. Typical experimental (observation-intervention-observation or OXO) designs are insufficient for evaluating complex interventions. In these designs, the approach for gathering evidence is constrained due to their single-intervention focus and standardized contextual set-up. To gain insight into the active components of complex interventions, one also needs to evaluate the context in which these interventions are implemented and the mechanisms underlying them (Berwick, 2008; Craig et al., 2008; Pawson & Tilley, 1997). Applying this suggestion led us to also include studies that used non-experimental, qualitative approaches to explore the local experiences of team members with care pathway implementation. We ensured the validity of the selection process by performing rigorous quality appraisals based on standardized theoretical frameworks for both types of evaluation studies.

We identified 20 team indicators and found that care pathways positively affected 17 of these indicators. The organizational conditions needed for successful pathways that we identified in the assessed papers are consistent with those of Evans-Lacko, Jarrett, McCrone and Thornicroft (2010). Overall, the level of evidence we found was rather low and sometimes conflicting. Twelve of the found positive effects are exclusively based on Level IV evidence, thus through non-experimental, qualitative studies on team members' perspectives. This implies that team members often do experience improvement in one or more team indicators after pathway implementation. However, due to methodological issues as lack of high-quality controlled studies and lack of use of validated indicators and tools, these positive effects are seldom rigorously proven. Further research using controlled trials, such the European Quality of Care Pathway (EQCP) Study (Vanhaecht, Panella, et al., 2010; Vanhaecht, Sermeus, Peers, et al., 2010) are necessary to elucidate these matters.

Most frequently positive effects were found on staff knowledge, interprofessional documentation, team communication and team relations. The potential of care pathways to increase staff knowledge is important taking into account the growing complexity of care delivery in an already knowledge-intensive environment. This increase in staff knowledge is due to standardization of care and the continual training upgrades that are inherent in care pathways. Through this, task uncertainty can be reduced and work engagement increased because of a perception of a higher level of competence by the team members. This could in turn influence staff turnover. In our review we also found a positive effect on work engagement and staff turnover. But it is still scarcely being studied. The systematic review of Rotter et al. (2010) confirms the finding that pathways have a positive effect on interprofessional documentation. Except for highly interdependent work environments as in intensive care or the operating room, teams in healthcare are mostly virtual teams with each professional having their own

workplace separate from each other. Care pathways can then serve as co-ordinating mechanisms assuring a necessary level of communication (Gittell, 2002). The positive effect of pathways on satisfaction was inconsistent, because we also found negative effects and no evidence of an effect. Job satisfaction can be influenced by a complex set of causal organizational and social factors. Therefore, it seems plausible that care pathway implementation would have only a minor or even no effect on job satisfaction.

Most frequently found negative effect were emerging team conflicts through pathway implementation. Although teams operate in a high social interdependent work environment, because teams in healthcare are temporary and interactive in nature and comprise different professionals with different professional backgrounds and cultures, group identity can be rather low. Degeling et al. (2003) concluded that this professional fragmentation influences each profession's response to necessary healthcare reforms, and thus can hinder the implementation of care pathways. Furthermore, as teams involved in pathway development frequently are newly formed work groups, these teams will have to struggle through the first storming stages of group development (Tuckman, 1965). However, Tjosvold (2008) stated that, when managed appropriately, conflicts can make teamwork even more effective. The increased workload through pathway implementation effect is rather striking, because one of the most important goals of pathways is to standardize care by decreasing variation and reorganizing care processes (Panella et al., 2003). Both are expected eventually to decrease non-value-creating activities and thus. contra intuitively, decrease workload. Perhaps during and directly after pathway implementation the team can perceive a higher workload due to the changing work processes. But the goal should be that after an adaption period workload should decrease. Nonetheless, higher workload can sometimes be required to assure higher quality of care.

The systematic review showed that care pathways have the potential to support interprofessional teams in enhancing teamwork. As care pathways are complex interventions, multiple behavioral and organizational components will influence the extent in which they can be integrated into everyday health care practice. This will in turn determine their actual effectiveness. According to the Normalization Process Model, the implementation process of complex interventions should therefore clearly be monitored and modified based on the individual organizational and team characteristics (May et al., 2007). Each pathway implementation process should therefore contain a clearly defined team approach and development strategy in their active components that could mediate pathway effectiveness on teamwork. The elements that will need to be included will be based on what is required to improve the effectiveness of the teams' own inputs, processes and overall performance.

For improving team inputs, a supportive organizational context for care pathways will need to pursue a service-line driven and team-based organization that puts both care processes and teams in the frontline of concern. We believe the organizational model of Clinical Microsystems could facilitate this (Nelson, Batalden, & Godfrey, 2007). In this model the hospital is built up of several microsystems that all contain dedicated interprofessional teams working together on a regular basis to provide care to discrete subpopulations including the patients. Each microsystem has their own clinical and business aims, linked processes, shared information environment and produces performance outcomes. Care pathways then can act as an integration system among teams involved in linked mircosystems. Secondly, concerning team processes, different types of team training could be considered (Baker et al., 2005). We see a mix of cross-training, self-correction, and team-building exercises as types of team training that could be useful in care pathway development. Through this training, roles and tasks of team members can be traded, interprofessional relations can be improved, feedback on performance is provided, short-and long-term team goals are set, and an overall team vision and shared mental model is built up. Through this protocol, high-performance teams can be established and more effective care pathways can be built.

#### **Conclusion**

Although evidence was of rather low quality, this systematic review provides a positive, but cautious, indication that a relationship between care pathways and teamwork exists. The absence of high-level evidence is partially due to the lack of high-quality designs and the failure to use validated team indicators in pathway effectiveness studies. Furthermore, as pathways are complex interventions, there is still a lack of knowledge concerning in which context conditions pathways can be effective, what mediating active ingredients need to be included, and on which aspects of teamwork they can have an effect. For care pathways to be effective, a clear link is needed between the indicators targeted for improvement and the pathway-intervention itself. Further research is necessary to elucidate these matters. Healthcare managers will need to be aware of the organizational contexts, mechanisms and conditions that must be present for a pathway to be successful. Furthermore, they will need to include in their pathways the right active elements that will promote interprofessional teamwork. Therefore, each care pathway will need to contain a clearly defined team approach, customized to the individual teams' needs.

#### Appendix A. Supplementary material

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.socscimed.2012.02.060.

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METHODOLOGY Open Access

# Eight-step method to build the clinical content of an evidence-based care pathway: the case for COPD exacerbation

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#### **Abstract**

**Background:** Optimization of the clinical care process by integration of evidence-based knowledge is one of the active components in care pathways. When studying the impact of a care pathway by using a cluster-randomized design, standardization of the care pathway intervention is crucial. This methodology paper describes the development of the clinical content of an evidence-based care pathway for in-hospital management of chronic obstructive pulmonary disease (COPD) exacerbation in the context of a cluster-randomized controlled trial (cRCT) on care pathway effectiveness.

**Methods:** The clinical content of a care pathway for COPD exacerbation was developed based on recognized process design and guideline development methods. Subsequently, based on the COPD case study, a generalized eight-step method was designed to support the development of the clinical content of an evidence-based care pathway.

**Results:** A set of 38 evidence-based key interventions and a set of 24 process and 15 outcome indicators were developed in eight different steps. Nine Belgian multidisciplinary teams piloted both the set of key interventions and indicators. The key intervention set was judged by the teams as being valid and clinically applicable. In addition, the pilot study showed that the indicators were feasible for the involved clinicians and patients.

**Conclusions:** The set of 38 key interventions and the set of process and outcome indicators were found to be appropriate for the development and standardization of the clinical content of the COPD care pathway in the context of a cRCT on pathway effectiveness. The developed eight-step method may facilitate multidisciplinary teams caring for other patient populations in designing the clinical content of their future care pathways.

**Keywords:** Critical pathway, Evidence based medicine, Standardization, Cluster randomized trial, Chronic obstructive pulmonary disease

#### **Background**

Standardization of the clinical care process through integration of evidence-based knowledge has proven to be an effective strategy for reducing unwanted variations in treatment and for minimizing the probability of medical errors [1]. However, major difficulties arise when introducing evidence and clinical guidelines into routine daily

practice, and many patients, as a result, do not receive appropriate care, or receive unnecessary or harmful care [2-5].

A possible tool to facilitate implementation of evidence into practice is a care pathway. Care pathways are complex interventions for mutual decision making, organization, and standardization of predicTable care for a well-defined group of patients during a well-defined period [6-8]. One of the active ingredients in care pathways is the integration of a set of evidence-based key interventions [8,9].

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Care pathways induce change at different levels of the organization (that is, patient, team, hospital); consequently, variability at individual level outcomes may reflect the impact of higher-level complexity processes. To deal with these multilevel effects, cluster randomized designs are strongly recommended when studying the impact of care pathways [10,11]. Importantly, in cluster randomized controlled trials (cRCTs) the care pathway under evaluation is implemented at different sites. Consequently, a challenge within cRCT designs is to standardize the intervention in order to deliver the 'same' intervention at the different sites under study [10,12-14]. Standardization in complex interventions refers to adaptation of the care pathway components to the context level, without compromising the integrity of the intervention being evaluated across multiple sites [10,14,15].

In 2009, the European Pathway Association (E-P-A) launched the European Quality of Care Pathways (EQCP) study, an international cRCT addressing the impact of a care pathway for chronic obstructive pulmonary disease (COPD) exacerbations [9]. In the context of the EQCP study, the clinical content of a model COPD care pathway - implementable at the different experimental sites - needed to be developed, including a set of clinically applicable evidence-based key interventions and a set of reliable process and outcome indicators. This paper describes the development of the clinical content of a care pathway for in-hospital management of COPD exacerbation.

#### **Methods**

The clinical content of an evidence-based care pathway for COPD exacerbation was developed based on the process design methodology developed by Berry *et al.* [16], and the guideline development methods of the American College of Chest Physicians (ACCP) [17], the World Health Organization (WHO) [18] and the Health-care Infection Control Practices Advisory Committee (HICPAC) [19]. Subsequently, based on the experiences of the COPD case, a generalized eight-step method for development of the clinical content of an evidence based care pathway was designed (Figure 1). This study was approved by the ethical committee of the University Hospitals Leuven as previously published in this journal [9].

#### Results

A set of 38 evidence-based key interventions and a set of 24 process and 15 outcome indicators were developed in eight different steps. Both sets are displayed in Additional file 1 and Additional file 2, respectively. In the following section, description and rationale for each development step is presented.

## Step 1: Selection of the care population and selection of an expert panel

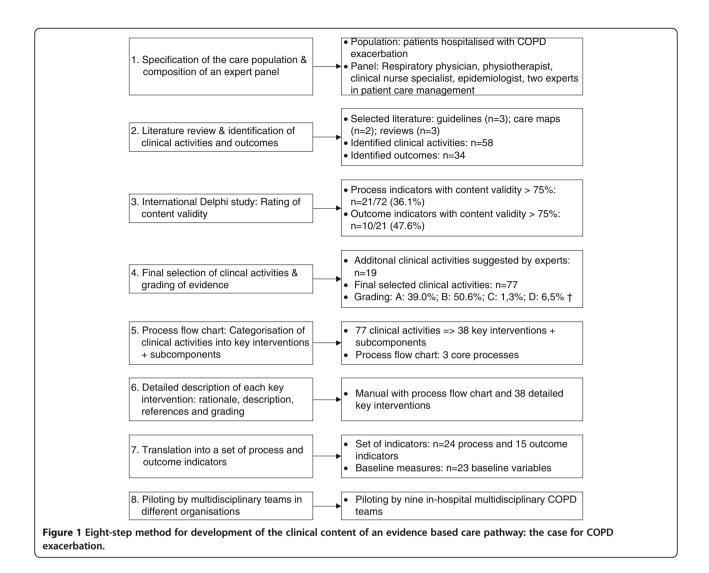
The patient population under study was specified as 'Patients hospitalized with COPD exacerbation'. To ensure clinical validity and feasibility of the end product, an expert panel was involved in each step of the development method. This panel was composed of the following: (i) three clinicians with internationally recognized clinical and scientific expertise in COPD exacerbations: a respiratory physician (MD) who is also president of the European Respiratory Society, a physiotherapist (TT) who specializes in pulmonary rehabilitation, and a clinical nurse specialist in COPD (CL); (ii) an epidemiologist (MP) who specializes in organization of primary and secondary chronic care; and (iii) two professors (WS, KV) in patient care management who have extensive clinical and scientific expertise in development and implementation of care pathways [8,18-21]. All six experts had extensive research experience.

## Step 2: Literature review and extraction of clinical activities

To identify all available evidence for integration in the evidence-based COPD care pathway, an extensive literature review was conducted by the main researchers, CL and KV (Figure 2). First, an initial literature search was carried out in April 2008 in the context of the Delphi study, and an updated search was performed in June 2011. In the following section, the updated search is described [22].

The following resources were explored: (I) websites of international respiratory societies: American Thoracic Society (ATS) (www.thoracic.org); British Thoracic Society (BTS) (www.brit-thoracic.org.uk); European Respiratory Society (ERS) (www.ersnet.org); Global Strategy for Diagnosis, Management, and Prevention of COPD (GOLD) (www.goldcopd.org); National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk); Scottish Intercollegiate Guidelines Network (SIGN) (www.sign.ac. uk); (II) Public resources for evidence-based clinical practice guidelines (www. guideline.gov, www.g-i-n.net); (III) electronic databases including Medline and Embase and Cochrane; (IV) available process flow diagrams founded on evidence-based medicine (www.mapofmedicine.com, http://group.bmj.com/products/evidence-centre.com).

For guidelines developed by international societies, only those guidelines were considered that were updated within the last five years. For PubMed and Cochrane, we used the MeSH terms 'COPD' combined with (i) 'practice guideline', (ii) 'disease exacerbation and patient care management', and (iii) 'outcomes'. For Embase, we used the MeSH terms 'chronic obstructive lung disease' combined with (i) 'practice guideline' and (ii) 'disease exacerbation and patient care', and (iii) 'outcomes'. Non-MeSH

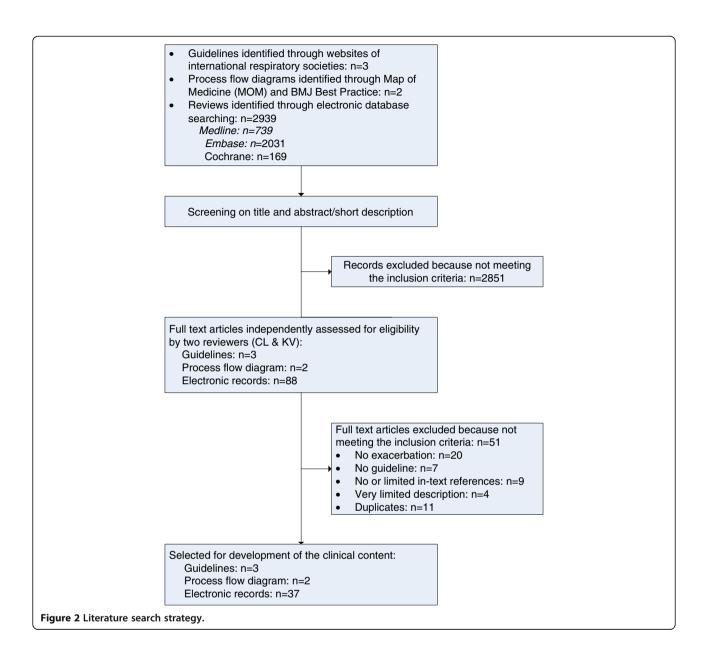


terms used in Embase were 'COPD' in combination with 'exacerbation and management'. Search limit parameters included: (i) published between 2005 and 2011, and (ii) written in English, French, German, Italian or Dutch.

Second, we performed a two-phase screening evaluation of publications selected from websites of the respiratory societies, Map of Medicine and the electronic databases. In the first phase, publications were appraised for relevance based on appropriateness of the title and abstract. If relevance was unclear, or if the abstract was unavailable, the publication was included for further appraisal of the full text. In the second phase, two independent researchers (CL and KV) reviewed the full text of the selected guidelines, reviews or process flow diagrams. The following inclusion criteria were used: (i) reportage of clinical processes and outcomes regarding in-hospital management of COPD exacerbation; (ii) evidence was reported in terms of guidelines, process flow diagrams, reviews or overview papers; (iv) published between 2005 and 2011;

(v) published in English, French, German, Italian or Dutch; and (vi) quality of underlying evidence can be appraised by in-text references. The literature research revealed initially three guidelines, one process flow diagram, and 2,939 digital records from the electronic medical databases (Figure 2). After exclusion of irrelevant publications (n = 2,851), and after appraisal of full text, three guidelines, two process flow diagrams, and 37 reviews were included for development of the evidence-based clinical content of the COPD care pathway [5,23-56].

Finally, the selected literature was thoroughly screened for identification of all possible clinical activities and outcomes related to in-hospital management of COPD exacerbation. The detected clinical activities were extracted and listed, and the corresponding literature sources were recorded. In total, 58 different clinical activities were extracted from the selected literature (Table 1, no. 1–58). Besides these, 34 outcome categories were identified (Table 2).



## Step 3: International Delphi study for rating of content validity

Content validity was rated for 72 process and 21 outcome indicators by conducting an international Delphi study with a panel composed of 35 medical professionals from 15 countries. This panel consisted of 19 medical doctors, 8 nurses and 8 physiotherapists. The detailed methodology and the results of this study were published elsewhere [57-60].

In summary, panelists were asked to rate the relevance for follow-up of the process and outcome indicators in care pathways for COPD exacerbations. Consensus was defined as agreement by at least 75% of the panel members that an indicator is relevant for follow-up. Consensus was reached for 26 of 72 process indicators (36.1%) and

10 of 21 outcome indicators (47.6%). Highest consensus was reached for the process indicators for oxygen therapy (100%), pulmonary rehabilitation (100%), and patient education (94.5 to 88.6%), and for the outcome indicators for understanding of therapy (91.4 to 85.7%) and self-management (88.6 to 88.2%) [60].

## Step 4: Final selection of the clinical activities and grading of evidence

First, the list of 58 extracted clinical activities (step 2), together with the Delphi results (step 3), were sent to the clinical experts of the panel (MD, TT and CL) with a request to complete two tasks: (i) to review the 58 identified activities for validity and feasibility; and (ii) if indicated, to propose any additional clinical activity they

#### Table 1 Clinical activities for management of patients hospitalized with COPD exacerbation

- 1. Medical history before exacerbation: prior measures of lung function (B)\* 37.
- 2. Medical history before exacerbation: spirometric classification of severity (B)
- 3. Medical history before exacerbation: documenting frequency and severity of attacks of breathlessness (B)
- 4. Medical history before exacerbation: documenting frequency and severity of chronic cough (B)
- 5. Medical history before exacerbation: history of chronic sputum production (B)
- 6. Medical history before exacerbation: documenting possible limitation of daily activities (B)
- 7. Medical history before exacerbation: prior arterial blood gas measurements in sTable condition (B)
- 8. Medical history before exacerbation: number of previous exacerbations in the previous year (B)
- 9. Medical history before exacerbation: number of previous hospitalizations (B)
- 10. Medical history before exacerbation: pre-existing co-morbidities (A)
- 11. Medical history before exacerbation: present treatment regimen (A)
- 12. Medical history before exacerbation: smoking status (B)
- 13. Medical history before exacerbation: sleeping and eating difficulties (B)
- 14. Assessment of symptoms: physical examination (B)
- 15. Assessment of differential diagnosis (B)
- 16. Assessment of co-morbidities (B)
- 17. Temperature (B)
- 18. Pulse rate (B)
- 19. Blood pressure (B)
- 20. Alertness (B)
- 21. Skin color (B)
- 22. Pulse oximetry (D)
- 23. Arterial blood gas measurement: At admission (B)
- 24. Arterial blood gas measurement: prior to discharge in patients hypoxemic during a COPD exacerbation (B)
- 25. Arterial blood gas measurement: in the following three
- months in patients hypoxemic during a COPD exacerbation (D)
- 26. Arterial blood gas measurement: after discharge in patients with long term oxygen therapy (LTOT) (B)
- 27. Chest X-ray (B)
- 28. ECG (B)
- 29. Blood examination: hematology (B)
- 30. Blood examination: biochemical tests (B)
- 31. Blood examination: theophylline level in patients on theophylline therapy at admission (B)
- 32. Sputum culture and anti-biogram (B)
- 33. Spirometry during hospitalization (not earlier than Day 3 because of acute condition) (C)  $\,$
- 34. Admission to ICU if exacerbation is life threatening (B)
- 35. Controlled oxygen therapy in hypoxemic patients (A)
- 36. Assisted ventilation if necessary (A)

- 37. Smoking cessation advice when active smoker (A)
- 38. Appropriate prescription of short-acting bronchodilatators (A)
- 39. Appropriate prescription of long-acting bronchodilatators
- (β-agonists and/or anticholinergics) (A) 40. Appropriate prescription of inhaled corticosteroids (A)
- 41 Assessment and the second s
- 41. Appropriate prescription of glucocorticosteroids: oral or intravenous (A)
- 42. Appropriate prescription of methylxanthines (theophylline or aminophylline) (A)
- 43. Antibiotics in patients if indicated (A)
- 44. Patient education information about recognition and treatment of exacerbation (A)
- 45. Patient education: instruction on how to use inhalers (A)
- 46. Chest physiotherapy: sputum clearance (A)
- 47. Referral to pulmonary rehabilitation (A)
- 48. Monitoring of fluid balance (A)
- 49. Fluid administration in dehydrated patients (A)
- 50. Supplementary nutrition in patients with BMI <20 (B)
- 51. Screening and update of vaccination status (B)
- 52. Deep venous thrombosis prophylaxis (A)
- 53. Treatment of co-morbid conditions (A)
- 54. Initiation of long-term oxygen therapy (LTOT) if the patient remains hypoxemic (A)
- 55. Assessment of medical discharge criteria (D)
- 56. Assessment and management of home situation (A)
- 57. Oral information and discharge letter regarding prescribed home therapy and follow-up appointment (B)
- 58. Arrangement of follow-up appointment four to six weeks after discharge (D)
- 59. Medical history before exacerbation: number of previous admissions to ICU (D)
- 60. Medical history before exacerbation: cardiovascular status (B)
- 61. Glucose monitoring (B)
- 62. CT THORAX: 1 X year (B)
- 63. ECHO CARDIO: 1 X year (B)
- 64. Patient education: information about the nature of COPD (A)
- 65. Patient education: self-management plan (A)
- 66. Patient education strategies for minimizing dyspnoea (A)
- 67. Patient education information about oxygen treatment (A)
- 68. Physiotherapy: breathing techniques (A)
- 69. Physiotherapy: Activities of Daily Life (A)
- 70. Physiotherapy: positioning (A)
- 71. Identification for pulmonary rehabilitation determinant (B)
- 72. Body mass index (BMI) determinant (A)
- 73. Screening for weight loss (A)
- 74. Referral to dietician in patient with obesity or cachexie (B)
- 75. Assessment and management of anxiety and depression (B)
- 76. Information letter for general practitioner (B)
- 77. Discharge checklist (B)

believe is essential for in-hospital management of COPD exacerbations and which is lacking in the current activity list of clinical activities. Second, a consensus meeting was held with the entire expert panel in order to make a final selection of the clinical activities. As a result, all 58 clinical activities were appraised to be valid and feasible. In addition, 19 clinical activities beyond the 58 original ones were included (Table 1, nos. 59–77). Interestingly, for almost all these additional clinical activities, a more

or less comprehensive description was available in the guidelines for management of stable COPD [27,32,61].

Finally, the strength of the evidence for the final 77 clinical activities was graded, so that clinicians know how much confidence they can place on the clinical recommendations included in the clinical care pathway [62]. The grading was performed by the clinical nurse specialist (CL) using the SIGN approach [63]. The grading approach of SIGN was chosen because this grading

#### Table 2 Identified outcomes for in-hospital management of COPD exacerbation

- Readmission: 30-day, 3-month, 6-month, 1-year
- · Number of hospital admissions
- Interval before next admission
- Frequency and severity of exacerbation
- · Mortality: in-hospital, 30-day, 3-month, 6-month, 1-year
- · Survival: 1-year
- · Length of stay (LOS)
- Level of understanding of inhaler therapy
- · Compliance with home oxygen therapy
- Performance of physical exercise
- · Smoking status: 30-day, 3-month, 6-month, 1-year
- · Symptoms of anxiety and depression
- Health-related quality of life (HRQL): symptoms, disability, morbidity and quality of life; psychological well-being)
- Health status
- Quality-adjusted life expectancy measure (QALY) and disability adjusted life years (DALY)
- Functional capacity
- · Exercise capacity
- Physical performance: 6-minute walking distance (6-MWD), 20-MWD, shuttle walk test, maximum workload, treadmill time, maximum oxygen uptake, quadriceps strength, hand grip force, maximal inspiratory mouth pressure
- Severity of breathlessness: dyspnea, symptoms at rest and during exercise

- $\bullet$  Inhaled  $\beta\mbox{-agonist}$  therapy is required no more frequently than every four hours
- Patient, if previously ambulatory, is able to cope with basic needs in his/her situation, in usual environment
- Patient is able to eat and sleep without frequent awakening by dyspnoea
- Patient has been clinically sTable for 12 to 24 hours
- Last measure of arterial blood gases (ABGs) were accepTable according to condition of the patient
- Patient and/or home caregiver fully understands correct use of therapy: oral medication therapy, inhaler therapy, oxygen therapy if home oxygen therapy

Patient, family, and physician are confident that the patient can manage successfully

- Lung function parameters: forced expiratory volume in one second (FEV<sub>1</sub>), forced vital capacity (FVC), inspiratory capacity
- · Quality of sleep
- Nutritional status
- Patients' perception of coordination between hospital and home healthcare
- Patient satisfaction with therapy and care
- Adverse event related to regular clinical examination by an investigator
- · Cost of illness (COI) analysis
- Absenteeism

system is very transparent and provides a simplistic grading of evidence [62-64]. Importantly, if the level of evidence could not be derived based on the literature selected in step 2, an additional literature search was performed in Medline, Embase and Cochrane. Search terms included 'COPD' and key words related to the particular key intervention. Primarily, the search for additional evidence was focused on reviews performed according to standard criteria for reviews [22]. If not available, an additional search for clinical trials was conducted. Subsequently, two other clinical experts of the panel (MD and TT) checked the final grading. As a result, 30 activities were graded as evidence for level A (39.0%), 41 activities as level B (53.2%), 1 activity as level C (1.3%), and 5 as level D (6.5%) (Table 1).

An extensive list of care activities was generated by following the above-mentioned steps. However, providing such an exhaustive list of 77 care activities to the multidisciplinary teams would likely not encourage them to use this evidence in practice. Therefore, the next two steps were specifically undertaken to distil the list of care activities to a set of key interventions that would be useable and manageable in clinical practice.

## Step 5: Clustering of clinical activities into key interventions and categorization into process flow diagram

First, the 77 clinical activities were clustered into key interventions with subcomponents, based on the following criteria: (i) clinical activities are inextricably linked to each other (that is, measurement of basal metabolic

index, advice on malnutrition, supplementary nutrition and so on were clustered into 'nutrition'); (ii) clinical activities need to be performed by a specific team member (that is, breathing exercises, positioning and so on were categorized under physiotherapy); (iii) clinical activities need to be performed at a specific time point or within a specific time span of the care process (that is, activities regarding discharge management). As a result, the 77 clinical activities were clustered into 38 key interventions, with 9 of them comprising 2 to 15 subcomponents.

Second, the key interventions were categorized into three core processes (diagnostic, pharmacological and non-pharmacological management), and subsequently presented by means of a process flow diagram. In addition, within each of three core processes, key interventions were grouped into care blocks based on the overall content of these key interventions (for example, education, ventilation). The process flow diagram with the 38 key interventions is displayed in Additional file 1.

#### Step 6: Detailed description of the key interventions

For each key intervention, the following components were included in the detailed description: (i) rationale, which addresses why it is of crucial importance that the key intervention is performed, and which describes expected impact on patient outcomes; (ii) description, which defines the exact content of the key intervention; (iii) in-text references and reference list; and (iv) grading of evidence. An example of a detailed description of a key intervention on arterial blood gas measurements is provided in Figure 3. In order to search for detailed

#### Arterial blood gas measurement

#### Argumentation

Measurement of arterial blood gases (ABGs) is essential to detect hypercapnia and to assess the severity of an exacerbation. Consequently, ABG values are the key determinant for initiating supplemental oxygen therapy, prescribing assisted ventilation, and prescribing home oxygen therapy. A PaO $_2$  < 8.0 kPa (60 mm Hg) and/or SaO $_2$  < 90% with or without PaCO $_2$  > 6.7 kPa (50 mmHg) when breathing room air indicate respiratory failure. In addition, moderate-to-severe acidosis (pH < 7.36) plus hypercapnia (PaCO $_2$  > 6-8 kPa; 45-60 mmHg) in a patient with respiratory failure is an indication for mechanical ventilation (Barbera et al., 1997; Calverley, 2000; Celli et al., 2004; Gibson et al., 2008; GOLD, 2009; NICE, 2004; Rodriguez-Roisin, 2006; Siafkas & Wedzicha, 2006).

In the Delphi study 82.9% of experts were convinced that the key intervention has a high impact on clinical outcomes and therefore should be included in the pathway.

Description: (Celli et al., 2004; Gibson et al., 2008; GOLD, 2009; NICE, 2004; Rodriguez-Roisin, 2006; Siafkas & Wedzicha, 2006)

Measurement of PaO<sub>2</sub>, PaCO<sub>2</sub>, H<sub>2</sub>CO<sub>3</sub>, SaO<sub>2</sub>, and pH by arterial puncture (a. radialis, brachialis, or femoralis) while breathing room air at admission. If measurement of ABGs while breathing room air is not feasible (severe cases), oxygen flow (I/min) should be noted. Twenty to 30 minutes should pass before rechecking the gas tensions when the FiO<sub>2</sub> has been changed.

#### References:

Barbera, J. A., Roca, J., Ferrer, A., Felez, M.A., Diaz, O., Roger, N., Rodriguez-Roisin, R. (1997). Mechanisms of worsening gas exchange during acute exacerbations of chronic obstructive pulmonary disease. *European Respiratory Journal*, 10, 1285-91.

Calverley, P.M. (2000). Oxygen-induced hypercapnia revisited. Lancet, 356:1538-1539.

Celli, B. R. & Macnee, W. (2004). Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. *European Respiratory Journal*, 23(6), 932-946.

Gibson G & Macnee W. (2008). Chronic Obstructive pulmonary disease: Investigations and assessment of severity. In: Siafkas (Ed), European Respiratory Monograph: Management of exacerbation of chronic obstructive pulmonary disease (pp. 24-40). Sheffield: European Respiratory Society Ltd.

Global Initiative for Chronic Obstructive Lung Disease (GOLD) (2009). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Last accessed: January 27, 2010. http://www.goldcopd.com/Guidelineitem.asp?l1=2&l2=1&intld=2003

National Institute for Clinical Excellence (NICE) (2004). Chronic obstructive pulmonary disease: national clinical guideline for management of chronic obstructive pulmonary disease in adults in primary and secondary care. *Thorax*, 59 (Suppl. 1), 1-53.

Rodriguez-Roisin, R. (2006). COPD exacerbations: management. Thorax 61, 535-544.

Siafkas N. M. & Wedzicha J. A. (2006). Management of exacerbation of COPD. In: Siafkas (Ed), European Respiratory Monograph: Management of exacerbation of chronic obstructive pulmonary disease (pp. 387-400). Sheffield: European Respiratory Society Ltd.

Figure 3 Example of detailed description of a key intervention: arterial blood gas measurement.

information on the description and the rationale, selected publications and their reference list were explored. Second, information from the additional literature search, performed to establish level of evidence (step 4), was included.

### Step 7: Translation into a set of process and outcome indicators

Besides the set of key interventions, a set of process and outcome indicators needed to be developed to verify compliance to key interventions and to follow up the impact on outcomes. First, to select the final set of indicators, the expert panel convened for a consensus meeting. The selection process was based on the (updated) literature search (step 2), the Delphi survey (step 3), and the developed set of 38 evidence-based key interventions (step 5) [60]. As a result, a set of 24 process and 15

outcome indicators was developed, which are displayed in Additional file 2. The 24 process indicators include measurements on performance of diagnostic, pharmacological and non-pharmacological interventions. The 15 outcome indicators include measurements on readmission, mortality, length of stay (LOS), understanding of inhaler therapy, compliance with home oxygen therapy, performance of physical exercise, smoking status, anxiety and depression, health-related quality of life, management at home, functional status, self-reported health condition, medical consumption and an economic evaluation. On the basis of their expertise, the panel also selected a set of 15 baseline variables, including medical, socioeconomic, demographic and COPD-specific data.

Subsequently, the selected indicators and baseline variables were operationalized into objective measurements [65]. Based on the guidance of the Agency for Health

Care Research and Quality (www.qualitymeasures.ahrq. gov) and the Joint Commission (www.jointcommission. org), each indicator and baseline variable was defined in an indicator protocol by the main researcher (CL). This process included defining of description, rationale or relation to quality, type of indicator (process, outcome, baseline), nominator and denominator, data collection method, data elements, data reporting (that is, proportion, relative proportion), criteria to meet expected outcomes, and references. An example of an indicator description is detailed in Additional file 3. Subsequently, the indicator protocol was mailed to the entire expert panel with a request to appraise each indicator description thoroughly for accuracy and feasibility. A meeting with the entire expert panel was convened to discuss the feedback and finalize the indicator protocol.

#### Step 8: Piloting by multidisciplinary teams

The set of 38 key interventions, and the set of 24 process and 15 outcome indicators, were piloted by nine Belgian experimental COPD teams in the context of the EQCP study [9]. The multidisciplinary teams included pulmonologists, nurses, physiotherapists, dieticians, social workers and occupational therapists. The piloting occurred in four phases. First, feasibility of data collection was evaluated during a clinical audit before pathway implementation. For this phase, 105 patients from 9 Belgium hospitals were included [9]. Mean age was 67 years (SD: 10.0), and 68.6% of the patients were male. Approximately half of the patients had severe COPD, 21% had moderate COPD and another 21.9% had very severe COPD. Overall, after data analyses we determined that data collection is feasible, and only minor adaptations with regard to the patient record analysis were included.

Second, during a workshop in which team members of all nine multidisciplinary COPD teams attended, the process flow diagram, including the 38 key interventions, was presented. Subsequently, all key interventions were extensively discussed. Third, the detailed set of key interventions was provided to the study coordinator of each hospital. We requested all members of the multidisciplinary COPD team to extensively review the key intervention set and subsequently to provide feedback within two weeks. As a result, the feedback given during the workshop and provided after extensive appraisal by all teams showed that teams were very enthusiastic about the process flow diagram and underlying key interventions. Moreover, they agreed by consensus that the set of key interventions was valid and applicable for use in their practice.

However, the teams provided four main remarks regarding: (i) usefulness of spirometry during exacerbation because results may be inaccurate due to the compromised condition; (ii) feasibility of referral to pulmonary rehabilitation with regard to condition of the

patient and availability of a rehabilitation center; (iii) type of inhaler medications and device (nebulizer vs inhaler); and (iv) finally content, workload and feasibility of patient education. First, with regard to spirometry, no hard evidence about accuracy and, thus, usefulness of spirometric tests during exacerbation is available and, thus, no specific guidance on whether or not to perform spirometric tests could be provided to the teams. This issue was specifically emphasized in the detailed set of key interventions. Concerning pulmonary rehabilitation, all teams were convinced about the importance of referring patients to rehabilitation, and consequently, during the workshop some alternatives with regard to availability of a rehabilitation center were discussed. Finally, with regard to inhaler therapy and patient education, a teaching workshop was organized and education tools for COPD teams and ready-to-use patient leaflets were provided.

Finally, the nine multidisciplinary COPD teams implemented the set of key interventions as an active component of their care pathway for in-hospital management of COPD exacerbation in the context of the EQCP study [9]. Six months after the start of development and implementation of the care pathway, the nine teams had the opportunity to report experiences, barriers and successful actions during a workshop. One major difficulty in implementing the educational package into the daily work routine was reported. Overall, the teams confirmed validity and clinical applicability of the set of 38 key interventions.

#### **Discussion**

A set of 38 evidence-based key interventions for inhospital management of COPD exacerbation was developed (see Additional file 1) and, subsequently, piloted and validated by multidisciplinary COPD teams from nine different hospitals. This overall approval indicates that the applied strategy is appropriate for the development and standardization of the clinical content of an evidencebased care pathway. Second, a set of 24 process and 15 outcome indicators was also developed (see Additional file 2). The pilot study showed that the measurements on the indicators were feasible for the multidisciplinary teams and the patients; only some minor adaptations were required. Subsequently, based on our experience and what we have learned from the COPD case, we designed a generalized eight-step method (Figure 1), with the aim to guide and inspire teams caring for other patient groups in designing the clinical content of their future evidencebased care pathways.

It is important to note that designing the care pathway content according to the eight-step strategy is a time-consuming process, especially with regard to the Delphi survey (step 3) and pilot testing (step 8). However,

results of the Delphi survey and piloting are essential to ensure that the key intervention set is widely, clinically applicable. This is especially important when conducting a cRCT, in which the 'same' care pathway intervention needs to be implemented by different teams at different sites and possibly in different countries [9]. Teams developing care pathways should carefully plan an implementation strategy and budget enough time in their project plan for proper development of the clinical content of their care pathway.

A surprising finding is that, based on review of the literature (Step 2), the Delphi study, and face-to-face expert opinion, advanced care planning was not included in the set of 38 key interventions. On one hand, this can be explained due to the focus on management of acute COPD exacerbation. On the other hand, it is essential that advanced care planning and end of life discussions are initiated in advance of a life threatening situation, which can arise after COPD exacerbation [66]. Therefore, we acknowledge that an additional key-intervention with detailed reference to and description of advance life care planning should be included in this key intervention set.

An important limitation in the current strategy is the lack of patient involvement [67]. Patients can bring a different perspective to the quality improvement process, as they are likely to prioritize different aspects of care compared to clinicians, including interpersonal and amenity aspects; for example, communication with healthcare staff and quality of the food, rather than the technical and clinical aspects [68]. We believe that patients, for instance, by contacting patient societies, should have been involved in three phases of the eight-step method: (i) step 4: Final selection of the clinical activities; (ii) step 7: Translation into a set of indicators; and (ii) step 8: Piloting of the final set of key interventions. Including patients in these phases could have provided extra activities and outcomes, important from the patient perspective. After implementation of the key interventions, it will be interesting to gather information on patient preferences and opinions by performing open interviews with the patient and relatives, or by performing walk-throughs together with the patient [69]. Also, when applying the evidence-based care intervention in daily practice, clinicians should ensure that each of their individual patients is involved in decision making [67]. In this context, it is also recommended to develop a patient version that includes a brief and understandable summary of the set of key interventions.

We believe that developing the clinical care pathway content by using this newly developed and validated eight-step method will facilitate adequate integration of evidence-based knowledge into daily practice. Since the beginning of the 1990s, evidence-based clinical practice guidelines for almost all domains of medicine have been available worldwide, accessible more recently via the

Internet [4,70,71]. However, we see high variability in the integration of knowledge from evidence-based guidelines into daily practice [4,72]. Common barriers for integration of evidence-based knowledge are disagreement with the evidence; lack of outcome expectancy; lack of time; and available evidence, such as guidelines being unnecessarily complex, and thus not so directly applicable for clinical practice [4,72,73]. This eight-step methodology can facilitate translation of evidence-based knowledge into clinically applicable key interventions, which can overcome barriers and assist clinicians both in selecting the best treatment options and in delivering safe and effective care [4]. However, besides providing a set of detailed evidence-based key interventions, consideration of factors like culture (safety, commitment to do better in practice, peer norms); teamwork; skills management; communication; leadership alignment; and support will be critical to successfully integrate evidence into practice and improve the care process [74]. In this context, care pathways can be very effective tools, as they bring all these pieces together [8,25,75].

Finally, we want to emphasize the potential role of professional medical associations in clinical content development for evidence-based care pathways. Many national and international societies have extensive clinical and research experience in the patient population of their clinical field, comprise a global network of experts in the field, have funding available and, last but not least, have comprehensive understanding and experience in synthesizing evidence-based knowledge and making this knowledge usable for daily clinical practice. Therefore, we believe that professional societies could play a major role in developing the clinical content of future evidence-based care pathways, especially in terms of clinical support, expert networking and input of resources.

### **Conclusion**

The set of 38 key interventions and the set of process and outcome indicators were found to be appropriate for the development and standardization of the clinical content of the COPD care pathway in the context of a cRCT on pathway effectiveness. The developed eightstep method may facilitate multidisciplinary teams caring for other patient populations in designing the clinical content of their future care pathways.

### **Additional files**

Additional file 1: Process flow diagram for in-hospital management of COPD exacerbation. This Additional file displays a process flow chart including 38 key interventions that should be performed for every patient entering the hospital with COPD exacerbation. The key interventions are classified under three core processes: Diagnostic, Pharmacological and Non-pharmacological management.

**Additional file 2:** Set of Process and outcome indicators for in-hospital management of COPD exacerbation. This Additional file displays a set of validated process and outcome indicators for audit of care for in-hospital management of COPD exacerbation.

**Additional file 3: Example of description of an indicator.** This Additional file displays the detailed description of an indicator according to the guidance of the Agency for Health Care Research and Quality (www.qualitymeasures.ahrq.gov) and the Joint Commission (www.jointcommission.org).

### Abbreviations

ABGs: Arterial blood gases; ACCP: American College of Chest Physicians; ATS: American Thoracic Society; BMI: Body mass index; BTS: British Thoracic Society; COI: Cost of illness; COPD: Chronic obstructive pulmonary disease; cRCT: Cluster randomized controlled trial; DALY: Disability adjusted life years; E-P-A: European Pathway Association; EQCP: European Quality of Care Pathways; ERS: European Respiratory Society; FEV<sub>1</sub>: Forced expiratory volume in one second; FVC: Forced vital capacity; GOLD: Global Strategy for Diagnosis Management, and Prevention of COPD; HICPAC: Healthcare Infection Control Practices Advisory Committee; HRQL: Health-related quality of life; LOS: Length of stay; LTOT: Long-term oxygen therapy; NICE: National Institute for Health and Clinical Excellence; QALY: Quality-adjusted life expectancy measure; SIGN: Scottish Intercollegiate Guidelines Network; WHO: World Health Organization.

### Competing interests

The authors declare that they have no competing interests.

### Authors' contributions

CL KV, WS, SD and MP contributed to the draft and the final version of the paper. MD supervised and was closely involved in the development of the clinical content of the care pathway intervention. MP, KV and WS have the scientific lead of the EQCP study. KV is international coordinator of the EQCP study. All authors have read and approved the final manuscript.

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# **ECRI**Institute

# **SPECIAL REPORT**

# Top 10 Health Technology Hazards for 2020

**Expert Insights from Health Devices** 







### SPECIAL REPORT

# Top 10 Health Technology Hazards for 2020

**Expert Insights from Health Devices** 

### **Executive Brief**

ECRI Institute is providing this abridged version of its 2020 Top 10 list of health technology hazards as a free public service to inform healthcare facilities about important safety issues involving the use of medical devices and systems. The full report-including detailed problem descriptions and ECRI Institute's step-by-step recommendations for addressing the hazards is available to members of ECRI Institute programs through their membership web pages.

### The List for 2020

- 1. Misuse of Surgical Staplers
- 2. Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards
- 3. Infection Risks from Sterile Processing Errors in Medical and Dental Offices
- 4. Hemodialysis Risks with Central Venous Catheters—Will the Home Dialysis Push Increase the Dangers?
- 5. Unproven Surgical Robotic Procedures May Put Patients at Risk
- 6. Alarm, Alert, and Notification Overload
- 7. Cybersecurity Risks in the Connected Home Healthcare Environment
- 8. Missing Implant Data Can Delay or Add Danger to MRI Scans
- 9. Medication Errors from Dose Timing Discrepancies in EHRs
- 10. Loose Nuts and Bolts Can Lead to Catastrophic Device Failures and Severe Injury

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### The Purpose of the List

The safe use of health technology-from simple devices to complex information systemsrequires identifying possible sources of danger or difficulty with those technologies and taking steps to minimize the likelihood that adverse events will occur. This list will help healthcare facilities do that.

Produced each year by ECRI Institute's Health Devices Group, the Top 10 Health Technology Hazards list identifies the potential sources of danger that we believe warrant the greatest attention for the coming year. The list does not enumerate the most frequently reported problems or the ones associated with the most severe consequences—although we do consider such information in our analysis. Rather, the list reflects our judgment about which risks should receive priority now.

All the items on our list represent problems that can be avoided or risks that can be minimized through the careful management of technologies. With the additional content provided in the full report, the list serves as a tool that healthcare facilities can use to efficiently and effectively manage the risks.

### **How Topics Are Selected**

This list focuses on what we call generic hazards—problems that result from the risks inherent to the use of certain types or combinations of medical technologies. It does not discuss risks or problems that pertain to specific models or suppliers.

ECRI Institute engineers, scientists, clinicians, and other patient safety analysts nominate topics for consideration based on their own expertise and insight gained through:

- Investigating incidents
- Testing medical devices in the ECRI lab
- Observing operations and assessing hospital practices
- Reviewing the literature
- Speaking with clinicians, clinical engineers, technology managers, purchasing staff, health systems administrators, and device suppliers

Staff also consider the thousands of health-technology-related problem reports that we receive through our Problem Reporting Network and through data that participating facilities share with our patient safety organization, ECRI Institute PSO.



After the topic nomination phase, professionals from ECRI Institute's many program areas, as well as external advisors, review these topics and select their top 10. We use this feedback to produce the final list, weighing factors such as the following:

- Severity. What is the likelihood that the hazard could cause serious injury or death?
- Frequency. How likely is the hazard? Does it occur often?
- Breadth. If the hazard occurs, are the consequences likely to spread to affect a great number of people, either within one facility or across many facilities?
- Insidiousness. Is the problem difficult to recognize? Could the problem lead to a cascade of downstream errors before it is identified or corrected?
- Profile. Is the hazard likely to receive significant publicity? Has it been reported in the media, and is an affected hospital likely to receive negative attention? Has the hazard become a focus of regulatory bodies or accrediting agencies?
- Preventability. Can actions be taken now to prevent the problem or at least minimize the risks? Would raising awareness of the hazard help reduce future occurrences?

All the topics we select for the list must, to some degree, be preventable. But any one of the other criteria can, on its own, warrant including a topic on the list. We encourage readers to examine these same factors when judging the criticality of these and other hazards at their own facilities.

Not all hazards on the list will apply at all healthcare facilities. Also note that the exclusion of a topic that was included on a previous year's list should not be interpreted to mean that the topic no longer deserves attention. Most of these hazards persist, and hospitals should continue working toward minimizing them. Rather, our experts determined that the topics listed here should receive greater attention in 2020.

### FOR MEMBERS ONLY: LOG IN TO ACCESS THE FULL REPORT AND SOLUTIONS KIT

This Executive Brief helps raise awareness of critical health technology hazards—a key step in patient safety efforts. The next steps involve taking action to prevent the problems from occurring. The 2020 Top 10 Health Technology Hazards Solutions Kit—available online to members of ECRI Institute programs—will help with that effort.

The Solutions Kit provides a comprehensive discussion of each topic, actionable recommendations for minimizing the risks of harm, and lists of useful resources for more information about each topic. Log in to your membership web page to access this valuable content.





# **Misuse of Surgical Staplers**

Surgical staplers are complex devices requiring meticulous technique to operate. Some models are used just to staple (seal) tissue, while others are designed to both staple and cut. Consequences of a staple line failing or staples being misapplied can be fatal. Patients have experienced intraoperative hemorrhaging, tissue damage, unexpected postoperative bleeding, failed anastomoses, and other forms of harm.

Although the overall adverse event rate is actually quite low relative to how frequently staplers are used, problems associated with the use and function of surgical staplers are regularly reported. In fact, a recent FDA analysis covered over 100,000 incident reports since 2011, including 412 deaths, 11,181 serious injuries, and 98,404 malfunctions. Most of these reports had not previously been accessible to the public.

In ECRI Institute's experience, adverse consequences can most often be traced to how the surgical stapler was used. That is, the device itself typically is found to have functioned as intended. Errors in use include selecting an incorrect staple size, clamping on tissue that is too thick or too thin, and clamping on, or firing over, another instrument or clip.

Avoiding such errors, as we detail in our recommendations, requires effective training and familiarity. Specifically, we recommend hands-on practice with the specific model of stapler to be used.







A recent FDA analysis covered over 100,000 incident reports since 2011, including 412 deaths, 11,181 serious injuries, and 98.404 malfunctions.





# **Adoption of Point-of-Care Ultrasound** Is Outpacing Safeguards

A lack of oversight regarding the use of point-of-care ultrasound (POCUS)-including when to use it and how to use it—may place patients at risk and facilities in jeopardy.

POCUS refers to the use of medical ultrasound by the treating clinician at the bedside. It is a powerful tool for diagnosis and for guiding interventional procedures in many clinical environments. POCUS scanners are typically highly portable, comparatively inexpensive, and easy to use—features that have fueled the technology's rapid and broad adoption throughout medicine.

At many healthcare facilities, however, safeguards for ensuring that POCUS users have the requisite training, experience, and skill have not kept pace with the speed of adoption. The lack of sufficient oversight increases the potential that patients will be adversely affected by problems associated with use, or lack of use, of the technology.

Patient safety concerns include POCUS not being used when warranted, misdiagnoses, inappropriate use of the modality, and overreliance on POCUS when a more comprehensive exam by an imaging specialist is indicated.

Policies and procedures should address institution-wide concerns, including user training and credentialing, exam documentation, and data archiving. And they should address specialtyspecific issues, such as developing exam protocols that conform to established guidelines and recommendations.



At many healthcare facilities, safeguards for ensuring that POCUS users have the requisite training, experience, and skill have not kept pace with the speed of adoption.





# **Infection Risks from Sterile Processing Errors in Medical and Dental Offices**

Insufficient attention to sterilization processes in medical offices, dental offices, and some other ambulatory care settings can expose patients to contaminated instruments, implants, or other critical items. As we've highlighted in previous editions of our Top 10 Hazards list, failure to consistently and effectively clean and disinfect or sterilize contaminated items before use can expose patients to virulent pathogens.

This concern exists in all healthcare settings where patients may come in contact with contaminated items, particularly those intended to enter sterile tissue or the vascular system. However, not all healthcare settings have similar resources for core infection prevention and control (IPC) practices. Settings that may lack the sterilization program resources commonly found in acute care facilities, for example, include medical offices (e.g., OB/GYN, dermatology), dental offices, and similar locations that are not serviced by a central sterile processing department.

During IPC consultations in these settings, ECRI Institute has observed numerous oversights and improper actions associated with sterilization processes. While the prevalence of such failures is unknown, the potential exists for this to be an insidious, widespread patient safety risk.

Key safety measures include designating a qualified staff member or contractor to support office IPC practices and providing appropriate training for, and conducting periodic competency testing of, benchtop sterilizer operators.









While the prevalence of sterilization process failures is unknown, the potential exists for this to be an insidious, widespread patient safety risk.





# **Hemodialysis Risks with Central Venous Catheters — Will the Home Dialysis Push Increase the Dangers?**

Here we examine the potential intersection of two ongoing developments in the treatment of end-stage kidney disease in the United States: Many hemodialysis patients receive treatment through a central venous catheter (CVC) well beyond the period when transition to another form of vascular access is recommended. And the U.S. federal government recently announced a push to increase the use of home treatment for kidney disease patients.

For appropriate patients, home hemodialysis can provide many long-term benefits. For patients who receive hemodialysis through a CVC, however, the risks of home dialysis may outweigh the benefits.

CVCs are typically placed through the jugular vein (or other large central vein), providing a pathway directly from the outside of the body to the patient's heart. As a result, the consequences of infection, clotting, disconnection (with a potential for massive blood loss), and air embolism can be severe.

In a healthcare setting, clinical staff are available to properly care for the catheter and address any concerns. In a home care setting, though, family members or other caregivers may be ill-equipped to manage the risks or to respond when a CVC problem occurs. The possibility that an increasing number of patients with CVCs might receive hemodialysis in the home raises concerns.



For patients who receive hemodialysis through a CVC, the risks of home dialysis may outweigh the benefits.





# **Unproven Surgical Robotic Procedures May Put Patients at Risk**

Surgical robotic systems are used to assist surgeons in performing a wide—and continually expanding-range of minimally invasive procedures. While the use of surgical robots in innovative ways or for new procedures can help advance clinical practice, such uses can also lead to injury or unexpected complications and the potential for poorer long-term outcomes.

With their mechanical wrists, surgical robots can offer the surgeon benefits such as improved dexterity, motion scaling, and tremor reduction. However, these systems also have limitationsthey may not provide tactile feedback on forces exerted on tissue, for example-and adverse events do occur. In some cases, complications from a robotic procedure may not appear for years. (In a 2019 Safety Communication, FDA noted the potential for late-developing complications associated with surgical robot use for certain cancer-related surgeries.)

Healthcare facilities need robust processes for approving the application of surgical robots in new procedures, as well as comprehensive programs for training, credentialing, and privileging surgeons and OR staff for those procedures. For their part, prospective patients should recognize that robotic procedures are not inherently better or worse than traditional minimally invasive procedures. The various surgical options available are likely to have trade-offs in terms of risks and benefits.



Facilities need robust processes for approving the application of surgical robots in new procedures, as well as comprehensive programs for training, credentialing, and privileging surgeons and OR staff.





# Alarm, Alert, and Notification Overload

More than ever before, clinicians have to divide their attention between direct patient care tasks and responding to prompts from medical devices and health IT systems. As the number of devices that generate alarms, alerts, and other notifications increases, so too does the risk that the clinician will become overwhelmed, creating the potential for a clinically significant event to go unaddressed.

The problem of alarm overload is well known. Just as important to consider, however, is the global notification burden-that is, the combination of alarms, alerts, and notifications from all sources, not just from a single medical device.

Patient care devices sound alarms and flash visual indicators. Phones buzz with calls or text notifications. EHR portals display pop-up clinical decision-support alerts. And nurse call systems beep and light up to indicate that a patient needs attention.

A global approach that considers all these sources is needed to prevent the kind of cognitive overload that can distract or desensitize clinicians or prompt them to use improper notification settings, all of which can lead to missed notifications and patient harm. In addition to implementing measures to reduce the overall notification burden, healthcare facilities should support activities that help clinical staff develop the critical thinking skills needed to mitigate cognitive overload.



A global approach is needed to prevent the kind of cognitive overload that can lead to missed notifications and patient harm.





# **Cybersecurity Risks in the Connected Home Healthcare Environment**

Remote patient monitoring technologies are increasingly being used for at-home monitoring to help clinicians identify deteriorating patients before they require hospitalization. As networkconnected medical technologies such as these move into the home, cybersecurity policies and practices that address the unique challenges involved must be instituted as well.

As with any networked medical device, connected devices used in the home must be protected against threats that could interrupt the flow of data, alter or degrade the device's performance, or expose protected health information. A cybersecurity issue that interrupts the transfer of data to the healthcare provider, for example, could lead to misdiagnosis or a delay in care.

Challenges include: the deployment may rely on the patient's home network, which the provider doesn't control; physical access to the device is limited, which can complicate troubleshooting and installing updates; and patient compliance can be difficult to sustain, particularly if the patient lacks proficiency using the device or has unwarranted fears about cybersecurity risks.

Recommendations include assessing system security during device procurement and addressing security considerations during installation, both at the patient's home and on the provider's network. The goal is not just to get the monitoring system to function, but to get it functioning securely.



Connected devices used in the home must be protected against threats that could interrupt the flow of data, alter or degrade the device's performance, or expose protected health information.

## **ECRI**Institute



# **Missing Implant Data Can Delay** or Add Danger to MRI Scans



Patients presenting for magnetic resonance imaging (MRI) studies must be screened for implanted devices to avoid harm. Some implants can heat, move, or malfunction when exposed to an MRI system's magnetic field. Thus, MRI staff must identify and follow any contraindications or conditions for safe scanning prescribed by the implant manufacturer.

Unfortunately, information about patient implants is often scattered throughout various information systems or records of patient encounters, if it is captured at all. Without a single place within the electronic health record (EHR) to store implant information, care providers have no reliable means for determining the type and location of any implants. Even screening interviews can be unreliable, as patients may not remember details about implants or may not be in a condition to respond.

Direct harm to the patient is possible if a scan is, inappropriately, conducted in the presence of an unidentified implant. Also, the patient's treatment can be adversely affected if a scan needs to be postponed while care providers search for implant information.

Healthcare facilities should work with their EHR provider to create an implant list stored within the patient record. Similar to an allergy list, an implant list collects all relevant information in one easy-to-access location.



Direct harm to the patient is possible if a scan is, inappropriately, conducted in the presence of an unidentified implant.





# **Medication Errors from Dose Timing Discrepancies in EHRs**

Missed or delayed medication doses can result from discrepancies between the dose administration time intended by the prescriber and the time specified within the automatically generated worklist viewed by the nurse. Depending on the patient's condition and the medication prescribed, these errors can have significant clinical consequences.

A combination of configuration and usability issues within the electronic health record (EHR) can contribute to such discrepancies. Consider the following scenario:

Late in the morning, a physician enters an order for a once-daily medication and assumes that the patient will be given the first dose that morning. At that facility, however, the default administration time programmed into the EHR for once-daily medications is 8:00 a.m. Because the order was placed later in the morning, the medication for that patient would not appear on the nurse's worklist until the following morning, unless the prescriber was aware of the default administration time and had specifically changed the time within the order.

Dose timing errors can be made less likely if an EHR order-entry system prominently displays the scheduled medication administration time, allows prescribers to easily modify that time, and includes a "now" option for medications that need to be administered as soon as possible.



Depending on the patient's condition and the medication prescribed, dose timing errors can have significant clinical consequences.





# **Loose Nuts and Bolts Can Lead** to Catastrophic Device Failures and Severe Injury

The nuts, bolts, and screws that hold together medical device components can loosen over time with routine use. Failure to repair or replace loose or missing mechanical fasteners can lead to severe consequences: Devices can tip, fall, collapse, or shift during use-any of which could lead to patient, staff, or bystander injury or death. Additionally, workflow can be impeded, compromising patient care, and devices can sustain significant damage.

Over the past two years, we have published nearly two dozen reports involving a wide variety of medical devices with loose fasteners. Affected equipment ranged from baby scale carts (putting newborns at risk) to massive angiography systems (which could cause devastating harm to anybody under a falling component).

This report illustrates how the failure of even simple components can have devastating consequences. As such, it serves as a reminder that device inspections are an important patient safety function. Clinical engineers should check the condition of all mechanical fasteners during such inspections, even if doing so is not explicitly stated in the instructions. Clinical staff, for their part, should alert appropriate personnel to any loose or missing fasteners, irregular device movement, or unusual noises coming from a device.



Affected equipment ranged from baby scale carts (putting newborns at risk) to massive angiography systems (which could cause devastating harm to anybody under a falling component).



### **ECRI Institute Resources for Addressing the Hazards**

Members of certain ECRI Institute programs can access resources such as the following to learn more about the topics included on this year's list:

### 1. Misuse of Surgical Staplers

4 ways to prevent harm from surgical staplers. ECRI Blog 2019 Jul 15.

Before a surgical stapler fails [guidance article]. Health Devices 2001 Oct.

Reclassification of surgical staplers [podcast]. Smart Healthcare Safety 2019 Jul 2.

Surgical stapler hazards (hazard #8). In: Top 10 technology hazards: high-priority risks and what to do about them. Health Devices 2009 Nov.

Surgical stapler misuse and malfunctions. Hazard #9-top 10 health technology hazards for 2017. Health Devices 2016 Nov 4.

Surgical staplers: recommendations to reduce the risk of commonly reported problems. Health Devices Alerts 2016 Mar 17 (Accession No. H0312).

Using the wrong size surgical stapler cartridge can injure patients [hazard report]. Health Devices 2009 Apr.

### 2. Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards

Advantages of cart-based point-of-care ultrasound scanners. Health Devices 2018 Sep 5.

Cleaning and disinfecting diagnostic ultrasound transducers: our recommendations. Health Devices 2018 Jul 25.

Evaluation background: cart-based point-of-care ultrasound scanners. Health Devices 2018 Aug 29.

Evaluation background: handheld point-of-care ultrasound scanners. Health Devices 2017 Sep 13.

Evaluation background: tablet-style point-of-care ultrasound scanners. Health Devices 2016 Mar 23.

Point-of-care ultrasound scanners: an introduction. Health Devices 2015 Apr 8.

Point-of-care ultrasound scanners: key purchasing considerations. Health Devices 2015 Aug 12.

Recommendations for reducing work-related musculoskeletal disorders in diagnostic ultrasound users. Health Devices 2016 Aug 17.

Work-related musculoskeletal disorders: point-of-care ultrasound users may be at risk too. Health Devices 2016 Aug 17.

### 3. Infection Risks from Sterile Processing Errors in Medical and Dental Offices

### Health Devices resources:

- Infection Reduction Technologies: The Essentials. This page contains our complete collection of guidance, tools, and other resources associated with infection reduction technologies.
- Cleaning and disinfecting diagnostic ultrasound transducers: our recommendations. Health Devices 2018 Jul 25.
- For lists of previous Top 10 Health Technology Hazard topics that address sterilization failures, see:
  - Infection Risks-Topics include mattress contamination and infection risks with heater-cooler devices.
  - Reprocessing/Sterilization Failures—Topics address failures associated with cleaning, disinfecting/sterilizing, and storing/ transporting endoscopes and other reusable instruments.

### Risk Management resources:

- Dental instrument sterilization workflow. Physician Practice Risk Management 2017 May 30.
- Device cleaning, disinfection, and sterilization. Concern #8-top 10 patient safety concerns for 2018. ECRI Institute PSO. 2018 Mar 9.
- Failure to sterilize and clean equipment potentially exposed thousands at New Jersey facility to HIV, hepatitis. Healthcare Risk Control 2019 Jan 2.

Product comparisons and technology assessments:

- Sterilizing units, ethylene oxide. Healthcare Product Comparison System. 2018 Apr 1.
- Sterilizing units, steam, tabletop. Healthcare Product Comparison System. 2019 Jul 1.
- Use of rigid instrument containers versus wrapped trays for instrument sterilization. Health Technology Assessment Information Service. 2018 Mar 22.

### 4. Hemodialysis Risks with Central Venous Catheters-Will the Home Dialysis Push Increase the Dangers?

Hemodialysis venous catheter components may disengage during routine use, quickly causing patient harm or death [ECRI Exclusive Hazard Report]. Health Devices Alerts 2019 Jul 11. Accession No. H0526.



### 5. Unproven Surgical Robotic Procedures May Put Patients at Risk

Relevant guidance from Health Devices:

- Evaluation background: surgical robotic systems and related devices for general surgery. Health Devices 2016 Dec 14.
- Robotic surgery: complications due to insufficient training. Hazard #8-top 10 health technology hazards for 2015. Health Devices 2014 Nov 24.
- Robotic surgery complications due to insufficient training. Hazard #9-top 10 health technology hazards for 2014. Health Devices 2013 Nov 1.

Selected reports from ECRI Institute's Health Technology Assessment Information Service:

- Da Vinci Xi robotic bariatric surgery (Intuitive Surgical, Inc.) for treating obesity. 2018 Dec 18.
- Da Vinci Xi robotic surgery (Intuitive Surgical, Inc.) for treating colorectal cancer. 2018 Nov 30.
- Da Vinci Xi robotic surgery (Intuitive Surgical, Inc.) for treating nonmalignant colorectal conditions. 2018 Nov 30.
- Da Vinci Xi robotic surgery (Intuitive Surgical, Inc.) for treating nonmalignant gynecologic conditions. 2018 Dec 18.
- Ion endoluminal system (Intuitive Surgical, Inc.) for minimally invasive peripheral lung biopsy. 2019 Jun 1.
- Mako robotic arm-assisted surgery system (Stryker Corp.) for total hip arthroplasty. 2018 Nov 13.
- Mako robotic arm-assisted surgery system (Stryker Corp.) for total or partial knee arthroplasty. 2018 Nov 13.
- Mazor X robotic guidance system (Mazor Robotics, Ltd.) for performing robotic-assisted brain and spine surgery. 2019 Jan 25.
- Navio Surgical System (Smith & Nephew, Plc.) for performing knee arthroplasty. 2019 Jun 26.

### Other resources:

- Reining in unbridled uses of robotic-assisted surgery. ECRI Blog 2019 Aug 12.
- The surgical robot invasion: training and safety [webinar]. 2013 Jun 12.

### 6. Alarm, Alert, and Notification Overload

Collections of ECRI Institute alarm management resources:

- Alarm Management: The Essentials. This page contains our complete collection of guidance, tools, and other resources for improving clinical alarm safety.
- The Alarm Safety Handbook and Workbook. ECRI Institute; 2014. These publications offer strategies, tools, and guidance for improving the management of clinical alarm systems.

Alarm Management Resources List. A starter list of resources describing recommendations from trusted organizations and the experiences of other healthcare institutions.

### Additional guidance from Health Devices:

- Improper customization of physiologic monitor alarm settings may result in missed alarms. Hazard #7-2019 top 10 health technology hazards. Health Devices 2018 Sep 26.
- Improving patient surveillance in telemetry: don't just rely on the monitor. Health Devices 2015 Sep 16.
- Missed alarms may result from inappropriately configured secondary notification devices and systems. Hazard #4-top 10 health technology hazards for 2018. Health Devices 2017 Nov 1.

Selected guidance from ECRI Institute PSO:

- Alarms: don't disconnect the human element from patient care. PSO Compass Points. 2019 Mar 12.
- Drug allergy alerts: don't ignore clinical decision support. PSO Compass Points. 2018 Sep 25.

### 7. Cybersecurity Risks in the Connected **Home Healthcare Environment**

- Cybersecurity: The Essentials. This web page features a collection of Health Devices resources on cybersecurity topics.
- Cybersecurity risk assessment for medical devices. Health Devices 2018 Aug 8.
- Evaluation background: smartphone-enabled ECG monitors. Health Devices 2018 May 2.
- Evaluation background: smartphone-enabled portable blood glucose meters. Health Devices 2017 May 17.
- Evaluation background: telehealth remote patient monitoring systems. Health Devices 2018 Feb 28.
- Selecting a remote patient monitoring solution: 8 key considerations. Health Devices 2018 Jun 5.

### 8. Missing Implant Data Can Delay or Add Danger to MRI Scans

MRI: The Essentials. This page contains our complete collection of guidance, tools, and other resources associated with magnetic resonance imaging technologies. Specific articles of interest include:

- Ferromagnetic objects in the MR environment. Hazard #9– top 10 technology hazards for 2010. Health Devices 2009 Nov;38(11):364-73.
- How to use equipment safely in the MR environment. Health Devices 2015 May 6.
- Safety labeling for the MR environment. Health Devices 2015 May 6.



The MR environment: knowing the risks. Health Devices 2015 May 6.

### 9. Medication Errors from Dose Timing **Discrepancies in EHRs**

Partnership for Health IT Patient Safety. Data snapshot: medication and treatment timing is often a challenge. Partnership Update; Summer Edition 2015.

### 10. Loose Nuts and Bolts Can Lead to Catastrophic **Device Failures and Severe Injury**

The following reports related to this topic were issued through ECRI Institute's Health Devices Alerts notification service:

- A29310: Siemens—SOMATOM go. Up and go. Now CT scanner tables: may be unstable. Health Devices Alerts 2018 Mar 8.
- A29621 01: Philips-CombiDiagnost image-intensified fluoroscopic x-ray systems: loose screws may cause collimator to fall and PE cable may cause electrical shock under certain circumstances. Health Devices Alerts 2018 Jan 16.
- A29828 01: Philips-Allura Xper systems: 7th or 8th extra monitors mounted on monitor ceiling suspension may fall. Health Devices Alerts 2018 Feb 15.
- A29848: Philips—Brilliance iCT, Brilliance iCT SP, and IQon Spectral CT computed tomography systems: screws securing reaction ring scanner's main bearing may come loose. Health Devices Alerts 2018 Jan 25.
- A30097: Toshiba—INFINIX VC-I interventional angiography systems: ceiling drive operation may become disabled during examination. Health Devices Alerts 2018 Feb 28.
- A30097 01: Toshiba—INFINIX fluoroscopic x-ray systems: ceiling drive operation may become disabled during examination. Health Devices Alerts 2018 Mar 8.
- A30656: Hellmut Ruck—PODOLOG MOON professional podiatry chairs: screws may loosen. Health Devices Alerts 2018 Jul 3.
- A30719: Maquet/Getinge—Emergency room examination tables: screws may loosen or fall out. Health Devices Alerts 2018 Jun 4.
- A30834 01: Maquet/Getinge—Volista surgical lights: light head shaft may break and cupola may detach [update]. Health Devices Alerts 2018 Jul 27.
- A31543: Siemens—Biograph mCT and Biograph Horizon CT/ PET scanners: system power connection screws may be loose, potentially causing the plug to overheat. Health Devices Alerts 2018 Nov 2.

- A31721: Virtual Imaging—RadPRO Mobile 40kW digital x-ray systems: collimator may separate from tube head mount, potentially falling from system. Health Devices Alerts 2018 Nov 21.
- A31826: Invacare—9805 and 9805P hydraulic patient lifts: caster may separate from lift base, potentially leading to patient falls. Health Devices Alerts 2018 Dec 12.
- A32060: Leica-M220 F12 surgical microscopes: optics may unintentionally drop into surgical field. Health Devices Alerts 2019 Jan 31.
- A32473 01: Roche—cobas p 501 and p 701 postanalytical units: tray input flap may detach from instrument. Health Devices Alerts 2019 Jul 11.
- A32556: GE—Various radiographic/fluoroscopic systems: CRT monitor may fall. Health Devices Alerts 2019 Jun 19.
- A32856: Siemens-Artis Q and zee systems: display suspension system ceiling-mounted support screws may loosen or snap off. Health Devices Alerts 2019 Jun 26.
- A33072: seca—Baby scale carts: wheels may loosen. Health Devices Alerts 2019 Jul 22.
- H0441: Hill-Rom—Model P870 long-term care beds: footboards may loosen, potentially contributing to a fall [ECRI Exclusive Hazard Report]. Health Devices Alerts 2018 May 10.
- H0445: Joerns—Hoyer HML400 patient lifts: bolts holding boom and mast may become loose, potentially leading to patient injury [ECRI Exclusive Hazard Report]. Health Devices Alerts 2018 May 22.
- S0347: OrthoScan—Mini C-arm mobile x-ray systems: front caster may fall out [ECRI Exclusive User Experience Network]. Health Devices Alerts 2018 Apr 26.

### Additional member resources:

- Health Technology Management: The Essentials. This web page features a collection of Health Devices resources on health technology management topics, including general departmental budgeting and planning, selection and purchasing, safe use, equipment maintenance and replacement, and overall policies and procedures.
- Caster failures. Hazard #4—top 10 health technology hazards: are you protecting your patients from these high-priority risks? Health Devices 2007 Nov 1.

# About ECRI Institute ECRI Institute is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings. ECRI's unbiased assurance in evidence-based research, medical device testing, and knowledge of patient safety are uniquely respected by healthcare leaders and agencies

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**ECRI**Institute

# Deloitte.

The hospital of the future How digital technologies can change hospitals globally

# **Executive summary**

The hospital of the future may look quite different than the hospital of today. Rapidly-evolving technologies and growing consumerism, along with demographic and economic changes, are expected to disrupt hospitals worldwide. Already, a growing number of inpatient health care services are being pushed to the home and outpatient ambulatory facilities; however, many complex and very ill patients will continue to need acute inpatient services.

With aging infrastructure in some countries and demand for more beds in others, hospital executives and governments should consider rethinking how to optimize inpatient and outpatient settings, how to best connect with consumers, and how to integrate digital technologies into traditional hospital services to truly create a health system without walls.



To learn what this hospital of the future may look like, the Deloitte Center for Health Solutions conducted a crowdsourcing simulation with 33 experts from across the globe. Participants included health care CXOs, physician and nurse leaders, public policy leaders, technologists, and futurists. Their charge was to come up with specific use cases for the design of digital hospitals globally in 10 years (a period that can offer hospital leaders and boards time to prepare).

The crowdsourcing simulation developed use cases in five categories, which are accessible and clickable along the bottom of this report:

- Redefined care delivery: Emerging features including centralized digital centers to enable decision-making, continuous clinical monitoring, targeted treatments (such as 3-D printing for surgeries), and the use of smaller, portable devices will help characterize acute care hospitals.
- <u>Digital patient experience:</u> Digital and artificial intelligence (AI) technologies can help enable on-demand interaction and seamless processes through a choice of devices to improve patient experience.
- Enhanced talent development: Robotic process automation (RPA) and Al can allow caregivers to spend more time providing care and less time documenting it; as well as help enhance development and learning among caregivers.
- Operational efficiencies through technology: Digital supply chains, automation, robotics, and next-generation interoperability can drive operations management and back-office efficiencies.

 Healing and well-being designs: The well-being of patients and staff members—with an emphasis on the importance of environment and experience in healing—will likely be important in future hospital designs.

Technology will likely underlie most aspects of future hospital care, but care delivery—especially for complex patients and procedures—may still require hands-on human expertise. Many future technologies can supplement and extend human interaction.

Many of these use case concepts and technologies already are in play. Hospital executives should be planning how to integrate technology into newly built facilities and retrofit it into older ones. A well-crafted strategy can lay the foundation for future investments in care delivery, talent, data management, and cyber security.

# Introduction

What might hospital care look like globally 10 years from now? The following scenario offers a preview:

Remy is visiting his hometown to accompany his father, John, to the hospital. A heart patient, John is being admitted for a 3-D printed mitral valve replacement at Metropolis Hospital. Remy is surprised: the facility looks nothing like it did when Remy had his appendix removed in his youth. A digital console nicknamed Welcome Packet is waiting for John at the entrance. It directs him to his room, and helps orient him to the hospital and his schedule. (John's admission was automatically processed prior to his arrival.) Remy notices the hospital's smart ergonomic layout, bright lighting, and noise-free rooms. With AI built into his securely stored, cloud-based health records, John can access information on anything related to his care—such as the risks and benefits of the 3-D printedenabled surgery—by using the monitor in his room or his own smartphone.

A wristwatch provided upon John's arrival remotely monitors his vital signs, analyzes them, and alerts caregivers to any significant patterns. Remy notes the absence of nurse stations, and watches robots deliver supplies and medications to patients' rooms. His father's hospital records are automatically populated through digital uploads, voice-capture sensors, and information from caregivers. Most of the routine charting and orders are entered through RPA and supported by AI. Discharge and post-discharge care are planned in advance using predictive analytics based on John's medical history, how well he is responding to his initial treatment, and his potential health related social factors (such as housing and family support).

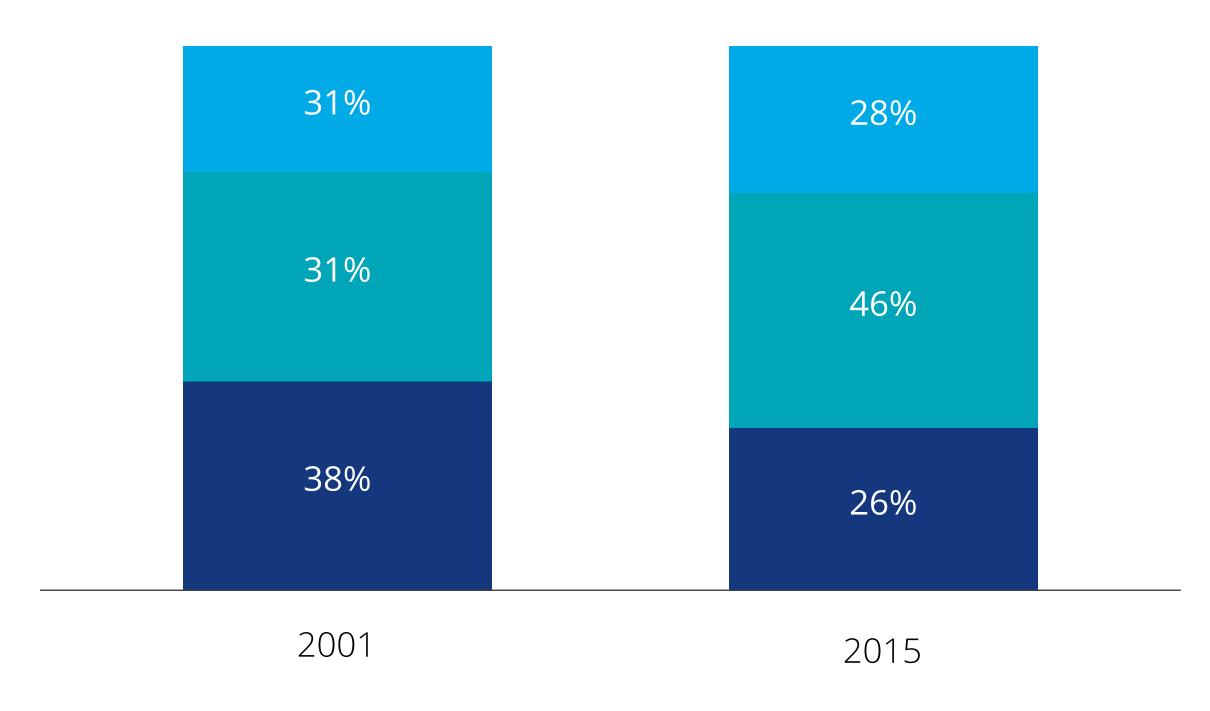
During a pre-op visit with the surgeon, Dr. Mace, Remy, and John are able to visualize the procedure in 3-D. The essential elements of this meeting are extracted by a listening device in Dr. Mace's wristwatch, and entered into John's hospital record—including the time and date: 5:43 p.m., October 1, 2027.

# Impetus for change

Several macro trends could have significant implications for how hospitals of the future are staffed, sized, and designed. Demographic and economic trends, coupled with advancing technologies and growing consumerism, are allowing more health care services to take place in outpatient settings and in the home (see Figure 1 on the following page), although some types of patients—for example, complex cases and the very ill—likely will still require inpatient hospital care. Around the world, health care leaders should consider how to address these trends by planning for appropriate investments in people, processes, and premises enabled by digital technologies.

The Deloitte Center for Health Solutions conducted a crowdsourcing simulation with 33 experts from diverse fields across the globe. The goal was to develop specific use cases to illustrate how hospitals, enabled by digital technologies, might look in 10 years. (See sidebar for methodology and simulation details.)

Figure 1: Average health care expenditure by service area: Organization for economic cooperation and development (OECD) countries



- Hospital inpatient services
- Outpatient services and long-term care
- Other (includes drug spending and government services)

Source: Health at a Glance 2001-2017, Organization for Economic Cooperation and Development

# **Crowdsourcing ideas for the global digital** hospital of the future

The Deloitte Center for Health Solutions conducted a crowdsourcing simulation in May 2017. Participants included 33 experts from all regions around the world—North America, South America, Europe, Asia, and Middle-East—with backgrounds in health care, policy, and technology.

By crowdsourcing use cases, the experts developed a vision for a hospital 10 years from now—a period that offers hospital leaders and boards time to prepare. The simulation was divided into three phases:

- Phase 1—The experts ideated, created, and collaborated on specific use cases—examples of what a hospital may look like in 10 years that could impact clinical care, patient experience, staffing, and physical plant. The participants created 53 use cases.
- **Phase 2**—The participants then voted on the 53 use cases to prioritize their impact on the status quo.
- Phase 3—The top 20 use cases were organized into five master themes: (1) refined care delivery, (2) digital patient experience, (3) enhanced talent development, (4) operational efficiencies through technology, (5) healing and well-being designs. An interdisciplinary group of participants sketched scenarios and potential implementation impacts for each theme based on the top use cases.

# The transformed, digital hospital of the future

The digital hospital of the future can leverage technologies that transform care delivery, patient experience, staff management, operations management, and hospital design.

# **Redefined care delivery**

Our crowdsourcing experts focused on how emerging technologies can help reduce inefficiencies and improve care outcomes.

# Centralized clinical command centers and digital continuous monitoring

What happens if an airplane loses an engine, or if two flights cross each other's paths while taking off? The nearest airport's air traffic control (ATC) system will quickly plot a new course. In the future, hospitals could have similar command centers that equip decision makers with real-time support tools to help them make quicker clinical and operational decisions.

ATC-like command centers already exist in some hospitals and industries including aerospace and aviation, oil and gas, and broadcasting. Why not more broadly at hospitals? First, digital data are the foundation of such centers, and many hospitals are late adopters of digital technologies. Second, hospital functional units tend to work in siloes. They produce large but discreet data, which can be difficult to collect, collate, and use for making actionable decisions. This situation is expected to change as emerging digital technologies help hospitals move from episodic to collaborative and longitudinal care. These technologies can create new ways to continually monitor patients and to integrate the data to chart the "flight paths" of individual patients and operational units.

For example, wearables and microfluidic sensors can be placed near patients and at locations frequented by patients (such as washrooms) where there is a fall risk or other hazards. The real-time data from such devices can form the clinical command center's foundation. Al can constantly monitor the data to alert hospital operators and caregivers, which can enable more efficient care and better outcomes. Through big-data analytics, machine learning, and AI, patient harm—or unintended consequences—can be predicted before they occur and suggested interventions can be fed to caregivers. Such command centers exist in some hospitals today (see sidebar on the following page) but wider adoption is expected in the coming years.

The digital hospital of the future includes an air traffic-like control system to continually monitor patients and integrate data to chart the "flight paths" of patients.

# Clinical command center in action<sup>1</sup>

In 2014, Cleveland Clinic launched a clinical command center named Bunker on the hospital's main campus under its eHospital program. At the bunker, a team of physicians, critical-care nurses, and technical staff monitors data on a digital wall an image of a patient's vital signs—in real time at the intensive care units (ICUs) of the main campus and community hospitals.

Each patient has a tile on the wall that provides their name, age, hospital location, and vital signs trend line. The risk status is a simple dot—green for low risk and red for high risk—that beeps intermittently. The team monitors red dots closely and alerts the unit staff about possible interventions.

The team uses analytical algorithms and multidimensional data to stratify patients based on risk and demographic profiles. The team also uses data from electronic health records (EHRs) to provide advanced alerts for patients that display higher risk levels. In the first half of 2015 alone, the bunker team reviewed data on more than 37,800 ICU patients.

With the visibility they provide into patient treatments and status, clinical command centers can help manage patient capacity and other operational processes. For example, using data on admissions, inter-facility transfers, and predictive analytics on possible days for discharge, command center analysts

can help staff manage patient flow and improve care delivery, better manage lengths of stay, and enhance the discharge process. These command centers also can track social media for open feedback and identify any patterns in comments to generate alerts for rapid response from appropriate leaders.

# Personal and portable care

An array of new technology advancements, including 3-D printing, robotics, nanotechnology, genetic coding, and therapeutic options can permit more personalized and accessible patient care. Many devices and equipment are getting smaller and more portable, and treatments will likely become more targeted—all of which can make future health care more mobile and precise. This, in turn, should increase staff and process efficacy and improve patient outcomes, as clinicians will be able to quickly find the best treatment option rather than try multiple interventions.<sup>2</sup> Personalization of medications, for instance, will be based on a patient's genetic profile and the use of precision medicine, whereas designs for 3-D-printed prostheses will be based largely on a patient's specific anatomy.

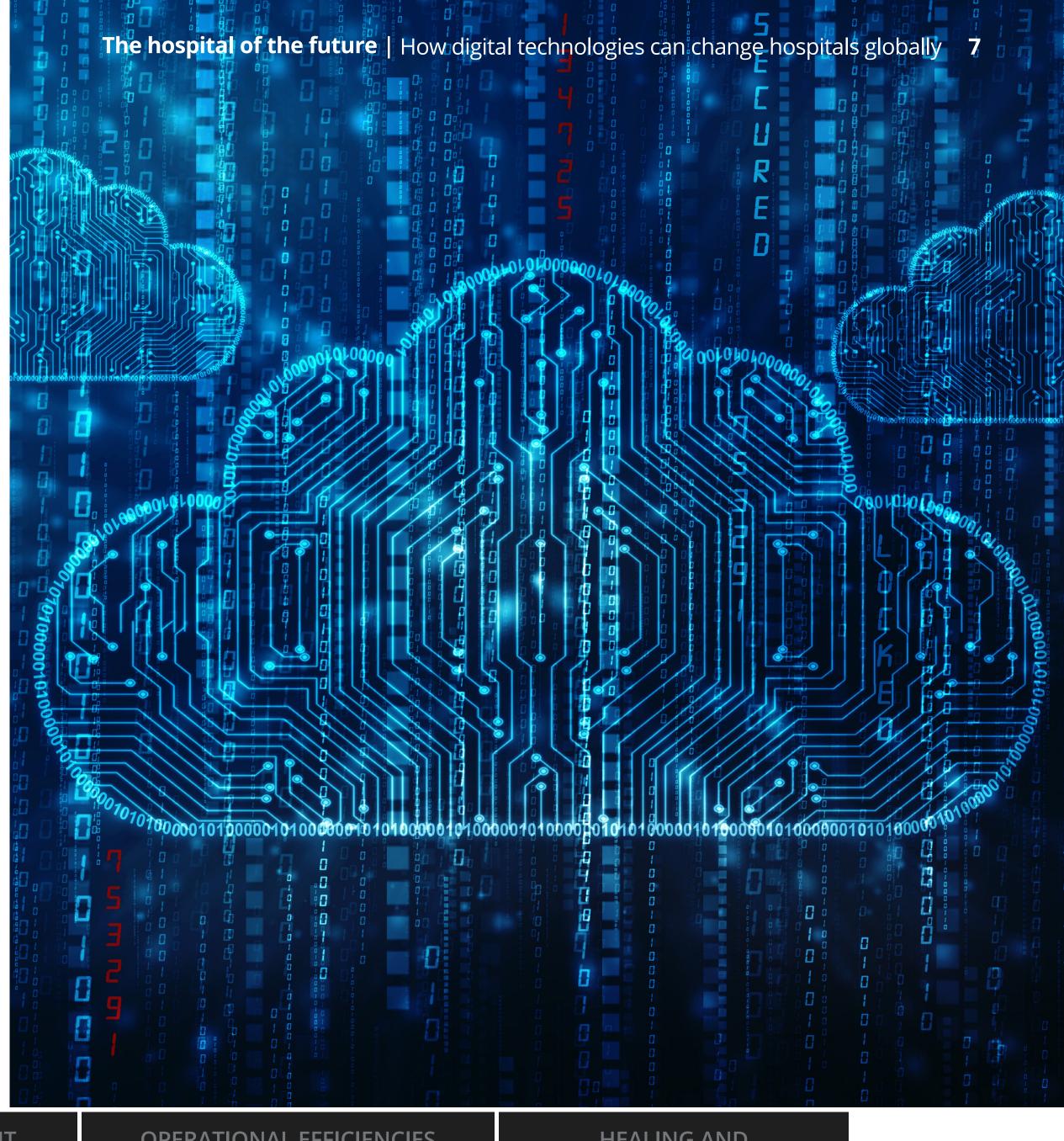
Furthermore, as medical equipment and sensors become smaller and more portable, clinicians may be able to perform various tests and procedures at a patient's bedside rather than transporting the patient to different areas of the hospital. Robots can be used to deliver medications to patients. Patient rooms can be built to include more equipment options, or the equipment can easily be moved to the patient. In certain countries, it is also possible that mobile hospitals may come to the patient. Additionally, medical interventions could become less invasive, resulting in better outcomes and faster recoveries.

# Cloud-based, interoperable electronic health records

The long-elusive goal of EHRs populated by interoperable data from different sources will likely be a reality in the hospital of the future. Coupled with AI, this can create process efficiencies and improve decision-making necessary to boost quality. Data can be better integrated into daily care, and patients can play a role in curating their own data.

Comprehensive, real-time patient data at the point of care can improve patient outcomes,<sup>3</sup> which means that sharing standardized data is likely to be part of future care delivery. This data can include genetic, social, and behavioral patient information, as well as financial, clinical, and administrative records. Data can be securely stored in the cloud and accessed on an as-needed basis—perhaps on a blockchain (a distributed, immutable record ledger of digital transactions that is shared and editable by various stakeholders). This can offer easy and secure data access from multiple locations and devices, and maintain the data at a lower cost than today's storage options.

With an expected large, continuing influx of data, many hospitals will need cognitive analytics to sort through and find the most important personalized data points and trends. This information can be proactively presented to clinicians, patients, and caregivers in an easy-to-understand format that seamlessly fits into their daily activities. Patients can own their data, add to and edit their health records, and proactively communicate with their caregivers. Importantly, the data can be easily unidentified for research purposes.



# **Digital patient experience**

The crowdsourcing simulation produced use cases to improve the patient experience. Hospitals of the future can better inform and educate patients, ease their anxiety, and empower them to actively participate in care before, during, and after the hospital stay.

# Digital and artificial intelligence technologies

Across the globe, consumers have grown accustomed to getting information when, where, and how they want it, be it news, weather forecasts, traffic updates, or restaurant options. Many expect the same quick answers to their health care questions. Increasing numbers of consumers are going online to measure fitness improvement, seek information on treatments and medications, and monitor health issues, according to the Deloitte 2016 Survey of US Health Care Consumers.4

In the near future, digital technology may improve the patient experience by providing real-time access to medical knowledge. Imagine an Al-powered, bedside virtual care assistant for an impatient patient that can answer or direct queries to the most appropriate person at the hospital. This virtual assistant can answer the patient's routine questions about diagnoses, expected recovery experiences and times, and daily medication schedules. In addition, the virtual assistant can act as a data repository for the patient's medical history, test results, consultation times, appointment schedules, and even stories from other patients with a similar diagnosis. Such accessible AI technologies are starting to exist and can help empower patients and their families.

# Virtual care assistant in action<sup>5,6,7</sup>

The Ohio State University's (OSU) Wexner Medical Center is a major US academic medical center. In 2012, in partnership with Epic Systems, researchers created OSUMyChart—a customized version of Epic's MyChart, which is an online portal solution for outpatients. OSUMyChart allows patients to see their health records, pose questions to physicians, view test results, and schedule appointments.

With growing interest in the application, OSU in 2013 extended OSUMyChart to inpatients in the form of bedside tablets. OSU piloted these tablets to patients in its James Cancer Hospital and Ross Heart Hospital. Patients could set medication alarms, directly schedule physician and relative visits, view test results, or read educational material pertaining to their diagnosis. Patients also could make minor requests for water, snacks, and even help going to the toilet without using a nurse call button.

OSU reported that patients using OSUMyChart "loved it," "felt more confident," and said they better understood their health care experience. Returning patients requested these tablets upon admission. The pilot's overall patient satisfaction was 95 percent, compared to 85 percent for those who did not have access to a tablet. Today, OSU has a bedside tablet in almost all of its patient rooms.

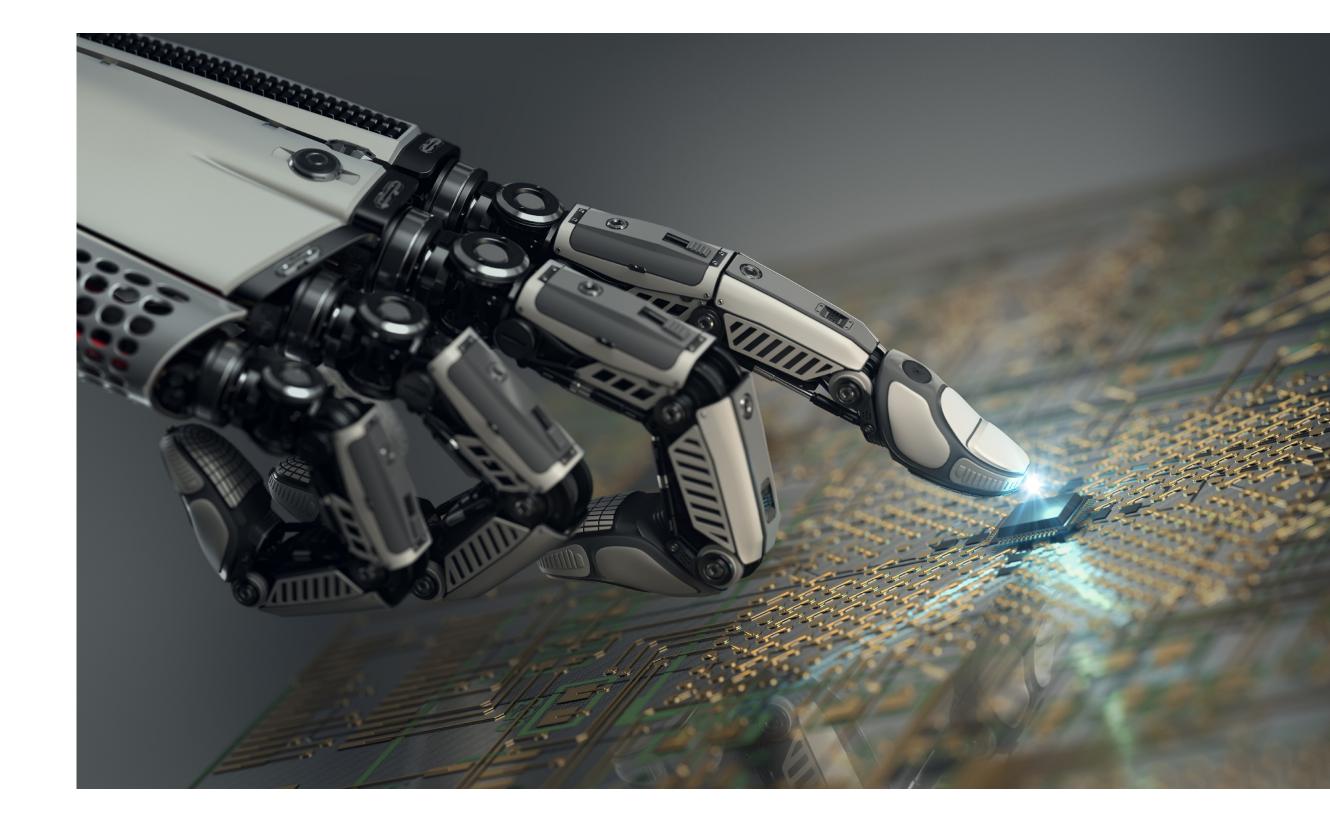
# Simplifying admission, discharge, and other processes

Hospitals frequently stumble in their admission and discharge processes, particularly when it comes to efficiency and patient satisfaction. Patients often complain about filling out multiple forms that ask for similar data, or receiving conflicting discharge instructions. As hospital processes go digital, staff can use Al to learn from and improve these processes.

In the near future, there will likely be no discrete patient registration process. Once a patient's physician advises admission, they can receive a personalized welcome package—an application on their own or a hospital device that helps to direct their experience. Clinical, financial, and demographic information can be pre-populated from the patient's records. As discussed earlier, these records can be cloud-based and easily accessible to key stakeholders. Al incorporated into the application can help physicians, medical staff, and patients converge on decisions such as modulating staffing needs, selecting room type, stocking required medication, determining diagnostic choices, and meeting non-medical support based on the patient's socio-demographic profile.

Al algorithms can be integrated into the discharge workflow, as well. Today, typically a nurse delivers tailored instructions that are based on the patient's condition, medical history, behavior, and attitude. Some patients require more time to understand and acknowledge the instructions than others. Nurses,

often working on multiple priorities, sometimes are not able to provide enough time for such patients. With all information in a single location, Al algorithms can create customized discharge guidelines that can be integrated into the virtual care assistant and delivered to the patient at discharge and throughout recovery. Patients can take as long as they need to understand the instructions, ask questions, and talk to nurses or other medical staff if human intervention is needed.





# How are newly planned hospitals envisioning patient experience?8

When Ireland's New Children's Hospital (NCH) opens in 2021, it will be one of the country's first digital hospitals. Construction of the government-sponsored hospital began in 2017, with a vision of elevating the patient experience through digital technologies.

The hospital board produced a short video showcasing how digitally integrated technologies can help patients throughout the care process—from admission to discharge—and post-discharge activities. The video follows the mother of a 10-year-old child, and highlights the role digital technology can play in future care and the patient experience. Consider these features:

- Physicians can use their own device to access the patient's secure, integrated EHR. It can include information about the patient's condition, medical history, family medical history, allergies, and current medications.
- During the admission process, the EHR can automatically capture details from the primary care physician; neither the patient nor family will be asked to fill out forms with redundant questions.
- All diagnostic and lab tests can be ordered directly from the physician's device, and results can be automatically captured by the EHR, with the physician receiving real-time notifications.

- Inpatient rooms, including beds and bedside devices, can be prepared based on patient demographics and preferences, as well as physician and nurse input.
- All patients can have bedside consoles that provide education, entertainment, and social media services along with pertinent medical information.
- Based on patient history, the EHR can automatically determine if the patient is a candidate for new treatments or clinical research that might improve outcomes.
- Post-discharge, patients can use a personal device to schedule appointments with various caregivers such as nutritionists, eye specialists, and pharmacists. The EHR can automatically capture results of these visits.

Imagine the art of the possible: How can digitally integrated technologies help patients throughout the care process—from admission to discharge and post-discharge activities?

# **Enhanced talent development**

Our crowdsourcing participants focused on three aspects of staff management—recruitment, scheduling, and learning and development. Recruitment and scheduling can achieve efficiencies through analytics use. Staff development can focus on continuous learning through virtual simulations and online courses.

# Intelligent staff recruitment and scheduling

Nurse and staff turnover—from 12 percent to as high as 50 percent at some hospitals—is a challenge in several countries.9 Turnover results in caregiver shortages and cost overruns for most hospitals' single-largest cost center labor. Digital technologies could help change this situation in the future.

Hospital recruitment increasingly can rely on cognitive analytics (CA) and RPA to help automate the candidate-selection process. Also, cloud-based capabilities can help filter resumes and profiles more quickly—both those that are submitted directly to an organization and those that are publicly available so administrators can focus on choosing the best candidates. Analytics also could play a role in determining salary and benefits, automatically comparing a candidate's experience to the market rate and organizational structure.

Similarly, CA can continue to be used for staffing models and deployment. As the workforce moves toward a gig economy—an economy in which workers with short-term contracts are more common than traditional full-time workers scheduling shifts can become more complicated. Also, with ongoing focus on improving patient outcomes globally, hospital executives will likely need to use acuity-based staffing analytics to study patient data and requirements to match them with the appropriate staffing competencies. This can help optimize

staffing, reduce unplanned overtime, and eliminate last-minute scrambles for contract staff, which can be expensive.

Technology—specifically IoT, radio-frequency identification (RFID), and CA also can track performance management. IoT and RFID devices can track when staff members arrive, determine how many patients they see, and determine the amount spent on patient care versus administrative tasks. CA can then review the data and determine where efficiencies can be improved. For instance, advanced-practice nurses might be able to delegate some of their activities to registered nurses, allowing them to practice at the top of their licenses. While some staff may feel that these technologies intrude on their work, if a level of trust is established between managers and employees, this barrier can be overcome.

# Intelligent staff scheduling in action<sup>10</sup>

Allina Health, a nonprofit health system based in Minnesota, uses technology from AMN Healthcare to automate its staffing-management process. The software allows Allina to forgo manual scheduling and track staff hours and costs. After four years, Allina saved more than \$4.8 million in staffrelated costs. Automation saved 120 hours per week previously spent in-sourcing, reviewing, scheduling, on-boarding, and invoicing for supplemental staff.

# **Virtual learning and development**

Virtual training will likely become more prevalent in the future. While hands-on, in-person medical training can never go away, virtual training can become more prevalent among students and seasoned clinicians. Virtual training can help surgeons map out their surgeries before conducting them—they can also share footage of the actual surgery with students and colleagues. Virtual training also can increase specialized expertise available to a larger audience, which can be particularly important when geography and costs are factors.

Continuing education credits for virtual training can be tracked with the help of applications or other programs, and can encourage health care professionals to keep up with training requirements. Furthermore, requirements can be tied to performance metrics based on objective criteria. Clinicians, for example, can be assigned courses in areas where they need additional training rather than just topics they want to learn more about. And to help retain staff and reduce burnout, clinicians also can be required—or at least, encouraged—to enroll in self-care classes that focus on mental and physical health. Some academic medical centers are currently developing VR programs to train surgeons.<sup>11</sup>



# **Operational efficiencies through technology**

The crowdsourcing exercise led to the development of use cases to reduce costs and improve revenue by using robotics and automation to trim inefficient processes.

# **Automation and robotics for care and ancillary services**

Within the walls of a typical 200-bed hospital, lab specimens, linens, materials, drugs, and other goods travel 371 miles a week.<sup>12</sup> In many ways, hospitals are mini-logistics companies that continuously move large volumes of material among labs, pharmacies, pantries, and administrative units. While this logistics function has cost, quality, and safety implications, it is not likely core to hospitals' mission of providing patient care. Consider this: Nurses typically spend less than two hours of a 12-hour shift on direct patient care. The remaining time, they are doing paperwork, searching for medications and supplies, coordinating lab results, and even helping deliver patient meals.<sup>13</sup>

Using robotics to automate hospital ancillary and back-office services can generate considerable cost and time efficiencies, and improve reliability. By simply touching a screen, nurses and other medical staff can summon robots for specific tasks. For instance, robots can deliver medications, transport blood samples, collect diagnostic results, and schedule linen and food deliveries either as a prescheduled task or a real-time request. Robotic processes also can be used for certain hospital revenue cycle and accounting/finance functions, such as scheduling and claims processing.





Around the world, some hospitals are incorporating robots into their processes, starting with operations management.

Japan's Toyohashi University of Technology has developed *Terapio*, a robot that can carry out routine hospital tasks, such as making hospital rounds, delivering medications and other items, and collecting records. For now, the robot follows a nurse or other medical staff. 14

Other hospitals are creating an ecosystem for autonomous robot operations. Hospitals of the future will likely have space overhead (such as heightened ceilings) or dedicated pathways for robots that allow for automated delivery of materials, supplies, and medications throughout the facility.

The South Glasgow University Hospital in Scotland, opened in 2015, is designed as a robot-friendly facility. The hospital has 26 robots that move medical equipment, linens, food, and waste. The robots have their own underground tunnel, through which they transport supplies, and a dedicated elevator. The robots are arranged in a line where they wait to be assigned tasks. As the first heads out, the next in line takes its place. The robot reaches the loading bay where materials, such as medical supplies, await pickup. After retrieving the supplies, the robot moves through the tunnel, calls the elevator, and heads to the appropriate floor. With continuous sensing, the robot can stop and call for help if an obstacle remains in place after a predefined time limit. Once it completes a task, the robot moves back to its "charging" pod. These robots now perform 10 percent of the hospital's operations tasks. As robots become more affordable, that figure could increase to 25 percent by 2025, resulting in additional cost and time efficiencies.15

How will robotics change operations management in the future design of hospitals across the world?

## **Blockchain and secure contracting** through next-gen technologies

As discussed earlier, many hospitals have invested significantly in data and operations management systems for EHR, supply chain, and revenue cycle functions over the past few years. Yet, interoperability, data security, and inefficient processes continue to challenge efficient operations management for many.

In the United Kingdom, a survey conducted by the National Health Service (NHS) found that more than half of acute care hospital respondents faced patient record access issues.<sup>16</sup> In the United States, 78 percent of hospital executives say they use manual processes for their supply chain management, which can lead to inflated costs and data integrity issues.<sup>17</sup>

Blockchain technology has the potential to revolutionize many of these operations processes. Blockchain is a distributed, immutable—write once and read-only—record of digital transactions that is shared among established stakeholders. Blockchain's strength lies in its data integrity—each new piece of data must be validated by the majority of the users in the network. With no central intermediary, a malicious hacker must target many users, rather than one, to alter the data. Here are a few examples of how blockchain can improve hospital operations processes:

Data interoperability: Blockchain can help health information exchanges (HIEs) alleviate security concerns. For example, each time caregivers provide patients with a service, they update their patients' health data on a blockchain-enabled HIE. Each blockchain member has a private key, which is secure, and a public key that acts as a visible identifier. Because

of these permission layers, patients can limit data access and share only the relevant parts of their medical records with their caregivers or other clinicians.

Supply chain management: Hospital materials management includes planning, purchasing, and tracking inventory of goods (such as medical supplies and drugs) across the supply chain—all areas where blockchain can create efficiencies and improve safety. Supply chain participants typically include retailers, wholesalers, distributors, and manufacturers, and they might be located around the globe. With such a complex chain, there may be low accountability in cases of delays or damage. Counterfeit products can be another risk. A blockchain-enabled supply chain management system can facilitate the transfer and ownership of material across the supply chain, and trace the process via a blockchain ledger over a peer-to-peer network.

Revenue cycle management: Blockchain can help improve the validity and efficiency of the hospital revenue cycle. Billing and payment errors are common, and can lead to payer denials and bad debt. Customers can lose trust in their hospitals if their bills are incorrectly coded. Implementing blockchain-based claims-adjudication and paymentprocess systems can eliminate the need for intermediaries between hospitals, physicians, insurers, and customers. It also can help reduce administrative costs. As more complex payment contracts become the norm, blockchainbased contracts will help automate calculations that are now done manually. For instance, a patient or an insurer can deposit currency guaranteeing that it is available, but not release it until the clinical outcome is achieved.

## **Healing and well-being designs**

The crowdsourcing exercise led to the development of hospital design use cases that can enhance patient healing and increase staff productivity.

## Hospitals will likely have prosocial designs for patient and staff well-being

Hospital stays can be frightening, stressful, and boring. Hospital executives increasingly acknowledge that a facility's design has the potential to promote good physical, spiritual, and mental health, and contribute to quicker patient recovery. Our crowdsourcing provided examples of a future hospital that incorporates a prosocial design with features such as:

• Customized patient rooms: People can get bored after a day of looking at the same smartphone wallpaper. Imagine how boring a hospital room looks to a patient after a week's stay—the dull environment could negatively impact the overall patient experience. Instead, imagine the walls of a hospital room pre-populated with pictures of the patient's family members, or photos from a recent trip. Along with these "picture" walls, a patient could customize music, make video calls with friends and family through the internet, or access entertainment through virtual reality headsets. The bed is customized to desired firmness, and the pillows are preselected to be feather, foam, or allergy-free. Bathrooms have integrated sensors that monitor unusual activities, such as patient falls, and trigger a call for immediate help. Customized patient rooms may be the new normal in hospitals of the future.



- Smart, ergonomic premises: A hospital that has attractive visitor lounges, dayrooms, and views of natural or green surroundings, such as healing gardens, can help reduce patient anxiety and expedite healing. Also, furniture that can be flexed to create space, smart table layouts (e.g., changing rectangular to radial), and offstage, staff-only spaces can reduce walking demands and employee stress.
- Modular lighting and noise management: Bright, ambient lighting that is non-intrusive and easily scalable to increase intensity when and where it's needed can bring about significant change in patient-centered care. Proper lighting can improve the patient experience, particularly in terms of mood and perception of pain. Also, hospital staff can benefit from innovations in lighting which, in turn, can contribute to improved patient care and alertness. Another environmental issue often considered a necessary evil is hospital noise; primarily staff conversation, alarms, and medical devices. There is a growing body of evidence that links hospital noise with sleep interruption, stress (e.g., increased blood pressure and heart rates), and re-admission for adults and children.<sup>18,19</sup> Hospitals in the future could have noiseless alarms on medical devices, soundscapes, noiseless paging, and health acoustic engineering to improve ambient noise.

## **Prosocial design in action**<sup>20,21,22,23</sup>



Sweden's state-owned Karolinska University Hospital began planning for a new facility in 2010—New Karolinska Solna (NKS)—to "meet the health care needs of the future." NKS opened its doors to patients in late 2016.

The hospital is proud of its state-of-the-art, prosocial design, which supports the healing process and stimulates both patients and staff. All inpatient rooms are private rooms and have modern designs, colors, and materials that create a feeling of comfort and help patients, visitors, and staff members navigate the facility.

The hospital's glass structure maximizes natural light and is intended to aid healing. NKS is also designed to be much quieter and calmer than a typical city hospital. The staff carries discreet buzzers instead of relying on alarms, pagers, or loudspeakers. "During the NKS project, we have prioritized human needs. The buildings and rooms have been designed with health care in mind, but they also provide a sense of well-being."—Charlotte Ruben, NKS architect.

The NKS hospital also features one of the largest-ever art investments for a hospital. There is \$13.2 million worth of paintings, sculptures, and design objects installed at strategic locations—staff facilities, staircases, and waiting rooms. "Art and culture in all its forms has both preventive and healing effects. At the new hospital, art will play its part in the medical toolbox," according to Gunnar Bjursell, professor emeritus, Karolinska Institute.

## Many hospitals will focus on safety and security—by design

Hospitals handle a large flow of people every day, and they are accountable for everyone's safety. Hospital employees need to be prepared for anything: theft, vandalism, physical assault, or even aggravated behavior by patients and relatives. Three-out-of-four surveyed US hospital security executives said security has become more challenging over the past few years.<sup>24</sup> And the United States is not alone. In Canada, hospital executives reported an assault rate of 20 incidents per 100 beds in 2015, according to a survey from the International Association for Healthcare Security and Safety.<sup>25</sup>

Many hospitals now have access to digital technologies to supplement onpremises physical security. They can systematically tag patient wristbands and employee and visitor badges with RFID tags that allow appropriate levels of access. The intent of RFID tracking is to be able to respond appropriately to an urgent situation, and to locate people in real time. The same tagging system can be extended to certain pieces of equipment, including any robotic helpers within the hospital.

Additionally, security cameras monitored by AI—using facial recognition and empathic expression detection—can identify dangerous situations as—or even before—they occur. For instance, a camera viewing an altercation between a visitor and a nurse will know where to focus its recording attention and to notify security immediately. Imagine, though, if that camera reads the expression

and vital signs of the upset visitor before anything happens. The AI notifies a counselor, gives a general outline of the situation, and the counselor de-escalates the confrontation. The system can work best when monitored by AI with human back-up for interpreting events that are too complex, and too human, for the Al to decipher.





### Digital hospital in action<sup>26,27,28</sup>

What does a hospital look like when it combines all of the elements we've discussed in this paper? Opened in April 2017, Sunshine Coast University Hospital in Queensland, Australia, is

an example. What sets the hospital apart is how it knitted digital technologies together to help hospital operations, clinicians, nurses, and other caregivers bring "new age" health care to the region.

Patients are directed via digital way-finder kiosks to their clinicians. RFID tags are used for equipment, devices, and patients. For instance, newborns will be fitted with skin-sensitive tags that emit a pleasant beep as mother and baby bond. An unfriendly beep sounds if someone other than the mother picks up the baby, or if there is an attempt to remove the tag. Motion detectors and easy-to-use touch pads are mounted on patient beds to alert staff, especially in the elderly care and dementia wards, to prevent falls or alert staff that a patient needs assistance with the toilet. Doctors use an application on their devices to dictate notes; the application employs enhanced voice recognition software to produce transcriptions, eliminating the need for medical administration staff to type notes.

The hospital prioritizes staff training and development. The facility houses a 20-room simulation suite that has fully equipped operating and ICU rooms with simulation patients and devices capable of running realistic scenarios for clinical staff.

Traveling through dedicated tunnels and elevators, robots assist with logistics tasks such as delivering linens, meals, and medical supplies; this gives staff more time for patient care.

More than 30,000 comments from hospital users, clinicians, and staff guided the 14-month design process. The result is a hospital infrastructure that enhances patient healing and staff productivity. And even though the facility's size is massive—it is equivalent to 100 football fields and has about 6,300 doors—the hospital is designed to help visitors, both first-time and repeat, feel at ease. In addition to user-friendly physical and digital maps, colorcoded wards and strips on the floors orient visitors and identify the shortest routes to their destinations. All patient rooms have tall windows that oversee landscaped gardens with 30,535 trees and shrubs. Inside, the bright, ambient lighting is sensitive to movement; there are no manual switches. To check on patients without disturbing them, nurses use a magnet-like device to open blinds, rather than opening the room door.

The hospital was built to be scalable from a physical and a digital perspective. It currently has a 450-bed capacity but can double to 900 beds in the future. The hospital also has the capacity for 40,000 IT touchpoints to scale up digital capabilities, if needed.

## The digital hospital of the future: Putting it all together

In the past, typically every major hospital design project started with the same discussion: How many beds do we need? This conversation is changing and bed count is no longer the primary design driver for many hospitals of the future. Many health systems are shifting their efforts to improve care quality, create more efficient processes, and enhance the patient and staff experience.

Health care executives with an aging hospital facility may have to decide whether to retrofit the structure or build something new. Building can offer greater flexibility to embed all of the digital elements discussed in this paper. Retrofitting an outdated facility could pose challenges due to limited space and flow options, and make it more difficult to fully embrace the hospital-of-the-future concept. Unfortunately, not all hospital leaders have the option to build something new; they should consider, therefore, prioritizing retrofitting elements based on their organizational strategy.

Whether building or retrofitting, a comprehensive, enterprise-wide digital strategy can be essential for creating the hospital of the future. Some hospitals, finding their operations disrupted by technology advances and economic trends, jump on the bandwagon by *going digital*—introducing digital technologies into their existing processes. However, over time, they may experience challenges—discreet implementation, issues with scalability and interoperability, lower staff knowledge and motivation—which lower the return on their digital investments.

Instead, hospital executives should consider *becoming digital*—building an enterprise wide digital strategy and weaving it into their organizational strategy, operations, and processes.



## Suggested next steps

In the coming decade, many US and European hospital executives plan to renovate or rebuild their aging infrastructure.<sup>29,30,31</sup> Similarly, increasing health care demand in emerging economies could drive considerable hospital planning and construction. For instance, spending on new hospital infrastructure in India is expected to reach \$200 billion by 2024, and China plans to add 89,000 new hospital beds by 2020.<sup>32,33</sup>

But there is no need to wait for a building boom to integrate emerging technologies into hospital operations. A number of digital solutions do not require new bricks and mortar or major facility redesign; they can be implemented in the near future to improve operational efficiencies and clinical outcomes. Among the solutions for hospital executives to consider:

Care delivered digitally. To improve cost, quality, and outcomes, hospitals can use digital technologies to engage differently with patients. Remote patient monitoring, telehealth, advanced analytics, and wearables can transform an existing hospital into a cost-efficient delivery system that engages more with patients for improved quality and outcomes.

Digitally enabled customer experience: Hospitals can elevate the customer experience by using digital solutions to aid omni-channel patient access, including customer apps, patient portals, personalized digital kits, and selfcheck-in kiosks. Additionally, digital technologies, such as IoT, augmented reality, and virtual reality can help customize patient needs during a hospital stay.

**Digitized operations:** Many back-office functions—finance, supply chain, human resources, and revenue cycle, among them—can benefit from robotics, advanced analytics, sensors, and automation to drive cost efficiencies. These functions also can be digitally improved by using cloudbased enterprise resource planning solutions to make them shorter, faster, and more responsive.

## Organizational capabilities for long-term success

Hospitals that integrate digital solutions into broader organizational capabilities can improve the potential for long-term integration success. The core elements of an enterprise digital strategy are:

Create a culture for digital transformation. It is essential that senior management understands the importance of a digital future and drives support for its implementation at all organizational levels.

Consider technology that communicates. Digital implementation is complex. Connecting disparate applications, devices, and technologies—all highly interdependent—and making certain that they talk to each other can be critical to a successful digital implementation.

Make needed investments manageable. Consider subscribing to certain technologies and services to help avoid significant upfront capital investments. Play the long game. Since digital technologies are ever-evolving, flexibility and scalability during implementation can be critical. The planning team should confirm that project scope includes adding, modifying, or replacing technology at lower costs.

Remember, data are core. While the requirements of data interoperability, scalability, productivity, and flexibility are important, they should be built upon a solid foundation of capturing, storing, securing, and analyzing data. Organizations should create a strong, system-wide data infrastructure.

Prepare for Talent 2.0. As hospitals invest in exponential technologies, they should provide employees ample opportunities to develop corresponding digital skills. An augmented workforce and use of new technologies requires current staff to learn new skills to manage and work alongside the robots and Al processes.

Maintain cyber security. With the proliferation of digital technologies, cyber breaches can be a major threat to hospitals of the future. Executives should understand that cyber security is the other half of digital implementation and allocate resources appropriately.

Many hospital executives have little choice today—maintaining antiquated assets is really not an option. Building a digital hospital of the future can require investments in people, technology, processes, and premises. Most of these investments will likely be upfront. In the short term, hospital leadership may not see immediate returns on these investments. In the longer term, however—as digital technologies improve care delivery, create operational efficiencies, and enhance patient and staff experience—the returns can result in higher quality care, improved operational efficiencies and increased patient satisfaction.

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