Computerization of workflows, guidelines, and care pathways: a review of implementation challenges for process-oriented health information systems

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ABSTRACT

Objective There is a need to integrate the various theoretical frameworks and formalisms for modeling clinical guidelines, workflows, and pathways, in order to move beyond providing support for individual clinical decisions and toward the provision of process-oriented, patient-centered, health information systems (HIS). In this review, we analyze the challenges in developing process-oriented HIS that formally model guidelines, workflows, and care pathways.

Methods A qualitative meta-synthesis was performed on studies published in English between 1995 and 2010 that addressed the modeling process and reported the exposition of a new methodology, model, system implementation, or system architecture. Thematic analysis, principal component analysis (PCA) and data visualisation techniques were used to identify and cluster the underlying implementation 'challenge' themes.

Results One hundred and eight relevant studies were selected for review. Twenty-five underlying 'challenge' themes were identified. These were clustered into 10 distinct groups, from which a conceptual model of the implementation process was developed.

Discussion and conclusion We found that the development of systems supporting individual clinical decisions is evolving toward the implementation of adaptable care pathways on the semantic web, incorporating formal, clinical, and organizational ontologies, and the use of workflow management systems. These architectures now need to be implemented and evaluated on a wider scale within clinical settings.

INTRODUCTION

Computer-based workflow is primarily concerned with the automation of business processes, in which documents, information, or tasks are passed from one participant or application to another for enactment, according to a set of procedural rules. Workflow activities and procedural rules used to manage the flow activities are identified by a workflow process definition. A *workflow management system* (WfMS) consists of software components to store and interpret process definitions, create and manage workflow instances as they are executed, and control their interaction with workflow participants and applications.[1]

Clinical workflow has been defined as 'the flow of care-related tasks as seen in the management of a patient trajectory: the allocation of multiple tasks of a provider or of coworking providers in the processes of care and the way they collaborate.'[2]

The application of WfMS to managing clinical workflow was first proposed by Dadam *et al*,[3] who noted the need to formally model clinical activities while not restricting the clinician's natural work processes, allowing flexibility and ad hoc variation in execution of clinical tasks. Quaglini *et al*[4] defined a methodology and architecture for integrating computer-interpretable clinical guidelines (CIGs)[i] with a commercial workflow engine for the management of acute stroke. The combination of a Petri net-based formalism for modeling clinical tasks, with a WfMS for managing the organizational process, was dubbed a 'careflow' system, in which the careflow process definition describes the tasks and defines their order of execution, while the execution engine provided some flexibility by allowing tasks to be skipped or substituted with other tasks outside those defined by the clinical guideline.

Schadow *et al*[8] also suggested that WfMS can be used to implement a standardized and defined route through evidence-based clinical processes. Such processes are known as *care pathways*, defined as 'structured multidisciplinary care plans that detail essential steps in the care of patients with a specific clinical problem [and] offer a structured means of developing and implementing local protocols of care based on clinical guidelines … [They] describe the tasks to be carried out together with the timing and sequence of these tasks and the discipline involved in completing the task.'[9]

Care pathways originated in nursing practice in the 1980s when the application of a business process management approach to the organization of clinical practice was used to improve the quality and efficiency of patient care.[10] Despite a long history, the care pathway concept remains unclear.[11] The term is often used interchangeably with clinical guidelines and protocols,[12] although each may be considered to be a different type of workflow with a different scope[13]:

- A clinical guideline provides recommendations for best practice for the clinical domain addressed by the guideline, but does not provide implementation details
- A clinical protocol provides a local, consensus view of a guideline with explicit steps for implementation

[i]In an effort to remove some of the barriers to the adoption and use of clinical guidelines at the point of care, several formalisms for encoding guideline content into a computer-interpretable format have been proposed. A number of comparative analyses of the most developed formalisms have been published.[5–7]

- A care pathway is a versioned document of a process, and includes actions recommended by one or more protocols and guidelines, activity role constraints, and sequencing constraints; it has goals and it provides a record of care and information about the patient state and a 'variance record,' that is, a method for documenting and recording where deviations from the planned pathway have occurred.[13]

Criticisms of care pathways may arise from the limitations of paper-based care pathway documents. It is difficult to tailor care pathway forms to the needs of the individual patient, and interdependencies between different pathways are not made explicit: multiple paths tend to be merged into a simple list of tasks,[14] leading to the claim that care pathways simply provide time-based 'cookbook' care.[15] In parallel with the development of CIG models, the 'computerization' of care pathways has been proposed as a way to overcome these limitations, to allow pathways to be integrated with guideline-based decision support and the electronic health record (EHR). *Electronic care pathways* ('e-pathways')[16] are defined as systematically developed, computerized care pathways that describe: (1) the clinical data sets used (representation of declarative knowledge); (2) the on-screen forms and user interface elements required; (3) the formal model of the roles, tasks, sequencing, and business rules of clinical workflow (representation of procedural knowledge); and (4) the messages to be exchanged between the systems that invoke the pathway.[16] Wakamiya and Yamauchi proposed five core requirements for electronic care pathway implementations: recording notes in the EHR, statistics and variance recording, provision of computerized physician order entry (CPOE), activity checklists, and editable pathway templates.[17]

Concerns about the duplication of effort, the lack of consistent standards, and the existence of numerous models have been raised by the care pathway and clinical guideline research communities.[16 18] At the same time, it has been suggested that computerized decision support systems (CDSS), CIGs, and WfMS are individually inadequate for providing support for longitudinal care processes. The current research challenge is to integrate the various theoretical frameworks and formalisms, in order to move beyond providing support for individual clinical decisions and toward the provision of process-oriented, patient-centered, health information systems (HIS).[19]

While previous systematic reviews have individually considered the effectiveness of computerized guideline[20–23] and care pathway implementations,[24] the question of how to integrate guidelines, care pathways, EHR, and clinical workflow has rarely been addressed.[19] Song *et al*[25] identified a number of challenges to implementing 'computer-aided healthcare workflows,' defined as the integration of guidelines and protocols with a HIS. Following Song *et al*, we define a *process-oriented health information system* as a HIS that formally models guidelines, workflows, or care pathways and provides support for clinical decisions that extend over time.

The aims of this review are (1) to identify the cross-cutting themes that describe the theoretical and practical challenges involved in developing process-oriented HIS; (2) to summarize approaches to developing such systems and integrating them with the EHR and clinical workflow; and finally (3) to develop a conceptual implementation model from the themes and approaches.

METHODOLOGY

When one wants to explore a phenomenon about which little is known, in order to gain greater understanding and develop hypotheses to explain the phenomenon, qualitative methods are an appropriate choice.[26] Therefore we reviewed the literature from this perspective, by treating each paper as a textual narrative from which to extract and categorize the underlying themes that describe the studies as a whole.

Qualitative *meta-synthesis* involves the interpretative analysis of the themes and categories from a representative sample of studies.[27] Within the qualitative research field, study heterogeneity is accepted,[27] so differences were compared and contrasted, and areas of commonality identified through a process of iterative, comparative analysis.

Search strategy and inclusion criteria

Searches were performed using ScienceDirect, Web of Science, PubMed, and the specialist health informatics *OpenClinical* web resource. Articles in English published since 1995 were considered in order to analyze how implementation processes have evolved over time. The broad search concepts of HIS, computerization, modeling, workflow, pathways, and guidelines were combined into search statements specific to each database queried (see appendix).

An initial screening of titles and abstracts excluded opinion pieces, editorials, letters, posters, studies related to non-computerized care pathways, and studies about other types of pathway, for example, biochemical, neural, or motor pathways. Papers on 'patient flows,' 'pathways to care,' and 'commissioning pathways' were also excluded at this stage as these focus on the larger goal of strategic planning rather than clinical workflow and decision making at the individual patient level. Reviews of CIG and workflow models were selected as background material, and were used as a source of additional citations.

Full text articles were screened and included if they met our three inclusion criteria: (1) the study addressed the modeling process for the computerization of clinical workflow, clinical guidelines, or care pathways within the context of a HIS; (2) the outcome was the exposition of a new methodology, knowledge model, framework, system implementation, or system architecture that instantiated the process under study; and (3) there was an evaluation, even if this was only formative and descriptive.

Data collection and quality assessment

Following Evans and Pearson,[27] we created a data collection form in Microsoft Excel to identify papers for review. The quality of each was judged using criteria from Burns[28] and Greenhalgh and Taylor,[26] such as a clearly formulated question, rationale for and description of setting and participants, methodological, theoretical, and analytical rigor, data audit trail, and justification of conclusions.

Information for each of these criteria from each study was entered into the data collection spreadsheet. Not all criteria were relevant for each paper (eg, model formulations and system architectures may not have any participants or data audit trail). Papers that could not meet the criteria were discarded.

Data abstraction and thematic analysis

Thematic analysis was carried out using an approach informed by qualitative concept analysis, in which research aims are defined in advance, and categories are brought to the material and continually refined against it, with the goal of reducing the material.[29] This was guided by the three-stage approach discussed in Miles and Huberman[30]: (1) initial, descriptive coding, developing toward (2) more interpretative coding (high-level concepts that encompass the descriptive coding performed in step 1) as knowledge of the phenomenon under study increases; and (3) pattern coding (emerging themes) toward the end of the analysis in which themes are developed that seek to explain and make causal links in the phenomenon. Researchers met weekly to discuss the emerging themes before agreeing on the final set.

Challenges identified by Song *et al*[25] and Wakamiya and Yamauchi[17] were used to help develop the initial working list of descriptive codes with which to annotate the data (step 1 described above). The list of codes was refined and enhanced as new themes emerged from the literature during analysis (step 2). The final set of pattern codes was used to thematically annotate each paper in the review (step 3). Up to five variables that reflected the study's key concerns, results, and conclusions, were assigned to each study—these were the 'challenge theme' variables, that is, factors that need to be addressed when developing a system.

RefViz[31] is a tool for clustering bibliographic references for visualization and analysis. We created a custom reference file in ISI ResearchSoft RIS format,[32] containing title, year, author, and challenge theme variables for each paper and imported it into RefViz. RefViz applies standard mathematical clustering algorithms to partition the data set into concept-based groups of similar papers based on the co-occurrence of themes between papers. RefViz's Galaxy view performs principal component analysis (PCA) in which a larger set of possibly correlated variables are transformed into a smaller, more fundamental set of independent variables.[33]

The co-occurrence and clustering of the challenge theme variables arising from the thematic analysis were explored using PCA in RefViz, in order to see if the set of variables could be transformed into a smaller number of principal components that further summarize the studies and from which an integrative, conceptual model of the implementation process could be developed.

REVIEW FINDINGS

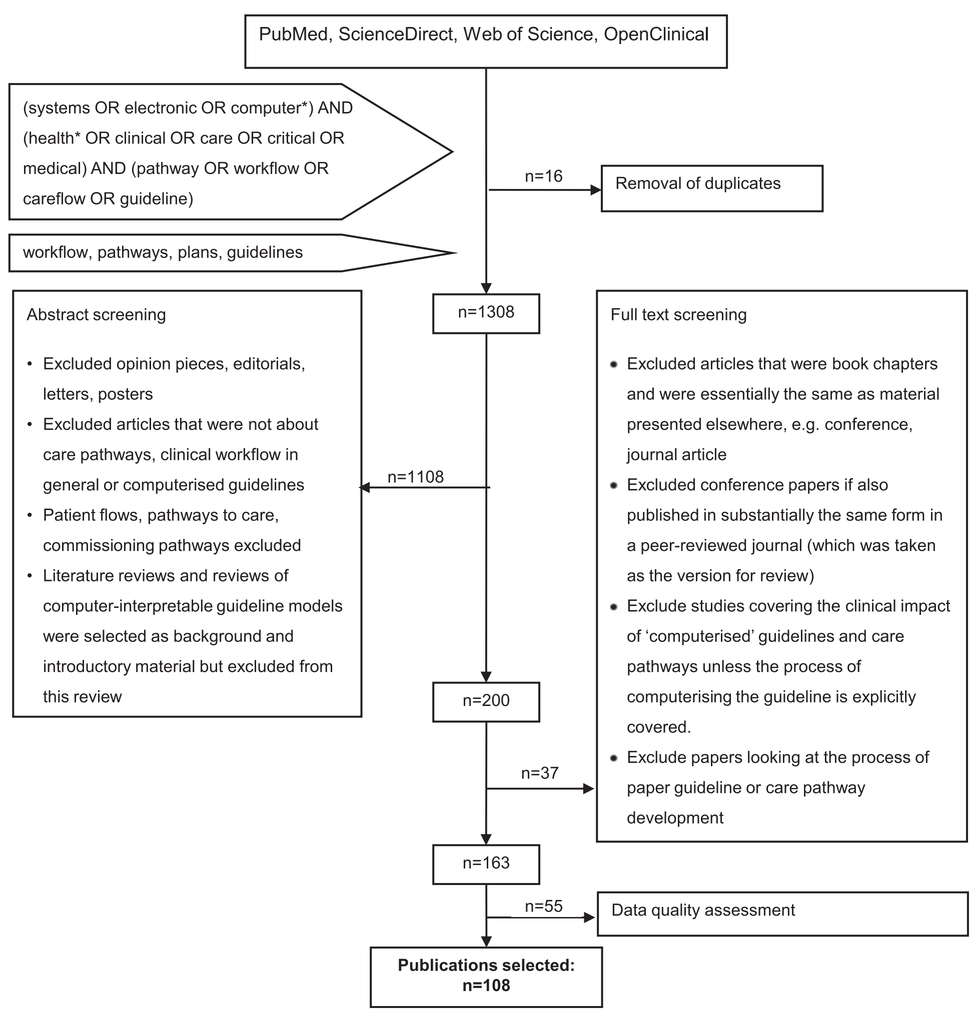
From 1308 screened citations, we retrieved 200 full text articles, and 108 met the inclusion and quality criteria for detailed review. The selection process is shown in figure 1.

Characteristics of selected publications

The review identified 79 journal articles,[4 8 12 14 17 34–107] and 29 conference proceedings papers.[3 108–135] Fifty-seven (53%) studies were conducted within an academic or commercial R&D, non-clinical environment. The remainder took place within university teaching hospitals and medical centers (n=16, 15%), outpatient clinics (n=8, 7%), and general hospitals, stroke units, or emergency or ICU departments (n=27, 25%).

Methods used by selected studies ranged from qualitative research involving usability evaluations (n=1) or questionnaires, interviews, and observational studies (n=20), to formal methods papers (n=26), model formulations (n=26), system case studies (n=20), prototype implementations (n=33), and system architectures (n=26). These categories were not mutually exclusive; a number of studies had multiple objectives: for example combining model formulation, prototype implementation, and system architecture.

Figure 1 Screening flow-chart.



Eight distinct knowledge model types were identified in the publications. Fifty-four publications (50%) focused on providing details of system architecture or system prototype implementation. Forty-four (41%) studies had evaluation results reported in the form of interviews, questionnaires, and observational case studies where the study size was quantified. The remaining studies reported informal evaluation in terms of the features of the model or method, or overall benefits of the system implemented.

Challenges in implementing process-oriented systems

The final set of the 25 challenge theme variables and their descriptions, derived from thematic analysis of the 108 papers, are shown in table 1.

The association between themes was explored using the Galaxy and Matrix views within RefViz. The weight of each theme within each cluster is calculated by RefViz's implementation of PCA and indicates the strength of association between the theme and the cluster, on a scale from −1 (strongest negative association) through 0 (no association) to +1 (strongest positive association). For space reasons, the complete matrix of association scores is not reproduced here. From this, 10 clusters were identified, from which we developed a concept map (figure 2).

In figure 2, each cluster is shown as a circle, where the radius of the circle is proportional to the number of papers in the cluster. Only the positively associated themes (ie, with non-zero or non-negative weights) are shown, and the thickness of the line is proportional to the strength of association between the cluster and the theme.

Table 2 provides a description of each challenge theme cluster, where the numeric group identifier relates to each cluster in figure 2.

Approaches to implementing process-oriented systems

Electronic health record integration

Twenty-six studies considered the problem of how to integrate a clinical process model with data in the EHR. Of these 26 studies, only three[68 79 121] were part of a system implementation within a clinical environment; the remainder were data modeling and/or integration studies within an academic institution. In terms of approach, the studies can be split into three categories:

- Studies that advocated the use of the same underlying data model for both the guideline or pathway knowledge model and the EHR, using models such as the HL7 Reference Information Model (RIM), Unified Service Action Model (USAM), or openEHR[8 111 116 120]
- Studies that attempted to *map* guideline or pathway knowledge model concepts to data items within the EHR via guideline expression languages (eg, GELLO),[67] the use of a 'virtual medical record' (VMR),[52 89 112 121 123] standardized vocabulary resources such as UMLS and SNOMED CT,[52 67 85 90 133] or a 'middleware' mapping ontology layer,[35 64] or manually, on a system-specific basis,[68 127] or via a translation table[54]

Table 1 Challenge themes: 25 variables identified from initial thematic analysis

Variable	Description
Clinical implementation	Implementing the model into a usable system that is congruent with individual and collaborative clinical workflow in a live, clinical environment
Clinician attitude	Beliefs in own self-efficacy, and relevance and quality of guidelines and pathways to clinical practice
Complexity	Ability to evaluate and check the model with reasonable run-time behavior (eg, polynomial time) in real-world scenarios
Data mapping	Mapping electronic health record (EHR) data to procedural tasks in the guideline or pathway; mapping guideline concepts to terminologies
Discrepancy	Potential for inconsistencies between the pathway documentation and the actual treatment process (as a result of staff miscommunication, misunderstanding, or model/implementation constraints)
Exception handling	Ability to handle unplanned deviations from the pathway or guideline (variance)
Execution	Executing the guideline or pathway model within the EHR; semantic interoperability
Expressivity	The need to adequately represent complex clinical information, rules, and exceptions in a formal model
Flexibility and adaptability	Adapting the pathway at run-time to individual patient (variance); handling incomplete or ambiguous patient data
Goal modeling	Modeling clinical and organizational processes is insufficient: the intention for each task needs to be explicit
Guideline translation	Guidelines are ambiguous and cannot easily be translated into logic rules; contain implicit knowledge that is incompletely specified
Information/rule extraction	Ability to automatically extract clinical knowledge and rules from guideline text
Localization	Adapting the pathway to local needs (consensus and collaboration). Domain experts creating shareable guidelines must agree on meaning and interpretation of the guideline
Maintenance	Need to keep guideline, pathway, and workflow model up to date with latest evidence or changes in clinical workflow
Model validation	Validation of encoded model against clinical relevance and expected results for the specific patient; explanation of reasoning
Model verification	Internal consistency of the model, well formedness, proofs of properties
Organizational change	Existing clinical workflow may need to be adapted in order to successfully implement the system. Staff buy-in, training, and workflow needs; changes of role (eg, increased data entry at point of care)
Organizational modeling	Need to model organizational workflow as well as medical knowledge; includes role-based access and security
Process modeling	Creating a computer-interpretable model of clinical processes from guidelines and local clinical knowledge
Reporting, querying, and visualization	Getting access to the data held in the system for reporting, statistics, visualization
Separation of concerns	Separation of medical knowledge from workflow knowledge that can be integrated into a combined clinical and organizational process model at run-time
System architecture	Selection of a suitable system architecture congruent with clinical workflow and organizational needs: for example, client-server, service-oriented architecture (SOA), semantic web, transport layer security, authentication, role-based access
Temporal abstraction	How to model temporal constraints and periodicity in guidelines and pathways
Tooling	Creation of easy to use tools to model guidelines, workflows, and pathways
User interface and usability	Accessing the data and guideline/pathway in an easy to use, easy to navigate way; data entry

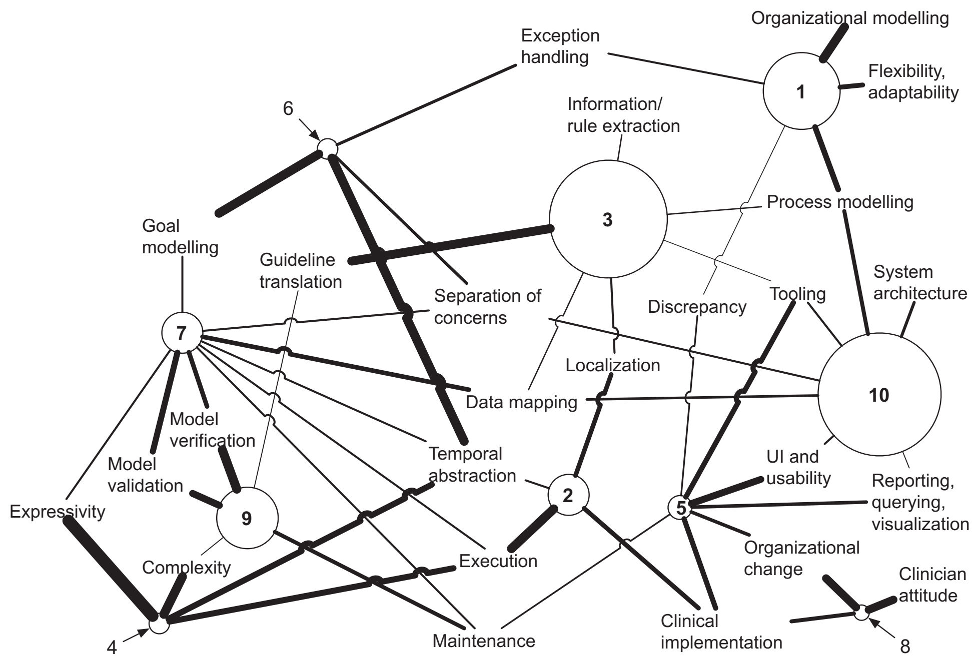


Figure 2 Concept map derived from RefViz Galaxy and Matrix analysis, showing association between study clusters and the 'challenge theme' variables. The radius of each circle is proportional to the number of studies in the cluster; the thickness of the line between cluster and theme is proportional to the strength of association between the cluster and the theme.

- Studies that recognized the need for EHR integration, but did not implement it.[45,57,108,110,114]

Clinical workflow integration and point-of-care use

Studies that considered the use of guidelines and pathways at the point of care can be divided into model formulations and practical implementations of systems.

A number of the model formulation studies suggest that the barrier to the accessibility of guidelines or care pathways might be addressed by developing an ontology that integrates organizational and clinical workflow with EHR data requirements[45,67,111,119]; however, these papers do not suggest how such point-of-care execution should be implemented in practice.

Table 2 Description of the challenge theme clusters shown in the concept map of figure 2

ID	Studies in the cluster	Cluster description
10	24 Studies[8,14,46,61,67,68,71,73,78,83,85,90,91,96,108,111,112,116,118,121,126,129,134]	Creating a procedural, clinical process model aided by knowledge acquisition tools and supported by the system architecture; mapping declarative concepts between a local electronic health record (EHR) or 'virtual medical record' model and the process model; user interface (UI) and usability design congruent with the model; separation of organizational, medical, and UI models
3	23 Studies[34–36,42,43,45,51,52,59,81,84,87,97,100,105–107,110,113,123,124,133]	Collaborative process between informaticians and domain experts of translating implicit, procedural knowledge into computable rules; extracting declarative and procedural knowledge into a process model; localization of the guideline/pathway for a specific institution and mapping to the local EHR
1	15 Studies[3,4,39,41,60,74,86,92–94,103,104,115,125,128]	Integration of clinical and organizational processes with regard to institution-specific clinical workflow and preferences; handling workflow exceptions (adaptive organizational workflow); bindings/congruence of enacted workflow with documented clinical processes
9	12 Studies[49,62,65,66,72,76,88,98,99,101,102,122]	Verification and validity of the clinical process model; formal proofs; model-driven update and maintenance of the knowledge base
7	8 Studies[35,44,47,48,57,58,70,79]	Clinical validity of EHR—guideline concept mappings; verification of rule-set completeness and consistency; verification and validation of temporal constraints and run-time execution
2	8 Studies[50,54,75,89,95,114,119,135]	Enactment of the model within local EHR/health information systems (HIS); handling clinician judgment, task sequencing, and temporal constraints, exceptions, variance (adaptive clinical workflow)
5	7 Studies[17,36,40,53,55,56,109]	Addressing usability barriers to implementation of a computerized guideline or pathway; integration with clinical and organizational workflow; development of new tools to support clinical workflow; modification of existing workflow to fit computerized workflow; reporting workflow/pathway statistics, and exceptions
6	4 Studies[12,77,82,132]	Formal modeling of clinical goals and their temporal constraints; separation of clinical and organizational knowledge; allowance for unplanned run-time deviations in the model
4	4 Studies[63,69,130,131]	Handling of complex temporal expressions within the pathway that provides adequate abstraction while remaining computable (trade-off between expressivity and complexity)
8	3 Studies[38,80,117]	Overcoming the organizational and individual barriers to implementation of a computerized workflow, guideline, or pathway; need for both computerized and real workflow to adapt to each other

We found that implementations of workflow integration with point-of-care use tended to be one of three types:

1. *Use of an integrated device for data collection, display, and guideline-based decision support*. Examples included the use of ICU bedside monitoring workstations providing real-time data trending, and care plan and test result information,[62] the use of mobile devices providing access to clinical guidelines,[97] and an emergency triage pathway implemented as a rules-based expert system in a mobile device.[96] Evaluation details for each of these, however, were brief, tending to focus on the hardware/software infrastructure and non-quantified statements about system accuracy.
2. *Use of electronic patient encounter forms that mirror the structure of existing paper forms*. Examples included a guideline-based system for reminders and order recommendations,[84] and a care pathway for proximal femoral fracture[91] where guideline-based recommendations were presented as default selections on the form (eg, automatically ticked checkboxes). Neither appeared to offer pathways tailored to the specific needs of the patient, nor made it clear how computer access would be available at all points of the clinical workflow.
3. *Augmented use of paper forms for system input and/or output*. Examples included a rules-based system using guidelines encoded in Arden Syntax that used optical character recognition (OCR) to scan paper forms, completed at the bedside, to provide patient-specific, point-of-care recommendations and reminders,[109] and a system that provided a printout of daily workflow tasks according to the care pathway modeled. The printed task lists could be used at the point of care as a clinical reminder, but patient-specific recommendations or decision support were not provided.[40]

System implementations: knowledge models, software, and architecture

Table 3 defines the eight distinct knowledge model types that were identified. In the studies retrieved, formal task-network models, which support the representation of both guideline concepts and workflow patterns, were the most commonly described and implemented.

These models were instantiated in the 54 studies that described a system architecture and prototype implementation (see table 4, available as an online data supplement at www.jamia.org). Eighteen of these (33%) explicitly implemented clinical workflow support via a defined workflow process and/or workflow engine; and 26 (48%) described integration with the EHR, but this appears to be largely limited to conceptual integration—few studies have implemented this in a live, clinical setting.[95] Eleven (20%) described both workflow and EHR integration.

System architectures ranged from standalone desktop[14 36 51 54 61 65 78 83 87 97–99 117] and web browser applications[43 72 119 126] to client-server systems[4 40 55 57 62 79 96 103 109 110 135] and distributed, web service applications.[3 39 45 59 69 71 74 89 92 93 111 118 121]

Systems (not mutually exclusive) included computerized guideline implementations[36 40 43 45 50 51 54 57 59 61 62 64 65 69 72 75 78 79 84 89 95–98 101 109–111 118 121 131] (n=31), computerized care pathway systems[14 55 83 91 108 114 117 119 126 134 135] (n=11), integrated guideline and WfMSs[4 71 89 103 104 111 118 129] (n=8), computerized clinical workflow systems[3 39 74 92 93] (n=5), and automated guideline formalization and verification applications[87 98 99] (n=3). For the pure guideline-based systems, for the clinical knowledge component there was a general trend from the use of ad hoc, procedural code toward the use of more formal, task-network models. For the care pathway systems, the trend was from the use of informal or unspecified models toward the use of a general workflow model with a task-network or semantic web formalism. Only two of these[91 117] appeared to meet all the requirements proposed by Wakamiya and Yamauchi.[17]

A number of studies suggested that integration of the care pathway or guideline with an organization's clinical workflow and EHR requires a tightly coupled architecture,[52 61 62 92 96 109 129] which arguably reduces system portability and interoperability but has the benefit of greater efficiency.[79] Others proposed a modular approach to reduce coupling between systems. These still tended to be database-centric, tied to specific mapping tables, database engines, or commercial workflow tools.[40 50 103 104] Those that integrated a guideline-based system with an existing EHR typically implemented an 'event listener' that monitors the EHR for new clinical events or data from which opportunities for decision support are identified and invoked,[4 62 75 89 95 104 135] although this can be inefficient in the use of network and database resources.[79]

Some recent approaches utilize a service-oriented architecture (SOA), where standard messaging interfaces (such as hypertext transfer protocol (HTTP) and simple object access protocol

Table 3 Frequency and description of knowledge model types used by studies

Knowledge model	Description
Document model (5 studies, 1 system implemented[93])	Human readable document with concepts represented in situ, usually preserving the original structure of the source document (Guideline Elements Mode (GEM) or other document-centric extensible mark-up language (XML) schema)
Semantic web (9 studies, 6 systems implemented[64 69 74 89 108 119])	Models proposed by the world wide web consortium (W3C) for representing information on the web (web ontology language (OWL) ontologies, Semantic Web Rule Language (SWRL) rules, OWL-S web services)
Formal workflow model (8 studies, 3 systems implemented[4 71 92])	Formalized workflow constructs underpinned by a formal mathematical model (Petri Nets, Yet Another Workflow Language (YAWL))
Object model (8 studies, 2 systems implemented[36 110])	Object-oriented techniques to model collection of hierarchical, interacting classes that represent guideline, workflow, or pathway concepts (Unified Modeling Language (UML), HL7 Reference Information Model (RIM), openEHR)
General task-network model (14 studies, 4 systems implemented[14 50 103 104])	Flowcharts or process maps without formal semantics (Program Evaluation Review Technique/Critical Path Method (PERT/CPM), activity-on-node)
General workflow model (14 studies, 11 systems implemented[3 39 74 91 93 103 104 114 118 129 134])	General workflow semantics (Business Process Modeling Notation (BPMN), Business Process Execution Language (BPEL))
Block-structured, procedural, logic rules (20 studies, 11 systems implemented[3 43 51 65 72 84 96–98 101 109])	Block-structured, procedural programming languages, and IF…THEN rules (Arden Syntax; decision tables)
Formal task-network model (48 studies, 23 systems implemented[4 36 40 45 54 57 59 61 62 71 75 78 79 87 89 95 99 111 118 121 126 131 135])	Guideline-based clinical tasks—actions, decisions, queries—that unfold over time, with a formal syntax and semantics (Guideline Interchange Format (GLIF), PROforma, Asbru)

(SOAP)) enable loose coupling between applications.[39,59,64,69,71,74,89,93,111,118] Semantic web-based care pathway architectures[64,69,74,89,108] augment the SOA approach by allowing dynamic, context-aware composition of workflows from individual web services. These use W3C standards such as OWL-S and SWRL for defining classes of services and resources, and the rules that relate them.

Toward a conceptual implementation model

A conceptual model of the implementation process was developed from the theme clusters shown in figure 2 and table 2, and by referencing each cluster back to the studies from which they were derived. The model is shown in figure 3 and described below.

Development of a process-oriented HIS is an iterative, collaborative process[34,43,45,46,52,68,70,81,83,106,115,121,127] that involves defining a clinical process model (*shaded in figure*) comprising formalized medical knowledge (usually from guidelines) (*top-left of figure*) and organizational workflow (*top-right of figure*). A graphical knowledge acquisition tool is typically used to assist in this task.[3,4,41,45,48,50,65,71,72,78,91,95,111,118,135] The model (typically derived from one or more of the types presented in table 3) represents an idealized view of the knowledge concepts, processes, and rules of clinical workflow required to enact the guideline or pathway, and tailored to local intervention strategies.

Medical knowledge formalization typically involves the use of an ontology for the guideline concepts and process logic,[4,12,42,44,45,50,52,64,66,67,69,70,74,75,96,103,108,119,123,126] and a standard medical terminology to map guideline concepts to terms in the EHR data model or VMR.[4,35,52,54,64,67–69,89,108,112,121,123,127,133] Extraction and formalization of rules from guideline statements can be automated, sometimes with a high degree of recall and precision,[42,87,124] via the use of linguistic phrase pattern templates[37,42] and information extraction pipelines.[87,113] Such techniques may be useful for facilitating automatic updates to the knowledge base.[88]

This generic model needs to be localized to the setting/institution.[4,52,89,101,127] This task can be commenced prior to modeling, to create a 'consensus' version of the guideline,[45,46,51,59,95] ready for formalization, or the encoded generic model can be shared among institutions, each adapting it according to local needs and data items available in the institution's EHR.[52,57,71,101,119,127] Localization also involves creation of an organizational workflow model, or addition of workflow concepts to the formalized medical knowledge model. Workflow modeling may make use of an organizational ontology[4,73,74,92,103] to formalize tasks, roles, and treatment goals.[4,12,44,82,90,132] Definition of temporal constraints, often not present in the guidelines themselves,[77] is required for activity sequencing and scheduling.[50,63,73,77,102,124,130–132]

Model checking techniques and tools provide formal means of verifying that encoded models are correct and consistent,[4,48,49,66,76,77,99,102] particularly when maintaining and updating them.[102] Simulated runs of the model are used to ensure that the output is clinically valid.[4,43,52,54,57,59,63,64,66,114,122,135]

To execute the clinical process model within a HIS, architecture, user-interface design, and mode of delivery need careful consideration in order to be congruent with actual clinical workflow.[14,17,36,56,61,85,91,96,109] This includes visualization of the run-time pathway,[61] design of on-screen forms based on the paper forms of a manual care pathway,[83,84,91] or automatic generation of forms directly from the pathway ontology or process model.[69] The enacted process should allow dynamic adaptation at run-time: this may be manual and clinician-led, where tasks can be skipped, repeated, or new tasks added,[3,41,57,93] or may be system-led via reasoning over new knowledge added to the ontology at run-time.[74,108]

Implementation in a live, clinical environment requires strategies for organizational change management to overcome inertia and allay concerns over lack of support and perceived threats to professional autonomy that workflow automation may bring.[38,80,117]

DISCUSSION

The conceptual model for the implementation of process-oriented systems comprises a distillation of the cross-cutting challenge themes that have been abstracted from 15 years of

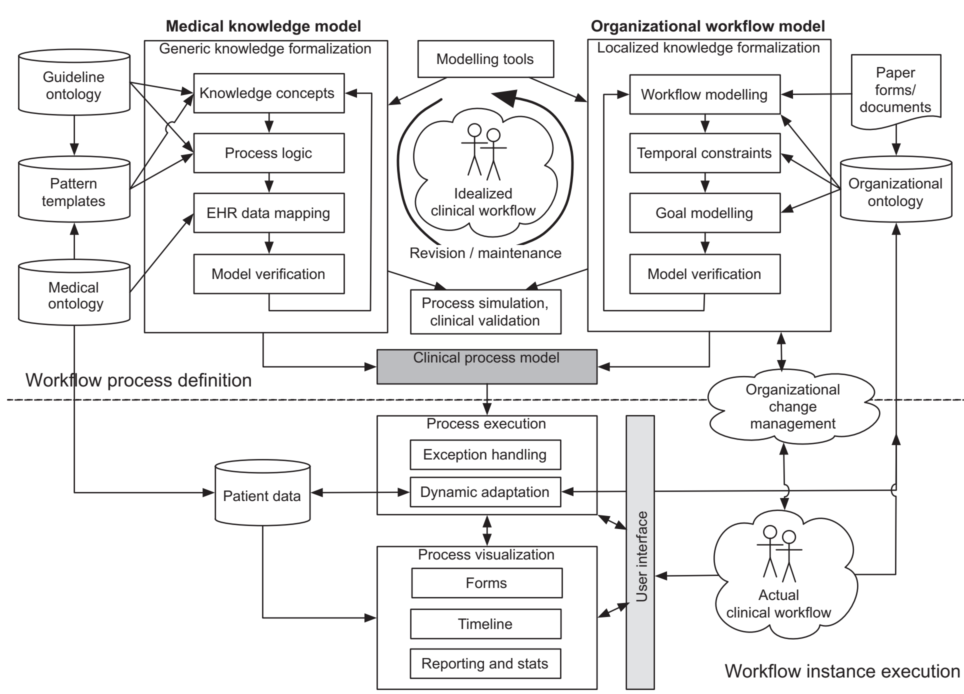


Figure 3 Conceptual model for implementing process-oriented health information systems.

published research. It attempts to provide a concise synthesis for practitioners and implementers, by summarizing the various approaches that have been proposed and implemented to date, while remaining neutral in terms of software, hardware, and knowledge/information model. The use of thematic analysis and PCA to summarize the findings of a large corpus of publications may be useful in future reviews, although further work is needed on applying and validating this technique.

In the system implementations that we reviewed, there was the assumption that real-world clinical processes are best represented by a formal model in which discrete events occur, performed by users with pre-defined roles. However, the application of computerized workflow systems to the complex, contextual nature of clinical workflow has recently been questioned.[2] It may not always be practical to decompose care-related tasks into a sequence of discrete workflow steps. Some tasks may be partially, or provisionally, completed while other tasks are carried out in parallel. New knowledge gained from downstream or parallel clinical processes may allow provisionally undertaken tasks to be completed, or may require them to be canceled.

The 'semantic web' approaches to solving this 'adaptive workflow' problem (which is a concern also discussed in the general literature on workflow systems[136 137]) have, in addition to the implementations described here, so far yielded a care pathway ontology[138 139] which appears to share many features of older task-network models. However, the crucial distinction is that the semantic web approaches represent an 'open world' view[140] that allows new facts and relationships to be expressed without the constraint of a pre-defined schema,[108] whereas earlier approaches only permit knowledge statements that are explicitly permitted by the schema. Full realization of these approaches would require a knowledge backbone of best practice on the semantic web,[138] and semi-automatic methods for transforming guideline text into a standard formalism, although recent work in this area has achieved some useful results.[42 87 124]

We have noted the transition from the reporting of standalone systems to the reporting of complete enterprise integration architectures.[89] Whether these architectures, in combination with semantic web approaches, can solve the problem of clinical workflow integration and adaptation, is an area of current research.[141] The implementation of adaptive, multi-agent, semantically aware, service-oriented workflows, incorporating formal models of clinical guidelines, appears to be a major challenge.[142]

By focusing on descriptive studies to provide a rich picture of a process, we have not considered any measures of the effect of these systems on clinical practice, nor which parts of the process are associated with successful outcomes. However, a recent systematic review of the effectiveness of clinical pathways noted that the poor quality of reporting of the pathway implementation process prevented analysis of factors that might be critical to success.[24] In the system implementation studies we selected, the implementation process was generally well described, but evaluations tended to be formative and weak. Future reporting of implementations should contain a richer evaluation of both the process and the outcome, to enable future systematic reviews to consider both aspects, and to determine the relative importance of the challenge themes identified.

Review limitations

Our review has only considered studies that were published in English in peer-reviewed journals or conference proceedings published between 1995 and 2010. Consideration of information from additional sources, for example, public- and privately-funded research consortia, technical reports, and professional textbooks, might lead to additional insights.

One criticism of attempting to carry out a meta-synthesis of qualitative research is that the results may have little validity, as they are based on a third level of interpretation, far removed from the original event.[27] Although development of the challenge themes was based on those identified in an earlier expert opinion paper,[25] these would need to be validated by other researchers to improve the reliability and validity of our findings.

CONCLUSION

We have surveyed the literature on the computerization of clinical workflow, guidelines, and pathways and have extracted the underlying, cross-cutting themes that describe the challenges to implementing process-oriented HIS using thematic analysis techniques. We have used PCA to cluster these themes into 10 distinct groups, from which a conceptual model of the implementation process was developed.

The development of systems supporting individual clinical decisions is evolving toward the implementation of adaptive care pathways on the semantic web, incorporating formal, clinical, and organizational ontologies, and the use of WfMS. Such architectures now need to be implemented and evaluated on a wider scale within clinical settings.

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APPENDIX

Database search strategy

The following broad search concepts were used to query ScienceDirect and Web of Science:

Concept 1: computer systems
(systems OR electronic OR computer*) AND

Concept 2: healthcare
(health* OR clinical OR care OR medical) AND

Concept 3: guidelines and workflows

(pathway OR workflow OR careflow OR guideline)

These three concepts were combined to perform a title search on ScienceDirect and Web of Science:

TITLE ((systems OR electronic OR computer*) AND (health* OR clinical OR care OR medical) AND (pathway OR workflow OR careflow OR guideline))

The following all-fields search statement was performed in ScienceDirect:

ALL (workflow pathways plans guidelines)

The following search statements were executed on PubMed and the results combined:

1. (electronic OR computer-interpretable OR computerized OR computerised) AND ((care OR clinical) pathway)
2. modelling AND ((clinical guideline) OR ((care OR clinical) pathway) OR workflow)
3. workflow AND ((care OR clinical) pathway)
4. (clinical guideline) AND ((care OR clinical) pathway)

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Notes