A Systematic Review of the Effects of Implementing Clinical Pathways Supported by Health Information Technologies

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# Abstract

### Objective

Health Information Technology (HIT) interventions include electronic patient records, prescribing and ordering systems. Clinical pathways are structured plans of care that enable the delivery of evidence-based healthcare. Our objective was to systematically review the effects of implementing HIT supported clinical pathways.

### Material and Methods

A systematic review protocol was developed including searches of the MEDLINE, EMBASE and Cochrane (CENTRAL) databases. We recorded data relating to study design, participant, intervention and outcome characteristics and formally assessed risk of bias.

### Results

Forty-four studies involving over 270,000 patients were included. Investigation methodologies included before-after (16/44 (36.3%)), non-comparative (14/44 (31.8%)), interrupted time series (5/44 (11.4%), retrospective cohort (4/44 (9.1%)) cluster randomised (2/44 (4.5%)) controlled before-after (1/44 (2.3%)), prospective case-control (1/44 (2.3%)) and prospective cohort (1/44 (2.3%)) study designs.

Clinical decision support (n = 25, 56.8%), modified electronic documentation (n = 23, 52.3%) and Computerised Provider Order Entry (n = 23, 52.3%) were the most frequently utilised HIT interventions. The majority of studies (n = 38/44, 86.6%) reported benefits associated with HIT supported pathways. These included reported improvements in objectively measured patient outcomes (15/44 (34.1%)), quality of care and healthcare resource utilisation that were identified in a sub-group analysis of higher quality studies.

### Discussion

Although most studies reported improvements in outcomes the strength of evidence was limited by the study designs that were utilised.

### Conclusion

Ongoing evaluations of HIT supported clinical pathways are justified but would benefit from study designs that report key outcomes (including adverse events) and minimise the risk of bias.

**INTRODUCTION**

Over the last decade, healthcare providers in the USA and UK have been incentivised to implement Health Information Technologies (HIT) through legislative and funding stimulus packages. In 2016 the UK government allocated £4.2 billion ($5.8 billion) to develop the IT infrastructure in the National Health Service (NHS) [4] and in the US the government has provided approximately $30 billion of investment subsidies since 2009 [6]. Examples of widely implemented HIT interventions include electronic patient records, and electronic prescribing and ordering systems [7].

There is evidence that HIT interventions (including clinical decision support tools, computerised order entry systems and electronic prescribing tools) may have a positive effect on health outcomes [8-13] . However, these benefits are not identified consistently across studies [7].

Like HIT, clinical pathways are a form of complex intervention that have been widely implemented in healthcare settings [14 15]. Numerous definitions of clinical pathways have been published [16] (see figure 1 for an example of a published definition). However, the most widely cited definitions identify the importance of multi-disciplinary team working and the delivery of care in a specific local context as being key to their effective implementation [2 17 18]. These definitions help to discriminate clinical pathways from other, more focussed, methods for supporting guideline implementation (for example, clinical decision support systems or order sets). These interventions may be applied more broadly across healthcare systems but they are less likely to address factors such as the coordination of multi-disciplinary teams or the contextual challenges associated with working in a specified healthcare setting.

Although it is clear that there are challenges associated with developing precise definitions of clinical pathways, their use seems to be widespread [14] and robust evaluations of their effects have also previously proven to be feasible [2 18]. Notably, a Cochrane meta-analysis of the effects of implementing traditional, paper-based clinical pathways was published in 2010 and identified that their use was associated with reductions in the complications of care, length of hospital stay and the cost of care[2].

Given that a number of widely implemented HIT interventions may be well suited to increasing the efficiency or effectiveness of clinical pathways (for example clinical decision support, electronic communication between health professionals and patients, and the standardisation of ordering or prescribing processes) we aimed to evaluate this relationship more closely. We developed a systematic review methodology with the objectives of describing the effects of HIT supported clinical pathways on health outcomes, and identifying the variables that may affect the effectiveness of these pathways.

### **METHODS**

### **Search Strategy**

A study protocol was developed in accordance with PRISMA guidelines[19] and registered on the PROSPERO database[20] prior to completing the review. The MEDLINE and EMBASE databases were searched to identify any studies involving the implementation of clinical pathways supported by the application of HIT. This search was supplemented by hand searching reference lists of included studies, a keyword search of the CENTRAL database and expert recommendation. Abstracts were included, and no date or language exclusion criteria were applied (two Japanese articles were excluded due to resource constraints).

All studies that reported an assessment of a clinical pathway intervention (defined as per the example above from Rotter et al. [2]), where the implementation involved the use of Health Information Technologies (as defined by the Cochrane Effective Practice and Organisation of Care (EPOC) taxonomy[21]) were included.

Titles and abstracts were screened independently by two reviewers. Full papers were scrutinised by two reviewers and consensus regarding inclusion or exclusion was reached after discussion.

All study types were included, however a pre-specified subgroup analysis was planned for randomised trials, controlled clinical trials (CCTs), controlled before and after studies (CBAs) and interrupted time series analyses (ITS).

### **Outcome Measures**

Primary and secondary outcome measures were pre-defined and are detailed below. We anticipated that included studies may be heterogenous in terms of included patient groups, settings and outcomes measured. We therefore proposed to categorise outcomes according to pre-specified domains, in accordance with recognised guidance for the evaluation of complex interventions [22].

#### Primary Outcome

Objectively measured patient outcomes;i.e.mortality, Patient Reported Outcome Measures (PROMs), biochemical markers of disease activity.

#### Secondary Outcomes

Given the breadth of potential settings and participants eligible for inclusion in the analysis, secondary outcomes will be reported and categorised under the following domains:

1. *Other Patient Outcomes* – i.e. Proxy measures of physical health and treatment outcomes.
2. *Quality (Process) Outcomes* – i.e. Measures of adherence to guidelines or quality of documentation.
3. *Healthcare Resource Utilisation and Access to Care* – i.e. length of stay or waiting times.
4. *Healthcare Professional Outcomes* – i.e. staff satisfaction or staff morale.
5. *Adverse Events*
6. *Patient Satisfaction*

### **Data Collection and Analysis**

Relevant data were recorded on pre-designed data extraction forms. Reports were interrogated to identify characteristics including; type of study; number of participants; population characteristics; and primary and other study outcomes. A quality and risk of bias assessment was completed for randomised trials, controlled clinical trials (CCTs), controlled before and after studies (CBAs) and interrupted time series analyses (ITS) using Cochrane, Effective Practice and Organisation of Care risk of bias criteria[23]. Study interventions were described according to the criteria outlined in the TIDieR checklist for reporting interventions [24] and these details were completed on a separate data collection form.

Statistical meta-analyses were planned, if studies of adequate quality (assessed by study type, see above, and formal risk of bias assessment) and homogeneity were identified. For studies not eligible for inclusion in a meta-analysis, a descriptive summary of the types of HIT interventions that were utilised and the outcomes that were reported was undertaken.

**RESULTS**

The search strategy identified 1377 studies (1158 excluding duplicates). Following title and abstract screening, the full texts of 147 studies were requested and forty-four studies met the criteria for inclusion in the review (see Figure 2. for PRISMA flow chart including the reasons for exclusion). The 44 included studies involved over 270,000 participants (study characteristics and quality assessments are summarised in the online supplementary files). Of the identified studies, 16/44 (34.1%) were ‘before and after’ studies (uncontrolled), 14/44 (31.8%) were non-comparative (case studies), 5/44 (11.4%) were interrupted time series studies, 4/44 (9.1%) were retrospective cohort studies, 2/44 (4.5%) were cluster randomised controlled trials and there were 1/44 (2.3%) controlled before-after, prospective case-control and prospective cohort studies respectively.

Of the included studies, 41/44 (93.2%) investigated the implementation of HIT supported clinical pathways in secondary or tertiary care settings and 3/44 (6.8%) were conducted in primary care settings. Adult participants were involved in 37/44 (84.1%) studies, while 7/44 (15.9%) studies included children.

### **Characteristics of HIT Utilised in the Implementation of Clinical Pathways**

The types of HIT interventions implemented in each study are summarised in the *Summary of Intervention Characteristics and Outcomes Table* included in the supplementary file. This table also includes summary data indicating whether the implementation of the pathway was associated with positive or negative outcomes in each of the reported domains. Descriptions of the most frequently utilised HIT intervention types are provided in Figure 3.

#### Clinical Decision Support

Clinical decision support (CDS) tools were the most frequently utilised HIT intervention and 25/44 (56.8%) studies reported their use. Seventeen (18/25 (72.0 %)) studies reported the development of CDS interventions that were fully integrated within the electronic health record (EHR). The remaining studies described CDS that were accessed via web-based portals or via a local, computerised order entry systems.

The majority of interventions (7/8 (87.5%)) included in the sub-group effects analysis included CDS tools [25-31]. Interventions involved both web-based and electronic health record embedded tools. Examples included modules for admission assessments, risk assessment, therapy and discharge planning [25], computerised order entry modules with CDS that utilised rules based on a patient’s clinical parameters to support the evidence-based investigation of paediatric appendicitis [26], and sepsis alerts designed to trigger earlier assessment and treatment for acutely unwell patients [30].

#### Electronic Documentation

Twenty-three (23/44 (52.3%)) studies included a description of the use of electronic documentation designed specifically for use as part of the pathway implementation process. Examples of the types of pathway specific documentation utilised in interventions included electronic checklists [31 32] and the use of structured data formats to allow automation of audit and variance analysis processes [33 34].

#### Computerised Provider Order Entry

Twenty-three (23/44 (52.3%)) studies included in the review also reported the use of modified Computerised Provider Order Entry (CPOE) systems. Computerised order sets (where a bundle of investigations, referrals or treatment orders are combined to ensure that patients with specific conditions receive standardised management) were used in the majority of studies that included CPOE interventions.

#### Automated Performance Feedback to Providers

Nine (9/44 (20.5%) studies reported the use of interventions that enabled peer-review or feedback processes designed to promote the adoption of recommended care processes. Examples included the development of live “dashboards” indicating unit level compliance with ventilator care-protocols [35]; automated requests for peer review when providers administered radiotherapy treatment courses outside the recommended ranges [36 37]; and the development of a pathway tool that provided automated interrogation of the EHR to detect episodes where emergency department clinicians may have missed diagnoses of acute coronary syndrome (ACS)[38].

#### Other

A number of other HIT interventions were also utilised to support the implementation of clinical pathways. In six (6/44 (13.6%) studies investigators reported the implementation of clinical pathways supported by clinical guidelines accessible directly via the electronic health record (e.g *info-buttons* or *context sensitive decision support*). Examples included the provision of access to locally developed [39] and national guidelines [40].

Other interventions included clinical pathways supported by web-based portals designed to increase standardisation of care across two regions in the UK [41 42], the development of an electronic tool to promote the capture of patient reported outcomes [33] and a mobile application designed to support pathway implementation by allowing patients to view their electronic health record (patient portal) [43].

### **The Effects of HIT Supported Clinical Pathways on Health Outcomes**

#### Objectively Measured Patient Outcomes

Twenty-one studies (21/44 (47.7%) included in the review described some association between the implementation of HIT supported clinical pathways and objectively measured patient outcomes. Fifteen studies (15/44 (34.1%)) reported improvements in objectively measured patient outcomes, five studies (11.4%) described equivocal effects and in one study (1/44 (2.3%)) the intervention was associated with complications associated with the use of therapeutic hypothermia [44]. Reported benefits included reductions in thromboembolic complications [45], mortality [33 46], myocardial infarction, stroke and retinopathy [27], and improvements in biochemical markers of glycaemic control (HBA1c) [40].

#### Secondary Outcomes

A number of associations with improvements in quality (or process) outcomes were also reported. Examples included reports of increased, or favourable rates of compliance with recommended practice such as the appropriate utilisation of investigations or therapeutic interventions [36 37 39 40 44 47-51].

Improvements in healthcare resource utilisation, including reductions in hospital Length of Stay (LoS) in association with the implementation of HIT supported clinical pathways were also reported [28 33 39 52]. However, these findings were not reported universally and in other studies the investigators did not identify any difference in LoS [25 26]. In one study the proportion of patients receiving their operation in a day case or outpatient setting increased after the introduction of a HIT supported clinical pathway [41] and in one study this was associated with a reduction in the length of waiting times for treatments and consultations [53]. Reductions in healthcare costs associated with the implementations of HIT supported clinical pathways were also described in one investigation [54].

Only 3/44 (6.8%) investigators reported adverse events associated with the implementation of HIT supported clinical pathways. In one study including patients following cardiopulmonary arrest, treated using a HIT supported therapeutic hypothermia clinical pathway, a higher proportion of patients developed refractory shock following pathway implementation [44]. In another study investigating the implementation of a computerised clinical pathway designed to standardise pre-operative assessments, some nursing staff reported a perception that they engaged in less eye contact with patients and that completion of documentation may have taken longer than when using paper records [41]. In another study involving standardisation of sedation weaning protocols for ventilated patients the introduction of the pathway was initially associated with an increase in mortality amongst older patients [55]. However, this pathway was modified once the investigators had identified this adverse finding and this increase was not found to persist following the introduction of the modified protocol.

A number of investigators also reported subjective descriptions detailing increased satisfaction or approval from staff or patients following the implementation of HIT supported clinical pathways [41 43 52].

### **The Effects of HIT Supported Clinical Pathways on Health Outcomes – Subgroup Analysis**

We identified eight studies (8/44, 18.2%) that were eligible for inclusion in the sub-group, effectiveness analysis. We identified five Interrupted Time Series Studies[26 28 30 31 56], two Cluster Randomised Trials[25 57] and one Controlled Before-After Study [27](see supplementary file for Study Characteristics and Results and Quality tables).

### Objectively Measured Patient Outcomes

Five studies reported the effects of HIT supported pathway interventions on objectively measured patient outcomes [27 28 31 56 57]. Reported effects included reductions in the rate of Central Line Associated Bloodstream Infections (CLABSIs) [31 56], reduced hazard ratios for myocardial infarction, stroke and retinopathy [27] and improvements in a schizophrenia symptom scale [25]. These results were not eligible for meta-analysis due to significant heterogeneity in terms of the outcome measurements reported and the populations that were investigated. A GRADE analysis of these results [58] identified that there is very low quality evidence that HIT supported clinical pathways improve objectively measured patient outcomes. The quality rating was down-graded due to the unrandomised nature of the majority of included studies, concerns about risk of bias in the included studies (see Results and Quality table in Supplementary file), evidence of inconsistency of effect and concerns regarding indirectness (due to the heterogeneous nature of the described interventions and outcome measures used).

### Quality Outcomes

Three studies reported the effects of HIT supported pathway interventions on quality outcomes [25 26 29]. Reported effects included a reduction in the time taken to initiate sepsis therapies [30] and a reduction in the rate of falls amongst inpatients [57]. A GRADE analysis of these results [58] identified that there is very low quality evidence that HIT supported clinical pathways improve quality outcomes. The quality rating was downgraded due to the unrandomised nature of the majority of included studies, concerns about risk of bias in the included studies (see Results and Quality table in Supplementary file), evidence of inconsistency of effect (one study reported no improvement in quality outcomes [26]) and concerns regarding indirectness (due to the heterogeneous nature of the described interventions and outcome measures used).

### Healthcare Resource Utilisation

Two studies reported a reduction in inpatient length of stay in association with the implementation of a HIT supported clinical pathway [25 28]. A GRADE analysis determined that there was very low quality evidence to support these findings. The quality rating was downgraded due to the unrandomized nature of one of the studies, due to concerns about risk of bias in the included studies (see Results and Quality table in Supplementary file) and due to concerns about the degree of imprecision of the results (due to limited reporting of the study data [25] and the use of statistical process control charts rather than a regression analysis with estimation of Confidence Intervals [59]).

### **DISCUSSION**

To our knowledge this is the first systematic evaluation of the effects of implementing HIT supported clinical pathways. As with previous systematic reviews of clinical pathway interventions, we identified challenges associated with defining and identifying the most appropriate studies for inclusion in the review [2 18]. To mitigate against these challenges, we used a previously validated definition of clinical pathways and included interventions that were described using alternative terminology when they met our pre-agreed definition of a pathway intervention. We also sought to improve the internal validity of our study by using two reviewers who worked independently to screen the results of our database searches. With these pragmatic mitigations we hope that this review will provide a useful resource for healthcare commissioners and providers tasked with evaluating the use of HIT supported clinical pathways as an approach to quality improvement.

Although most of the studies that we identified reported improved outcomes following the implementation of HIT supported clinical pathways, our assessments were limited by a number of factors. These included the study designs that were utilised, the risk of bias noted in included studies and the number of studies that reported measures of our primary outcome. Due to the heterogenous nature of the studies that were eligible for inclusion in the effects analysis we were unable to complete a meta-analysis of the effects of HIT supported clinical pathways.

Only a minority of included studies (21/44 (47.7%)) reported the effects of implementing pathways on objectively measured patient outcomes (the pre-specified primary outcome for this systematic review). Previous systematic evaluations of HIT interventions have identified similarly heterogeneous and process focussed outcome reporting [60 61] and studies of HIT interventions have also been recognised to be vulnerable to outcome reporting and publication bias[62 63]. Therefore, although we anticipated that the studies included in this review may describe a heterogenous range of outcome domains, we had anticipated that more studies would report on the health outcomes directly experienced by patients. We would suggest that this represents a limitation in relation to the meaningful evaluation of the effects of HIT supported clinical pathways, and that future studies of HIT interventions could be enhanced by the inclusion of objectively measured patient outcomes.

We also note that reports of adverse events associated with the implementation of HIT supported clinical pathways were only described in three cases [41 44 55]. A balanced appraisal of any healthcare intervention requires a consideration of both the benefits and disadvantages or risks [64-66], however, the majority of studies included in this review did not describe methodologies for actively identifying or reporting adverse findings. Based on the results of this review, it is therefore difficult to assess with certainty, whether adverse events were under-reported or not. We would suggest that future investigations of the effects HIT supported clinical pathways would benefit from the use of study protocols that allow investigators to actively identify and report adverse events.

Although a significant majority of the studies we identified reported an association between the implementation of HIT supported clinical pathways and improvements in outcomes, the interpretation of these results was limited by the methodological quality of the included studies. Only eight of the identified reports were eligible for inclusion in a sub-group analysis of studies that employed methodologies designed to minimise the risk of bias (Interrupted Time Series (ITS) studies, cluster Randomised Controlled Trial (cRCT) and a controlled before-after study). The remaining studies (n = 36) employed study designs such as non-comparative reporting (i.e. case studies, n = 14) or uncontrolled before and after designs (n = 16). It therefore remains difficult to draw firm conclusions regarding the effects of implementing HIT supported clinical pathways, as the results of these studies are likely to be significantly affected by biases introduced during the implementation and assessment phases of the evaluations.

We also note that the relative heterogeneity of the small number of studies eligible for inclusion in the sub-group effects analysis impacted upon the results of the GRADE analysis of the effects. For all of the outcomes that were assessed using the GRADE analysis the quality score was downgraded in part due to concerns regarding the directness (generalisability) of the reported effects. One reason for this is that the included studies utilised a relatively heterogeneous range of interventions and outcome measures. We also note that of the eight studies included in the sub-group effects analysis, one identified no benefits associated with implementation of the HIT supported clinical pathway [26] and the authors of the other study provided no statistical analysis of the benefits that they did report[25].

Noting the limitations described above, our assessment of the narrative review of the included studies suggests that HIT supported clinical pathway interventions with “active-ingredients” (such as clinical decision support and automated feedback, audit or reporting processes) may represent the most promising area for future research. These interventions tended to be utilised in order to try and ensure that clinical teams managed patients according to recommended practice and would therefore seem well suited to supporting the objectives associated with the implementation of clinical pathways.

Given the ongoing investment in HIT there is a need for investigation of the implementation of these technologies using robust study designs that minimise the risk of bias. It would also be helpful for future evaluations to carefully consider the outcome measures that they report, to ensure that these are likely to be of relevance to key stakeholders. Ideally these outcome sets should include objectively measured patient outcomes and adverse events to allow a full appraisal of the effects of the intervention being investigated.

Due to a lack of high-quality studies there is only limited evidence to support the hypothesis that HIT supported clinical pathways improve objectively measured patient outcomes or other health care outcomes. However, the majority of identified reports do suggest that the implementation of these pathways may be associated with benefits and they do not seem to be associated with a high rate of adverse events.

# **CONCLUSION**

Ongoing evaluations of HIT supported clinical pathways are justified but would benefit from study designs that report key outcomes (including adverse events) and minimise the risk of bias.

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**Competing Interests**

None Declared.

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*A clinical pathway is a structured, multi-disciplinary plan of care where*

(Meets at least three of the following criteria)

1. *The intervention is used to channel the translation of guidelines or evidence into local structures*
2. *The intervention details steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or any other inventory of actions*
3. *The intervention had time-frames of criteria-based progression (i.e. steps were taken if designated criteria were met)*
4. *The intervention aimed to standardise care for a specific clinical problem, procedure or episode of care in a specific population*

**Figure 1. Definition of a Clinical Pathway (Adapted from [2])**

**Context Sensitive decision support (Info-Buttons)**

*“a knowledge retrieval tool embedded in an EHR that automatically links to knowledge resources tailored to the specific EHR* [Electronic Health Record] *context.”[1]*

**Computerised Provider Order Entry (CPOE)**

*“CPOE refers to a variety of computer-based systems that share the common features of automating the medication* [or other treatments, referrals or investigations] *ordering process and that ensure standardized, legible, and complete orders.” [3]*

**Electronic Documentation**

Paper-based clinical pathways tend to be implemented using bespoke pathway documentation. This may include prompts or checklists that are designed to encourage clinicians to complete vital tasks associated with the recommended care process. A standardised layout may facilitate audit of clinical practice and variance analysis.

**Clinical Decision Support**

“*Clinical decision support (CDS) provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. CDS encompasses a variety of tools to enhance decision-making in the clinical workflow*”[5]

**Figure 3. Summarised definitions of HIT interventions utilised in reported implementations of clinical pathways**