Refereed papers

The use and effectiveness of electronic clinical decision support tools in the ambulatory/primary care setting: a systematic review of the literature

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ABSTRACT

Background The 1999 Institute of Medicine (IOM) report *To Err is Human* alerted the healthcare industry and the public to the lack of consistency in the delivery of quality care to the US population. Clinical decision support systems (CDSS) have become a leading response to this report, and to the growing demand for the promotion of standards-based care delivery. The objective of this paper is to evaluate the recent literature for both the types and effectiveness of electronic CDSS in the primary care setting.

Methods An electronic search of the literature was conducted utilising MEDLINE (1996–2006), CINAHL (1982–2006) and all EBM Reviews – Cochrane DSR, ACP Journal Club, DARE and CCTR. The search included various combinations of the MeSH search terms 'clinical decision support systems', 'primary health care', 'ambulatory care' and 'practice guide-lines' and was limited to articles published from 2000 to 2006. Studies were selected for review if they involved either non-randomised observational or randomised controlled trials (RCTs) utilising CDSS

as a single intervention, were performed in an ambulatory primary care setting and included quantifiable outcome measures.

Results Seventeen studies were included in the review, including five non-randomised observational studies and 12 RCTs. Thirteen studies (76%) found either positive or variable outcomes related to CDSS intervention with four studies (24%) showing no significant effect.

Conclusion Although there is validation that CDSS has the potential to produce statistically significant improvement in outcomes, there is much variability among the types and methods of CDSS implementation and resulting effectiveness. As CDSS will likely continue to be at the forefront of the march toward effective standards-based care, more work needs to be done to determine effective implementation strategies for the use of CDSS across multiple settings and patient populations.

Keywords: ambulatory care, clinical decision support systems, primary health care

Introduction

Information technology is sweeping the healthcare industry, with all sectors of the industry actively implementing new technology or pursuing ways to use existing technology more effectively. The past few years have been ripe with state and federal initiatives aimed at expanding and implementing information technology and using it to address the prevalent issues related to discrepancies in the quality and cost of health care. In 1999 the first Institute of Medicine (IOM) report *To Err is Human*¹ was published and high-lighted for the first time widespread inconsistencies throughout the healthcare industry related to medication errors and adverse drug events. More recently, a highly publicised RAND study found that patients consistently received recommended care only 55% of the time, regardless of the size or experience of the clinical setting.²

Nine years after the release of the first IOM report, and five years after the aforementioned RAND study, quality issues still abound within the healthcare industry. Clinical decision support systems (CDSS) have been touted as a viable solution to these pressing concerns. Owing to the fact that the majority of health care delivery takes place in the outpatient setting, the use of CDSS in this setting is pertinent. This review seeks to evaluate the recent progress of CDSS as an effective tool for promoting quality outcomes in the ambulatory/primary care setting.

Methods

Study identification and selection

CDSS has been defined as 'an automated process for comparing patient-specific characteristics against a computerised knowledge base with resulting recommendations or reminders presented to the provider at the time of clinical decision making'.³ Although fairly specific in definition, the implementation of CDSS varies greatly. The three primary components of CDSS that are identifiable in almost all implementations and that render CDSS different from other types of decision support include:

- an automated process for delivery of alerts or reminders
- patient-specific content resulting from the comparison of patient information against a set of knowledge 'rules' or guidelines
- delivery of alerts or reminders at the point of care.

This search focused on CDSS studies used specifically in the primary care, outpatient clinic setting. An electronic search of the literature was conducted utilising MEDLINE (1996–2006), CINAHL (1982–2006) and all EBM Reviews – Cochrane DSR, ACP Journal Club, DARE and CCTR (up to 2006). Included in the search strategy were MeSH search terms 'clinical decision support systems', 'primary health care', 'ambulatory care', 'practice guidelines' and combinations thereof, to produce an initial retrieval of 274 citations. A title and abstract review narrowed the search to the 17 studies selected. Articles selected for final review met the following inclusion criteria:

- English language studies published from 2000 to 2006
- RCTs or non-randomised observational trials
- Ambulatory, out-patient settings utilising only primary care providers
- Use of at least one comparable control group
- Use of quantifiable outcome measures.

Primary reasons for exclusion were that studies were performed in the in-patient setting or were published prior to 2000. The authors selected 2000–2006 as a publication range since rapid changes in both the healthcare environment and in healthcare information technology are quickly making older studies less noteworthy.

Study evaluation

The 17 studies included in the final review were independently reviewed, with scoring differences compared for final decision. RCTs were evaluated using a 100-point evaluation tool that has been cited in the literature and used previously for similar reviews.^{4–6} Non-randomised, controlled or observational studies were assessed using a 10-point rating scale that has also been cited in similar reviews of CDSS in the literature and is designed to accommodate evaluation of non-randomised trials.^{3,7,8} Minimum scoring requirements for inclusion in the final review were set at 50 for RCT's and five for non-randomised or observational trials.

Results

Of the 17 studies^{9–25} included in this review, 12 studies utilised an RCT design and five studies were nonrandomised controlled or observational (Table 1). Selected studies utilised CDSS for a variety of purposes, including prevention/screening (2), drug dosing (2), medical management of acute diagnoses (4) and chronic disease management (11). One study utilised prevention/screening, medical management and disease management, and is therefore included in all three categories.¹¹ The majority of the studies reviewed (67%) utilised CDSS for chronic disease management. This is in contrast to findings published prior to 2000, which routinely found CDSS used most often for prevention/screening and drug dosing. Additionally, three recent systematic reviews of CDSS^{3,6,7} cited the percentage of studies using CDSS for chronic disease management as less than 25% of those reviewed.

Author(s)	Pub date	Study design	CDSS category	Automated prompt	Embed vs stand alone	Setting	Funding	Country
Feldstein <i>et al</i>	2006	RCT	Disease Management	Yes	Embed	Community	PharmCo	USA
Smith et al	2006	Observational	Drug Dosing	Yes	Embed	Community	Government	USA
Apkon <i>et al</i>	2005	RCT	Disease Management Med Management Prevention	Yes	Embed	VA	Government	USA
Bassa <i>et al</i>	2005	Observational	Disease Management	No	Embed	Community	PharmCo	Spain
Bloomfield et al	2005	Observational	Disease Management	Yes	Embed	VA	Government	USA
Samore <i>et al</i>	2005	RCT-cluster	Medical Management	No	Stand- alone	VA	Government	USA
Sequist et al	2005	RCT-cluster	Disease Management	Yes	Embed	Academic	Government	USA
Steele <i>et al</i>	2005	NRCT	Prevention	Yes	Embed	Community	Government	USA
Tierney et al	2005	RCT-cluster	Disease Management	Yes	Embed	Academic	Government	USA
McMullin et al	2004	NRCT	Drug Dosing	Yes	Embed	Community	Vendor	USA
Filippi <i>et al</i>	2003	RCT	Disease Management	Yes	Embed	Community	Unknown	Italy
Meigs et al	2003	RCT-cluster	Disease Management	No	Stand- alone	Academic	Mixed	USA

Table 1 Continued

Author(s)	Pub date	Study design	CDSS category	Automated prompt	Embed vs stand alone	Setting	Funding	Country
Tierney et al	2003	RCT-cluster	Disease Management	Yes	Embed	Academic	Government	USA
Rollman et al	2002	RCT-cluster	Disease Management	Yes (simulated)	Embed	Academic	Government	USA
Christakis et al	2001	RCT	Disease Management	Yes	Embed	Academic	NonProfit	USA
McCowan et al	2001	RCT-cluster	Disease Management	No	Stand-alone	Community	PharmCo	UK
Montgomery et al	2000	RCT-cluster	Disease Management	Yes	Embed	Community	Government	UK

Studies included in this review were more likely to be embedded in an existing electronic medical record (EMR; 82%) than used as a stand-alone system, and to be utilised with automated prompt functionality (76%) rather than requiring provider action for activation. Thirteen of the studies reviewed were conducted in the USA (76%), with studies also conducted in the United Kingdom (2), Italy (1) and Spain (1). Studies which received governmental funding exclusively (US and UK) accounted for 53% of the studies reviewed, with the remainder funded by a pharmaceutical company (partial and full funding; 24%), a software vendor (6%), another not-for-profit entity (6%) or an unknown funder (6%). Six of the studies were performed in university affiliated clinics (35%), three at Veterans' Affairs (VA) facilities (18%) and eight in community based practices (47%), including two health maintenance organisation (HMO) practices.

RCTs

Study descriptions

RCT studies that met the criteria for this review (see Table 2) were overwhelmingly centered on disease management, with 75% of the studies implementing CDSS around chronic disease management initiatives. CDSS for disease management targeted cardiovascular disease (4),^{11,15,21,25} diabetes (3),^{15,19,20} asthma (2),^{17,24} and osteoporosis (1).⁹ (For clarification, Sequist *et al* addressed both diabetes and coronary artery disease management, and their study is therefore included on both counts.) The remaining three RCT studies addressed medical management of acute disease, including depression (1),²² upper respiratory infections (1)¹⁴ and otitis media (1).²³

There were 1573 providers and 40326 patients represented in the studies reviewed. One study²⁴ required an estimation of providers based on the data provided. Since CDSS is primarily focused on altering provider behaviour, the unit of randomisation in most CDSS studies was the provider. Randomisation at the patient level was sometimes utilised, but since randomisation is never blinded in these studies there is always the potential for contamination if a single provider is caring for both intervention and control patients. Often, to avoid contamination, cluster randomisation was used. Nine of the studies reviewed were randomised at the provider, practice or community level, while eight used cluster randomisation either between clinics or groups of providers that work closely together. Only two studies were randomised at the patient level.9,11

Study outcomes

One of the challenges in conducting a review of CDSS studies is the variability not only of the CDSS interventions studied, but also the variability in primary outcomes. Primary outcomes often included multiple endpoints measuring both provider and patient outcomes. Provider outcomes (e.g. ordering frequency of procedures or lab tests, prescribing appropriate medications, adding diagnoses) were more common with 83% of the studies using these either exclusively or in combination with patient outcomes. Patient outcomes (e.g. specific lab or result values, cardiovascular risk factors, patient initiated encounters) were used less frequently since they are not as easily measured, rely on patient compliance and generally require longer periods of assessment. Although only four studies reviewed used patient outcome measures (with one study using these exclusively²²) almost all of the studies reviewed or discussed the need for more research utilising patient outcomes to better assess the longrange effectiveness of CDSS.

The use of multiple primary outcomes in most studies required that findings be categorised as positive (all primary outcomes have positive findings), neutral (no statistically significant difference found in any primary outcomes) or variable (combination of both positive and neutral findings for primary outcomes). There were no studies that demonstrated a negative finding (patient harm or deterioration related to the intervention). Of the 12 RCTs reviewed, the results were split equally with four studies finding definitive positive primary outcomes,^{9,14,19,23} four with variability in primary outcomes,^{11,15,20,24} and four with neutral findings in primary outcomes.^{17,21,22,25}

Studies with neutral findings had several limitations that make these findings less emphatic and worth noting. For example, Montgomery *et al*²⁵ utilised a CDSS with limited interventional capacity (identification of cardiovascular risk factors) and yet had aggressive patient outcome goals (reduction in cardiovascular risk). Two studies allowed for the CDSS intervention to be easily sidestepped and ignored,^{17,21} while a fourth study used CDSS for depression diagnosis and management, which has long been recognised as a diagnosis often avoided by primary care physicians.²²

Studies with variable findings tended to have a large number of primary outcomes that were reported either separately^{11,20} or vaguely.²⁴ By including more than one or two primary measures, there were often positive findings offset by neutral findings, making it difficult to determine overall effectiveness of the CDSS. One study¹⁵ reported inconsistencies in the same outcome, annual cholesterol exam, for patients with diabetes (P<0.001) and patients with coronary artery disease (P=0.92), a disease in which cholesterol

Author(s)	Pub date	Study design	Score	CDSS	Pts/Enc	Providers	Indication	Outcome allocation	Primary outcome(s)	Improvemen in primary outcome
Apkon et al	2005	RCT	89	Multiple Types	1902	12	Preventive Care, Medical Management, Disease Management	Combination	Compliance with 24 measures 12 measures for prevention/ screening; 12 measures for acute/chronic disease management	Variable
Christakis <i>et al</i>	2001	RCT	80	Medical Management	1339	38	Otitis Media	Provider	Prescriptions for antibiotic therapy < 10 day duration	Yes
Feldstein et al	2006	RCT	87	Disease Management	311	159	Osteoporosis Post-fracture	Provider	Bone densometry or osteoporosis medication prescribed	Yes
Filippi <i>et al</i>	2003	RCT	88	Disease Management	15343	300	Diabetic patients > 30 years with at least 1 CVD Risk Factor	Provider	Anti-platelet therapy prescribed	Yes
McCowan et al	2001	RCT- cluster	52	Disease Management	477	17	Asthma	Combination	Compliance with clinical outcome criteria for asthma Patient initiated consults, practice initiated reviews, acute exacerbations, # hospitalizations, symptoms on assessment, medication use	Variable

Meigs <i>et al</i>	2003	RCT- cluster	83	Disease Management	1098	66	Diabetes	Combination	8 measures for Diabetes mgmt Frequency: HbA1c, LDL,, blood pressure, eye exam, foot exam; Therapy goals: HbA1c, LDL, systolic/ diastolic blood pressure	Variable
Montgomery et al	2000	RCT- cluster	81	Disease Management	614	85	Hypertension	Patient	Patients with 5 year CHD >/ = 10%	No
Rollman <i>et al</i>	2002	RCT- cluster	84	Medical Management	200	17	Depression	Patient	HRS-D scores (indication of depression recovery) at 3 and 6 months	No
Samore <i>et al</i>	2005	RCT- cluster	83	Medical Management	13081	176	Acute Respiratory Infection	Provider	Antimicrobial use for common acute respiratory infections	Yes
Sequist <i>et al</i>	2005	RCT- cluster	81	Disease Management	4549	194	Coronary Artery Disease (CAD), Diabetes	Provider	Compliance with summary reminders for diabetes and CAD Diabetes: Frequency of cholesterol panel, HbA1c, eye exam; Meds: ACE inhibitor with hypertension, Lipid lowering therapy for LDL \geq 130 CAD: Frequency of cholesterol panel; Meds: aspirin, beta-blocker, lipid lowering therapy for LDL \geq 130	Variable

Table 2 Con	tinued									
Author(s)	Pub date	Study design	Score	CDSS	Pts/Enc	Providers	Indication	Outcome allocation	Primary outcome(s)	Improvement in primary outcome
Tierney et al	2003	RCT- cluster	77	Disease Management	706	201	Heart Failure, Ischemic Heart Disease	Provider	Compliance with treatment criteria Meds: ACE inhibitor, Beta- blocker, aspirin, diuretic, long-acting nitrate, anti- hyperlipidemia medication, calcium blocker; Vaccination: pneumococcal	No
Tierney <i>et al</i>	2005	RCT- cluster	72	Disease Management	706	274	Asthma, COPD	Provider	Compliance with treatment criteria Vaccination: flu, pneumococcal; Freq: pulmonary function test; Medications: ipratorpium, inhaled beta-agonist, theophylline, inhaled corticosteroid, oral corticosteroid	No

measurement is generally considered routine management. A meta-analysis by Balas *et al*⁶ further validated such unpredictability in outcomes in a review of 33 studies utilising CDSS for prevention and screening.⁶ Despite an overall increase in improvement of 13.1% (95% CI), there was marked variability in outcomes related to specific endpoints, from 5.7% improvement in documentation of pap smears to 18.3% for influenza vaccination.

The RCT studies showing definitive positive findings were generally well-designed studies with a single, quantifiable primary outcome that was targeted toward provider adherence to CDSS. Primary outcome measures in these studies included ordering of procedures (bone densometry) and prescribing medication therapy (anti-platelet, antimicrobial and osteoporosis therapy). These studies were straightforward, targeted studies that did not attempt to capture data on multiple diseases or interventions.

All of the RCTs reviewed acknowledged limitations of generalisability related to the patient population studied. Additionally, limitations cited included small sample size or a poorly designed study,²⁴ possible contamination of control groups,^{11,22} inconsistent use of CDSS by randomised providers,^{17,19–21} selection bias based on EMR usage/proficiency²⁵ and confounding factors without statistical control.²³

Observational non-randomised trials

Study descriptions

The types of CDSS interventions seen in the nonrandomised and observational studies were more equally distributed between disease management (40%), drug dosing/prescribing patterns (40%) and prevention/ screening (20%). Although fewer studies were included in this group, publication dates for all five studies were between 2004 and 2006, indicating recent work with all five studies reporting data collection no more than four years prior to publication (see Table 3). Although these studies were all conducted in community practice settings instead of academic settings, 60% received government funding with the remaining 40% coming from software vendor and pharmaceutical companies.

This group of studies included over 459 000 patients and over 339 providers. The large patient sample size is misleading as one study¹⁰ was conducted using an HMO patient population of 450 000 patients with a primary outcome of prescriptions generated/10 000 members/month. Owing to the calculation of the outcome measure, there was no need to determine the exact number of patients for which the CDSS was applicable, and therefore this number was not reported. A second study¹² conducted at a single site practice with over 400 patients did not include the exact number of providers involved, and thus the number of providers was estimated based on data provided.

Study outcomes

The findings in all five studies in this group (100%) showed statistically significant improvement in primary outcomes related to use of CDSS. CDSS interventions varied in this group of studies, just as with RCT studies; however, the primary outcomes in all but one study were aimed at providers and included a single primary outcome measure. This removed the issue of variable findings and facilitated study interpretation and review. Primary outcomes in this group included medication prescribing patterns (3), 10,13,18 screening for latent tuberculosis infection (LTBI) (1)¹⁶ and achievement of therapy treatment goals (summary cholesterol results) for hypercholesterolemia (1).¹² As expected, all five studies reported limitations related to non-randomised study design with little or no adjustments for baseline differences between measurement groups. In addition, generalisability issues due to patient population characteristics were discussed and at least two of the studies contained selection bias with study inclusion related to EMR system use by providers.12,18

Discussion

The authors reviewed 17 studies of CDSS intervention in the primary care/ambulatory setting. Although this is a small review, the concentration on recent publications offers insight into current and future trends in this highly visible and rapidly developing area of study. This review reinforced previous work by showing positive correlation between the use of CDSS in the ambulatory setting and improved outcomes.⁵ Overall, 76% of the studies reviewed had either partial or complete improvement in outcomes documented. Nine of the studies found definitive positive outcomes, with an additional group of four studies showing improvement for some of the outcomes measured.

There are several factors worth noting as a result of this review. First, more research is certainly needed involving the effectiveness of CDSS on patient outcomes in order to adequately understand the usefulness of CDSS in the clinical setting. Since clinical decision support has a primary function aimed at providing information to the provider at the point of care for decision making and intervention, outcomes which measure process or provider behaviour are often used as a proxy for patient outcomes. Garg⁷ and colleagues support this position based on the

Author(s) Pub date	Study design	Score	CDSS	Pts/Enc	Providers	Indication	Outcome allocation	Primary outcome(s)		
	0							Improvement in primary outcome		
Bassa <i>et al</i>	2005	Prospective, before/after	6	Disease Management	404	Unknown	Hyper- cholester- olemia	Patient	Achievement of therapy goals Cholesterol, LDL, HDL	Yes
Bloomfield et al	2005	Prospective, before/after	6	Disease Management	9015	92	Ischemic heart disease with low HDL	Provider	Lipid lowering medication therapy	Yes
McMullin et al	2004	Retro- spective cohort	7	Drug Dosing	6254	38	New prescriptions	Provider	Prescription costs	Yes
Smith <i>et al</i>	2006	Prospective, observa- tional	7	Drug Dosing	450000	209	Elderly patients	Provider	Prescriptions/10 000 member per month for two drug classes contraindicated for elderly patients Certain benzodiazepines, tricyclic antidepressants	Yes
Steele <i>et al</i>	2005	Prospective NRCT	6	Preventive/ Screening	249	Unknown	Latent tuberculosis infection (LTBI)	Provider	Adherence to LTBI screening criteria	Yes

small patient populations in most CDSS research to date, but clearly state that further research targeting the effect on patient outcomes is needed. Donabedian²⁶ discussed the necessity of determining the effect of any intervention on patient outcomes as the ultimate goal, but suggested that a relationship exists between process and outcomes. Additionally, the relatively short study periods for the studies reviewed make it difficult to ascertain the long-term effect on patient outcomes support the assertion that the impact of CDSS on patient outcomes has merit as an interim platform to justify the continuing role of CDSS in clinical care.

Second, there is wide variation and interpretation in CDSS implementation, and most studies can truly speak only to the effectiveness of a particular CDSS product used in a particular setting. Differences in system requirements and clinician interaction vary greatly between studies. For instance, one system may require that users respond to every CDSS prompt in acknowledgement of the content whereas other systems allow easy avoidance of all prompts. Some research studies were excluded from this review where the primary endpoints measured were subjective (patient-reported) measures of improvement,²⁷ if the intervention mixed computer-generated CDSS with non-electronic forms of decision support²⁸ or if a decision-support intervention was utilised that was not in real time or not delivered at the point of care.²⁹ Until variations such as these are controlled, it is difficult to assess generalisability of any given CDSS system.

Third, CDSS systems are evolving rapidly and maturing quickly, as is physician acceptance of the use of practice guidelines in the routine provision of care. To determine the effectiveness or usability of CDSS interventions based on research performed even five to ten years ago is biased and misleading. Additionally, the predominance of CDSS interventions which have been developed within academic settings limits generalisability to other settings, most particularly the community based practice setting.³⁰ Significant change in the mindset of providers related to practising evidence-based medicine is likewise evolving. As recently as four or five years ago, there was frequent discussion of the difficulties involved with physician acceptance of guideline-based care algorithms.^{17,31} In a 1999 publication by Cabana *et al*,³² the authors reported on the myriad of barriers to guideline acceptance, ranging from a lack of knowledge to the inertia of routine practice patterns. By 2003, research by Bates and colleagues³³ had progressed to the point of addressing specific criteria needed for guideline acceptance as it relates to CDSS, including CDSSsupported guideline concordance and the identification of recommended actions which are patient specific, timely and user-friendly. Improvements in CDSS tools, a heightened awareness of the inconsistency in quality care and the rapid progression toward performance-based reimbursement, have helped facilitate changes in the mindsets of physicians to be more accepting of both clinical guidelines and the systems which promote their use.

The fourth factor of note is the urgent need for more research in the ambulatory/primary care setting to evaluate the use and effectiveness of CDSS in this environment and to determine successful implementation strategies. RCTs, especially related to the management of chronic disease, are necessary to gain the acceptance and attention of the industry. Likewise, multi-site, multi-application trials across varied practice settings are needed to enable generalisability of the concept of CDSS. Clearly a limitation of this study is the decision by the authors to include observational, non-controlled trials in this review. Garg et al⁷ comment on the frequency of such trials in the literature as well as the challenges and limitations faced in analysing the positive effect of CDSS due to the wide variation in outcome measures, even among RCTs. These issues are consistent in our work, as are variations in the randomisation unit (cluster versus patient versus provider). Although the observational trials strengthened the case for an overall positive effect of CDSS on improved outcomes (71%), excluding these studies would still have resulted in the same conclusions (67%) in this review. Furthermore, the inclusion of the studies provided a broader range of discussion of the current body of knowledge surrounding CDSS.

Recent publications are attempting to address this need partially through the determination of CDSS features that correlate with improved outcomes.^{8,33} The study by Kawamoto⁸ identified four features that, when all were present in a CDSS application, correlated with 94% improvement in outcomes. Likewise, Bates³³ reported on the 'ten commandments' for effective clinical decision support, citing workflow efficiency and highly directive prompts as two primary factors necessary for wide-scale adoption of CDSS. Research in this area must also focus on the use of the highly complex systems necessary for the chronic disease management that is largely dealt with in the ambulatory/primary care setting.

In a recent editorial, Sidorov postulates that electronic health records have been insufficient in decreasing errors and reducing the cost of health care.³⁴ Chaudhry provides a counterbalance to that view by stating that '[CDSS and] health information technologies are tools that support the delivery of care – they do not, in and of themselves, alter states of disease or of health'.³⁰ In June 2006, the American Medical Informatics Association (AMIA) announced their 'Roadmap for National Action on Clinical Decision Support', giving further validation to the value of CDSS in the 90

current industry.³⁵ The comments of Sidorov remind us that EMRs and CDSSs have not proven to date to be the 'magic pill' for an ailing healthcare system. However, one must also consider CDSS for what it is – a tool that, along with an EMR, can augment the delivery of care in much the same way as a laboratory test does – by providing additional information about the patient's state of health from which the provider can make a more educated and informed decision. It involves much more than just the implementation of a software application. It requires adaptation by clinicians to use and engage in the refinement of CDSS both as a process and as a tool, as we move toward the goal of healthcare delivery that is consistent, effective, efficient and of high quality.

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CONFLICTS OF INTEREST

None.

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