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A Taxonomic Description of Computer-Based Clinical Decision Support Systems

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ABSTRACT

Objective: Computer-based clinical decision support systems (CDSSs) vary greatly in design and function. Using a taxonomy that we had previously developed, we describe the characteristics of CDSSs reported in the literature.

Methods: We searched PubMed and the Cochrane Library for randomized controlled trials (RCTs) published in English between 1998 and 2003 that evaluated CDSSs. We coded each CDSS using our taxonomy.

Results: 58 studies met our inclusion criteria. The 74 reported CDSSs varied greatly in context of use, knowledge and data sources, nature of decision support offered, information delivery, and workflow impact. Two distinct subsets of CDSSs were seen: patient-directed systems that provided decision support for preventive care or health-related behaviors via mail or phone (38% of systems), and inpatient systems targeting clinicians with online decision support and direct online execution of the recommendations (18%). 84% of the CDSSs required extra staffing for handling CDSS-related input or output.

Conclusion: Reported CDSSs are heterogeneous along many dimensions. Caution should be taken in generalizing the results of CDSS RCTs to different clinical or workflow settings.

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Keywords: *decision support systems, clinical; classification*

INTRODUCTION

There is growing interest in the use of computer-based clinical decision support systems (CDSSs) to reduce medical errors (1) and to increase health care quality and efficiency (2). CDSSs are "software that is designed to be a direct aid to clinical decision-making in which the characteristics of an individual patient are matched to a computerized clinical knowledge base, and patient-specific assessments or recommendations are then presented to the clinician and/or the patient for a decision" (3). Despite the seeming specificity of this definition, CDSSs are complex technologies that vary greatly in design, function, and use. Some CDSSs generate paper reminders to outpatients (4), others are directed towards physicians and are fully integrated with an electronic medical record (5), and still others page inpatient care providers with laboratory or other alerts (6). Evaluating or making policy on CDSSs as if they were more alike than different could be problematic if, as is likely, differences in CDSS design, function, and use are related to differences in effectiveness (7, 8), generalizability of success, and workflow impact.

To better understand CDSSs, a system is needed to characterize differences among them. In previous work (9, 10), we developed and tested the Clinical Decision Support Systems Taxonomy (CDSS Taxonomy) to describe the technical, workflow, and contextual features of CDSSs (Table 1). While there have been other CDSS taxonomies (11-14), ours was the first designed specifically for furthering the science of CDSS evaluation rather than being part of broad reviews for technical (11) or information technology management (13) audiences. Our CDSS Taxonomy classifies CDSS features in five broad categories: Context, Knowledge and Data Source, Decision Support, Information Delivery, and Workflow. In this paper, we use the

CDSS Taxonomy to generate a comprehensive description of CDSSs that were evaluated in English-language randomized controlled trials (RCTs) in recent years.

METHODS

Literature Search

Using keywords for computer and decision support systems (Appendix), we searched PubMed and the Cochrane Library for RCTs in English about CDSSs published between May 1998 and December 2003. To capture a spectrum of systems, we broadly defined a CDSS as any computer system that assists physicians or patients with clinical decision-making. We restricted the search to RCTs reporting on clinical outcomes (as opposed to systems-related outcomes, such as user satisfaction) as a way to identify reasonably mature systems. We excluded RCTs of systems that were directly therapeutic (e.g., radiographic therapy dosing or computer-assisted surgery) and, because they do not directly assist with decision-making, systems that were strictly educational or that displayed only test results. We also excluded RCTs in which the effect of the CDSS intervention could not be isolated from other interventions that participants received; such study designs precluded clear characterization of the CDSS as a distinct entity. Meta-analysis and review articles were used to locate additional reports.

CDSS Coding and Analysis

Each CDSS trial was reviewed by at least one of the authors and coded using the CDSS Taxonomy (available at http://rctbank.ucsf.edu/CDSStaxonomy/), which consists of five categories: Context, Knowledge and Data Source, Decision Support, Information Delivery,

and Workflow (Table 1). These categories are composed of 26 axes along which 108 descriptors of CDSS characteristics are grouped.

Coding was performed using a Microsoft Access 2000 [Microsoft Corporation, Redmond, WA] data-entry interface that provided pick lists of the allowed descriptors for each of the 26 axes. The interface allowed one or more descriptors to be checked, as appropriate. When no or multiple descriptors were equally plausible, the axis was coded as *undefined*. We calculated the frequency of each descriptor's coding, and analyzed contingency tables using Fisher's exact test. Only p values <.01 were deemed statistically significant given the number of statistical tests we performed.

A subset of RCT articles was reviewed by two of the authors to assess inter-rater agreement using Cohen's kappa (15) for each of the 108 taxonomy descriptors. All inter-rater disagreements were reconciled in consultation with the third author, and the reason for the disagreement was recorded. All analyses were performed using Stata 8.0 [StataCorp, College Station, TX].

RESULTS

Literature Search and Study Selection

The literature search generated 151 studies. Ninety-three were excluded: of these, 27 were not RCTs; 16 reported nonclinical outcomes; 12 were educational or directly therapeutic; and 38 were not CDSSs, were a pilot system, or had effects that could not be isolated. This resulted in 58 included studies (Table 2). Eight of the studies described more than one CDSS intervention, with some software systems evaluated in more than one implementation. Thus, we coded a total of 74 CDSS scenarios reflecting the evaluation of 58 distinct CDSS software

systems. The number of participants in the trials ranged from 10 to 36,225 (median = 648). Clinician sample size, when applicable, was infrequently reported, but when given it ranged from 32 to 1,100 (median = 113).

Characteristics of CDSSs

The 74 CDSS scenarios reviewed varied greatly in their characteristics. We used the framework provided by the CDSS Taxonomy to describe, analyze, and understand these variations. Reported totals may not add up to 100% because, for some CDSSs, some of the axes were undefined or were coded with more than one descriptor.

Context

The Context axes of the CDSS Taxonomy describe the setting, objectives, and other contextual factors of a system's use. Seventy-seven percent of the CDSSs were used for outpatient care, 19% for inpatient care, and 5% for care not affiliated with a healthcare entity (e.g., mass mailings to patients within a geographic region). Table 3 illustrates the variation in clinical tasks by clinical setting, with prevention/screening (39%), drug dosing (32%), and chronic disease management (23%) predominating in outpatient settings, and drug dosing (50%) predominating in inpatient settings. Overall, the most common clinical tasks supported by the CDSSs reviewed were drug dosing (32%) and prevention/screening (31%).

Another Context characteristic is the target decision maker—the person whose actions the CDSS is designed to influence directly through its recommendations. Sixty-two percent of the CDSSs targeted the physician or another clinician as decision maker, while 46% targeted the patient. All 14 of the inpatient systems targeted physician decision makers, with one CDSS

targeting physicians and respiratory therapists. Seventy-nine percent of the patient-directed systems focused on prevention/screening or health-related behaviors (Table 4). None of the systems targeted concurrent decision-making by physician and patient together.

The vast majority (96%) of the CDSSs reviewed were designed to optimize the clinical outcomes of patients. Only three systems (4%) were designed to optimize system-based outcomes, such as cost or resource utilization. Only one system was designed to improve a physician-centered outcome (compliance with clinical documentation requirements). Forty-one percent of the CDSSs delivered decision support at the point of care, which we had defined in the CDSS Taxonomy as decision support delivered during a shared clinician-patient encounter. Forty-nine percent of the systems delivered decision support outside the point of care (e.g., a patient update e-mailed to a physician), and 12% of the systems were used during or between visits. Systems were more likely to be point-of-care if the target decision maker was a clinician rather than a patient (70% vs. 64%, $p < .0001$).

Another important contextual characteristic of CDSSs is the presence of complementary organizational behavior modification programs, such as financial incentives for increasing compliance with the recommendation or sessions led by opinion leaders to generate "buy-in" to CDSS objectives. However, no reports mentioned or described any such programs. A related contextual characteristic concerns contextual barriers to completion of a recommended action, such as socioeconomic factors that could interfere with a patient's ability to arrange transportation to a follow-up appointment. We identified contextual barriers to the completion of a recommended action in 46% of the outpatient CDSSs and in all four of the community-based CDSSs, but in none of the inpatient systems ($p < .001$).

Knowledge and Data Source

The Knowledge and Data Source axes of the CDSS Taxonomy describe the source of the clinical knowledge and the source and format of clinical data used by the CDSSs. Sixty-one percent of the CDSSs in our sample incorporated evidence-based clinical knowledge derived from national guidelines and/or randomized trials, with no difference in the proportion of clinician- versus patient-directed systems that were evidence based ($p = .61$). The predominant sources of clinical data were the electronic medical record (EMR) (45%) and the paper chart (22%). Only one of the articles on CDSSs described using a standard vocabulary (SNOMED CT, [SNOMED International, Northfield, IL]) to code clinical data.

Decision Support

The Decision Support axes describe the nature of the decision-making targeted and the nature of the decision support offered. Eighty-six percent of the CDSSs targeted nonurgent decisions primarily related to drug dosing (32%) and prevention (31%). Sixteen percent supported clinical decisions requiring immediate action (e.g., responding to critical lab values, emergent surgery), with inpatient systems being more likely than outpatient to address clinically urgent issues ($p = .005$).

Thirty-one percent of systems recommended actions that were logistically complex—defined as actions consisting of interdependent steps, steps spread out over time or multiple locations, or steps involving several actors (e.g., a physician ordering a mammogram, and the patient scheduling and completing it). Seventy percent recommended logistically simple, one-step actions. Recommendations for logistically complex action were significantly more likely to be issued by CDSSs used for prevention/screening ($p < .0001$).

Seventy-four percent of the CDSSs provided decision support in the form of explicit recommendations (e.g., "patient is due for mammogram") as opposed to implicit

recommendations (e.g., "selective serotonin reuptake inhibitors have been shown to be an efficacious treatment for major depression"). Sixty-four percent of the CDSSs did not require the target decision maker to acknowledge the recommendations, or required only a noncommittal response (e.g., "press Escape to continue"). Three of the four CDSSs that required a substantive response (e.g., must explain why a recommendation was not being followed) were inpatient, clinician-directed systems.

Seventy-six percent of the systems used rule-based reasoning engines. Others relied on neural networks (3%), probabilistic models (3%), or the end-user being guided by a manual algorithm (4%).

Information Delivery

The Information Delivery axes describe how CDSSs deliver their action recommendations to target decision makers. Seventy percent of the CDSSs we reviewed "pushed" unsolicited recommendations to their target decision makers. Of the remaining 17 CDSSs, 13 (76%) were stand-alone systems that required target decision makers to initiate a session of decision support to "pull" recommendations.

The format in which recommendations were delivered varied according to the target decision maker (Table 5). For patients, the most common were postal mail (67%) and telephone (21%). For physicians, the most common formats were online within an integrated EMR-CDSS session (33%), online via a stand-alone CDSS (35%), and printouts attached to a paper chart (24%). Forty-nine percent of the CDSSs provided an explanation of the recommendation, and 21% were able to provide further information or clarification of the recommendation if the target decision maker—who was more likely to be a physician than a patient ($p < .009$) in these systems—requested it.

The CDSS Taxonomy defines a CDSS as offering "action integration" when users are provided with single-click ability to execute a logistically simple recommendation (e.g., users can click an online order entry form to order a recommended drug dose). Of the 40 CDSSs that made logistically simple recommendations, 40% featured action integration, especially those that delivered their recommendations via integrated EMR-CDSS sessions ($p = .001$).

Workflow

Workflow integration (71), workflow flexibility, and staffing impact are crucial but often difficult-to-characterize features of a CDSS. We coded CDSSs as being moderately integrated to well integrated with clinical workflow if the CDSS did not require substantial additional work, such as a receptionist needing to enter patient demographic information into a stand-alone CDSS during the patient registration process. Thirty-one percent of the CDSSs were coded as being moderately integrated to well integrated, but we were unable to code workflow integration in another 31% of the systems because of incomplete reporting. Workflow integration was more often seen with action integration ($p = .033$) and when the EMR was the delivery format ($p = .004$), but not when the EMR was the clinical data source ($p = .68$).

Workflow flexibility is an aspect related to workflow integration. We coded CDSSs as having workflow flexibility if the target decision maker could choose when to process the CDSS's recommendations, such as a "View later" button for a lab test reminder. "Pull" CDSSs have workflow flexibility by definition. Among the 24 "push" CDSSs, all of which targeted clinicians, 83% had workflow flexibility, and 80% of these systems "pushed" their recommendations at the point of care.

A CDSS's staffing impact is also characterized by whether a human intermediary is required to input data or to handle output (e.g., clip printout of recommendations to paper

chart for target decision maker to see). In our sample, 30% of systems required a data input intermediary, and 51% required at least one output intermediary; the requirement for a data input or output intermediary could not be determined for 45% and 16% of systems, respectively (Table 6). Intermediaries were required especially for outpatient and community-based clinical settings (Table 7). Physicians served as the data input intermediary 9% of the time, other clinicians (e.g., nurses) 23%, nonclinician staff 59%, and patients 9%. Inpatient systems were less likely to require data input intermediaries ($p = .016$). Overall, only 16% of the CDSSs did not require either an input or an output intermediary, suggesting that CDSS-associated staffing burdens are common.

Undefined axes

The CDSS studies we reviewed often did not provide sufficient information to substantiate coding of a descriptor. Twenty-one of the 26 axes were coded as *undefined* for at least one of the 74 CDSS scenarios. Six axes were coded as undefined at least 20% of the time: interactivity of delivery (22%), response requirement (23%), workflow integration (31%), explanation availability (35%), data input intermediary (45%), data coding method (69%), update mechanism (92%) (how the knowledge base of the CDSS is updated), and presence of external behavior modification programs (93%).

Inter-rater agreement

A subset of 20 articles was co-reviewed by two of the authors. Inter-rater agreement was 100% for 30 of the 108 descriptors. Of the remaining 78, the kappa was greater than 0.6 for 17 descriptors (indicating at least moderate agreement) and greater than 0.45 for another 17 descriptors (indicating fair agreement). For descriptors like ours, which are binary and not uniformly distributed, however, Cohen's kappa is known to underestimate inter-rater

agreement. Thus, overall, inter-rater agreement was at least fair to good for 59% (64/108) of the descriptors. Reasons for disagreement included ambiguous reporting (62%), misapplication of the taxonomy (21%), data entry error (10%), and differences in clinical knowledge and experience between reviewers (7%).

DISCUSSION

The enthusiasm for the potential of CDSSs to improve clinical care has stimulated a growing literature of CDSS evaluation studies. Previous reviews (7, 8, 10) have described enormous variety among CDSS features and the clinical scenarios in which they are used. Our previously reported CDSS Taxonomy (9) systemizes the description of the technical, workflow, and contextual features to increase understanding of what CDSSs have been developed and how they have been deployed. The comprehensive and versatile multi-dimensionality of the taxonomy attends to the content as well as the process of decision support, functioning at once to "zoom in" on the moment of clinical decision making and to capture the upstream and downstream events and players (e.g., data input and output intermediaries). Using this taxonomy, the present study provides a systematic characterization of recent CDSSs that were mature enough to have been evaluated in RCTs. Although the CDSSs showed great variability, the bulk of CDSSs we reviewed operated in outpatient settings by pushing explicit, evidence-based recommendations for logistically simple, nonurgent clinical actions to clinicians or patients.

Overall, two distinct subsets of CDSSs emerged. Representing 38% of our sample, the first consisted of patient-directed systems that provided decision support for preventive care or health-related behaviors via mail or telephone. A second subset, 18% of systems reviewed,

consisted of inpatient systems targeting a clinician decision maker with online delivery of decision support (EMR or stand-alone CDSS) that obviated manual data entry and provided action integration. As CDSS evaluation and technologies evolve, additional subsets will likely emerge, and we anticipate a shift in thinking towards "classes" of CDSSs, analogous to classes of anti-hypertensives. The unique mechanisms of action of these classes will necessitate development of separate evidence bases for different types of CDSSs, as opposed to a single evidence base.

Implications of CDSS diversity

Our demonstration of the wide diversity of CDSS technologies and implementations argues for greater attention to this heterogeneity when devising policies for promoting various types of CDSS use. For example, policies that promote CDSSs integrating computerized physician order entry with an EMR (e.g., (5)) may require substantial adaptation to be applicable to stand-alone CDSSs that have different technological and workflow characteristics. To guide such policies, more information is needed on which CDSS characteristics and settings are most strongly associated with clinical effectiveness. Our findings suggest that, when pooling CDSS trials for meta-analysis, careful exploration of heterogeneity along our CDSS Taxonomy axes may be fruitful for identifying such predictors of clinical effectiveness. For example, a recent study exploring reasons for the ineffectiveness of a CDSS (72) identified several potential contributing factors, which, restated in CDSS Taxonomy terms, included lack of individually customized recommendations, lack of workflow flexibility, lack of action integration, and logistically complex action recommendations. It is therefore inadvisable to simply pool CDSSs for meta-analysis without regard to the heterogeneity of CDSS characteristics highlighted here—doing so would mix "apples and oranges."

Caution must also be used in extrapolating the success of any particular effectiveness study: a reported success may be contingent on contextual factors or workflow accommodations specific to a given operational context. For example, three separate studies reported on the implementation of DAWN AC [4S Information Systems Ltd., Cumbria, England], an anti-coagulation initiation and maintenance decision support system. One study described an inpatient implementation (16) while the other two studies were outpatient-based (17). Although all three studies showed that DAWN AC produced anti-coagulation control comparable to clinician-driven management, the results of the inpatient investigation were less robust than the two outpatient investigations. The investigators of the inpatient investigation concluded that because of the inherent unpredictability of anti-coagulation initiation in medically ill inpatients, inpatient anti-coagulation maintenance was less amenable to computer-based decision support than outpatient anti-coagulation maintenance. This example highlights the importance of the clinical and work context in defining the CDSS, and, ultimately, in determining its effectiveness. As this example demonstrates, because a CDSS is as much its technical features, or *content*, as its workflow and contextual *process*, it would be inappropriate to apply the results of the outpatient implementations to an inpatient scenario. The same software in different contexts becomes different CDSSs.

Common precepts about CDSSs

This taxonomic description sheds light on some common precepts about CDSSs. One precept is that CDSSs should provide explanations of their recommendations, and that target decision makers (e.g., physicians) should be involved in their development (3). However, only 49% of reviewed systems had explanation capabilities, and only 11% described involvement of physician users with development of the knowledge base. Because of

incomplete reporting, these percentages may be underestimates, but improvements are nevertheless needed in understanding whether explanations and various types of user buy-in are indeed associated with effectiveness. If so, more CDSSs should incorporate these features. Second, there is increasing agreement that quality improvement programs, including those using CDSSs, should be evidence-based (73). We found that 62% of the CDSSs we reviewed used national guidelines and/or randomized trials in constructing their knowledge bases, a heartening finding, but there is room for improvement. Third, there is increasing recognition of the role of contextual social factors in the success of implementation of healthcare informatics (71). We believe that the Potential Barriers axis of the taxonomy highlights an important dimension of contextual constraints on CDSS success to which designers and evaluators of CDSSs should be attentive. Our findings also suggest the under-reporting of complementary behavior modification programs (e.g., target user buy-in programs), more detailed descriptions of which will enhance our understanding of their role in CDSS effectiveness. Finally, it is commonly assumed that decision support is best provided at the "point of care," which we define to be a shared clinician-patient encounter, a clinic visit in the outpatient setting, or any time during a visit to the emergency department or a stay in an inpatient setting. Using this definition, we found that only 41% of CDSSs delivered their recommendations at the point of care, but rather than being a shortcoming, this finding reflected an appropriate avoidance of the point of care when possible. With clinicians feeling increasingly time-pressured during patient encounters, more research is needed to define what decision support belongs at or outside the point of care.

Limitations

There are several limitations to our study. One is that we included only CDSSs that have been evaluated in published RCTs that report on clinical outcomes. This exclusion biases our study towards more mature CDSSs, which may incorporate older technology, and towards "home grown" CDSSs developed in academic centers. However, RCTs of CDSSs are often cited to support claims of effectiveness (7, 8), and we believe it is therefore of value to characterize CDSSs from RCTs. Our exclusion of RCTs in which the effect of the CDSS intervention could not be isolated from other intervention(s) may also have biased our sample towards clinician-directed systems, as excluded trials were often of patient-directed CDSSs that were used in conjunction with patient education initiatives.

A second limitation derives from the frequently encountered ambiguous or incomplete reporting of CDSS design and function. We commonly found that reports omitted important details regarding the steps taken to generate an episode of decision support. An example is the following text from a study on influenza vaccine reminders (18): "Using the computerized billing data, we identified all patients assigned with [a primary care physician from our institution] who had…an ICD-9 code of asthma, end-stage renal disease, nephritic syndrome, diabetes, sickle cell disease, or ischemic cardiomyopathy. The patient's date of birth, gender race, and martial status were retrieved from the computerized demographic information." Because of the vague reference to "we" and the use of the passive voice, it is not clear whether the CDSS interfaced with the billing system automatically, or whether this was a manual process. These two possibilities are equally plausible yet considerably different with respect to the CDSS's technical sophistication and workflow burden, characteristics that are critical for understanding the design and generalizability of this system.

Such reporting ambiguities precluded precise application of our CDSS Taxonomy, which limits the accuracy and strength of our correlative conclusions. In addition, incomplete, ambiguous reporting reduced our inter-rater agreement. Rates of inter-rater agreement also reflect the inherent but not insurmountable challenge of "creating order in the chaos" that is the breadth and diversity of CDSSs.

Thirty-eight percent of our sample consisted of patient-directed CDSSs that provided decision support by mail or telephone. Given the rapid diffusion of e-mail and other information technologies among the public (74), however, our results may underestimate the prevalence of electronic delivery formats in newer patient-directed CDSSs.

CONCLUSION

Our taxonomic description shows that CDSSs are highly variable in design, function, and use. They are complex interventions functioning in complex healthcare systems, and, as such, are challenging to design, implement, and evaluate. In the face of this complexity, we have applied the CDSS Taxonomy to provide, to our knowledge, the most comprehensive multi-faceted description of published CDSSs to date, which should help further the evaluative science of CDSSs. Improved reporting along the lines suggested by our CDSS Taxonomy, increased recognition of the emerging subsets, or classes, of CDSSs and their respective evidence bases, and the fine-tuning of policies to promote adoption of CDSSs with respect to the heterogeneities described here will enhance our understanding of how CDSSs work and the conditions in which they are most effective.

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Appendix

For PubMed search: decision making, computer assisted; decision support systems, clinical; diagnosis, computer assisted; reminder systems; medical records systems, computerized; point of care systems; automatic data processing; computer-assisted instruction; decision support techniques; drug therapy, computer-assisted; expert systems; hospital communication systems; online systems; software; therapy, computer-assisted; clinical laboratory information systems; hospital information systems; ambulatory care information systems; clinical pharmacy information systems; radiology information systems

For Cochrane: decision making, computer assisted; decision support systems, clinical; diagnosis, computer assisted; reminder systems; drug therapy, computer-assisted; expert systems; software; therapy, computer-assisted; clinical laboratory information systems; hospital information systems; ambulatory care information systems; clinical pharmacy information systems; radiology information systems.

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Table Legends

Table 1.

The CDSS taxonomy consists of 26 axes in five broad categories. The 26 axes are described using 108 descriptors (e.g., "Outpatient" and "Teaching Institution" for the Clinical Setting axis). Sample descriptors are noted in parentheses for selected axes. CDSS = clinical decision support system; EMR = electronic medical record.

Table 2. CDSS scenarios coded. ADEs = adverse drug events; ARDS = acute respiratory distress syndrome; CPOE = computerized physician order entry; CDSS = clinical decision support system; EKG = electrocardiogram; EMR = electronic medical recored; ED = emergency department; HIV = human immunodeficiency virus

Table 3. Clinical tasks by clinical setting.

Table 4. Clinical tasks by target decision maker. The target decision maker is the person whose actions the CDSS is designed to influence directly through its recommendations. Clinicians include physicians, nurses, and other care providers.

Table 5. Delivery format by target decision maker.

Table 6. Clinical data source and need for data input intermediary. A data input intermediary is defined as an individual who is required to transcribe and/or manually enter information from the data source into the CDSS. The two systems with no clinical data used were generic

reference systems, one a videodisc for patients with breast cancer, and one an index of primary care clinical guidelines.

Table 7. Intermediaries needed by clinical setting, for systems that provided sufficient information to determine this.