Summer Institute / HIT Series



Clinical Decision Support Systems & Population Health Analytic

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- School of Public Health
- School of Medicine

2 hrs / ~100 slides

Overview

- CDSS Overview
- CDSS Design to Implementation
- ***** Knowledge Management
 - Acquisition
 - Generation
 - Representation
 - Guidelines
 - Integration
- Case Studies
 - Indiana (Regenstrief)
 - Vanderbilt
 - Harvard (BWI)
 - Utah (Intermountain)

CDSS in Practice

- Diagnostic DSS
- Patient DSS
- Population DSS
- CDSS Legal
- Resources
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CDSS Overview

CDSS Overview → **Reasoning**

Deduction

Deductive reasoning is based on the principles of logical implication. It allows us to infer conclusions, the degree of truth of which is only a function of the <u>degree of truth of the premises</u>. The results of logical inference may be <u>used as a premise for further</u> <u>deductions</u>. Thus, if A implies B and if B implies C, then, via transitivity, A implies C.

Induction

Inductive reasoning makes <u>generalizations</u> based on specific examples to formulate general <u>rules</u>. Inductive reasoning <u>produces inferences</u> that are valid to a certain degree of credibility or probability.

Abduction

Abductive reasoning is referred to as the <u>scientific method</u>. It attempts to establish links between observations such as cause and effect. Hypotheses may help formulate a rule to establish <u>a link between the preceding and subsequent facts</u> (e.g., a diagnosis hypothesis), or they may concern the <u>formulation of a new rule</u> (e.g., a scientific discovery).

CDSS Overview → **Reasoning** (cont.)



Different types of reasoning

CDSS Overview → **Steps in Medical Decision**

Identify the Problem

Diagnostic decisions begin with the <u>primary interpretation of clinical data</u>. <u>Abductive</u> reasoning is used.

Structure the Problem

<u>Several interpretations</u> of the same data or parts of that data are possible. Diagnostic hypotheses are formulated by structuring the information. Reasoning may be <u>deductive</u> (e.g., for a pathognomonic sign), <u>inductive</u> (e.g., diagnosing a transmissive disease in a population of subjects at risk), or <u>abductive</u>.

Choose the Solution

Starting from a <u>number of working hypotheses</u>, the expected signs and symptoms may be obtained by deduction and, if necessary, by the <u>complementary examinations</u> required to obtain them. By induction and/or abduction, the physician may <u>eliminate hypotheses</u> that do not correspond to the observations. The results of complementary examinations may help to <u>reduce the uncertainty</u> over the clinical situation and eliminate hypotheses or solicit new ones.

CDSS Overview → **Steps in Medical Decision** (cont.)

Identify the problem	 Possible alternatives Possible patient states Clinical information that cannot be obtained 			
Structure the problem	 Develop a strategy Account for frequency of diseases Search for pertinent data 			
Choose the solution	Comparative evaluation of different hypothesisSynthesis and choice			

Structure of the decision-making process

CDSS Overview → **History of CDSS**

- Definition: Computer-based clinical decision support (CDSS) can be defined as the use of the computer to bring relevant knowledge to bear on the health care and well being of a patient.
- Efforts to automate aspects of health care began in earnest as far back as the early 1960s. CDSS has been more a research pursuit than a practical one.
- Common types of decision support → recognizing that a laboratory test result is out of normal range; a medication being ordered has a dangerous interaction with another; determining that a patient is now due for a flu shot.
- Transition from academic settings into the commercial application has been slow and harder than expected
- Relationship between CDSS and healthcare providers has gone through different phases – health informatics maturation.

CDSS Overview → **History of CDSS** (cont.)

Phase of relationship	Duration (date ranges approximate)	Hallmarks
A long infatuation	1960–1985	Enthusiasm for clinical decision support, research, new ideas
A troubled courtship	1985–1998	Successful implementations, evaluations showing benefit, but limited dissemination
Renewed passions	1998–2003	Knowledge explosion, safety and quality agendas
Building the foundations for a lasting relationship	2003-	National agendas, call to action, roll out of electronic health records (EHRs), computer- based provider order entry (CPOE), electronic prescribing (eRx), personal health records (PHRs)
A new party to the relationship	2004-	Recognizing knowledge management as a necessary infrastructure

Relationship between computers as source of clinical decision support and providers and recipients of health care

CDSS Overview → **History of CDSS** (cont.)

- Necessity of CDSS:
 - Demand for prevention has increased due to the rise in medical error (Institute of Medicine report → To Err Is Human)
 - Computer-based physician order entry (CPOE) systems, coupled with CDSS, have been proposed as a key element of systems' approaches to improving patient safety.
 - CDSS have the potential to change the way medicine has been taught and practiced.
- Features of CDSS:
 - Aim: make data available, optimize problem-solving and decision making
 - **User**: provide it to a healthcare provider or scientist
 - Data: select knowledge that is pertinent, and/or to process data to create the pertinent knowledge
 - Engine: carry out some sort of inferencing process, algorithm, rule, or association
 - Action: perform some action, usually to make a recommendation

CDSS Overview → **Components of CDSS**

CDS Component	Description
Purpose	The task or process of clinical care for which the CDS is intended
Structure	The components specifying the way CDS is to be carried out
• Decision model	The method of organizing or analyzing data and knowledge to arrive at a recommendation
 Knowledge base 	The knowledge content used by CDS
 Information model 	The manner of representing and naming the clinical and decision support parameters used by the inferencing method to arrive at a recommendation
 Result specification 	The output of the decision model
 Application environment 	The manner in which the CDS interacts with host applications and users to obtain data, communicate results, and enable the host application to make recommendations or perform actions

Components of clinical decision support

CDSS Overview → **Types of CDSS**

- A variety of systems can potentially support clinical decisions (e.g. Medline and any literature database)
- Decision support systems have been incorporated in healthcare information systems for a long time, but these systems usually have supported retrospective analyses of financial and administrative data.
- Although these retrospective approaches can be used to develop guidelines, critical pathways, or protocols to guide decision making at the point of care, such retrospective analyses are not usually considered to be CDSS.
- CDSS differ among themselves in: the timing at which they provide support (before, during, or after the clinical decision is made), how active or passive the support is, how easy they are for clinicians to access, and whether the information provided is general or specialty-based, and if it is knowledge based or non-knowledge based.



CDSS Design to Implementation

CDSS Design to Implementation

Knowledge generation & validation



Three intersecting and interacting life cycles underlying clinical decision support systems technology.

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CDSS Design to Implementation (cont.)

- (1) Knowledge Generation and Validation (KG)
- (2) Knowledge Management and Dissemination (KM)
- (3) CDSS Implementation and Evaluation (IE)



CDSS Design to Implementation (cont.) Error prevention Quality **Identify current** The strategy Cost-effectiveness high priority foci Chronic disease mgt proposed is an Syndromic surveillance iterative one. A key challenge is to get it started. Establish/refine infrastructure Use infrastructure to develop/deploy CDS for high priority foci

Priorities for CDSS are likely to fall into five main areas (top). The three interrelated life cycle processes involved in generation of knowledge, knowledge management, and incorporation into functional CDSS require infrastructure for supporting them (middle). The result of applying these life cycle processes to the priority areas will be knowledge bases and authoring and implementation tools (lower). The whole process iterates as we learn more about how to create infrastructure to support it, and as priorities change.

CDSS Design to Implementation (cont.)

6 Application environment



An idealized conceptual model of CDS design components and their interactions with the host application environment.



Knowledge Management (Acquisition, Generation, Representation, Integration)

Knowledge Acquisition (KA)

KM → Knowledge Acquisition



The classical view of knowledge engineering (top) vs interactive transfer via a computer model (bottom)

KM → Knowledge Acquisition → Computer Based KA (cont.)

Change PREMISE? (YES or NO) ** YES Want to see the current version? (YES or NO) ** NO Change (C), Delete (D), or Add (A) a component: ** C Which component? (enter number): ** 2 Enter the new component: ** PORTAL OF ENTRY IS THE GI TRACK More changes to this PREMISE? (YES or NO) ** NO Change rule's conclusion? (YES or NO) ** NO This is my understanding of your rule:

RULE200

The expert indicates what corrections need to be made and is able to verify that the revised rule is what was intended



A mixed-initiative knowledge-acquisition dialog between MYCIN and an infectious disease expert

Knowledge Generation (KG)

KM \rightarrow **Knowledge Generation** \rightarrow **Methods for DSS**

 Decision support systems utilize a broad variety of methods besides simple algorithms. Each of these methods uses particular means of reasoning:

Method	Reasoning	Explanations	Learning
Mathematical models	Algorithmic	No	No
Statistical and Probabilities	Inductive	Limited	Automatically by Induction
Expert Systems	Deductive, Abductive	Yes	Difficult, Supervised
Neural Network	Inductive	No	Supervised or Automatic

Methods for Decision Support Systems

KM → **Knowledge Generation** → **Methods for DSS** (cont.)

- Decision support models in health care can be: quantitative and qualitative
- Quantitative Models: is often based on <u>well-defined statistical methods</u> and makes use of training sets of patient data. <u>Prior probabilities for the occurrence of diseases</u> are generally incorporated into the statistical models.
- Qualitative Models: uses features that are generally <u>proposed by experts</u> and that are based on clinical studies. In this category the decision support methods use <u>symbolic</u> reasoning methods such as logical deduction (Boolean logic If Then)
- Some DSS systems may incorporate both models → <u>Bayesian Network (Quantitative and Qualitative)</u>.





Decision-support models in health care can be grouped into different categories. The main categories are the quantitative (statistical) and the qualitative (heuristic) decision-support models, which can also be further split into subcategories.

KM \rightarrow **Knowledge Generation** \rightarrow **Quantitative Methods for DSS** (cont.)

Supervised Learning: In supervised learning the <u>researcher tells the computer the</u> <u>disease or health status of each patient in the</u> <u>training set</u>.

The computer is then asked to order the features according to discriminatory power between disease A and disease B.

Unsupervised Learning: In unsupervised learning the computer is also given the training set of features. However <u>the truth (information</u> <u>on what disease belongs to which patient) is</u> <u>not known</u>.

The computer is then used to discover by what clusters of feature sets the difference disease groups can best be characterized. This process is called clustering.

Disease	Sign A	Sign B	Sign C
А	Yes	No	5.67
А	No	No	5.98
В	No	Yes	7.89
Α	Yes	Yes	5.91
В	No	Yes	6.72

Disease	Sign A	Sign B	Sign C
?	Yes	No	5.67
?	No	No	5.98
?	No	Yes	7.89
?	Yes	Yes	5.91
?	No	Yes	6.72



Classification tree for the bivariate outcome problem. Cases are recursively partitioned according to the attribute-value pair that best divides the cases into "euthyroid" or not. The resulting partitions easily can be visualized in this simplified two dimensional problem.



Computer-Derived Decision Tree for the Classification of Patients with Acute Chest Pain





Without variable transformation, logistic regression will not work for all cases because the problem is not linearly separable.



Artificial neural network with a hidden layer of nodes. For didactic purposes, activation functions in this example correspond to step functions that define partitions similar to the ones in the classification tree.

Evaluation of Supervised Models

- Discrimination assesses how well the models can potentially discriminate positive and negative cases. Area under ROC curve can be used.
- Calibration assesses how close the model's estimated probability is to the "true" underlying probability of the outcome of interest.
 - Poor calibration is often caused by limited representation of the population to which models will be applied at the model construction phase
- <u>Receiver Operating Characteristic (ROC) Graph</u>
- In pattern recognition the goal is to map entities to classes → classification accuracy is compared among methods
- Classification \rightarrow true positive, false positive, true negative, false negative
- ✓ Sensitivity = TP / TP + FN \rightarrow TP Rate = sensitivity
- ✓ **Specificity** = TN / TN + FP \rightarrow FP Rate = 1 specificity





Normal distribution + Histogram

Normal Population



Normal distribution + Normal Population

Example: WBC more than a certain amount means...

Disease Population



Normal distribution + Disease Population

Example: WBC more than a certain amount means...


Example: WBC more than a certain amount is 100% diagnostic of the disease



Example: WBC more than a certain amount is somehow diagnostic of the disease

Sensitivity = TP/(TP+FN) Specificity = TN/(FP+TN)







Sensitivity = TP/(TP+FN) Specificity = TN/(FP+TN)





FP: Type I error (p-value) FN: Type II error

Sensitivity and Specificity details





ROC Curves of the left diagrams

The Receiver Operating Characteristic (ROC) curve is used to assess the accuracy of a continuous measurement for predicting a binary outcome

The ROC graph is a two-dimensional graph that depicts the trade-offs between benefits (true positive rate) and costs (false positive rate).





- The area under the ROC curve (AUC) provides a single statistic (the C-Statistic) for comparing classifiers → accuracy of the classifiers.
- The value of AUC ranges from 0.5 (flipping a coin) to 1 (best class). Calculation can be based on trapezoids under the curve.



- Precision (reliability) refers to the fidelity of the measurement; if the measurement is repeated on the same subject, the same result will be obtained.
- Accuracy (validity) refers to the tendency of measured values to be symmetrically grouped around the variable's true value.



KM → Knowledge Generation → Unsupervised Learning Models (cont.)



Nearest neighbor (NN) classifier. There are two classes: A (triangles) and B (diamonds). The circle represents the unknown sample, X. For the NN rule, the nearest neighbor of X comes from class A, so it would be labeled class A. Using the k-NN rule with k = 4, three of the nearest neighbors of sample X come from class B, so it would be labeled as B.





Unsupervised Learning (Clustering)

KM \rightarrow **Knowledge Generation** \rightarrow **Expert Systems**



General architecture of an expert system



Representation of the elements involved in heuristic reasoning. For inferencing, different strategies can be used: forward reasoning and backward reasoning.

KM → Knowledge Generation → Systematic Review and Meta-Analysis

- Evidence-Based Medicine (EBM) → formalizes the principles and methods of reviewing and synthesizing evidence that have been developing over several decades.
- Systematic Review (SR): comprehensive, rigorous, and unbiased review and synthesis of up-to-date evidence provides the most reliable information to inform health practice.
- Meta-Analysis (MA): a systematic review that uses statistical methods to combine results across several studies to address specific questions
- <u>Meta-Analysis Example</u> → A meta-analysis combining 33 studies found a highly statistically significant result of approximately 20 percent reduction of overall mortality by the adoption of streptokinase therapy; however, FDA did not approve its use till two larger studies showed the same results in 1988. Thousands of lives could have been saved meanwhile!

KM → Knowledge Generation → Systematic Review and Meta-Analysis (cont.)



Standard forest plot (left panel) and a cumulative meta-analysis (right panel) of intravenous streptokinase therapy for acute myocardial infarction;

KM → Knowledge Generation → Systematic Review and Meta-Analysis (cont.)

■ Publication Bias → unpublished studies with negative results threaten the validity of a meta-analysis. The inverted funnel plot is the most popular method used to detect publication bias → small studies have greater variability (wide end of funnel) and larger studies have smaller variability (narrow neck of funnel) → missing publications will show an asymmetric funnel suggesting publication bias



Knowledge Representation (KR)

$KM \rightarrow Knowledge Representation$



IF NOT (erythema AND pus AND adenopathy) THEN CONCLUDE "non-infectious cause"

IF erythema AND NOT (pus AND adenopathy) THEN CONCLUDE "viral pharyngitis"

IF erythema AND pus AND NOT adenopathy THEN CONCLUDE "viral pharyngitis"

IF erythema AND pus AND adenopathy THEN CONCLUDE "streptococcal pharyngitis"

Decision rule represented as production rules (right). This collection of production rules represents the same knowledge as the decision tree (left).



KM → **Knowledge Representation** (cont.)

```
let lastTroponin: Observation = Observation-select(code=
   ("SNOMED-CT", "102683006")).sortedBy(effectiveTime.high).last()
let threshold : PhysicalQuantity =
   Factory.PhysicalQuantity( "1.5, ng/dl")
let threshold_for_osteodystrophy : int = 70
let myocardial_infarction :Boolean = if lastCreatinine <> null and
   lastCreatine.value.greaterThan(threshold)
 then
   true
 else
   false
 Endif
if myocardial_infarction then
    whatever action or message
else
    whatever action or message
endif
```

Example of GELLO encoding a simple guideline.

Knowledge Integration (KI)

$KM \rightarrow Knowledge Integration$

Setting	Target users	Workflow context	CDS content
Inpatient	Clinicians	Computerized order entry	Drug–allergy contraindication alert Drug–drug interaction alert Drug dosage recommendation or alert Corollary order recommendation Order set presentation
		Laboratory result entered into system	Page to responsible clinician regarding critical lab values
	Pharmacists	Medication order processing	Drug–allergy contraindication alert Drug–drug interaction alert Drug dosage alert
Outpatient	Clinicians	Review of patient information Encounter documentation E-prescribing	Patient summary with disease management and health maintenance recommendations Documentation template containing data collection and action recommendations Drug–allergy contraindication alert Drug–drug interaction alert Drug dosage recommendation or alert
	Nurses Patients	Patient intake Between visits	Standing orders (e.g., for vaccination) Letter or phone call to remind patient of overdue health maintenance procedures

Commonly leveraged CDS opportunities within the clinical workflow



Case Studies (Indiana, Vanderbilt, Harvard, Utah)

Clinical Decision Support Systems



Regenstrief Institute

(Indiana University)

History of Regenstrief Medical Record System (RMRS) CDSS

Clinical Decision Support Systems

Case Studies → **Indiana** (cont.)



The first **Regenstrief mainframe**, a PDP-11/44.

An example of a reminder report.

Processes that ran overnight culled through medical record data to generate these printed reports used during subsequent patient encounters

SURVEILLANCE	REPORT	09-JUN-76
PATIENT'S NAME		
OBGERVE		
PVC SZATA		
	COBID" (DIOURIN)	
	De- (LENTE U 100)	
	08" (LENTE U 100)	
CONSIDER	D (DIOOX	IN>
AL CAUL OF CAULAC A 13-FED-75 PVC'S/MIN-0	NHYTHMIA SINCE L	AST "PVC'S/MIN" > 2
DIGOXIN		
BECAUSE OF THESE AND	NISK OF DIG TOXIC	TTY SINCE LAST
	1911 8- 2.25	
K+SPARERS (DYAZ	IDE)	



An early Medical Gopher station in Wishard Memorial Hospital



Screen shot from the first version of the Medical Gopher. It provided an immediate forum to generate <u>reminders in real time</u> for providers as they ordered therapies for patients.

An example of suggested orders in the Medical Gopher based upon cost and efficacy data.

Suggestion after ordering an expensive SSRI antidepressant

Gopher Console					
TEST3, PATIENT 999-3 M W BACKLOAD Order# 000K, .67s 01/05/04 09:43A Action FLUOXETINE (Price = \$0.04) 1) ORDER Generic fluoxetine at Wishard is \$0.04 per 10 mg or 20 mg cap. Generic tricyclics are also inexpensive and may be tried first in most patients. Fluoxetine has no beneficial effect on neuropathy.					
RECUTTENDED BLOCKING ORDERS SSRIs among top \$ drugs at Wishard — \$900,000 per yr for sertraline and \$600,000 per yr for paroxetine. Generic fluoxetine only 3 cts for 10 or 20 mg caps compared to paroxetine (\$2.70 for 10 mg, \$1.40 for 20 mg,\$1.44 for 30 mg) or sertraline (\$1.50 for 100 mg and \$1.49 for 25 mg)					
1. OMIT FLUOXETINE If pt meets one of the following P&T criteria for use (pregnancy, 5 wks between d/c of fluoxetime and start of MAOL, drug interaction with fluoxetime, ADR or allewgy to fluoxetime, preexisting sexual dysfunction or anorexia secondary to a medical condition, stable on other SSRL) - may order 2. OMIT SERTRALINE If this is a Revise or Renew RX and the patient has been on SSRL for >= 6 mo consider tapering SSRL and evaluating for necessity of continued antidepressant therapy If restarting an SSRL use 3. OMIT FLUOXETINE unless the patient meets one of the criteria above Other SSRLs available at Wishard 4. OMIT CITALOPRAM 5. OMIT PAROXETINE					
4=Select Order, Number=Action, F3=Edit Order, F8=Accept All, ESC					
Esc Enter Store Clear Restore Edit Suspend IoDo INQ PgDn HeTp \Longrightarrow					

Gopher Console			- D X			
TEST3, PATIENT 999-3 BACK	LOAD Order#	000K, .13	s 01/04/04 08:42PM			
1.Patient ID 2.Date 3 999-3 04 JAN 2004 0 7.Main Reason 8	Time 4.Patient' 18:25PM C5 Any Orders	s Ward5.Bed# W6155	A MAMLIN, BURKE			
9. Rxs 10	9.Rxs 10.Tests 11.0					
1. KETOCONAZOLE 200 mg > 1.	1.					
1) WARNING - CISAPRIDE can be dangerous in patient with : KETOCONAZOLE. ESC to cancel, ENTER to proceed : 2						
<pre><esc> <ent> <store></store></ent></esc></pre>						
1) Continue ordering CISAP						
2) Explain interactions with 2) Pack out of this order		MULIN REGULAR				
D ORDERS						
3) FERROUS SULFATE 28) IV LOCK (heparin flush)						
4) RANITIDINE	29) K CI	29) K CL INJ				
Other Rx options	30) LORA	0) LORAZEPAM				
5) ACETAMINOPHEN	31) LORA	ZEPAM INJ				
6) ADMISSION ORDER MENU LOW	ACUITY 32) Mg-A	11 Hydroxides	Susp			

Drug-drug interaction

C	Gopher Console								
	rest3, Pai	LIEN	T 999–3	BACKLOAD Ord	der#	000K,	. 13s	01/04/04 =Page 1 of	08:43PM
	1.Patient	ID	2.Date	3.Time	4.Patient	s Ward5.	Bed#	6.Doctor	
l	CISAPRIDE <> KETOCONAZOLE								
	Serious cardiac arrhythmias including, vtach, vfib, torsades de pointes, and QT prolongtion EFFECT: Decreased metabolism of cisapride leads to inc serum concentrations of cisapride MECHANISM: MAJOR-cardiotoxicity CLIN SIG: Concurrent use is CONTRAINDICATED-fatalities have occurred								

Drug-drug interaction details



CDSS in Practice (*Diagnostic DSS, Patient DSS, Population DSS*)

Clinical Decision Support Systems

Population DSS (Pop-DSS)

Population DSS \rightarrow **Introduction**


Population DSS \rightarrow **HIE and Population HIT** \rightarrow **Clinical Informatics**



Population DSS \rightarrow **HIE and Population HIT** \rightarrow **Public Health Informatics**



Population DSS \rightarrow **HIE and Population HIT** \rightarrow **HIE Role**



Population DSS \rightarrow **HIE and Population HIT** \rightarrow **Population Health Informatics**



Population DSS \rightarrow **HIE and Population HIT** \rightarrow **CDS Continuum**





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Population DSS \rightarrow **Groupers** \rightarrow **eACG (EHR-based ACG)**

acg.jhsph.edu

 ACG system offers a unique approach to measuring morbidity that improves accuracy and fairness in evaluating provider performance, identifying patients at high risk, forecasting healthcare utilization and setting equitable payment rates.



Population DSS → Groupers → eACG (EHR-based ACG) (cont.)

- Billions of dollars per year are now routinely exchanged using ACGs in almost every US State and in 16 + nations. Healthcare of as many as 100+ million patients is actively managed and monitored using ACGs on all continents. Over 700+ peer reviewed articles have been published that apply and evaluate ACGs.
- Other EHR-only data: Lab results; Vital Signs; Medical and Family history...
- New applications: Real time population health / community surveillance; Real time clinical action for individual consumer; Functional Status / Frailty



Clinical Decision Support Systems

Population DSS \rightarrow **Groupers** \rightarrow **ACG History (1975 – 2015)**





Population DSS → VHA Population Health Framework and BMI Trajectory

- Aim (1): Contextualize obesity factors within **VHA's population health framework**
- Aim (2): Design a scalable pop-health 'technical' platform and develop a pilot for obesity
- Aim (3): Derive and evaluate "VHA's Obesity Trajectory Population-based Risk Prediction Model" to measure the GIS-clustered population-based factors that affect the management of obesity









Population DSS → VHA Population Health Framework and BMI Trajectory (cont.)



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Population DSS → VHA Population Health Framework and BMI Trajectory (cont.)









Name	Owner
VHA Corporate Data Warehouse	VHA
American Community Survey	Census
Census 2010	Census
National Health and Nutrition Examination Survey	CDC
Food Access Research Atlas + Others	USDA
National Vital Statisitcs Report	CDC
Reference USA	RefUSA
Open Street Map	OpenMap
Moderate Resolution Imaging Spectroradiometer	NASA
Consumer Expenditure Survey	BLS
Uniform Crime Reporting Statistics (FBI)	FBI
Maryland Food Systems	MD
USDA Detailed Maps Baltimore	USDA
ArcGIS Internal Datasets	ESRI
Satellite data	Google

Interactive Web-based Real-time Geo-Temporal Exploration of Obesity Data (Showing averages of 2014 for MD)



CDSS Legal

CDSS Legal

- Negligence theory (malpractice) holds that service providers must uphold the standards of the community for quality and reliability.
- Strict product liability (injuries and compensation) applies when the <u>purchaser is</u> <u>harmed as a result of a defect</u> in that product.
- Since the patient and not the care provider is the individual who physically suffers from errors in the clinical process while the purchasers are the care providers, it <u>could be</u> <u>argued that strict product liability would not</u> <u>apply to DSS systems</u>.



CDSS Legal (cont.)

- Formal legal precedents for dealing with clinical decision-support systems are lacking at present.
- Under negligence law (which governs medical malpractice), a product or activity must meet reasonable expectations for safety. The principle of strict liability, on the other hand, states that a product must not be harmful.
- As with other medical technologies, physicians will be liable in such circumstances if the use of consultant programs has become the standard of care in the community.
- The evaluation of complex decision-support tools is challenging; it is difficult to determine acceptable levels of performance when there may be disagreement even among experts with similar training and experience.
- Current policy of the Food and Drug Administration (FDA) in the United States indicates that such tools will not be subject to federal regulation if a trained practitioner is assessing the program's advice and making the final determination of care (in contrast medical devices are subject to federal laws)

CDSS Legal (cont.)

- FDA identifies four types of devices:
 - Educational and Bibliographic Software (<u>exempt</u> from regulation)
 - Software intended only for use in performing traditional library functions
 - ► Accounting, communication, educational software
 - Software Components (incorporated in medical devices <u>regulated</u>)
 - infusion pumps; pacemakers; ventilators
 - magnetic resonance imaging devices; diagnostic X-ray systems
 - clinical laboratory instruments; blood grouping instruments
 - **Software Accessories** (attached to medical devices <u>regulated</u>)
 - radiation treatment planning; conversion of pacemaker telemetry data
 - conversion, transmission or storage of medical images
 - off-line analysis of EEG data; digital analysis of EEG data
 - calculation of rate response for a cardiac pacemaker
 - **Stand-Alone Software** (CDSS regulation is <u>debated</u>)
 - blood bank software systems
 - ▶ DDSS, CDSS, HIS, EHR, EMR

CDSS Legal (cont.)





Additional Resources

Resources – Books



Title	Change the name of the book!
Authors	Robert A Greenes
Year	2007 / 2011
Hardcover	Yes
Publisher	Elsevier
Language	English
ISBN	978-0-12-369377-8

Resources – Web

Associations:

- AMIA (American Medical Information Association): www.amia.org
- IMIA (International Medical Information Association): www.imia-medinfo.org
- HIMSS (Healthcare Information and Management Systems Society): www.himss.org
- Academy Health (HIT Interest Group): www.academyhealth.org

Government and Non-for-profit:

- ONC: www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds
- Open CDS: www.opencds.org
- HIMSS: www.himss.org/library/clinical-decision-support
- AHRQ: healthit.ahrq.gov/ahrq-funded-projects/clinical-decision-support-cds-initiative

Journals:

- JAMIA (Journal of AMIA): jamia.bmj.com
- JMIR (Journal of Medical Internet Research): www.jmir.org
- IJMI (International Journal of Medical Informatics): www.ijmijournal.com
- HIJ (Health Informatics Journal): jhi.sagepub.com
- ACI (Applied Clinical Informatics): aci.schattauer.de

Summary

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