

CHI • Centre for Health Informatics

## Standards for Electronic decision support In Australia – from inter-operability to safety

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## Categories of DSSS

- **Level One:** Provides categorised information that requires analysis by users.
- **Level Two:** Presents trends of patients' changing clinical status and alerts to out-of-range
- **Level Three:** Uses inference engines to operate on a specific knowledge
- **Level Four:** learning capabilities

• Full EDSS Report [www.health.gov.au/healthonline](http://www.health.gov.au/healthonline)

## Potential benefits from EDSS

1. **Improved patient safety** eg
  - reduced medication errors, adverse events
  - improved medication and test ordering.
2. **Improved quality of care** eg
  - increasing time for direct patient care
  - increased application of clinical guidelines, facilitating use of evidence
  - improved clinical documentation and patient satisfaction
3. **Improved efficiency in health care delivery** eg
  - by reducing costs through faster order processing, reductions in test duplication
  - decreased adverse events
  - changed patterns of drug prescribing favouring cheaper but equally effective brands.

## Status of EDSS Worldwide

1. Literature review of EDSS
2. Selective Medline search for EDSS that:
  - i. Are in routine use
  - ii. Are used by clinicians
  - iii. Used within the last 5 years
  - iv. Provide clinical rather than management support
  - v. Are not embedded into medical instruments
3. 55 papers identified

## Percentage of EDSS in the reviewed literature at each of the four system levels (N=55)

Level	Percentage
Level 1	16.4%
Level 2	20.0%
Level 3	60.0%
Level 4	3.6%

## Settings in which reviewed EDSS were implemented (N=55)

Setting of Projects	Percentage
Hospital	54.6%
Laboratory	21.8%
Primary Care	16.4%
Hospital Pharmacy	3.6%
Specialist Rooms	1.8%
Community Pharmacy	1.8%

### Countries in which reviewed EDSS were implemented (N=55)

Location	Percentage
USA	54.6%
UK	10.9%
Norway	7.3%
Canada	3.6%
France	3.6%
Netherlands	3.6%
Sweden	3.6%
Finland	1.8%
Germany	1.8%
Ireland	1.8%
Japan	1.8%
Spain	1.8%
Thailand	1.8%

### Impact of EDSS in evaluation studies reviewed (n=55)

	Impact measured (number of studies)		Impact not measured (% of studies)
	Improvement demonstrated	No significant impact	
<b>Process variables</b>			
Decision Confidence	12	3	40 (73%)
Patterns of care	15	4	36 (66%)
Adherence protocol	10	4	41 (75%)
Efficiency/Cost	10	2	43 (78%)
Adverse effects	12	3	40 (73%)
<b>Clinical outcomes</b>			
Morbidity	1	5	49 (89%)
Mortality	0	3	52 (95%)

### Inventory of Australian EDSS

- Initial contact list of 125 names
- Same inclusion criteria as lit review
- Telephone interviews identified
  - 30 systems in first draft report
  - 35 systems in final draft report
  - 36 systems currently

### Project settings by location

Project location	Setting of projects							Total No
	Prim Care	Hosp	Hos Pharm	Comm Care	Comm Pharm	Path	Multi	
Multistate	8	2			1	2	4	17
NSW	2	3		1				6
Victoria	3	2					1	6
Queensland		1						1
WA								0
SA	1	1						2
Northern Territory		1						1
Tasmania					1		1	2
<b>Total (%)</b>	<b>14 (40)</b>	<b>10 (28)</b>	<b>0</b>	<b>1 (3)</b>	<b>2 (6)</b>	<b>2 (6)</b>	<b>6 (17)</b>	<b>35 (100%)</b>

### Levels of decision support and estimated frequency of use

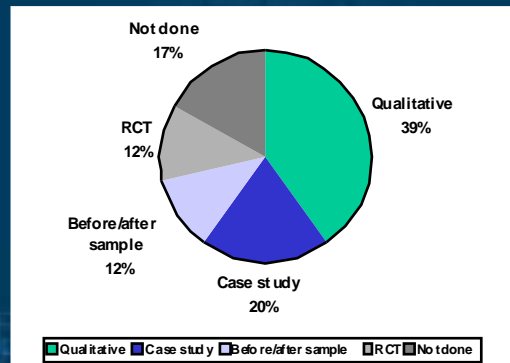
Setting	N	Level of support				Frequency of use			
		L1	L2	L3	L4	<10	10-100	>100	
		Primary Care	14	4	9	1		1	2
Hospital	10	4	4	1	1			5	5
Community	1	1							1
Hosp Pharm	0								
Comm Pharm	2	1	1					1	1
Pathology	2				2	1	1		
Multiple	6	5	1			1	2	3	
<b>Total (%)</b>	<b>35 (100%)</b>	<b>15 (43)</b>	<b>15 (43)</b>	<b>2 (6)</b>	<b>3 (9)</b>	<b>3 (9)</b>	<b>11 (31)</b>	<b>21 (60)</b>	

### Systems functions and knowledge sources

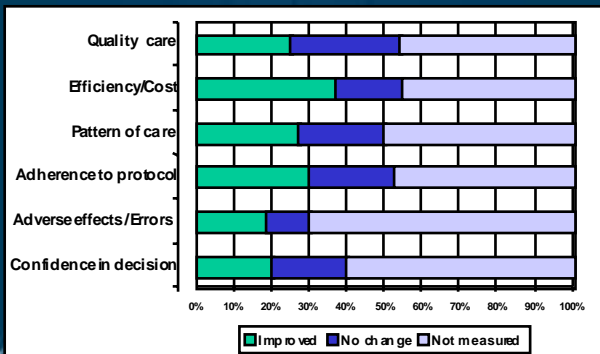
Setting	No of systems	System functions					Knowledge sources		
		Info retrieval	Alerts	Diagnosis	Therapy	Clin audit	Published	Commercial	In-house
Primary Care	14	14	4	5	9	4	9	3	7
Hospital	10	9	6	2	7	4	6	7	7
Community Care	1	1	1				1		
Hospital Pharmacy	0								
Community Pharmacy	2	1	2		1	1	1	2	1
Pathology	2		1	2	1				2
Multiple settings	6	1	3		1	2	4	1	3
<b>Total (%)</b>	<b>35 (100%)</b>	<b>26 (74)</b>	<b>17 (48)</b>	<b>9 (26)</b>	<b>19 (54)</b>	<b>11 (31)</b>	<b>21 (60)</b>	<b>13 (37)</b>	<b>20 (57)</b>

## How safe and effective are our systems?

## Evaluation methodologies



## Process measures used



## Limitations of Evaluation Studies

- Few studies done
- Majority of studies undertaken in the United States
- Most focused on POE (eg prescribing support) thus evidence of the impact of other EDSS is limited
- Most EDSS internally developed and customized
- Concentration on technical and functionality issues, explain less than 20% of IT failures
- Evidence that even good systems will not be adopted unless organisational and professional (eg work practice) issues are understood and addressed
- Improvements in compliance with guidelines evident, however compliance is variable and related to many factors

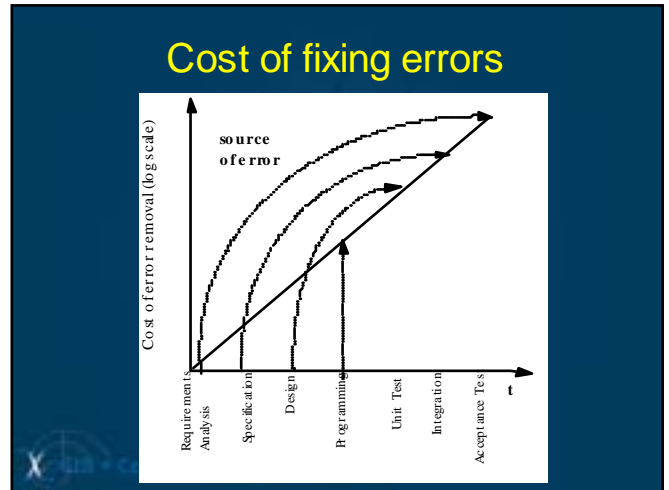
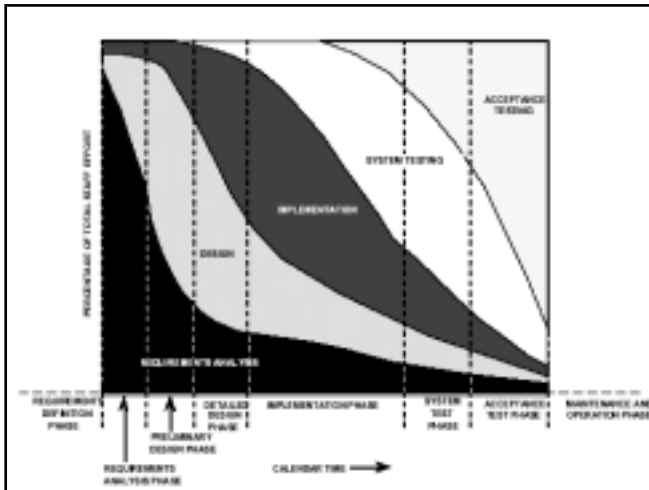
## Taskforce EDSS lifecycle

1. Knowledge synthesis
2. Knowledge representation <- **STANDARDS**
3. System design, implementation
4. Knowledge usage
5. Evaluation of outcomes

A linear model – “get the knowledge right and wrap it up in software”.

## Stages in EDSS development

1. Requirements analysis
2. Functional Specification
3. Architecture Design
4. Software Programming
5. Unit Test
6. System Integration
7. Acceptance Test.
8. User Training
9. Outcomes Assessment



## The role of standards

- Interoperability:
  - to facilitate sharing data, knowledge, inferences between systems
  - Technical compliance test “in vitro”
- Safety/effectiveness
  - to mandate satisfactory performance
  - Operational compliance “in vivo”

## Where can we apply standards to EDSS?

### 1 - Development process assessment

What process was used to develop the EDSS?

- Did it comply with best practice standards of evidence synthesis and software development?
- Is adequate documentation available?
- What maintenance procedures are in place to assure us that as the evidence base changes, the EDSS keeps up with new knowledge?
- Checks of the evidential basis of an EDSS would also fall within this category.

### 2 - Mechanism assessments

Is the system well constructed?

- We look inside the EDSS system, and determine if its components are well built.
- What knowledge representation schema are used
- Does EDSS use a recognised terminology or ontology?
- Is its knowledge base syntactically and semantically correct?

### 3 - Functional assessments

How does the system perform when it is used?

- We look at the EDSS as a black box, and are interested in the system's outputs, given a specific set of inputs.
- These 'in-vitro' laboratory assessments might consist of running the EDSS against standardised tests.

### 4 - Operational assessments

How does system perform in the real world?

- Does its in-vitro functional assessment translate to in-vivo performance in the real world?
- Is it useable within the resource constraints of the clinical context eg how long does it take to get an answer?
- How much training is needed to ensure operators are experienced?
- How easy is it to check the reasoning behind the system's suggestions?
- How does it interact with other software systems eg patient data systems that may link to it?

### 5 - User assessments

How competent is a user to operate the EDSS?

- Have they undergone accredited training?
- Are they aware of the limitations of the system, its typical error modes,
- Do they understand when to seek further advice when they are unsure about the advice offered by the system?

### Interoperability and Safety/Effectiveness standards

- Are (relatively) orthogonal:
  - A safe system may not interoperate
  - An interoperable system may not be safe
- We need to have standards for BOTH
- Safety will be a higher priority issue to the public and to government
- How do we strike a balance in implementing both given our resources?