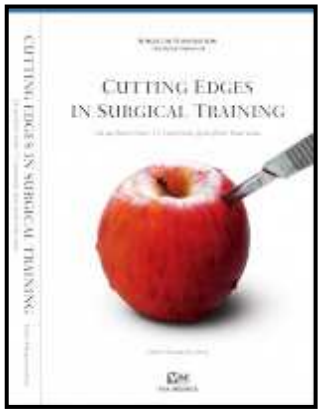
Full **L**ife-cycle **C**urriculum **D**evelopment
Breaking **D**own the **S**ilos

2nd World Congress on Surgical Training

Gothenburg, Sweden

16-19 June, 2013



Presenter Financial Disclosure Slide*

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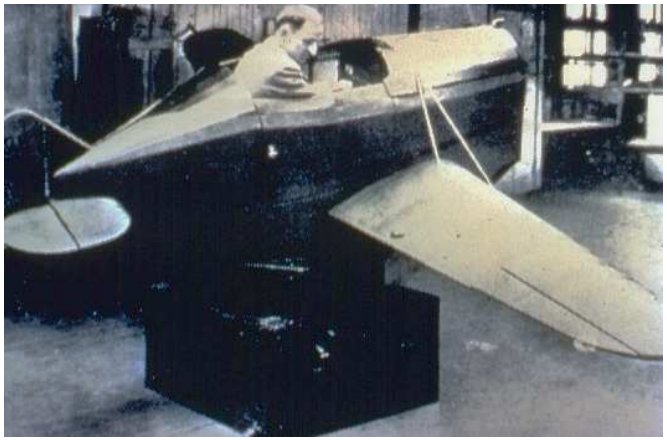
Financial Support:	None (… but still hoping !)
Consulting:	*Ethicon Endosurgical
Grant Support	Intuitive Surgical, Inc (educational grant)
Investment	*InTouch Technologies, Inc

* There will be no discussion of products from these companies8*

Simulation
An 86 Year Heritage*

- 1927 First simulator (flight) with a curriculum (course) = Link Trainer
- Behavioral Psychologists, Psychometricians and Statisticians
- US Army Air Command



Edwin Link – Link Simulator 1927

* These are the expressed views of the presenter and do not reflect official policies of the Department of Defense (DoD), the US Army or other federal agency.

Simulation

Dateline June 18, 2013

Headlines that did not make the news

June

1985 Gaba DM, DeAnda A A comprehensive anesthesia simulation environment: re-creating the operating room for research and training. *Anesthesiology* 1988 Sep;69(3):387-94

1987 Ethicon Endosurgery awards educational grant for first virtual reality surgical simulator

1991 The Southern Surgeons Club. A prospective analysis of 1518 laparoscopic cholecystectomies. N Engl J Med 1991;324:1073-1078.

1993 Virtual Reality Surgical Simulation: The First Steps. Satava RM. Surg Endosc 1993: Jun p 203-05 (Submitted June, 1991)

1999 _____. To Err is Human: Building a Safer Health System. National Academy Press; Washington DC, November, 1999

2002 Seymour NE, , Gallagher AG, Roman SA, O'Brien MK, Bansal VK, Andersen D, Satava RM. Virtual Reality Training Improves Operating Room Performance: Results of a Randomized, Double-blinded Study. Ann Surg 236: 458-64, 2002

2006 American College of Surgeons accredits 7 Accredited Educational Institutes

2013 *NY Times:* Over 3,300 Patients from Medical Errors in USA Hospitals Today

Washington Post: 10 Boeing 747 airplanes crash in accident, killing over 3,300 passengers

Definitions (OED*)

1. Outcomes Measures: *[descriptive] quantifiable consequence(s) of an action, set of actions, or procedure*
2. Metrics: *a set of figures [numbers] or statistics that measure results.*
   a. Quantitative*: a value or component that may be expressed in numbers*
   b. Qualitative*: distinctive [unambiguous] attribute or characteristic possessed by something*

1. Training: *the action of teaching a person a particular skill or type of behavior*
2. Assessment: *the measurement of a learner's potential for attainment, (or their actual attainment) . . . of performance*
3. Test: *a procedure intended to establish the quality, performance, or reliability of something, especially before it is taken into widespread use*
4. High Stakes Test: *a test with important consequences for the test-taker.*

* Oxford English Dictionary

Definitions*

Curriculum	1. The subjects comprising a program of study in a school or college 2. The content and specifications of a course of study
Competent	Having the necessary ability, knowledge or skill to do something successfully
Proficient	A high degree of skill or expertise
Expert	Being very knowledgeable or skillful in a particular area
High Stakes Test	Test that has major consequences or is the basis of a major decision [Conducted by an independent, external body]
Certification	Confirmation that a certain level of achievement has been reached [Awarded by an accredited authority after high stakes test]

* Oxford English Dictionary

Definitions*

Outcomes Measure

Quantifiable consequences of an action, set of actions, or procedure
[The final result that is to be measured
[Time, speed, accuracy, leadership, communication skill]

Metric

The mathematical description of a entity, object, location, etc possesses some notional property, as observed by an individual or group: [seconds, mm, repeats command (unambiguous)]

Score

Number of points, goals,, etc. achieved ... during performance . . .

Benchmark

A point of reference against which things may be compared
[This is NOT the score Score = 100%]

Standard

Performance metric set by an accreditation body
This is an “external” metric

Training

Act of teaching a particular skill or type of behavior
The faculty member actively instructs

Assessment

Evaluation of the nature, ability, or quality of performance
[The faculty only observes- (if feedback given, then it is considered teaching or training]

Outcomes Measures and Metrics

Outcomes Measures

- The prime determinant of the entire educational process
- Set by key stakeholders in training & certification (societies, boards, etc)
- Measures include correct and incorrect (errors)
- Must be unambiguous, measurable, relevant and practical

Metrics

- Must support an outcomes measure ("no measurement, no metric")
- Useful both in training and assessment (formative feedback)
- Used in generating final results reporting (summative feedback)
- Applicable to high stakes testing
- Quantitative whenever possible – accurately measurable or binomial
- If Qualitative, unambiguously defined (for IRR$\geq$ 0.80)

* Once determined, can be used by industry to build a simulator

Fundamental Principles

Training and Assessment

are

Two sides of the Same Coin

Fundamental Principles

Objective Metrics

and

Training to Proficiency

Standardized Curriculum (Course)

Suggested template

- Outcomes &Metrics
- Anatomy
- Steps of Procedure

Cognitive
- Knowledge
- Psychomotor
- Team & commo

- **Errors** [avoid, recognize, remediate]

TEST

- Skills Training [Psychomotor, Team Training & Communication
- Outcomes Reporting

ASSET Curriculum Template

(Adopted for the FRS curriculum development)

Course

- Needs Assessment (Requirements Document)
  - Inventory and Gap Analysis (see separate pre-course template)
  - Goals and Objectives
- Outcomes Measures
  - Includes Societies, Boards, ACGME, etc input to determine outcomes measures
  - Benchmarked to criterion measures by experienced/expert surgeons/physicians
  - Criterion - unambiguously defined with quantitative measures
- Didactic Component (Cognitive skills)
  - Pre-didactic suggested readings
  - Anatomy or laboratory model description
    - Task deconstruction & task analysis to develop procedural steps & assessment tools
    - Steps of Procedures
      - Skills and Techniques
      - Supplies, equipment and set-up
    - ERRORS - unambiguously described with quantitative measures

- PRE-TEST (before skills training begun)

- Technical Skills Training (Psychomotor skills AND team training skills)
  - Formative assessment with feedback
  - Summative Assessment with feedback
  - Competency –based set by repetition until benchmark criteria met – 2 consecutive trials
- Debriefing
  - Review errors and learning curve
  - Outcomes Measures Results Reporting

Participating Organizations

- ***American Association Gynecologic Laparoscopy (AAGL)*** +
- ***American College of Surgeons (ACS)*** +
- American Congress of OB-Gyn (ACOG)
- ***American Urologic Association (AUA)*** +
- American Academy of Orthopedic Surgeons (AAOA)
- American Assn of Thoracic Surgeons (AATS)
- American Assn of Colo-Rectal Surgeons (ASCRS)
- American Assn of Gynecologic Laparoscopists (AAGL)
- **Florida Hospital Nicholson Center** *
- **U.S. Department of Defense (DoD)** *
- U.S. Department of Veterans Health Affairs (VHA)
- **Minimally Invasive Robotic Association (FRS-MIRA)***
- Society for Robotic Surgery (SRS)
- ***Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)*** +
- American Board of Surgery (ABS)
- Accreditation Council of Graduate Med Education (ACGME)
- Association of Surgical Educators (ASE)
- Residency Review Committee (RRC) – Surgery
- Residency Review Committee - Urology
- Royal College of Surgeons-Ireland (RCSI)
- Royal College of Surgeons-London (RCSL)

*** Funding Organizations**
+ Executive Committee

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Errors

Definition

"the state or condition of being wrong in conduct or judgment" - OED

"a deviation from accuracy or correctness" (does not imply "fault")

Characteristics

- Very difficult but important to unambiguously define
- May be individual or 'system" and overt (immediate) or latent
- Can be with or without "*consequences*" (James Reason "Human Error")
- Not all errors are relevant – define minor and critical errors
- Mistake - a fault from misjudgment, carelessness, or forgetfulness

Application

- Arguably the most important measure of skill or judgment
- Fundamental principle behind patient safety (No errors)
- Must train student in most common errors (avoid, recognize, remediate)

Subject Matter Experts

Profession of the Participants

1. Clinical nurses active in curriculum development
2. Medical Educators
3. Behavioral Psychologists, Psychometricians and Statisticians
4. Representatives of: Surgical societies, international surgical societies, certifying boards, federal regulators in accreditation
5. Engineers, computer programmers, simulation experts

   (*If building a device to support the training)*

Setting Measures, Metrics and Assessment

Consensus Conference Methodology

1. Subject matter Experts (SME) chosen on scholarly activity (literature review, publications, workshop participation in standards/curriculum, conference presentations, etc), in addition to clinical acumen and/or position in the various governing organizations. Representatives of 12 surgical societies were chosen by the societies, frequently the chair of their education, curriculum and/or research committee.

2. Consensus Conference convened as 2 day workshop

3. Use of Modified Delphi method (communal brainstorming) to identify elements (outcomes, tasks, etc) during consensus conference

4. Classic Delphi method (anonymous) afterwards (via email) to refine element matrix, with multiple iterations until consensus achieved

Methodology for Consensus Conference

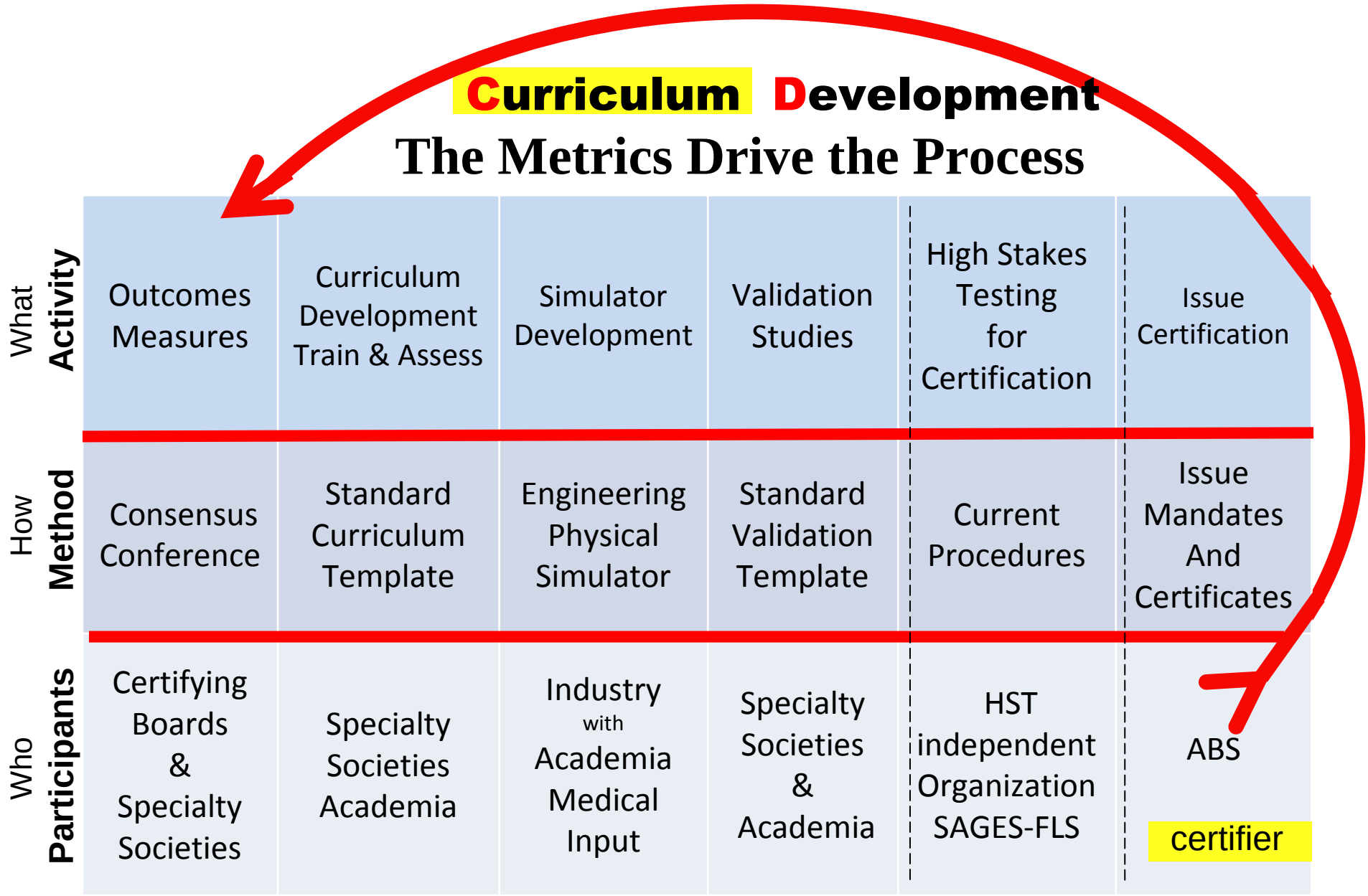
1. Modified Delphi Method (in person)
    a. Select subject matter experts (SME)
2. Classic Delphi Method (via email)
    a. Includes participants from each conference (cumulative)
3. Public Forum (when indicated)

Methodology for Full Life-cycle Curriculum Development

Criteria Consensus Conferences

1. Outcomes Measures (Conf #1)
2. Curriculum Development (Conf #2.0 & 2.5)
3. Validation Study Design (Conf #3)
4. Validation Trials
5. High-stakes Testing (HST) (Conf #4 –Separate from Curriculum)

Full Life Cycle Development



Role for Developing Metrics

Each component has a different need for assessment and metrics

DEVELOP CURRICULUM				VALIDATE	HST	CERTIFY
OUTCOMES MEASURES	DIDACTIC COGNITIVE	PSYCHOMOTOR SKILLS	TEAM TRAINING	VALIDATION TRIAL	HIGH STAKES TEST	LICENSE

Metrics need input by training & certifying or licensing bodies	Metrics developed for the outcomes need to be consistent across the different components of the curriculum development	Benchmarks for metrics are set by experts at beginning of trial	Metrics set by indepen-dent testing body	If HST results poor - feedback changes metrics

Outcomes Measures Methodology

Defining the required skills and tasks

Task Deconstruction - Task Analysis

Methodology for identifying outcomes measures

	Tasks and Sub tasks	Outcomes Measures	Metrics Quantitative or Qualitative	Common Errors Assessment Tools	Measurement Methodology Assessment Tools
Cognitive Skills	Identify structures of Calot Triangle	Common Duct, Cystic Duct, cystic artery	Must identify all 3 structures	Not identifying all three structures	Question/answer Identify on image
Psychomotor Skills	Laparoscopic knot tying	Two throws, does not break, Knot tight	Surgeon knot first throw Second knot tight Total 4 knots Total time 2 min	Suture breaks Knot slips >0.5kg force applied Not surgeon knot Unable to complete in 2 minutes	Broken suture Grasp one end of suture, apply 0.5kg force (measured Time Observed or video
Team Training Skills	Position instrument ports	Communication between surgeon, assistant and nurse	Assistant receives trocar from nurse Assistant confirms site with surgeon	Trocar not available Assistant places port without confirmation from surgeon	Observe real time or though video analysis Unambiguously defined check list

Principles of psychomotor skills exercise design

1. Multiple learning objectives that incorporate multiple tasks
2. Agnostic to type of device
3. Easy to administer (to insure Inter-Rater Reliability (IRR))
4. Cost effective (multiple tests/module)
5. High fidelity or real physical models for test mode. Training can be lower fidelity
6. VR and physical models are derived from same CAD/CAM model.
7. Preference for tasks that have existing evidence of validity

Psychomotor skills matched to psychomotor tasks

Skill \ Task	Running suture	Dome with four towers	Vessel dissection + clipping	UTSW 4th arm retraction + cutting	Energy and Mechanical cutting
Eye hand instrument coordination	S	P	S	S	S
Needle Driving	P				
Atraumatic handling	S	P	P	P	S
Safety of operative field			S		
Camera		P			
Clutching		P			
Dissection (Fine/Blunt)			P		
Docking					
Knot tying	P				
Instrument exchange					
Cutting			P	P	P
Energy sources					P
Foreign body management					
Suture handling	P				
Wrist articulation	P	P	S	S	S
Multi arm control				P	
Clip applying			P		

P = primary skill that task measures S = secondary skill that task measures

Developing the Didactic Section from the Skills/tasks

From outcomes measures to didactic portion of curriculum

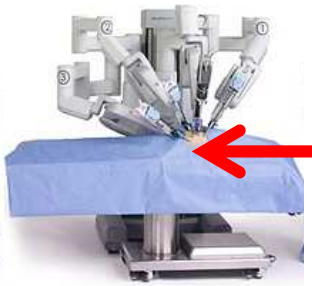
Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
Situation awareness	Awareness of the status and readiness of the people and equipment essential to the operation.	Unaware of Robot-Patient-Assistant –team state	Maintain awareness of the robotic, patient, and team status that is out of view.	Missed communication. Missed information. Missed changes in patient status and injuries, missed changes in robotic status	0	0	1	8	35	1
Eye-hand instrument coordination	Using the manual controls to accurately manipulate bedside instruments and perform tasks. Passing objects between the instruments.	Ineffective targeting	Efficient hand coordination and accurate and efficient movement of instruments	Time and economy of motion	0	0	3	6	33	2
Needle driving	Accurate and efficient manipulation of the needle.	Tearing tissue, Troughing the needle, Needle scratching, Wrong angle on entry/exit, Adjacent organ injury, Needle damage, Needle positioning, Needle dropping, Holding out of field-of-view, Poor accuracy	Accurate and efficient placement of needle through targeted tissue, Following the curve of the needle, without associated tissue injury	Time, accuracy, tissue damage, material damage	0	0	3	6	33	3

Curriculum Development

Didactic Knowledge Skills (Sample)

Skill Title	Description	Desired Presentation Format (Images/checklists/videos..)
Trocars placement:	• Correct choice of trocar • Correct allignment of robotic arm • Correct position of Ports placement ***Errors*** • trocar entrance injury • port-site injury • Not checking for injuries after placement • Tip of the trocar not visualized during insertion • Inserting trocar in areas of previous scars or incisions • incorrect position, spacing and location, • incorrect insertion depth	Video demonstrations of safe use of open cutdown, Verress needle, and Optiview techniques. Ideally video showing injuries occurring Video of arm collisions at the bedside due to inappropriate trocar placement Video or picture showing injury to port site when port not inserted appropriately Images of correct and incorrect port positions (outside view and inside)

Psychomotor Skills Development
Identical simulation for all methods



Real objects for skills on real robot

Real

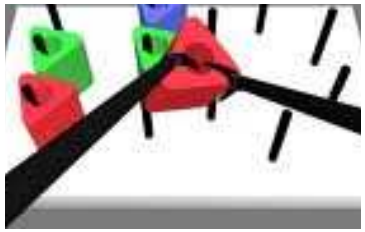
Stereolithography

“Backpack”

Virtual

Virtual objects for skills on real robot

Virtual



CAD/CAM

Virtual

Virtual objects for skills on VR simulator

Virtual objects for skills on VR simulator

Psychomotor Multi-skill Device Design

Requires extending the training to the full capability of the device

Includes same skill set as Fundamentals of Laparoscopic Surgery - FLS

Also includes tasks beyond FLS that are unique to robotic surgery

Consists of 7 specific Tasks that include all 25 Skills

Unique dissection tasks

3-dimensional platform (Dome shape)

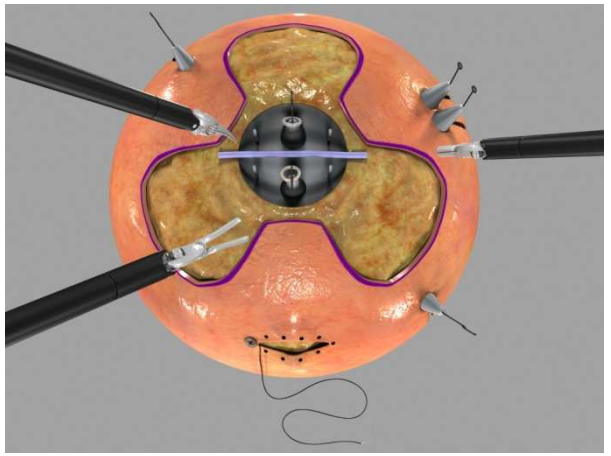
Includes all 7 tasks on single device

Real device created from virtual prototype

Very low cost, compatible with other simulations

Software version is open source

Can “print out” supplies



Team Training and Communication (Sample)

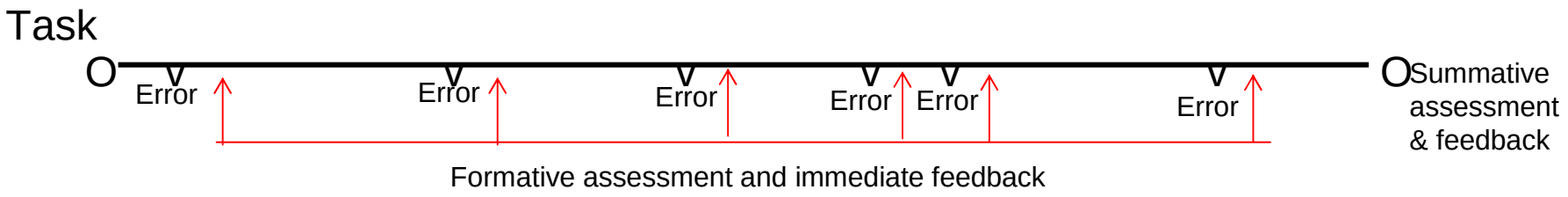
Checklist 1: Pre-operative
Checklist 2: Robotic Docking
Checklist 3: Intraoperative (see below)
Checklist 4: Undocking
Checklist 5: Debriefing

Checklist 3: Intraoperative Checklist (Pauses at Critical Steps in the Procedure and time-based - hourly)

•Is there “call-out”team communication concerning instrument usage and transfer?
•Are all foreign objects accounted for (i.e. white boarding) and removed?
•Are the periodic checks occurring to discuss case progression, team member continuity, and other issues?
•Has there been regular communication with anesthesia?

Assessment Tools
Crucial Principles

- Choose assessment strategy based upon type of behavior and context for rating
- Design the assessment tool to match the fidelity of the training (simple vs complex)
- Training and assessment are two sides of the same coin
- Use formative assessment and feedback as much as possible (ie deliberate practice)



Assessment Tools
Types of Measurements

- Quantitative measures – have numerical measures (metrics)
  - Easy to score
  - Computer-based whenever possible
- Qualitative measures- have descriptive measures
  - using Likert or similar scales (eg, Global Rating, GEARS, etc)
    - must use unambiguous descriptors*
    - more difficult to score to obtain IRR $\geq$ 0.80
- Applies to both correct actions and errors

* Terms such as "poor-average-excellent" or "adequate-inadequate" are too ambiguous

Assessment Strategies
Frequency Measures

- Often binomial – either occurred or did not occur
- Discrete time frame - most valuable when events occur in short time frame (usually seconds) -[see discrete event measures – “chunking”]
  - Some difficulty for “ongoing” or repeated identical events (eg coagulation, dissection, suturing, etc)
  - Good for assessing progress over time (between trials, as in learning curve)
  - Can also give direct quantitative measure (amount of time, pressure, etc

Assessment Strategies
Discrete Event Measures - "Chunking"

- Entire event is discrete– (correct/incorrect performance of entire task
  - one score for entire event/task, not by minute or number of times
  - must have clear beginning and ending (choose correct suture, tying a knot, # of sutures/inch, etc)
- Very good approach for checklist

Assessment Strategies
Interval Recording Measures

Behavior	1	2	3	4	5	6 . . .'n' (mins)
Apply cautery	0	x	x	x	0	x
Burn wrong tissue	0	0	0	x	0	0
Clip cystic duct (prox)	0	0	x	0	0	0
Clip misapplied	0	0	x	0	0	0
Clip cystic duct (distal)	0	0	0	x	0	0
Clip misapplied distal	0	0	0	0	0	0
Cut between clips	0	0	0	0	x	0
Cut common duct	0	0	0	0	x	0

zz

Assessment Strategies Challenges

- Hawthorne Effect - if learner knows they are being assessed, it affects their performance
- Assessment drift - over time, assessor 'drifts' from original criteria, thus need to retrain the assessor
- Assessor bias* * - if a trainer, lenient (teaching mindset), but if an assessor, more stringent (criteria mindset)
- Assessor objectivity - must assess what they see, not what they think learner is capable of

** Although training and assessment are two sides of the same coin, there are different requirements and mindsets for trainer (mentor) and assessor (proctor)

NOTE: During the Pilot Trial of assessment of performance of tasks – include group who created the initial task analysis and definitions

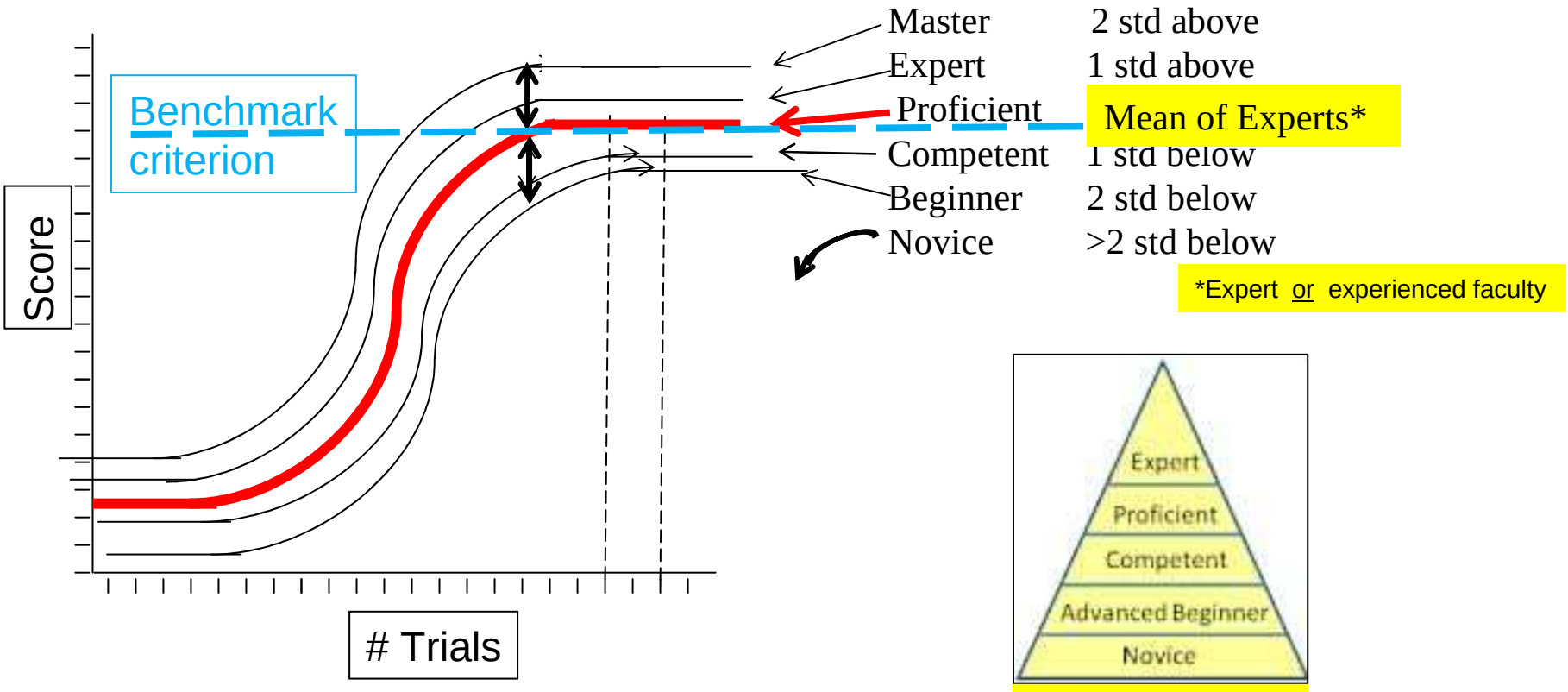
Setting

the

Benchmark

Setting Benchmark Criteria for Any Curriculum

* Applies to all aspects of curriculum including didactic, team training and psychomotor skills



Dreyfus and Dreyfus model

Validation Study Design Conference

Choose "Validity" Types	Outcomes & Metrics	Design Validation Study	Choose Participating Institutions	Determine Benchmark Metrics	Conduct Multi-institutional Trial	Analyze & Publish Results

- Design Validation Trial Criteria
  - Define the validation types (Face, content, concurrent construct, predictive)
  - Define the validation measures
  - Design the study (RCT?)
- Design Multi-Institutional Study
  - 10 independent sites (ACS-AEI accredited Institute)
  - Faculty in at least 3 specialties (8 participants, of which ≥2 are faculty) – n= 250
  - Establish benchmark proficiency criteria by faculty
  - Conduct the trial
  - Analyze and publish results

Questions ?

“Breaking Down the Silos”

New Tools

and

Techniques

Types of Assessment

1. Diagnostic: *measures the learner's achievement on entry to their course of study [baseline] in order to identify their individual learning needs and their strength . . . [and] can be carried out through aptitude tests*
2. Formative: *ongoing process . . . which takes place throughout the learner's course of study and provides them with the [immediate] feedback and guidance necessary to enable them to improve their performance*
3. Ipsative [iterative]: *learners are assessed against their own previous level of attainment.*
4. Summative: *takes place at the end of their course of study, and measures the learner's attainment against the specified learning objectives [outcomes measures] of the syllabus or program*

Requirements for Curriculum

1. Basic skills across all specialties
2. Specialties will develop own independent fundamentals beyond the Basic FRS
3. Skills and tasks leverage off FLS (comparative effectiveness)
4. Robotic device/system agnostic
   a. No skill is dependent upon any existing system
   b. Some skills are planned but not available on existing systems

Subject Matter Experts

1. Clinicians active in clinical practice
2. Medical Educators
3. Behavioral Psychologists, Psychometricians and Statisticians
4. Representatives of:
   a. Surgical societies, international surgical societies (RCS, ACS, etc)
   b. Residency review committees of graduate medical education
   c. Certification & accreditation organizations
      i. surgical boards or surgical societies (eg RCS)
      ii. federal regulators in accreditation
5. Engineers, computer programmers, simulation experts
6. Minister of Defense and Aviation (MoDA)

How to Define/score Errors

Identify	Consensus Conference of “experts”
Define	Unambiguous Test for Inter-rater reliability (IRR $\geq$ 0.80)
Observation	Evaluate specific interval (eg q 1 min) Score “X” for each error each minute Insure IRR $\geq$ 0.80 (repeat if necessary)

ERROR	1	2	3	4	5	6	7	. . .	COMMENTS
Non-visualize Triangle of Calot			x						Poor quality of dissection
Non dissect cystic a.									
Non-isolate cystic d.				x					Jct of cystic-common duct not visualized
Clips on cystic duct crossed						x			Dropped 1 clip, crossed the double clip