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Curriculum "Practice of Cardiac Pacing"

Released jointly by the Board of the German Cardiac Society (GCS) and the German Medical Association (GMA)

Revised on behalf of the Commission on Clinical Cardiology by

Curriculum "Practice of Cardiac Pacing" – Time Schedule

1 Basic Principles (12TU)
1.1 Historical Perspectives of Cardiac Pacing
1.2 Pacing Devices and Codes (NBG-Code)
1.3 Drug Treatment of Bradyarrhythmias
1.4 Pathophysiology/Diagnosis/Differential Diagnosis
1.5 Indications for Permanent and Temporary Pacing
1.6 Fundamentals of Cardiac Electrostimulation
1.7 Implantation Techniques and Complications
1.8 Regulatory and Legal Aspects*

2 Pacing Modes (8 TU)
2.1 Rate Responsive Pacing
2.2 Hemodynamics of Cardiac Pacing
2.3 Device and Mode Selection
2.4 Pacemaker Timing Cycles

3 Pacemaker Malfunction (8 TU)
3.1 Pacemaker Malfunction
3.2 Interference in Cardiac Pacemakers*
3.3 Pacemaker Mediated Tachycardia

4 Programming and Follow-up (12 TU)
4.1 Diagnostic Pacemaker Functions
4.2 Pacemaker ECG Analysis
4.3 Follow-up
4.4 Programming
4.5 Troubleshooting

5 Summative Assessment

1 TU (Teaching Unit) = 45 min.

5 days: Basic Course: 1.1–2.3, Advance Course: 2.4–4.2, Final Course: 4.3–5 (4 days: Basic Course: 1.1–2.4, Advance Course: 3.1–5) (6 days: Basic Course: 1.1–1.8, Advance Course: 2.1–3.3, Final Course: 4.1–5)

The course does not include an instruction in the use of the programming devices of the various manufacturers. This should be done by the supplier in

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* The subjects 'Interference in Cardiac Pacemakers' and 'Regulatory and Legal Aspects' should be presented by a specialist in the field, e.g. a biomedical engineer

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the local clinic or practice or in a separate programmer course.

1 Basic Principles

1.1 Historical Perspectives of Cardiac Pacing

- Brief historical review of cardiac pacing

1.2 Pacing Devices and Codes (NBG-Code)

- Representation of the NBG pacemaker code:
  VVI, AAI, DDD, DDI, VDD, VAT, SSI, SST, and its combinations with rate modulation (xxxR) and/or antitachyarrhythmia functions (xxxxP).
- Explanation of the various applications of the NBG-code:
  - Description of device type (e.g. SSIR),
  - Description of the programmed mode (e.g. DDI in a DDD-pacemaker),
  - Description of the current pacing mode as seen on the surface ECG (e.g. VAT-mode of a DDDR-pacemaker with programmed DDD-mode),
  - Description of a particular pacing system (e.g. 'single-lead'-VDD).

1.3 Drug Treatment of Bradyarrhythmias

- Differential representation of the role of drug therapy in acute and emergency treatment and in long-term treatment.
- Pathophysiologic rationale for using parasympatholytics and sympathomimetics in sinus bradycardia, AV-block and reflex syncope.
- Indications, mode of application, contraindications, possible side effects and risks.
- Review of long-term outcome.
- Special considerations in antiarrhythmic drug treatment of pacemaker patients including drug device interactions.

1.4 Pathophysiology/Diagnostics/ Differential diagnosis

1.4.1 Sick Sinus Syndrome (SSS)

- Classification
  - Persistent sinus bradycardia
  - Bradycardia-tachycardia syndrome
  - Intermittent sino-atrial block or sinus arrest
  - Chronotropic incompetence.
- Clinical symptoms
  Physiology and pathophysiology of the sinus node including its autonomic control, relevance for the interpretation of diagnostic tests, pathological-anatomical findings, etiologic-pathogenetic correlation.
- Non-invasive tests:
  Rest ECG, Holter ECG, exercise ECG (in the diagnosis of SSS, for assessment of chronotropic incompetence).
- Pharmacological tests: Atropine, autonomic blockade, others.
- Invasive tests:
  Estimation of sinus node recovery time.
- Presentation of the various tests including the technical approach, typical results and discussion of possible false-positive and false-negative findings.
- Graduation of diagnostic tests according to their diagnostic significance.
- Definition of chronotropic incompetence.
- Frequency and manifestation of combinations of SSS and AV conduction defects (binodal disease, BND) or carotid sinus syndrome.

1.4.2 AV-Block (AVB), Bundle Branch Block (BBB) and Bradyarrhythmia in Chronic Atrial Fibrillation (BAA)

- Physiology and pathophysiology of the AV conduction system and its autonomic control, pathological-anatomical findings, etiologic-pathogenetic correlation (including bradyarrhythmia in chronic atrial fibrillation, postoperative AVB and AVB after catheter ablation).
- Clinical symptoms.
- Classification of AV block according to surface ECG criteria.
- Classification of AV block according to intracardiac ECG criteria.
- Non-invasive tests:
  Rest ECG, Holter ECG, exercise ECG.
- Pharmacologic provocations: Ajmalin, Disopyramide i.v.
- Invasive Tests:
  Recording of the His bundle electrogram, assessment of the Wenckebach point.
- Presentation of the various tests including the technical approach, typical results and discussion of possible false-positive and false-negative findings.
- Presentation of combinations of AV block and SSS (binodal disease, BND) or carotid sinus syndrome.

1.4.3 Reflex Syncope

- Physiology and pathophysiology of reflex mediated cardiovascular regulation, clinical symptoms, etiologic-pathogenetic correlation.
- Definition of carotid sinus hypersensitivity.
- Definition of carotid sinus syndrome (CSS).
- Definition of vasovagal syndrome/neurocardiogenic syncope.
- Definition of the reflex components (cardioinhibitory/vasodepressor response).
- Technique of carotid sinus massage and interpretation of the results.
- Technique of tilt table testing with and without pharmacologic provocation.
- Demonstration of typical recordings of a pure cardioinhibitory response, a pure vasodepressor response as well as mixed responses of cardioinhibition and heart rate independent vasodepressor component. Evaluation of the differential diagnosis of reflex mediated syncope (vasovagal reaction, neurocardiogenic or malignant vasovagal syncope, orthostatic hypotension, glossopharyngeal neuralgia, deglutition syncope, micturition syncope, other vagally mediated reflex responses, e.g. eyeball-heart reflex, gastrointestinal stretch reflex).
- Presentation of combinations of CSS and SSS or AV-block or chronic atrial fibrillation.

1.5 Indications for Permanent and Temporary Pacing

1.5.1 Indications for *Temporary* Pacing

- In drug induced bradyarrhythmias, bradycardia in acute (inferior) myocardial infarction, postoperatively after cardiac surgery, during catheter ablation, perioperatively during extracardic surgery and in various reversible conditions (e.g. cerebral edema after severe head injury).

1.5.2 Indications for *Permanent* Pacing

- Representation based on the guidelines of the German Cardiac Society.

1.5.3 Presentation of Newer, Currently Evolving and Controversial Indications Pacing for

- HOCM,
- Heart failure and AV block I or interventricular conduction disorder,
- Neurocardiogenic syncope,
- Long QT syndrome,
- Prevention of atrial tachyarrhythmias,
- Rejection diagnosis in orthotopic heart transplantation (including presentation of the pathophysiology and current clinical results).

1.6 Fundamentals of Cardiac Electrostimulation

- Important basic electrical quantities and their relationships (voltage, current, impedance, charge, energy, Ohm's law, etc.).
- Presentation of various pacemaker power sources and their characteristics
  - Cell impedance and discharge curves of lithium iodine batteries,
  - Evaluation of the estimated replacement time (BOS, IRI, ERI, EOS).
- Components, materials and design characteristics of various pacing leads with reference to particular advantages, disadvantages and risks.
- Differences between unipolar and bipolar stimulation and sensing.
- Differences between anodal and cathodal stimulation.
- Biophysical characteristics of the electrode-myocardium interface with relevance to stimulation (charge consumption) and sensing and discussion of concepts for optimizing the pacing system
  - Presentation of the biophysical characteristics of the phase boundary (Helmholtz layer),
  - Influence of fibrous tissue formation on stimulation and sensing,
  - Influence of leakage current on charge consumption and stimulation impedance,
  - Influence of a microporous surface structure and the geometric and electrochemical surface area on sensing, stimulation impedance and threshold,
  - Influence of steroid elution on long-term threshold behavior,
  - Advantages, disadvantages and risks of high impedance leads.
- Fundamental law of electrostimulation:
  - Definition and explanation of chronaxy and rheobase,
  - Methods for calculation of charge and energy consumption,
  - Assessment of a capture safety margin with the strength-duration curve,
  - Monitoring lead performance and comparing different leads using chronaxy and rheobase.
- Calculation of overall charge consumption and longevity.

1.7 Implantation Techniques and Complications

1.7.1 Pre-Implantation

- Patient information and informed consent on
  - Anesthetic, intra-, peri- and postoperative risks,
  - Necessity of regular follow-up visits,
  - Possible pacemaker malfunctions and interference,
  - Possible occupational limitations.
- Choice of anesthetic procedure.
- Indications for site choice: right/left pectoral/abdominal approach considering patients' habits, workplace environment as well as concomitant diseases.

1.7.2 Implantation Technique

- Venous access via the cephalic vein, subclavian vein puncture, (preparation of external/internal jugular vein); epicardial lead fixation
- Lead selection for the atrium and ventricle: active/passive fixation, uni-/bipolar, length, insulation material etc (see also section 1.6).
- Lead placement in the right atrium, right ventricle, coronary sinus: procedure, position confirmation, intraoperative identification of malpositioning.
- Special considerations in pediatric pacing.
- Pacemaker pocket: preparation, fixation of lead and generator, local antisepsis.
- Intraoperative measurements:
  - Stimulation threshold, – Intrinsic signal amplitude, – Slew-rate, – Lead impedance,
  - Testing for extracardiac stimulation.

  For every test presentation of its relevance, the measuring technique and acceptable values for different type of leads and different underlying rhythm disorders.
- Generator change.

1.7.3 Complications

Presentation of typical complications and recommendations for prevention and management

- intraoperative:
  - Asystole, ventricular fibrillation, atrial fibrillation,
  - Myocardial perforation and penetration,
  - Pneumothorax, hemothorax, air embolus,
  - Left heart implantation;
- peri-/postoperative
  - Pocket hematoma,
  - Primary and secondary pocket infection,
  - Primary and secondary infection of the entire pacing system: presentation of diagnosis, approach to infections of the pocket and/or the lead, technique for extraction of chronic transvenous leads (transvenous/surgical approach).
  - Erosion and ulceration,
  - Painful pacemaker pocket,
  - Septicemia, endocarditis,
  - Allergy, pacemaker erythema,
  - Pectoral or diaphragmatic twitching
  - Thrombosis,
  - Lead dislodgement (micro-, macro dislodgement, Twiddler's syndrome).

1.8 Regulatory and Legal Aspects

1.8.1 Synopsis of Legal Regulations

- Medizingeräteverordnung (MedGV) (former national control, replaced by MPG).
- Medizinproduktegesetz (MPG) (national implementation of Active Implantable Medical Devices Directive 90/358/EEC and MDD 93/42/EEC).
- Medizinprodukte–Betreiberverordnung. (MPBetreibV) (implementing regulation to the MPG).
- Gerätesicherheitsgesetz (Provision and Use of Work Equipment Regulations).
- Röntgenverordnung (RöV) (Ionizing Radiation Regulations).
- Richtlinien für Krankenhaushygiene und Infektionsprävention (Guidelines for hospital hygiene and prevention of infections).
- CE-mark.
- Clinical Investigations with/without CE-mark.
- Technical expertise and special competency.

1.8.2 Detailed Regulations Applying to the Physician with Regard to Pacemakers

- Putting into service and use of medical devices (according to the MPG)
  - ECG with/without intracardiac recording, programmer, pacing systems analyzer (PSA),
  - Medical devices log book, inventory list, user instruction (by supplier at time of putting into service), person responsible for devices, technical knowledge,
  - Product safety test, notification of incidents, etc.
- Use of implantable devices and accessories
  - CE-mark, use before date (UBD), reuse, resterilization.
- At implantation
  - Facilities, hygiene regulations, radiation protection, insulation protection, etc.

1.8.3 Regulations Applying to the Pacemaker/ ICD Patient

- Driving restrictions occupational/private.
- Use of a seat belt.

2 Pacing Modes

2.1 Rate Responsive Pacing

- Presentation and characterization of parameters proposed for rate adaptation.
- Description and characterization of available sensors with presentation of their advantages, disadvantages and possible malfunctions as well as available clinical data and study results (body activity, QT interval, minute ventilation, PEA, VIP sensors).
- Classification of sensors:
  - Physiologic/non physiologic (e.g. body activity) sensors,
  - According to their response time,
  - According to their sensitivity and specificity with regard to workload.
- Combinations of sensors and characteristics of available realizations.
- Differences between feed-forward (open-loop) and closed-loop systems.
- Problems of optimizing hemodynamics in rate responsive systems.

2.2 Hemodynamics of Cardiac Pacing

- Importance of atrial contraction for optimizing stroke volume.
- AAI or DDD pacing compared to VVI pacing at rest and during exercise,
  presentation of the varying role of atrial contraction at different stages of exercise and
  at different stages of left ventricular dysfunction.
- Presentation of the importance of an optimally timed AV delay in dual chamber pacing:
  Contribution to cardiac output at rest and during exercise and in comparison to the heart rate increase during exercise, evaluation of optimal AV interval, presentation of practical evaluation methods.
- Contribution of heart rate increase to cardiac output during exercise.
- Definition of pacemaker syndrome.
- Determinants of the 'pacemaker effect' during VVI pacing
  (including AV desynchronization arrhythmia during dual chamber pacing):
  - Lacking atrial contribution to ventricular filling,
  - Asynchronous ventricular contraction,
  - Tricuspid and mitral valve insufficiency,
  - Vasodepressor reflex responses mediated by cardiac mechanoreceptors (including increased ANP release).
- Influence of atrial based pacing as compared to ventricular pacing on exercise capacity, incidence of atrial fibrillation and thrombo-embolic complications in the long-term outcome as well as on mortality of pacemaker patients (presentation of existing evidence and currently ongoing trials).

2.3 Device and Mode Selection

- Presented in order of the various pacing modes (VVI/R, AAI/R, DDI/R, DDD/R, VDD) with regard to the various pacing indications (SSS, AVB, BAA, CSS, BND).
- Discussion of the hemodynamic, clinical and electrophysiologic aspects of the various pacing modes and presentation of indications and contraindications as well as necessary diagnostics (e.g. exclusion of sinus node disease before single lead VDD implantation).
- Development of a flowchart for mode selection.
- Presentation of special pacing algorithms (e.g. rate drop response in CSS).

2.4 Pacemaker Timing Cycles

- Conversion of time interval to rate per minute.
- Marker channel annotations (P, A, R, V).
- Relating intracardiac events to surface ECG waveforms.
- Fusion, pseudofusion, pseudopseudofusion.
- Timing cycles.
  Importance of understanding pacemaker timing cycles in the comprehension of pacemaker electrocardiography and the recognition and prevention of pacemaker malfunctions
  - Rate parameters
    Lower rate limit (LRL), upper rate limit/maximum tracking rate (URL, MTR) sensor indicated rate (SIR), maximum sensor rate (MSR), hysteresis rate limit (HRL),
  - Refractory periods
    Atrial refractory period (ARP), ventricular refractory period (VRP)
    postventricular ARP (PVARP), total ARP (TARP)
    atrial blanking (AB), ventricular blanking (VB)
    postatrial ventricular blanking (PAVB), postventricular atrial blanking (PVAB)

prematurity window (e.g. WARAD: window of atrial rate acceleration detection),
- AV intervals
  AV interval (AVI), PV interval (PVI)
  rate adaptive AV interval, AV interval hysteresis (positive, negative).

- Control mechanisms
  - Pacing modes
    AAI, VVI, DDI, DDD, sensor-driven,
  - Timing systems
    Atrial based (A-A) timing, ventricular based (V-V) timing
    combined timing systems,
  - Crosstalk
    AV crosstalk, VA crosstalk
    Safety window pacing/ventricular safety pacing,
  - Interference detection
    Noise sampling period (NSP).
- T-wave sensing.
- Rate limit behavior,
  Upper rate limit
  Wenckebach mode, n:1 block mode, mode switch, sensor controlled upper rate limit (e.g. CVTL: conditional ventricular tracking limit).
  Lower rate limit
  Rate hysteresis, search hysteresis, rate drop reaction.
- Tachyarrhythmia detection
  Mode switch, fallback, CVTL,
  pacemaker mediated tachycardia (PMT) algorithms.

3 Pacemaker Malfunction

3.1 Pacemaker Malfunction

Presented in order of possible causes, with examples of ECGs and/or x-rays as well as recommendations for prevention and management:

- Pacing device:
  - Hardware-, software component failure, manufacturing design deficiencies.
- Leads:
  - Lead fracture, insulation failure, disconnection, lead transposition, macro-, micro-dislocation.
- Programming:
  - Mode, sensitivity, PVARP, rate responsive parameters, etc.
- Cardiovascular origin (including iatrogenic causes):
  - Arrhythmias (supraventricular, ventricular), retrograde ventriculo-atrial conduction, threshold increase (e.g. at myocardial infarction, congestive heart failure, change in drug therapy).
- Electromagnetic Interference (EMI).

3.2 Interference in Cardiac Pacemakers

3.2.1 Biological Basics, Possible Effects and Symptoms of Interference:

Asystole, parasystole, myocardial damage, noise reversion mode, component damage, phantom reprogramming.

3.2.2 Technical Basics

- Sources of interference
  - Electromagnetic fields:
    Presentation of the influence of different fields: (up to 60 Hz, household appliances; up to 30 MHz, 30–100 MHz, 100 MHz–2.5 GHz),
  - Static/dynamic magnetic fields,
  - Galvanic current,
  - Ionizing radiation.
- EMI protection
  - Shielding, electronic filters, noise reversion mode, uni/bipolar mode,
  - Study results on interference immunity of existing pacemaker models,
  - Technical limits of optimizing EMI protections in present-day pacemakers,
  - Recommendations for precautions and optimal pacemaker programming.

3.2.3 Interference Sources and Recommendations for Prevention

- Radio equipment
  Cordless phones, cellular phones: analog/digital (GSM), car phones, CB radios, radio-control equipment, radio/TV transmitters, radar.
- Electronic article surveillance systems, metal detectors, electromagnetic fields (at stores, airports, security equipment, etc.).
- Household appliances
  Microwave ovens, hair-dryers, shavers, electric drills, loudspeaker magnets, gardening tools, etc.
- Workplace environment
  Arc welders, transformers, high voltage lines, car electrics, railway engines, electrical engineering, electric steel plants, lifting magnets, etc.
- Medical environment
  Therapeutic radiation (diathermy, microwave, ultrasound, ionizing), electrocautery, magnetic resonance imaging, defibrillation, dental equipment, neurostimulation, lithotripsy, etc.
- Military environment
  Military airport, radar, etc.
- Recommendations for patient education.

3.3 Pacemaker Mediated Tachycardia

- Definition of Pacemaker Mediated Tachycardia (PMT).
- Classification of PMT
  - Pacemaker circus movement tachycardia (PCMT),
    - Antidromic PCMT by retrograde VA conduction,
    - Orthodromic PCMT (e.g. by lead transposition),
  - PMT by synchronization to supraventricular tachycardia,
  - PMT by oversensing,
  - PMT of rate responsive systems (Sensor-Mediated Tachycardia) by
    - Sensor oversensing, – positive feedback, – inappropriate programming,
  - PMT by special algorithms (e.g. rate drop response algorithm),
  - PMT by hardware component failure ('runaway-pacemaker').
- Presentation with ECG examples, explanation of possible causes and discussion of various algorithms and programming options for PMT prevention
  - PMT algorithms for detection and/or prevention of PMT,
  - Mode switch algorithms
    Presentation of various existing mode switch concepts.

4 Programming and Follow-up

4.1 Diagnostic Pacemaker Functions

- Telemetry
  - Battery status, lead impedance,
  - Threshold measurement, signal amplitude measurement,
  - Marker channel, intracardiac ECG (IEGM),
  - Retrograde conduction test, etc.
- Holter functions
  - Event counters ('statistics'),
  - Heart rate Holter (1–24 hrs), sensor simulation,
  - Rate histogram, AV histogram, sensor histogram, etc.,
  - Signal amplitude histograms, lead impedance trend, etc.,
  - Event recording (marker, IEGM).

(Presentation should include examples and comments on typical use.)

4.2 Pacemaker ECG Analysis

- Presentation of normal paced ECGs
  - with different pacing modes (AAI, VVI, DDI, VDD, DDD),
  - with multiple ECG leads (e.g. detection of left ventricular stimulation).
- Presentation of typical malfunctions (with various pacing modes)
  - Stimulation disorders (exit block, loss of capture, no output),
  - Sensing disorders (undersensing, oversensing),
  - Detection disorders (i.e. intrinsic event falling in device refractory period),
  - Variable AV intervals,
  - Inappropriate pacing mode,
  - Significance of the timing system (atrial based, ventricular based, combined timing).
- Development of a stepwise process for analyzing paced rhythms.
- Pacemaker ECG quiz:
  - Participants' analysis of at least 20 pacemaker ECGs,
  - Tutorial discussion of solutions.

4.3 Follow-up

4.3.1 Logistics of a Pacemaker Clinic

- Staff requirements.
- Equipment resources.
- Documentation.
- Quality assurance.

4.3.2 Methods of Structured Pacemaker Follow-up

- Follow-up protocol
  - Clinical interim history and medication review,
  - Brief cardiac physical assessment (neck veins, skin color, edema, dyspnea, blood pressure),
  - Evaluation of the pacemaker pocket,
  - ECG,
  - Electronic device assessment.
- Regular follow-up (6 month intervals)
  - Minimum requirement for regular follow-up:
    Analysis of intrinsic rhythm, pacing effectiveness, sensing effectiveness,
    Battery status, telemetry inquiry (if applicable).
- Extended follow-up (2 year intervals)
  - Indications for early/more frequent follow-up visits,
  - Additional measurements at extended follow-up:
    Pacing and sensing thresholds, muscle sensing threshold, lead impedance,
    retrograde conduction analysis, Wenckebach period, sensor behavior, intracardiac ECG,
    AV-delay optimization, interrogation of all available diagnostics, reprogramming of all programmable parameters.

- Optional procedures:
  - Holter ECG, event/loop recorders, chest x-ray, fluoroscopy, echocardiography, exercise ECG.

4.3.3 Measuring Guide

(Including practical guidance to conducting measurements and interpretation of results)

- Knowledge of underlying conduction disorder (indication for implantation).
- Assessment of patient's underlying rhythm.
- Determination of battery capacity and longevity.
- Lead impedance measurement.
- Assessment of stimulation threshold and programming of voltage and pulse width.
- Assessment of sensitivity threshold and muscle sensing threshold and programming of sensitivity and polarity.
- Retrograde conduction test, determination of far-field-R-wave sensing (in dual chamber systems).
- Determination of Wenckebach period (in AAI(R) and DDI(R) systems).
- Evaluation of sensor function.

4.4 Programming

- Programming guide
  (Presentation of basic programming parameters in view of possible inadvertent reactions and interactions of parameters, including standard recommendations):
  - Pacing mode,
  - Lower rate limit/basic rate (LRL),
  - Upper rate limit/maximum tracking rate (URL, MTR),
  - Maximum sensor rate (MSR),
  - Rate adaptive parameters in non auto-regulating sensors (threshold, acceleration, slope, deceleration, etc.),
  - AV-interval,
    atrial sensed PV-interval (PVI), atrial paced AV-interval (AVI)
    rate adaptive P/AVI, P/AVI-hysteresis
    P/AVI optimization (e.g. by echo/Doppler measurement),
  - Rate hysteresis,
  - Floating interval ('rate smoothing', 'flywheel' etc.),
  - Rate drop response (rate acceleration following hysteresis, search hysteresis),
  - PVARP,
  - PMT-algorithms,
    PVARP-extension, PVC synchronous atrial stimulation,
    special PMT-algorithms see section 3.3 (Pacemaker Mediated Tachycardia),
  - Ventricular safety pacing (safety window pacing),
  - Ventricular blanking period, atrial blanking period,
  - Amplitude, pulse width, sensitivity, polarity see section 4.3.3 (Measuring Guide).

4.5 Troubleshooting

- Presentation of typical pitfalls with the aid of an ECG simulator.
- Development of analytical approaches and solutions with all participants.

5 Summative Assessment

Multiple Choice examination or similar.