Clinical Economics [CLINECS]

This is a virtual academic course challenging both students and teachers.

It was the teachers job to prepare PowerPoint Presentations (PPPs) and Videos for this course and it will be the students job to use this material to learn more about Evidence-Based Medicine and Clinical Economics (CLINECS), and to provide a structured feedback as requested below.

The videos were produced by Prof. Luis Correia and Prof. Franz Porzsolt at the Bahiana School of Medicine and Public Health, Salvador/Bahia/Brasil. Mai/June 2017. The **Unique Selling Proposition (USP)** are the **onstage controversial academic discussions.** We request our students to learn from these contriversial discussions. The students have to critically appraize the presented teaching material and identify potential mistakes and errors that may explain some of the shown controversies.

In the 1st semester of CLINECS our students are requested to read and assess the quality of the first semester teaching material (marked in blue). Just follow the Outline of the course and pay attention only to the blue marked PPPs and Videos. Please assess the quality of all blue marked PPPs and Videos by using the Questionnaire presented in sections 0 or V.

In the 2^{nd} semester of CLINECS the students will get a different type of questionnaire. They have to use this 2^{nd} semester questionnaire to assess several dimensions of all presentations and videos and have to provide the reasons for justification of their assessments.

The production of these videos was supported by a grant of the Deutscher Akademischer Austausch Dienst (**DAAD**) and of the Virtual University of Bavaria (**Virtuelle Hochschule Bayern, VHB**) and **Deggendorf Institute of Technology (DIT**) to Prof. Franz Porzsolt.

Ulm / Germany, August, 2017

Franz Porzsolt MD, PhD

Outline of the course [last update 170828]

0: Definition and need of CLINECS

- 1. Definition of CLINECS
- 2. Need of CLINECS

I: Scientific decisions first, management decisions second, political decisions third.

- 1. Video #11, #12, #18
- 2. Objectives in health care
- 3. The importance of the precise definition of the goal.
- 4. Differences of scientific, management and political decisions.
- 5. The effect of preferences and values.
- 6. Video #1, #23
- 7. Applicability of Gregory Mankiw's 10 Economic Principles to health care.
- 8. How independent are patients, doctors, scientists, journals, editors, writers, readers, managers, politicians?
- 9. Video #2
- 10. Six steps of EBM (PICO or POIC). Why should we consider it?

11. Video #3, #4, #5

12. Examples of political decisions with insufficient scientific support (PREFERE, Mammography-, Colonoscopy-, Melanoma-Screening)

II: Why most assumptions in healthcare are only partially correct or wrong.

- 1. Video #7, #8, #9, #17
- 2. Video #19
- 3. The problem of healthcare efficiency.
- 4. The significance of the correct study question
- 5. Video #6, #20
- 6. The biased solution of the efficiency problem (efficacy-effectiveness-gap).
- 7. The biased solutions of screening and diagnostic problems
- 8. The biased diagnostic progress: stage migration [Will Rogers Phenomenon],
- 9. Video #10
- 10. The biased assessment of QOL: match/mismatch of study question and applied tool, response shift and recall bias.
- 11. The most frequent forms of bias in explanatory clinical trials (RCTs).
- 12. Tacit knowledge definition, chances and risks: assessment and appraisal, TACT experiment.

III: Scientific essentials for making reliable health care decisions.

- 1. Video #13. #14, #15, #16
- 2. The implicit and explicit definition of objectives in health care.
- 3. The surrogates and clinical endpoints of mortality, morbidity, HRQOL.
- 4. The assessment of validity of Randomized Controlled Trials. The USP method.
- 5. The assessment of validity of systematic reviews.
- 6. The assessment of diagnostic methods.
- 7. The assessment of screening methods.
- 8. Comparing economic risks in screening/diagnosis and in treatment decisions.
- 9. The assessment of Health-related Quality of Life (HRQOL): concept, objectives, assessment tools.

IV: Solutions of the effectiveness and efficiency problems.

- 1. The worst mistake in healthcare research: Not to phrase the right question right:
 - a. define the objectives (perspective of observer, intended aim of action [primary or secondary or tertiary prevention?], assessed endpoint, time of assessment) and
 - b. describe the confirmation of the objectives (relative frequency of achieved endpoints, completeness of achieved endpoints [completely, mostly, barely, not at all and new problems], the speed of achievement, and its sustainability).
 - c. Demonstration of superiority, equivalence, or non-inferiority?
 - d. Explain what you want to do: describe an observation or test a hypothesis?

2. "How to do" section.

a. How to select the right tool: explanatory or descriptive or empirical study. The history of clinical trials and the role of preferences/values. Differences of Randomized Controlled Trials (RCTs), Pragmatic Controlled Trials (PCTs), Clinical Registries (CRs), and Empirical Controlled Trials (ECTs).

- b. How to optimize the PCTs: Definition of Inclusion-/Exclusion Criteria, Onesided and two-sided tests. When to use the Intent-To-Treat-principle. When to test for superiority or equivalence or non-inferiority?
- c. Video #21, #22
- d. How to assess the validity of data that are used to support clinical guidelines [USP: Usability of Scientific Publications and/or PCTs].
- e. Video #24
- f. How to make the most efficient (best clinical but affordable) decisions in health care. Defining and avoiding Overuse and Underuse. Minimum numbers (Mindestmengen)
- g. The Y-nurse concept: The application of the results of Outcomes Research and of Patient Safety Research to daily clinical practice will increase the efficiency of health care by saving lives, increasing the quality of life, and reducing the costs of care.
- 3. "Learning and co-operating with others" section.

a. Biomedical Ethics (The 5 principles).

b. Medical Education.

c. Internal Medicine/Evidence-based Medicine.

d. Business Administration (Financing/Budgeting). Dr. Bettina Hailer

e. General Surgery.

f. The 5 sections of Anesthesiology.

g. Healthcare Communication.

h. Health Politics (AMNOG process).

i. Legal aspects in health care.

Prof. Dr. Franz Porzsolt cand.med. F.Lobmeyer Dr. Oscar Kamga

Dr. Stephan Paschke

Prof. Dr. Manfred Weiss

Ingrid Hernandez

Jürgen Geier

Ass. jur. Christopher Geier

V: From Evidence-based Medicine to Clinical Economics [CLINECS]:

The Videos of the Advanced Course on Evidence-based Medicine are referenced #1 to #24.

1. Prof. Luis Correia. (25 min.) Why the Human Mind is not Sensible Enough to Scientific Evidence. https://vimeo.com/225314720/16dcdaa6a9

2. Prof. Franz Porzsolt. (14 min.)

Taking Internal Beliefs into Consideration in Critical Appraisal of External Evidence. https://vimeo.com/225591046/473e7c0b94

3. Prof. Luis Correia. (29 min.)

The Basis for the Null Hypothesis Principle in medical thinking. https://vimeo.com/225997256/bfb76ce5e1

4. Prof. Luis Correia (23 min.)

Extreme Plausibility Principle and its Variants.

https://vimeo.com/226472607/91ab1c743a

5. Prof. Luis Correia (45 min.)

Proof of Concept Principle

https://vimeo.com/226464219/765188e602

6. Prof. Franz Porzsolt (14 min.)

The Very First Step in Critical Appraisal: is the Hypothesis Worth to be Tested? https://vimeo.com/226940563/3e6e5ec1b6

7. Prof. Luis Correia (42 min.)

Why most Published Studies are False.

https://vimeo.com/227125886/5ccc7a92b8

8. Prof. Franz Porzsolt (16 min.)

The Prevalent Phenomenon of Publication Bias

https://vimeo.com/227126329/c36e29b4b3

9. Prof. Franz Porzsolt (7 min.)

Identifying Results too Good to be True ("Smelling" Studies)

https://vimeo.com/227449274/287403a31f

10. Prof. Franz Porzsolt (31 min.)

Defining the Right Outcomes in Clinical Trials

https://vimeo.com/227461761/1d120d84e4

11. Prof. Luis Correia (23 min.)

Good and bad primary outcome definition on trials

https://vimeo.com/226940713/d0c5f276f3

12. Prof. Luis Correia (12 min.)

Self-fulfilling prophecies as primary outcomes of trials

https://vimeo.com/227774805/cf13422242

13. Prof. Franz Porzsolt (13 min.)

The Weakness of Randomization: It cannot control for preferences

https://vimeo.com/226940916/522d39f341

14. Prof. Correia (37 min.)

Common traps in composite end-points

https://vimeo.com/227931687/c1e7255886

15. Prof. Franz Porzsolt (27 min.)

The counterintuitive (but adequate) intent to treat analysis

https://vimeo.com/227774968/cf8a3f1477

16. Prof. Luis Correia (18 min.)

The ideal meta-analysis is the one we already know the main result

https://vimeo.com/227932948/f6e8e28c07

17. Prof. Franz Porzsolt (64 min.)

Examples for lacking adherence to five perspectives

https://vimeo.com/228722828/31c764b544

18. Prof. Luis Correia (38 min.)

The problem and the value of surrogate end-points

https://vimeo.com/228873253/c8d9c3c996

19. Prof. Luis Correia (12min.)

The different paradigms of efficacy and effectiveness

https://vimeo.com/228874044/c8e02cb534

20. Prof. Franz Porzsolt (52 min.)

How to measure effectiveness (the model of Pragmatic Controlled Trial) -

https://vimeo.com/228874287/0224759956

21. Prof. Luis Correia (25 min.)

Level of evidence has little to do with strength of recommendation

https://vimeo.com/229006722/5fe340d3de

22. Prof. Franz Porzsolt (20 min.)

Inconsistencies among guidelines

https://vimeo.com/228969257/0edac608f3

23. Prof. Franz Porzsolt (22 min.)

Principles of economy applied to medical decisions

https://vimeo.com/228981838/ac98d42869

24. Prof. Luis Correia (41 min.)

The choosing wisely concept (45 min)

https://vimeo.com/229006495/ab0e1f9d57