

# Treatment-Related Health Outcomes: Adaptation to Lebanese Patients

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# Introduction

- ▶ Growing movement to focus the evaluation of health care on the assessment of the end results, or outcomes.
- ▶ Outcomes are associated with medical care delivery systems and specific medical interventions.
- ▶ Objective: maximize the net health benefit derived from the use of finite health care resources.
- ▶ Serious lack of information all over the world.



# Types of Health Outcomes

- ▶ Five D's: death, disease, disability, discomfort, and dissatisfaction.
- ▶ More comprehensive conceptual framework model (the ECHO model): economic, clinical, and humanistic outcomes.
  - ▶ Clinical: medical events occurring as a result of disease or treatment (clinical practice & clinical pharmacy)
  - ▶ Economic: direct, indirect and intangible costs compared with the consequences of a medical intervention (health economics & pharmacoeconomics)
  - ▶ Humanistic: patient satisfaction, self-assessed function and well-being → Health related quality of life (QOL)



# Phases of Clinical Drug Development

Phase	Disadvantage
<ul style="list-style-type: none"><li>▶ Phase 0: preclinical testing; laboratory and animals studies; assess safety and biologic activity</li><li>▶ Phase I: 20-80 healthy volunteers; determine safety and dosage range</li><li>▶ Phase II: 100-300 patient volunteers; evaluate efficacy; look for side effects</li><li>▶ Phase III: 1000-3000 patient volunteers; confirm efficacy, monitor adverse reactions from longer term use</li></ul>	<p>Selected Healthy/Diseased population. Ideal setting</p>
<p>Phase IV: Additional post-marketing testing required (Pharmaco-epidemiology)</p>	<p>Extended population Real Life setting</p>



# Usefulness of Pharmacoepidemiology

- ▶ When monitoring long term or rare side effects
- ▶ Effect on populations not introduced in clinical trials: pregnant women, elderly, children...
- ▶ Observational long term beneficial effects of drugs (support practice guidelines)
- ▶ Possibility of assessing **Health Outcomes (5Ds & ECHO model)**



# Pharmacoeconomic Value

## Balance of economic, humanistic and clinical outcomes:

- ▶ Economic: Cost compared with the consequences of treatment alternatives
- ▶ Humanistic: Consequences of disease or treatment on patient functional status or QOL along several dimensions (physical, social, general health and well-being, and life satisfaction)
- ▶ Clinical: Medical events that occur as a result of disease or treatment (safety and efficacy endpoints)



# Pharmacoeconomic Methodologies

- ▶ Cost-of-illness evaluation
- ▶ Cost minimization analysis
- ▶ Cost-benefit analysis
- ▶ Cost-effectiveness analysis
- ▶ Cost-utility analysis → Quality of life assessment



# Quality of Life Assessment (QOL)

- ▶ Physical, social, and emotional aspects of patients' well-being that are relevant and important to the patient
- ▶ Examines drug effects in areas not covered by laboratory or physiologic measurements
- ▶ Outcome unit = QOL score, patient preferences, patient satisfaction...





# Definition of QOL

- ▶ No consensus on its definition
- ▶ “Multidimensional concept referring to a person’s total well-being, including his or her psychological, social and physical health status”, Schron and Shumaker.
- ▶ “The value assigned to duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment or policy”, Patrick and Erickson.
- ▶ Commonly measured dimensions:
  - ▶ Physical health and functioning
  - ▶ Psychic health and functioning
  - ▶ Social function and role
  - ▶ Perception of overall well-being



# QOL Measure: Instrument Taxonomy

- ▶ Generic (general) instruments: applicable to all conditions, interventions and populations
  - ▶ Health profile (e.g. SF36, SIP, HUI-Mark III)
  - ▶ Measures based on patient's preference (economic: e.g. QALY)
- ▶ Specific instruments
  - ▶ Disease (e.g. asthma, diabetes...)
  - ▶ Population (e.g. elderly, children...)
  - ▶ Function (e.g. sexual, social...)
  - ▶ Condition or problem (e.g. pain, personal satisfaction...)



# QOL Measure: Properties

- ▶ QOL increasingly seen as a result of a treatment (outcome): subjective impact
- ▶ Problem: subjective measure
- ▶ *Physiological measurement can change because of an intervention without change of QOL, and vice versa.*
- ▶ Psychometry: Measurement of psychological constructs such as QOL.
- ▶ Developed instruments must be tested → confidence in measurement



# Psychometric Properties

- ▶ Conceptual and measurement models
- ▶ Internal validity (measures what it is supposed to measure)
- ▶ Reproducibility (reliability/external validity)
- ▶ Responsiveness to change
- ▶ Interpretability (cost to respondent and administration)
- ▶ Alternatives forms
- ▶ Cultural and linguistic adaptation



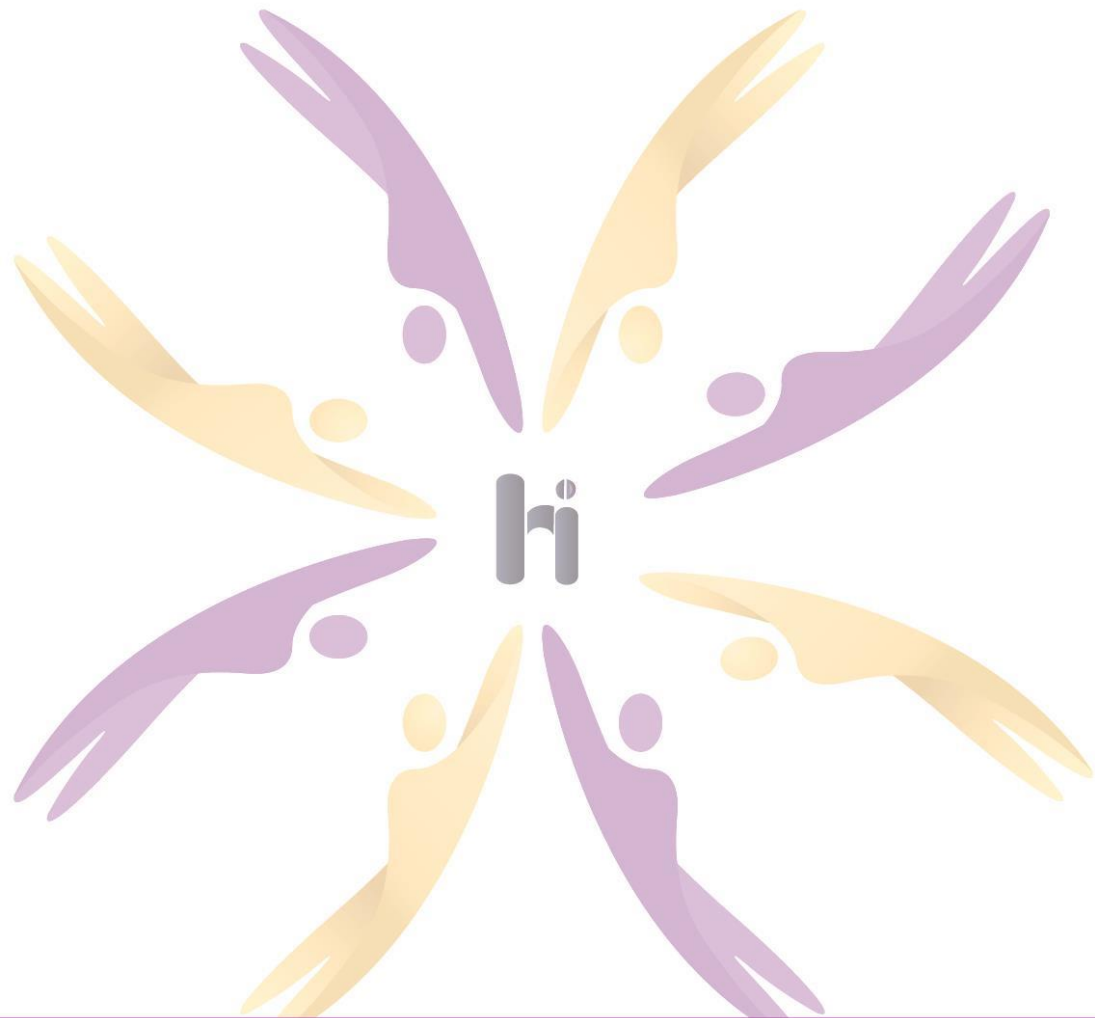
# Lebanese-Generated Scales

OBJECTIVE	SCALE NAME	PUBLICATION
Development of a risk of stroke score	ROSS	Al Hajj M, Salameh P, Rachidi S, Hosseini H. Development of a risk of stroke score in the Lebanese Population. Clinical Epidemiology and Global Health, 2018. Accepted, under press.
Development of a Diagnosis Score for Stroke.	DS-STROKE	Al Hajj M, Salameh P, Rachidi S, Hosseini H. Development of a Diagnosis Score for Stroke in the Lebanese Population. Clinical Epidemiology and Global Health, 2018. See: <a href="https://www.sciencedirect.com/science/article/pii/S2213398418300307">https://www.sciencedirect.com/science/article/pii/S2213398418300307</a>
Validation of the Mini Pediatric Asthma Quality of Life Questionnaire	MP-AQLQ	Hallit S, Waked M, Raheison C, Hallit R, Layoun N, Salameh P. Validation of the Mini Pediatric Asthma Quality of Life Questionnaire and Identification of Risk Factors Affecting Quality of Life among Lebanese Children. Journal of Asthma, 2018. Accepted, under press.
Validation of the Geriatric Depression Scale - 30	GDS-30	Hallit S, Hachem D, Kheir N, Hallit R, Daher MC, Salameh P. An Arabic Version of the Geriatric Depression Scale (30-Items): Psychometric Properties and some Findings in a Lebanese Elderly Sample. Psychopathology, 2018.
Arabic version of the long International Physical Activity Questionnaire	IPAQ	Helou K, El Helou N, Mahfouz M, Mahfouz Y, Salameh P, Harmouche-Karak M. Validity and reliability of an adapted Arabic version of the long International Physical Activity Questionnaire. BMC Public Health, 2018; 18:49. See: <a href="https://link.springer.com/epdf/10.1186/s12889-017-4599-7">https://link.springer.com/epdf/10.1186/s12889-017-4599-7</a>
Patient-Pharmacist relationship measurement tool.	PPR	Bou Raad E, Hallit S, Iskandar K, Zeenny R, Salameh P. Validation of a Patient-Pharmacist Relationship Measurement Tool in Lebanon. Research Reviews: Pharmacy & Pharmaceutical Sciences, 2017; 6(2): 1-10. See: <a href="https://www.researchgate.net/publication/317598445_Validation_of_a_Patient-Pharmacist_Relationship_Measurement_Tool_in_Lebanon">https://www.researchgate.net/publication/317598445_Validation_of_a_Patient-Pharmacist_Relationship_Measurement_Tool_in_Lebanon</a>
Geriatric Anxiety Scale among Lebanese elderly population	GAS	Hallit S, Hallit R, Hachem D, Daher MC, Kheir N, Salameh P. Validation of the Arabic version of the Geriatric Anxiety Scale among Lebanese population of older adults. IPA Bulletin, 2016. Available on: <a href="https://www.researchgate.net/publication/315716394_Validation_of_the_Arabic_version_of_the_Geriatric_Anxiety_Scale_among_Lebanese_population_of_older_adults">https://www.researchgate.net/publication/315716394_Validation_of_the_Arabic_version_of_the_Geriatric_Anxiety_Scale_among_Lebanese_population_of_older_adults</a>
Short Geriatric Depression Scale in Lebanese elderly population	GDS-5	Hallit S, Hachem D, Kheir N, Hallit R, Daher MC, Salameh P. Validation of Geriatric Depression Scale in Lebanon (GDS-5). Journal of Psychopathology 2017. See: <a href="https://www.researchgate.net/publication/311589271_validation_of_the_arabic_version_of_the_geriatric_depression_scale_among_the_lebanese_population_of_older_adults">https://www.researchgate.net/publication/311589271_validation_of_the_arabic_version_of_the_geriatric_depression_scale_among_the_lebanese_population_of_older_adults</a>
Screening Scale for CVD	SS-CVD	Nasser Z, Bou Abbass L, Leveque A, Salameh P. Outdoor air pollution improves the validity of a Screening Scale for cardiovascular disease (CVD) in clinical settings. Clinical Epidemiology & Global Health, 2015. See: <a href="http://www.sciencedirect.com/science/article/pii/S221339841500041X">http://www.sciencedirect.com/science/article/pii/S221339841500041X</a>



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OBJECTIVE	SCALE NAME	PUBLICATION
Scale for risky behaviors among youth	RIPS-LB	Salameh P, Salamé J, Waked M, Barbour B, Zeidan N, Baldi I for the Lebanese National Conference on Health in University research group. Risk perceptions, motives and behaviours in university students. International Journal of Adolescence and Youth, 2014; 19(3): 279-292. See: <a href="http://bit.ly/1v0XvtU">http://bit.ly/1v0XvtU</a> or <a href="http://www.ncbi.nlm.nih.gov/pubmed/25431509">http://www.ncbi.nlm.nih.gov/pubmed/25431509</a> or <a href="http://www.tandfonline.com/doi/pdf/10.1080/02673843.2014.919599">http://www.tandfonline.com/doi/pdf/10.1080/02673843.2014.919599</a>
Diagnostic score for COPD in epidemiological & clinical settings	DS-COPD	Salameh P, Khayat G, Waked M. Diagnostic score for COPD: Validation of the DS-COPD in clinical settings. Clinical Epidemiology and Global Health, 2013. Accepted, under press. Available at: <a href="http://www.sciencedirect.com/science/article/pii/S221339841300050X">http://www.sciencedirect.com/science/article/pii/S221339841300050X</a> Salameh P, Khayat G, Waked M. Could symptoms and risk factors diagnose COPD? The Diagnosis Score of COPD [DS-COPD] development. Clinical Epidemiology 2012, 4: 247-55. Available on: <a href="http://www.dovepress.com/articles.php?article_id=11103">http://www.dovepress.com/articles.php?article_id=11103</a>
Young Adults Cigarette Dependence Scale	YACD	Salameh P, Jomaa L, Farhat G, Zeghondi H, Gerges N, Issa C, Sabbagh MT, Chaaya M, Barbour B, Waked M, Salamé J, Saadallah-Zeidan N, Baldi I. The Lebanese National Conference for Health in Universities study group. The Young Adults' Cigarette Dependence (YACD) Score: An improved tool for cigarette dependence assessment in university students. Addictive Behaviors, 2013; 38(5): 2174-9. Available at: <a href="http://www.sciencedirect.com/science/article/pii/S0306460313000208">http://www.sciencedirect.com/science/article/pii/S0306460313000208</a>
Lebanese Cigarette Dependence Scale	LCD	Salameh P, Khayat G, Waked M. The Lebanese Cigarette Dependence (LCD) Score: A comprehensive tool for cigarette dependence assessment. International Journal of Behavioral Medicine, 2012. Available at: <a href="http://www.ncbi.nlm.nih.gov/pubmed/23494718">http://www.ncbi.nlm.nih.gov/pubmed/23494718</a>
Respiratory Toxics Exposure Score	RTES	Salameh P, Khayat G, Waked M. Validation of the Respiratory Toxics Exposure Score (RTES) for chronic obstructive pulmonary disease screening. International Journal of Occupational Medicine & Environmental Health 2011; 24(4): 339-47. Available on: <a href="http://www.ncbi.nlm.nih.gov/pubmed/22086449">http://www.ncbi.nlm.nih.gov/pubmed/22086449</a>
Psychological distress in the Lebanese population	BDS-22	Salameh P, Barbour B. Psychological distress in Lebanese young adults: Construction and validation of the BDS-22 scale. International Journal of Culture and Mental health, 2011; 1-15. Available on: <a href="http://www.tandfonline.com/doi/abs/10.1080/17542863.2011.563043#preview">http://www.tandfonline.com/doi/abs/10.1080/17542863.2011.563043#preview</a>
Lebanese Waterpipe Dependence Scale	LWDS-11	Salameh P, Waked M, Aoun Z. Narguileh smoking: Construction and validation of the LWDS-11 dependence scale. Nicotine & Tobacco Research 2008; 10(1): 148-59. Available at: <a href="http://www.ncbi.nlm.nih.gov/pubmed/18188755">http://www.ncbi.nlm.nih.gov/pubmed/18188755</a> OR <a href="http://www.tobaccocontrol.gov.lb/SiteCollectionDocuments/waterpipe%20dependence.pdf">http://www.tobaccocontrol.gov.lb/SiteCollectionDocuments/waterpipe%20dependence.pdf</a>
Psychological distress in obese adults	PSO	Abou Abbass L, Mansour Z, Elias E, Nasser Z, Godin I, Salameh P. Development and initial validation of a brief scale for assessing psychological distress in obese adults. Clinical Epidemiology & Global Health, 2015. See <a href="http://www.sciencedirect.com/science/article/pii/S2213398415000469">http://www.sciencedirect.com/science/article/pii/S2213398415000469</a>



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