



## Curriculum Vitae

Personal information **Mirjana Huic**

Work experience

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### HTA/EBM expert

*HTA/EBM Consulting Center* [ 13/01/2020 – Current ]

**City:** Zagreb

**Country:** Croatia

Management, scientific (research) and consulting activities (as international HTA expert) related to HTA and EBM (on pharmaceuticals, medical devices, medical procedures and other health technologies, in different life cycles), as well as to clinical pharmacology and toxicology. National and international collaboration in HTA reports: from April 2020-November 2022 as external expert in the production of HSS/Horizon Scanning Living Document for Covid-19 interventions of Austrian Institute for HTA (AIHTA). On behalf of AIHTA, participated in production of EUnetHTA Rolling and Rapid Collaborative Reviews for COVID-19 therapeutic treatments. In 2020 appointed by the European Commission as expert in Screening Panel in the field of certain high-risk medical devices. From 2021 acting as expert in the COVID-19 therapeutics sub-group of the European expert group on SARS-CoV-2 variants. Involvement in EU projects: EUCAPA (European Capacity Building for Patients) and ASCERTAIN (Affordability and Sustainability improvements through new pricing, Cost- Effectiveness and Reimbursement models to Appraise innovative health technologies). Member of ISPOR and Cochrane Croatia (Coordinator for HTA). Educational activities on HTA and EBM for different stakeholders at national and international level. Dissemination of HTA information for public. Scientific publications. Peer-reviews.

### Head of HTA Department

*Ministry of Health of the Republic of Croatia* [ 01/01/2019 – 25/12/2019 ]

**City:** Zagreb

**Country:** Croatia

MoH Croatia took over from the former Agency for Quality and Accreditation in Health Care and Social Welfare on 01/01/2019, see below, so-called universal takeover, when the original beneficiary is replaced by a new entity and all rights and obligations are transferred to this new entity

### Assistant Director and Head of Department for Research, Development and Health Technology Assessment

*Agency for Quality and Accreditation in Health Care and Social Welfare* [ 10/07/2009 – 31/12/2018 ]

**City:** Zagreb

**Country:** Croatia

Management of HTA Department. Scientific activities related to HTA. Establishment process and conduction of a transparent, evidence based HTA

process in Croatia with HTA recommendations for Croatian health care policy and decision makers. International collaboration in HTA production and different EU projects (EUnetHTA JAs 1, 2 and 3; FP7 project EQUIPT; TAIEX; H2020 project SELFIE) and international scientific societies like ISPOR, ISPOR HTA Roundtable Europe, HTAi. Activities in the HTA Network (i.e., on HTA Network Strategy Paper for EU cooperation on HTA; HTA Network Reflection paper on Reuse of Joint Work in national HTA activities; HTA Network MWP 2016-2020); activities related to the WHO national HTA focal point (i.e., WHO Status of Health Intervention and Technology Assessment in Member States Survey; WHO guidance: Setting up HTA system). Educational activities on HTA and EBM for different stakeholders. Dissemination of HTA information for public and scientific publications. Production of HTA information for the Agency web page. Expert in EUnetHTA Task Force on HTA and Medical Device/IVD Regulation. Expert in EU Council Working group for drugs and medical devices related to the Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Expert in ISPOR HTA Council WG.

### Head of Institute for Clinical Medical Research

*University Hospital "Sestre milosrdnice"* [ 01/09/2008 – 09/07/2009 ]

**City:** Zagreb

**Country:** Croatia

Management of Institute. Scientific support in preparation and conduction of RCTs on pharmaceuticals and medical devices and other national and international scientific projects. Scientific articles publishing. Continues education on EBM, clinical research and writing of scientific articles.

### Editor for Evidence-Based Medicine

*Croatian Medical Journal, Zagreb University School of Medicine* [ 09/2006 – 09/2011 ]

**City:** Zagreb

**Country:** Croatia

Critical appraising of scientific articles. Search methodology for clinical studies. Writing and editing, peer-reviews. Development of web pages for Evidence-based medicine. Development of Evidence-based patient information and decision-making help for patient, with aim for better quality and performance of the health care system. Evaluation of completeness and effects of clinical trials registration. Invited expert in research: The SPIRIT (Standard Protocol Items for Randomized Trials) Initiative Delphi. Invited expert in Public Reporting of Clinical Trial Outcomes & Results: the PROCTOR Working Group. Preparation of reports: The Procedure for the Ethical Review of Protocols for Clinical Research Projects in the Croatia, for EFGCP Report on The Procedure for the Ethical Review of Protocols for Clinical Research Projects in the European Union (International Journal of Pharmaceutical Medicine).

### Clinician - Specialist in clinical pharmacology and toxicology at Section of Clinical Pharmacology, Department of Internal Medicine

*University Hospital Centre Zagreb and Zagreb University School of Medicine* [ 07/1992 – 09/2006 ]

**City:** Zagreb

**Country:** Croatia

Clinical work with patients (internal medicine, clinical pharmacology and toxicology; emergency department); hospital clinical pharmacology consultant. Educational activities (undergraduate and postgraduate). Scientific (research) activities. Preparing (Investigators brochure, Protocols, Test lists, Patient inform consent form), conducting, reporting and monitoring of clinical studies (i.e., coinvestigator in bioequivalence studies on healthy volunteers and patients; RCTs). Expert activities in the Croatian Adverse Drug Reactions Monitoring Programme (as a part of the WHO ADR Monitoring Programme: preparing annual report for

Croatian MoH, regulation rules for monitoring ADRs and AEs of medical devices in Croatia, training sessions for monitoring AEs and ADRs in clinical trials, Periodic Safety Update Report of drugs for registration procedure).

### Medical doctor at Geriatric department

*Psychiatric Hospital "Sv. Ivan"* [ 06/1991 – 07/1992 ]

**City:** Zagreb

**Country:** Croatia

Clinical work with geriatric patients.

### Medical doctor - Trainee

*Psychiatric Hospital "Sv. Ivan"* [ 04/1989 – 04/1990 ]

**City:** Zagreb

**Country:** Croatia

Medical doctor – Trainee.

## Education and training

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### Medical Doctor

*Zagreb University School of Medicine* [ 1983 – 1989 ]

**Address:** 10000 Zagreb (Croatia)

### MSc - Allergology and Clinical Immunology

*Zagreb University School of Medicine* [ 1989 – 1990 ]

**Address:** Zagreb (Croatia)

### Specialist in clinical pharmacology and toxicology

*Section of Clinical Pharmacology, Department of Medicine, Zagreb University Hospital Center, Zagreb* [

1996 – 2002 ]

**Address:** Zagreb (Croatia)

### PhD - Clinical pharmacology and toxicology

*Split University School of Medicine* [ 2011 – 2013 ]

**Address:** Split (Croatia)

### Education in economic analysis of health technologies

*Ministry of Health of the Republic of Croatia and University of York, UK* [ 2013 ]

**Address:** Zagreb (Croatia)

### Education in pharmacoeconomic

*ISPOR* [ 2014 ]

**Address:** Montreal (Canada)

## Additional information

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### Publications *Scientific articles*

1. Csanádi M, Kaló Z, Rutten-van Molken M, Looman W, Huic M, Ercevic D, Atanasijevic D, Lorenzovici L, Petryszyn P, Pogány G, Pitter J, Zemplényi A. Prioritization of implementation barriers related to integrated care models in Central and Eastern European countries. *Health Policy*. 2022 Nov;126(11):1173-1179.
2. Ballini L, Wild C, Djuric O, Mayer-Ferbas J, Willemsen A, Huic M; EUnetHTA COVID-19 Task Force Group. European Network for Health Technology Assessment's Response to COVID-19: Rapid Collaborative Reviews on Diagnostic Tests and Rolling and Rapid Collaborative Reviews on Therapeutics. *Int J Technol Assess Health Care*. 2022 Mar 8;38(1):e22.
3. Looman W, Struckmann V, Köppen J, Baltaxe E, Czipionka T, Huic M, et al. Drivers of successful implementation of integrated care for multi-morbidity: Mechanisms identified in 17 case studies from 8 European countries. *Soc Sci Med*. 2021 May;277:113728.
4. Daubner-Bendes R, Kovács S, Niewada M, Huic M, Drummond M, Ciani O, et al. Quo Vadis HTA for Medical Devices in Central and Eastern Europe? Recommendations to Address Methodological Challenges. *Front Public Health*. 2021 Jan 8;8:612410.

5. Kaló Z, Zemplényi A, Rutten-van Mólken M, Looman W, Huić M, Tandara Haček R, et al. Development of transferability guidance for integrated care models with special focus on Central and Eastern European countries. *Croat Med J*. 2020 Jul 5;61(3):252-259.
6. Németh B, Goetsch W, Kristensen FB, Piniashko O, Huić M, Tesař T, et al. The transferability of health technology assessment: the European perspective with focus on central and Eastern European countries. *Expert Rev Pharmacoecon Outcomes Res*. 2020 Aug;20(4):321-330.
7. Kristensen FB, Husereau D, Huić M, Drummond M, Berger ML, Bond K, et al. Identifying the Need for Good Practices in Health Technology Assessment: Summary of the ISPOR HTA Council Working Group Report on Good Practices in HTA. *Value Health*. 2019 Jan;22(1):13-20.
8. Leijten FRM, Hoedemakers M, Struckmann V, Kraus M, Cheraghi-Sohi S, Zemplényi A, et al. Defining good health and care from the perspective of persons with multimorbidity: results from a qualitative study of focus groups in eight European countries. *BMJ Open*. 2018 Aug 30;8(8):e021072.
9. Rutten-van Mólken M, Leijten F, Hoedemakers M, Tsiachristas A, Verbeek N, Karimi M, et al. Strengthening the evidence-base of integrated care for people with multi-morbidity in Europe using Multi-Criteria Decision Analysis (MCDA). *BMC Health Serv Res*. 2018 Jul 24;18(1):576.
10. Németh B, Kulchaitanaroaj P, Lester-George A, Huic M, Coyle K, Coyle D, et al. A utility of model input uncertainty analysis in transferring tobacco control-related economic evidence to countries with scarce resources: results from the EQUIPT study. *Addiction*. 2018 Jun;113 Suppl 1(Suppl 1):42-51.
11. Ettinger S, Stanak M, Szymański P, Wild C, Tandara Haček R, Erčević D, et al. Wearable cardioverter defibrillators for the prevention of sudden cardiac arrest: a health technology assessment and patient focus group study. *Med Devices (Auckl)*. 2017 Nov 14;10:257-271.
12. Huic M, Tandara Hacek R, Svajger I. HEALTH TECHNOLOGY ASSESSMENT IN CENTRAL, EASTERN, AND SOUTH EUROPEAN COUNTRIES: CROATIA. *Int J Technol Assess Health Care*. 2017 Jan;33(3):376-383.
13. Kaló Z, Gheorghe A, Huic M, Csanádi M, Kristensen FB. HTA Implementation Roadmap in Central and Eastern European Countries. *Health Econ*. 2016 Feb;25 Suppl 1(Suppl 1):179-92.
14. Zechmeister-Koss I, Huić M, Fischer S; European Network for Health Technology Assessment (EUnetHTA). The duodenal-jejunal bypass liner for the treatment of type 2 diabetes mellitus and/or obesity: a systematic review. *Obes Surg*. 2014 Feb;24(2):310-23.
15. Guegan EW, Huić M, Teljeur C. EUnethta: further steps towards European cooperation on health technology assessment. *Int J Technol Assess Health Care*. 2014 Nov;30(5):475-7.
16. Kleijnen S, Toenders W, de Groot F, Huic M, George E, Wieseler B, et al. European collaboration on relative effectiveness assessments: What is needed to be successful? *Health Policy*. 2015 May;119(5):569-76.
17. Pokhrel S, Evers S, Leidl R, Traperro-Bertran M, Kalo Z, Vries Hd, et al. EQUIPT: protocol of a comparative effectiveness research study evaluating cross-context transferability of economic evidence on tobacco control. *BMJ Open*. 2014 Nov 24;4(11):e006945.
18. Huić M, Nachtnebel A, Zechmeister I, Pasternak I, Wild C. Collaboration in health technology assessment (EUnetHTA joint action, 2010-2012): four case studies. *Int J Technol Assess Health Care*. 2013 Jul;29(3):323-30.
19. Hulstaert F, Neyt M, Vinck I, Stordeur S, Huić M, Sauerland S, et al. Pre-market clinical evaluations of innovative high-risk medical devices

- in Europe. *Int J Technol Assess Health Care*. 2012 Jul;28(3):278-84.
20. Zechmeister-Koss I, Huic M. Vascular endothelial growth factor inhibitors (anti-VEGF) in the management of diabetic macular oedema: a systematic review. *Br J Ophthalmol*. 2012 Feb;96(2):167-78.
  21. Huić M, Marušić M, Marušić A. Completeness and changes in registered data and reporting bias of randomized controlled trials in ICMJE journals after trial registration policy. *PLoS One*. 2011 Sept 21;6(9):e25258.
  22. Mittermayer R, Huić M, Mestrovic J. Kvaliteta zdravstvene zastite, akreditacija nositelja zdravstvene djelatnosti i procjena zdravstvenih tehnologija u Hrvatskoj: uloga agencije za kvalitetu i akreditaciju u zdravstvu [Quality of health care, accreditation, and health technology assessment in Croatia: role of agency for quality and accreditation in health]. *Acta Med Croatica*. 2010 Dec;64(5):425-34.
  23. Francetić I, Kalenić S, Huić M, Mercep I, Makar-Ausperger K, Likić R, et al. Impact of aminoglycoside cycling in six tertiary intensive care units: prospective longitudinal interventional study. *Croat Med J*. 2008 Apr;49(2):207-14.
  24. Kovacić N, Huić M, Ivanis A. Citation analysis of the Croatian Medical Journal: the first 15 years. *Croat Med J*. 2008 Feb;49(1):12-7.
  25. Huić M. Fifteenth anniversary of the Croatian Medical Journal: still moving ahead. *Croat Med J*. 2008 Feb;49(1):1-7.
  26. Francetic I, Bilusic M, Macolic-Sarinic V, Huic M, Mercep I, Makar-Ausperger K, et al. Inadequate use of preventive strategies in patients receiving NSAIDs. *Clin Drug Investig*. 2005;25(4):265-70.
  27. Erdeljic V, Francetic I, Macolic Sarinic V, Bilusic M, Makar Ausperger K, Huic M, et al. Use of gastroprotective agents in recommended doses in hospitalized patients receiving NSAIDs: a drug utilization study. *Pharm World Sci*. 2006 Oct;28(5):318-25.
  28. Huić D, Labar B, Huić M, Radman I, Dodig D, Mrsić M. Splenectomy? No, thank you! *Eur J Nucl Med Mol Imaging*. 2004 Dec;31(12):1677.
  29. Huić M, Francetić I, Bakran I, Macolić-Sarinić V, Bilusić M. Acquired coagulopathy due to anticoagulant rodenticide poisoning. *Croat Med J*. 2002 Oct;43(5):615-7.
  30. Huic M, Vrhovac B, Macolic-Sarinic V, Francetic I, Bakran I, Giljanovic S. How safe are bioequivalence studies in healthy volunteers? *Therapie*. 1996 Jul-Aug;51(4):410-3.
  31. Wolf-Coporda A, Lovrić Z, Huić M, Francetić I, Vrhovac B, Plavsić F, et al. Determination of bioequivalence of two furosemide preparations; the effect of high doses of furosemide on some pharmacokinetic parameters. *Int J Clin Pharmacol Res*. 1996;16(4-5):83-8.
  32. Vrhovac B, Sarapa N, Bakran I, Huic M, Macolic-Sarinic V, Francetic I, et al. Pharmacokinetic changes in patients with oedema. *Clin Pharmacokinet*. 1995 May;28(5):405-18.
  33. Huic M, Macolic V, Vrhovac B, Francetic I, Bakran I, Giljanovic S. Adverse drug reactions resulting in hospital admission. *Int J Clin Pharmacol Ther*. 1994 Dec;32(12):675-82.

*International HTA Reports (EUnetHTA joint assessments and other assessments)*

Anti-VEGF in diabetic macular oedema: A systematic review; The pre-market clinical evaluation of innovative high-risk medical devices; Prognostic tests for breast cancer

recurrence; Abdominal Aortic Aneurysm (AAA) screening; Fecal Immunochemical Test (FIT ) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening; Intravenous Immunoglobulins in MCI and Alzheimer disease; Structured Telephone Support (STS) in adults with chronic heart failure; Duodenal-jejunal bypass sleeve (EndoBarrier®) for the treatment of obesity with or without type 2 diabetes; Transcatheter mitral valve repair in adults with chronic mitral valve regurgitation; Canagliflozin for the treatment of Diabetes Mellitus Type 2; Ramucirumab (Cyramza®) in combination with Paclitaxel as second-line treatment for adult patients with advanced gastric or gastro-oesophageal junction adenocarcinoma; New pharmaceuticals in Chronic Hepatitis C; Wearable cardioverter-defibrillator (WCD) therapy in primary and secondary prevention of sudden cardiac arrest in patients at risk; Antibacterial-coated sutures versus non-antibacterial-coated sutures for the prevention of abdominal, superficial and deep incisional, surgical site infection (SSI); Alecensa as monotherapy is indicated for the first-line treatment of adult patients with ALK+ advanced NSCLC; Continuous glucose monitoring (CGM real-time) and flash glucose monitoring (FGM) as personal, standalone systems in patients with diabetes mellitus treated with insulin; Ustekinumab for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies;

HSS/Horizon Scanning Living Document for Covid-19 interventions of Austrian Institute for HTA (AIHTA) (2020-2022); EUnetHTA Rolling and Rapid Collaborative Reviews for COVID-19 therapeutic treatments on behalf of AIHTA (2020-2022); Huic, M. and Reinsperger, I. (2023): Oral and parenteral preexposure prophylaxis (PrEP) to prevent HIV in people at risk: a systematic review of clinical effectiveness and safety with assessment of organisational, economic, patients/social, ethical and legal elements. HTA-Projektbericht 152.

#### *National HTA Reports*

##### *Pharmaceuticals*

Insulin glargine and insulin detemir in combination with oral antidiabetic therapy in patient with type 2 diabetes mellitus: HTA, 2012; Sitagliptin and sitagliptin with metformin therapy in patients with type 2 diabetes mellitus: HTA, 2012; Afatinib, erlotinib, gefitinib, crizotinib and pemetrexed in patients with non-small-cell lung cancer, NSCLC: HTA, 2015; Sofosbuvir for treating chronic hepatitis C: HTA, 2015; Drugs for treating adult men with hormone resistant metastatic prostate cancer: HTA, 2015; Ibrutinib for treating adult patients with chronic lymphocytic leukaemia (CLL) and adult patients with relapsed or refractory mantle cell lymphoma (MCL):HTA, 2015; Nusinersen (Spinraza) for the treatment of patients with spinal muscular atrophy (SMA) ); HTA, 2017 and 2019.; Brentuximab vedotin for treating adults with relapsed or refractory CD30-positive Hodgkin lymphoma or with relapsed or refractory systemic anaplastic large cell lymphoma, sALCL: HTA, 2018; Alectinib (Alecensa®) as monotherapy for the first line treatment of adult patients with ALK-positive advanced non-small cell lung cancer (NSCLC): HTA, 2018; Atezolizumab (Tecentriq®) as monotherapy for the second line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC): HTA, 2018; Daratumumab (Darzalex) u kombinaciji s lenalidomidom i deksametazonom ili bortezomibom i deksametazonom, za liječenje odraslih bolesnika s multiplim mijelomom koji su primili barem jednu prethodnu terapiju: HTA, 2018; Karfilzomib (Kyprolis) u kombinaciji s lenalidomidom i deksametazonom ili samo s deksametazonom, za liječenje odraslih bolesnika s multiplim mijelomom koji su primili barem jednu liniju liječenja: HTA, 2018; Iksazomib (Ninlaro) u kombinaciji s lenalidomidom i deksametazonom, za liječenje odraslih bolesnika s multiplim mijelomom koji su primili barem jednu prethodnu terapiju: HTA, 2018; Ataluren (Translarna) za liječenje Duchenneove mišićne distrofije koja je posljedica besmislene mutacije u distrofin genu, u pokretnih bolesnika: HTA, 2018

##### *Medical devices or IVDs*

Serological testing of cornea donors (on Epstein-Barr virus, Cytomegalovirus and Toxoplasma gondii): Rapid HTA, 2011; VEGATEST expert medical device: Rapid HTA,



2012; Transcatheter Aortic Valve Implantation-TAVI: HTA, 2012; Tandem mass spectrometry in expanded newborn screening for inherited metabolic disorders: HTA, 2012; Particle Beam Radiation Therapies for Cancer: HTA, 2013; Intensity-Modulated Radiation Therapy, IMRT: HTA, 2013; Endovascular abdominal aortic aneurysm (AAA) repair: HTA, 2013; Biofeedback and Neurofeedback treatments for psychiatric disorders: HTA, 2014; Impact of triclosan-coated sutures on surgical site infection: HTA, 2014; Antibacterial-coated sutures versus non-antibacterial-coated sutures for the prevention of abdominal, superficial and deep, surgical site infection (SSI): HTA, 2017; Continuous glucose monitoring (CGM real-time) and flash glucose monitoring (FGM) as personal, standalone systems in patients with diabetes mellitus treated with insulin: HTA, 2018.

**Projects** *Previous EU projects:*

1. **TAIEX Project, Health Technology Assessment; main principles, HTA process and report** [2010]
2. **EUnetHTA JA1, JA2 and JA3** [2010 – 2021]
3. **EQUIPT - European-study on Quantifying Utility of Investment in Protection from Tobacco** [2013 – 2016]
4. **SELFIE - Sustainable intEgrated care modeLs for multi-morbidity: delivery, FInancing and performance** [2015 – 2019]

*Ongoing EU projects:*

1. **EUCAPA** (European Capacity Building for Patients)
2. **ASCERTAIN** (Affordability and Sustainability improvements through new pricing, Cost- Effectiveness and Reimbursement models to Appraise iNnovative health technologies)

**Memberships** Croatian Society of Clinical pharmacology and Therapeutics; European Forum for Good Clinical Practice (EFGCP); Past member of Council of Science Editors; ISPOR; Past member of ISPOR HTA Council; ISPOR HTA Round Table Europe; Health Technology Assessment International (HTAi); The European network for Health Technology Assessment (EUnetHTA); EU HTA Network; Cochrane Croatia (HTA Coordinator)

Former Chair of the EUnetHTA Plenary Assembly (2012-2014) and former Co-chair of ISPOR HTA Roundtable Europe (2013-2016); 2016 - the ISPOR Distinguished Service Award received

**Other Relevant Information**