

**NEZADOVOLJENA MEDICINSKA POTREBA- KLINIČKI ASPEKT****Radmila Veličković Radovanović\***

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Nezadovoljena medicinska potreba (NMP) podrazumeva nedostatak raspoložive terapije/dijagnostike za određene bolesti, stanja ili simptoma. NMP zahteva definisanje populacije pacijenata (npr. za lečenje ozbiljnog stanja/oboljenja, ograničenog ili bez modaliteta lečenja) ili dugoročnu društvenu potrebu (npr. za prevazilaženje razvoja bakterijske otpornosti na antimikrobne lekove) (1). Identifikovanje određenog stanja ili bolesti kao NMP-u ima za cilj da signalizira značaj zdravstvene politike, stimuliše istraživačke aktivnosti i podstakne razvoj inovativnih lekova, dijagnostike ili zdravstvenih tehnologija u ovim oblastima (2). Lista NMP za 2019. uključuje: amiotrofičnu lateralnu sklerozu, rekurentni glioblastom, karcinom pankreasa. Nezadovoljena medicinska potreba kao alat za kreiranje politike koncepta NMP treba da pomogne istraživačkim i zdravstvenim zajednicama da razlikuju hitnije zdravstvene potrebe pacijenata i društva od mnoštva drugih zdravstvenih potreba. Pristup inovativnim terapijama, uključujući nove, esencijalne inovativne lekove varira u velikoj meri, sa značajnim razlikama između zemalja i kontinenata na globalnom nivou. Ipak, postoje NMP u dijagnostici/lečenju psorijaze, multiple skleroze, karcinoma, retkih bolesti. Postoji esencijalna potreba za novim antibioticima kako bi se pravazišla rastuća antimikrobna otpornost, posebno u lečenju gram-negativnih patogena kao što je *Acinetobacter baumannii* (2). Iz perspektive pacijenata, inovacije su potrebne u promovisanju i/ili očuvanju kvaliteta života; što su takođe ključne tačke. Perspektiva svakog pacijenta je individualna u skladu sa njihovim iskustvom sa bolešću, a stavovi svake grupe o nezadovoljenim potrebama oblikovane su vlastitom stručnošću i mišljenjem. Farmaceutska strategija stimuliše inovacije u oblastima nezadovoljenih medicinskih potreba (npr. neurodegenerativnih i retkih bolesti, karcinoma kod dece, specifične populacije pacijenata) (3).

**Literatura**

1. Watkins, R. R., Du, B., Isaacs, R., & Altarac, D. Pathogen-Targeted Clinical Development to Address Unmet Medical Need: Design, Safety, and Efficacy of the ATTACK Trial. *CID*, 2023;76: S210–S214.
2. Sharma M, Walia K, Bansal N. Unmet needs for management of drug-resistant infections: low- and middle-income countries' viewpoint. *DTI*. 2022; 31;16:78-80.
3. Vreman, R. et al. Unmet Medical Need: An Introduction to Definitions and Stakeholder Perceptions. *Value health*. 2019; 22(11):1275-1282.

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## UNMET MEDICAL NEED – CLINICAL ASPECT

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An unmet medical need (UMN) is a condition or symptom whose treatment or diagnosis is not addressed adequately by available therapy. An UMN includes an immediate need for a defined population or a longer-term need for society (e.g., to address the development of resistance to antibacterial drugs) (1). It plays an important role in investment and priority-setting decisions by a range of stakeholders, including Regulators, HTA Agencies, Payers, academics and the pharmaceutical industry (2). Identifying a particular condition or disease area as an UMN is intended to signal its health policy significance, stimulate research activities and intensify the development of innovative treatments, diagnoses or health technologies in these areas. List UMN for 2019. include: amyotrophic lateral sclerosis, recurrent glioblastoma, pancreatic cancer. UMN should help to shape policy and action from early phase research, through clinical development to pricing and reimbursement to how a new medicine is used in practice. Access to innovative therapies, including novel, essential innovative medicines, varies widely, with significant differences in per capital use across countries and continents globally. Still, there are UMN for psoriasis, multiple sclerosis, cancers that related to diagnostics and treatment. There is a crucial need for novel antibiotics to stem the tide of antimicrobial resistance, particularly against difficult to treat gram-negative pathogens like *Acinetobacter baumannii* (2). From the patients' perspective, innovation is also needed in promoting and/or preserving quality of life; these are also key endpoints. EU pharmaceuticals framework better in order to stimulate innovation in areas of UMN (neurodegenerative, rare diseases and pediatric cancers) (3).

### References

1. Watkins, R. R., Du, B., Isaacs, R., & Altarac, D. Pathogen-Targeted Clinical Development to Address Unmet Medical Need: Design, Safety, and Efficacy of the ATTACK Trial. *CID*, 2023;76: S210–S214.
2. Sharma M, Walia K, Bansal N. Unmet needs for management of drug-resistant infections: low- and middle-income countries' viewpoint. *DTI*. 2022; 31;16:78-80.
3. Vreman, R. et al. Unmet Medical Need: An Introduction to Definitions and Stakeholder Perceptions. *Value health*. 2019; 22(11):1275-1282.

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