

DAFTAR PUSTAKA

- Aasheim, V., Nilsen, A. B. V., Reinar, L. M. & Lukasse, M. (2017) Perineal techniques during the second stage of labour for reducing perineal trauma. *Cochrane Database Syst Rev*, 6Cd006672.
- Abramowitch, S. D., Feola, A., Jallah, Z. & Moalli, P. A. (2009) Tissue mechanics, animal models, and pelvic organ prolapse: a review. *Eur J Obstet Gynecol Reprod Biol*, 144 Suppl 1S146-58.
- Åkeflo, L., Elmerstig, E., Bergmark, K. & Dunberger, G. (2023) Barriers to and strategies for dealing with vaginal dilator therapy–Female pelvic cancer survivors’ experiences: A qualitative study. *European Journal of Oncology Nursing*, 62102252.
- Alperin, M., Cook, M., Tuttle, L. J., Esparza, M. C. & Lieber, R. L. (2016a) Impact of vaginal parity and aging on the architectural design of pelvic floor muscles. *Am J Obstet Gynecol*, 215(3): 312 e1-9.
- Alperin, M., Kaddis, T., Pichika, R., Esparza, M. C. & Lieber, R. L. (2016b) Pregnancy-induced adaptations in intramuscular extracellular matrix of rat pelvic floor muscles. *Am J Obstet Gynecol*, 215(2): 210 e1-7.
- Alperin, M., Lawley, D. M., Esparza, M. C. & Lieber, R. L. (2015) Pregnancy-induced adaptations in the intrinsic structure of rat pelvic floor muscles. *Am J Obstet Gynecol*, 213(2): 191 e1-7.
- Altenstetter, C. (2012) Medical device regulation in the European Union, Japan and the United States. Commonalities, differences and challenges. *Innovation: The European Journal of Social Science Research*, 25(4): 362-388.
- Ankarbranth, C. & Martenson, M. (2013) Strategy for using Prototypes in the Product Development Process. *Department of Technology Management and Economics*, Master, Chalmers University of Technology.
- Ashton-Miller, J. A. & Delancey, J. O. (2009) On the biomechanics of vaginal birth and common sequelae. *Annu Rev Biomed Eng*, 11163-76.
- Barca, J. A., Bravo, C., Pintado-Recarte, M. P., Asúnsolo, Á., Cueto-Hernández, I., Ruiz-Labarta, J., Buján, J., Ortega, M. A. & De León-Luis, J. A. (2021) Pelvic floor morbidity following vaginal delivery versus cesarean delivery: systematic review and meta-analysis. *Journal of Clinical Medicine*, 10(8): 1652.
- Beckmann, M. M. & Stock, O. M. (2013) Antenatal perineal massage for reducing perineal trauma. *Cochrane Database Syst Rev*, (4): CD005123.
- Berardi, M., Martinez-Romero, O., Elias-Zuniga, A., Rodriguez, M., Ceretti, E.,

- Fiorentino, A., Donzella, G. & Avanzini, A. (2014) Levator ani deformation during the second stage of labour. *Proc Inst Mech Eng H*, 228(5): 501-508.
- Betran, A. P., Ye, J., Moller, A. B., Zhang, J., Gulmezoglu, A. M. & Torloni, M. R. (2016) The Increasing Trend in Caesarean Section Rates: Global, Regional and National Estimates: 1990-2014. *PLoS One*, 11(2): e0148343.
- Brito, L. G., Ferreira, C. H., Duarte, G., Nogueira, A. A. & Marcolin, A. C. (2015) Antepartum use of Epi-No birth trainer for preventing perineal trauma: systematic review. *Int Urogynecol J*, 26(10): 1429-36.
- Bulchandani, S., Watts, E., Sucharitha, A., Yates, D. & Ismail, K. M. (2015) Manual perineal support at the time of childbirth: a systematic review and meta-analysis. *BJOG*, 122(9): 1157-65.
- Catanzarite, T., Bremner, S., Barlow, C. L., Bou-Malham, L., O'Connor, S. & Alperin, M. (2018) Pelvic muscles' mechanical response to strains in the absence and presence of pregnancy-induced adaptations in a rat model. *Am J Obstet Gynecol*, 218(5): 512 e1-512 e9.
- Ciurana, J. (2014) Designing, prototyping and manufacturing medical devices: an overview. *Int J Comput Integr Manuf*, 27(10): 901-918.
- Cunningham, F. G., Leveno, K. J., Bloom, S. L., Spong, C. Y., Dashe, J. S., Hoffman, B. L., Casey, B. M. & Sheffield, J. S. (2014) *William's Obstetrics*, New York:McGraw-Hill Education/Medical.
- Curtin, S. C., Gregory, K. D., Korst, L. M. & Uddin, S. F. (2015) Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data From the Birth Certificate, 2013. *Natl Vital Stat Rep*, 64(4): 1-13, back cover.
- Dahlke, J. D., Mendez-Figueroa, H., Maggio, L., Hauspurg, A. K., Sperling, J. D., Chauhan, S. P. & Rouse, D. J. (2015) Prevention and management of postpartum hemorrhage: a comparison of 4 national guidelines. *American journal of obstetrics and gynecology*, 213(1): 76. e1-76. e10.
- Daucher, J. A., Clark, K. A., Stolz, D. B., Meyn, L. A. & Moalli, P. A. (2007) Adaptations of the rat vagina in pregnancy to accommodate delivery. *Obstet Gynecol*, 109(1): 128-35.
- Departemen Kesehatan RI (2010) Peraturan Menteri Kesehatan Republik Indonesia Nomor 1190/Menkes/Per/VIII/2010 Tentang Izin Edar Alat Kesehatan Dan Perbekalan Kesehatan Rumah Tangga. Jakarta: Departemen Kesehatan Republik Indonesia.
- Dhital, B., Gul, E. N. F., Downing, K. T., Hirsch, S. & Boutis, G. S. (2016) Pregnancy-Induced Dynamical and Structural Changes of Reproductive

Tract Collagen. *Biophys J*, 111(1): 57-68.

- Dietz, H. P. (2014) Pelvic floor trauma in childbirth. *O&G Magazine* Melbourne: Royal Australian and New Zealand College of Obstetricians and Gynaecologists.
- Dietz, H. P. & Schierlitz, L. (2005) Pelvic floor trauma in childbirth - myth or reality? *Aust N Z J Obstet Gynaecol*, 45(1): 3-11.
- Dietz, H. P., Shek, K. L., Chantarasorn, V. & Langer, S. E. (2012) Do women notice the effect of childbirth-related pelvic floor trauma? *Aust N Z J Obstet Gynaecol*, 52(3): 277-81.
- Dietz, H. P. & Wilson, P. D. (2005) Childbirth and pelvic floor trauma. *Best Pract Res Clin Obstet Gynaecol*, 19(6): 913-24.
- Diez-Itza, I., Arrue, M., Ibanez, L., Paredes, J., Murgiondo, A. & Sarasqueta, C. (2011) Influence of mode of delivery on pelvic organ support 6 months postpartum. *Gynecol Obstet Invest*, 72(2): 123-9.
- Eickmeyer, S. M. (2017) Anatomy and Physiology of the Pelvic Floor. *Phys Med Rehabil Clin N Am*, 28(3): 455-460.
- Ellis, T. J. & Levy, Y. (2010) A Guide for Novice Researchers: Design and Development Research Methods. *Proceedings of Informing Science & IT Education Conference (InSITE)*, 107-118.
- Fairchild, P. S., Low, L. K., Kowalk, K. M., Kolenic, G. E., DeLancey, J. O. & Fenner, D. E. (2020) Defining "normal recovery" of pelvic floor function and appearance in a high-risk vaginal delivery cohort. *Int Urogynecol J*, 31(3): 495-504.
- Gharacheh, M., Ranjbar, F., Hajinasab, N. & Haghani, S. (2021) Acceptability and safety of the menstrual cups among Iranian women: a cross-sectional study. *BMC Women's Health*, 21(1): 1-8.
- Gregory, K. D., Jackson, S., Korst, L. & Fridman, M. (2012) Cesarean versus vaginal delivery: whose risks? Whose benefits? *American journal of perinatology*, 29(01): 07-18.
- Hallock, J. L. & Handa, V. L. (2016) The epidemiology of pelvic floor disorders and childbirth: an update. *Obstetrics and Gynecology Clinics*, 43(1): 1-13.
- Handa, V. L., Blomquist, J. L., Roem, J. & Munoz, A. (2018) Longitudinal study of quantitative changes in pelvic organ support among parous women. *Am J Obstet Gynecol*, 218(3): 320 e1-320 e7.
- Hauck, Y. L., Lewis, L., Nathan, E. A., White, C. & Doherty, D. A. (2015) Risk

factors for severe perineal trauma during vaginal childbirth: a Western Australian retrospective cohort study. *Women Birth*, 28(1): 16-20.

- Hillebrenner, J., Wagenpfeil, S., Schuchardt, R., Schelling, M. & Schneider, K. T. (2001) [Initial experiences with primiparous women using a new kind of Epi-no labor trainer]. *Z Geburtshilfe Neonatol*, 205(1): 12-9.
- Hoyte, L., Damaser, M. S., Warfield, S. K., Chukkapalli, G., Majumdar, A., Choi, D. J., Trivedi, A. & Krysl, P. (2008) Quantity and distribution of levator ani stretch during simulated vaginal childbirth. *Am J Obstet Gynecol*, 199(2): 198 e1-5.
- Hsieh, W. C., Liang, C. C., Wu, D., Chang, S. D., Chueh, H. Y. & Chao, A. S. (2014) Prevalence and contributing factors of severe perineal damage following episiotomy-assisted vaginal delivery. *Taiwan J Obstet Gynecol*, 53(4): 481-5.
- Hulstaert, F., Neyt, M., Vinck, I., Stordeur, S., Huić, M., Sauerland, S., Kuijpers, M. R., Abrishami, P., Vondeling, H., Flamion, B., Garattini, S., Pavlovic, M. & van Brabandt, H. (2012) Pre-Market Clinical Evaluations of Innovative High-Risk Medical Devices in Europe. *International Journal of Technology Assessment in Health Care*, 28(03): 278-284.
- Kamira, O. & Rizkalla, N. (2023) Indonesian Women Perspective: The Exploration of Factors Influencing the Adoption of Menstrual Cup. *Journal of Business and Management Review*, 4(2): 129-148.
- Kamisan Atan, I., Shek, K. L., Langer, S., Guzman Rojas, R., Caudwell-Hall, J., Daly, J. O. & Dietz, H. P. (2016) Does the Epi-No((R)) birth trainer prevent vaginal birth-related pelvic floor trauma? A multicentre prospective randomised controlled trial. *BJOG*, 123(6): 995-1003.
- Kavvadias, T. & Hoesli, I. (2016) The EpiNo(R) Device: Efficacy, Tolerability, and Impact on Pelvic Floor-Implications for Future Research. *Obstet Gynecol Int*, 20163818240.
- Kementerian Kesehatan RI (2017a) Peraturan Menteri Kesehatan Republik Indonesia Nomor 17 tahun 2017 tentang Rencana Aksi Percepatan Pengembangan Industri Farmasi dan Alat Kesehatan. Jakarta: Kementerian Kesehatan Republik Indonesia.
- Kementerian Kesehatan RI (2017b) Peraturan Menteri Kesehatan Republik Indonesia Nomor 63 Tahun 2017 tentang Cara Uji Klinik Alat Kesehatan yang Baik. Jakarta: Kementerian Kesehatan Republik Indonesia.
- Kok, J., Tan, K. H., Koh, S., Cheng, P. S., Lim, W. Y., Yew, M. L. & Yeo, G. S. (2004) Antenatal use of a novel vaginal birth training device by term

primiparous women in Singapore. *Singapore Med J*, 45(7): 318-23.

Kovacs, G. T., Heath, P. & Heather, C. (2004) First Australian trial of the birth-training device Epi-No: a highly significantly increased chance of an intact perineum. *Aust N Z J Obstet Gynaecol*, 44(4): 347-8.

Krofta, L., Havelkova, L., Urbankova, I., Krcmar, M., Hyncik, L. & Feyereisl, J. (2017) Finite element model focused on stress distribution in the levator ani muscle during vaginal delivery. *Int Urogynecol J*, 28(2): 275-284.

Lemeshow, S., Hosmer Jr, D. W., Klar, J. & Lwanga, S. K. (1990) *Adequacy of sample size in health studies*, Chichester: John Wiley & Sons.

Martins, J. A., Pato, M. P., Pires, E. B., Jorge, R. M., Parente, M. & Mascarenhas, T. (2007) Finite element studies of the deformation of the pelvic floor. *Ann N Y Acad Sci*, 1101316-34.

Mascarello, K. C., Horta, B. L. & Silveira, M. F. (2017) Maternal complications and cesarean section without indication: systematic review and meta-analysis. *Rev Saude Publica*, 51105.

Mehroolhassani, M. H., Yazdi-Feyzabadi, V., Mirzaei, S., Zolala, F., Haghdost, A.-A. & Oroomiei, N. (2020) The concept of virginity from the perspective of Iranian adolescents: a qualitative study. *BMC public health*, 20(1): 717.

Mitchell, M. A., Bisch, S., Arntfield, S. & Hosseini-Moghaddam, S. M. (2015) A confirmed case of toxic shock syndrome associated with the use of a menstrual cup. *Can J Infect Dis Med Microbiol*, 26(4): 218-20.

Moinuddin, M., Christou, A., Hoque, D. M. E., Tahsina, T., Salam, S. S., Billah, S. M., Kuppens, L., Matin, M. Z. & Arifeen, S. E. (2017) Birth preparedness and complication readiness (BPCR) among pregnant women in hard-to-reach areas in Bangladesh. *PloS one*, 12(12): e0189365.

Mullins, E., Evans, D., Viner, R., O'Brien, P. & Morris, E. (2020) Coronavirus in pregnancy and delivery: rapid review. *Ultrasound in Obstetrics & Gynecology*, 55(5): 586-592.

Nakamura, M. U., Sass, N., Elito Junior, J., Petricelli, C. D., Alexandre, S. M., Araujo Junior, E. & Zanetti, M. R. (2014) Parturient perineal distensibility tolerance assessed by EPI-NO: an observational study. *Einstein (Sao Paulo)*, 12(1): 22-6.

National Institute for Health and Care Excellence (2022) National Institute for Health and Care Excellence: Clinical Guidelines. London: National Institute for Health and Care Excellence (NICE).

Nsingo, M., Tsietso, S., Drapek, L., Nkele, I., Chabner, B., Efstathiou, J. & Dryden-

- Peterson, S. (2020) Vaginal Dilator Utilization in Patients Receiving Curative Radiation for Cancer of the Cervix: A Prospective Study in Botswana. *International Journal of Radiation Oncology, Biology, Physics*, 108(3): e463.
- Nyakang'o, S. B. & Booth, A. (2018) Women's perceived barriers to giving birth in health facilities in rural Kenya: A qualitative evidence synthesis. *Midwifery*, 671-11.
- Orejuela, F. J., Gandhi, R., Mack, L., Lee, W., Sangi-Haghpeykar, H., Dietz, H. P. & Ramin, S. M. (2018) Prospective evaluation of the safety and feasibility of a pelvic floor dilator during active labor. *International Urogynecology Journal*, 291485-1492.
- Pangastuti, N. (2016) Robekan Perineum pada Persalinan Vaginal di Bidan Praktek Swasta (BPS) Daerah Istimewa Yogyakarta Indonesia Tahun 2014-2016. *Jurnal Kesehatan Reproduksi*, 3(3): 179-187.
- Parente, M. P., Jorge, R. M., Mascarenhas, T., Fernandes, A. A. & Martins, J. A. (2008) Deformation of the pelvic floor muscles during a vaginal delivery. *Int Urogynecol J Pelvic Floor Dysfunct*, 19(1): 65-71.
- Patnana, A. K., Chugh, A., Chugh, V. K., Kumar, P., Vanga, N. R. V. & Singh, S. (2021) The prevalence of traumatic dental injuries in primary teeth: A systematic review and meta-analysis. *Dental Traumatology*, 37(3): 383-399.
- Presiden RI (2016) Instruksi Presiden Republik Indonesia Nomor 6 Tahun 2016 Tentang Percepatan Pengembangan Industri Farmasi dan Alat Kesehatan. Jakarta: Sekretariat Kabinet Republik Indonesia
- PT Sugih Instrumendo Abadi (2019) Profil Singkat PT Sugih Instrumendo Abadi.
- PT Swayasa Prakarsa (2019) Company & Product Profile PT Swayasa Prakarsa 2019.
- Putra, I. G. N. E. (Year) Addressing gender inequality to improve maternal health in Indonesia: A narrative literature review. *In: Proceedings of the International Conference on Applied Science and Health*, 2019. 89-100.
- Raizada, V. & Mittal, R. K. (2008) Pelvic floor anatomy and applied physiology. *Gastroenterol Clin North Am*, 37(3): 493-509, vii.
- Richey, R. C. & Klein, J. D. (2014) Design and Development Research. *In: Spector, J. M., Merrill, M. D., Elen, J. & Bishop, M. J. (eds.) Handbook of Research on Educational Communications and Technology*. 4 ed. New York: Springer Science+Business Media.

- Rizkianti, A., Afifah, T., Saptarini, I. & Rakhmadi, M. F. (2020) Women's decision-making autonomy in the household and the use of maternal health services: an Indonesian case study. *Midwifery*, 90102816.
- Rostaminia, G., Peck, J. D., Van Delft, K., Thakar, R., Sultan, A. & Shobeiri, S. A. (2016) New Measures for Predicting Birth-Related Pelvic Floor Trauma. *Female Pelvic Med Reconstr Surg*, 22(5): 292-6.
- Ruckhaberle, E., Jundt, K., Bauerle, M., Brisch, K. H., Ulm, K., Dannecker, C. & Schneider, K. T. (2009) Prospective randomised multicentre trial with the birth trainer EPI-NO for the prevention of perineal trauma. *Aust N Z J Obstet Gynaecol*, 49(5): 478-83.
- Ryan, K. M., Drumm, A. D., Martin, C. E., Krumpfer, A.-K. & Krumpfer, J. W. (2020) Synthetic Methods and Applications of Functional and Reactive Silicone Polymers. *Reactive and Functional Polymers Volume One: Biopolymers, Polyesters, Polyurethanes, Resins and Silicones*, 301-328.
- Sakina, A. I. & Siti A, D. H. (2017) Menyoroti budaya patriarki di Indonesia. *Share: Social Work Journal*, 7(1): 71-80.
- Salive, M. (2017) Pragmatic clinical trials: Testing treatments in the real world. National Institute of Aging.
- Schwertner-Tiepelmann, N., Thakar, R., Sultan, A. H. & Tunn, R. (2012) Obstetric levator ani muscle injuries: current status. *Ultrasound Obstet Gynecol*, 39(4): 372-83.
- Shek, K. L., Chantarasorn, V., Langer, S., Phipps, H. & Dietz, H. P. (2011) Does the Epi-No Birth Trainer reduce levator trauma? A randomised controlled trial. *Int Urogynecol J*, 22(12): 1521-8.
- Shek, K. L., Green, K., Hall, J., Guzman-Rojas, R. & Dietz, H. P. (2016) Perineal and vaginal tears are clinical markers for occult levator ani trauma: a retrospective observational study. *Ultrasound Obstet Gynecol*, 47(2): 224-7.
- Shields, L. E., Goffman, D. & Caughey, A. B. (2017) Postpartum Hemorrhage. *Obstetrics and Gynecology* 130(4): E168–86.
- Sindhvani, N., Bamberg, C., Famaey, N., Callewaert, G., Dudenhausen, J. W., Teichgraber, U. & Deprest, J. (2017) In vivo evidence of significant levator ani muscle stretch on MR images of a live childbirth. *Am J Obstet Gynecol*, 217(2): 194 e1-194 e8.
- Smith, L. A., Price, N., Simonite, V. & Burns, E. E. (2013) Incidence of and risk factors for perineal trauma: a prospective observational study. *BMC Pregnancy Childbirth*, 13(59).

- Tunis, S. R., Stryer, D. B. & Clancy, C. M. (2003) Practical clinical trials: increasing the value of clinical research for decision making in clinical and health policy. *Jama*, 290(12): 1624-1632.
- US Food and Drug Administration (2020) Medical Device Material Performance Study Siloxane Safety Profile. New York: US Food and Drug Administration.
- van Delft, K., Sultan, A. H., Thakar, R., Schwertner-Tiepelmann, N. & Kluivers, K. (2014) The relationship between postpartum levator ani muscle avulsion and signs and symptoms of pelvic floor dysfunction. *Bjog*, 121(9): 1164-71; discussion 1172.
- Warashinta, D. L., Astari, A. M. & Merdikawati, A. (2021) Analysis of the use of menstrual pad, tampons, and menstrual cup during menarche. *Journal of Community Health and Preventive Medicine*, 1(2): 24-31.
- Wei, J. T. & De Lancey, J. O. (2004) Functional anatomy of the pelvic floor and lower urinary tract. *Clin Obstet Gynecol*, 47(1): 3-17.
- WHO Department of Reproductive Health and Research (2013) Department of Reproductive Health and Research Annual Technical Report 2012. Geneva: WHO.
- Zhou, F., Wang, X. D., Li, J., Huang, G. Q. & Gao, B. X. (2014) Hyaluronidase for reducing perineal trauma. *Cochrane Database Syst Rev*, (2): Cd010441.