9th World Congress on

Rare Diseases and Orphan Drugs

June 17-18, 2019 | Berlin, Germany

Special Session

Day 1

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Shmuel Prints

NDC Medicine, Israel

The final battle: Wisdom of the crowd against medical mysteries

An extraordinary diagnostic delay is a key problem in the rare diseases field. According to public health studies, the greatest loss of time occurs in primary and secondary outpatient care. The inability of most physicians to recognize rare diseases in their daily practice is commonly explained by a low suspicion. This notion misses a main culprit in the clinical diagnostic workup that prevails in modern medicine the classification algorithm. It perfectly recognizes frequent diseases, and at the same time inevitably neglects rare ones. From this point of view, crowdsourcing a diagnosis for mysterious patients' cases has an undoubted methodological advantage. By simultaneously introducing a patient with an unusual combination of symptoms to a wide range of doctors, we increase the likelihood that among them there is someone who has seen a similar clinical picture before. Educational medical websites, that present already-solved rare cases as a riddle for training doctors, shows that the correct diagnosis arises among some physicians in a short matter of time. Recent researches proved that it takes the same accuracy to solve patients with an unclear diagnosis in medical forums and other discussion platforms for doctors. Our web-based platform, NDC Medicine, offers a unique solution for fast and accurate diagnosis of medical mysteries by harnessing the power or crowdsourcing and AI. It solves three main problems of current crowd sourcing platforms for undiagnosed patients: a) Quality case presentation. b) Gathering all possible diagnoses. c) Shortlisting the best ones using Artificial Intelligence. Ending the diagnostic odyssey for millions of patients worldwide has never been so close.

Recent Publications

1. Michael L Barnett, Dhruv Boddupalli, Shantanu Nundy, et al., (2019) Comparative accuracy of diagnosis by collective intelligence of multiple physicians vs. individual physicians. JAMA Netw Open. 2(3):e190096.

2. Nick Black, Fred Martineau and Tommaso Manacorda (2015) Diagnostic odyssey for rare diseases: exploration of potential indicators. Policy Innovation Research Unit in Department of Health Services Research & Policy, London School of Hygiene & Tropical Medicine.

3. C Heneghan, P Glasziou, M Thompson, et al., (2009) Diagnostic strategies used in primary care. BMJ. 338:b946.

4. Ashley N D Meyer, Christopher A Longhurst and Hardeep Singh (2016) Crowdsourcing diagnosis for patients with undiagnosed illnesses: an evaluation of crowdmed. J Med Internet Res. 18(1):e12.

Biography

Shmuel Prints is an Internal Medicine and Public Health Specialist with over 30 years of experience in Russia and Israel. His greatest passion is diagnosing rare diseases and medical mysteries. Five years ago, he has realized that the diagnostic delay of rare diseases has a systematic reason and offered a web-based discussion as a solution. Since then, he developed the idea into a practical tool and founded NDC Medicine, a digital-health startup for diagnosing medical mysteries, now in the proof of concept stage.

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Scientific Tracks & Abstracts

Day 1

SESSIONS

Treatment and Advanced Therapies for Rare Diseases | Economic aspects of Rare Diseases and Orphan Drugs | Rare Nutritional and Metabolic Diseases | Rare Musculoskeletal Diseases | Rare Hereditary Diseases

Chair: Vesna Aleksovska, International Gaucher Alliance, Macedonia

SESSION INTRODUCTION

Title: Red blood cell-encapsulated enzymes: An innovative therapeutic approach to overcome challenges of enzyme replacement therapies for rare diseases
Emmanuelle Cecile Dufour, Erytech Pharma, USA

Title: The Economics and Sustainability of Orphan Drugs
Carina Schulmann Schey, University of Groningen, Netherlands

Title: New therapies in genetic skeletal diseases achieved through drug repurposing
Michael Darren Briggs, Newcastle University, UK

Title: Nitisinone in the treatment of alkaptonuria
Lakshminarayan Ranganath, Royal Liverpool University Hospital, UK

Title: Change in gonadotropins in postmenopausal women: Effects of parity
Ekhator C N, Ambrose Alli University, Nigeria

Title: Clinical case of congenital hyperinsulinism in infant born by mother with type 2 diabetes
N B Belykh, Omsk State Medical University, Russian Federation

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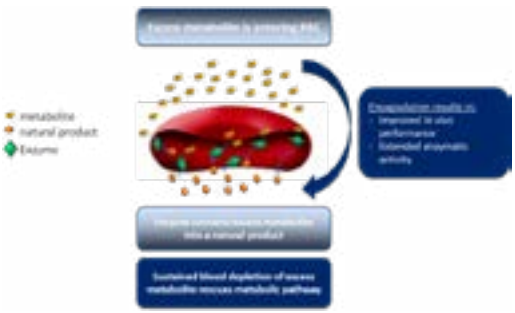
Red blood cell-encapsulated enzymes: An innovative therapeutic approach to overcome challenges of enzyme replacement therapies for rare diseases

Emmanuelle Cecile Dufour
Erytech Pharma, USA

Many inborn errors of metabolism (IEM) disorders are due to defects in single genes encoding key metabolic enzymes. In most cases, clinical manifestations of these disorders are driven by the over-abundance of a metabolite or the scarcity of an essential metabolite. Though rare, IEM disorders can have devastating consequences for patients and their families. While some Enzyme Replacement Therapies are commercially available for a few IEM disorders, the clinical benefits of these approaches are often outweighed by the emergence of hypersensitivity and the rapid clearance of enzymes. Therefore, there is a high need for better tolerated and longer-acting replacement enzymatic activity to alleviate the burden of IEM disorders. RBCs are the most abundant cell type in the human body and their biology is characterized by a long lifespan and access to all tissues and organs. Thanks to their biocompatibility and shielding properties, they can serve as a circulating bioreactor when loaded with enzymes. ERYTECH is a leader in RBC therapeutics. Its ERYCAPS® platform enables the encapsulation, at industrial scale, of active drug substances inside RBCs using hypotonic loading, which has been shown to maintain all the RBC functionalities. ERYTECH has demonstrated that RBC-encapsulated enzymes exhibit substantially improved *in vivo* performance vs. non-encapsulated enzymes, including extended enzymatic activity. Results from two early programs using enzyme-loaded RBCs in *in vivo* models for Arginase-1 Deficiency and Classical Homocystinuria will be presented. These promising results combined with ERYTECH's extensive clinical experience with RBC therapeutics, support the possibility that RBC-loaded enzymes may provide superior safety and efficacy as compared with traditional ERT approaches for the treatment of IEM disorders.



Recent Publications

1. Gay F, et al. (2017) Methionine tumor starvation by erythrocyte-encapsulated methionine gamma-lyase activity controlled with per os vitamin B6. Cancer Med. 6(6):1437-1452.
2. Bourgeaux V, et al. (2016) Drug-loaded erythrocytes: on the road toward marketing approval. Drug Des Devel Ther. 10:665-76.
3. Thomas X and Le Jeune C (2016) Erythrocyte encapsulated l-asparaginase (GRASPA) in acute leukemia. Int J Hematol Oncol. 5(1):11-25.

4. Yew N, *et al.,* (2013) Erythrocytes encapsulated with phenylalanine hydroxylase exhibit improved pharmacokinetics and lowered plasma phenylalanine levels in normal mice. Mol Genet Metabol. 109(4):339-344.
5. Bourgeaux V, *et al.,* (2012) Efficacy of homologous inositol hexaphosphate-loaded red blood cells in sickle transgenic mice. Br J Haematol. 157(3):357-369.

Biography

Emmanuelle Cecile Dufour has obtained her PhD in Biochemistry and has been working with Erytech Pharma for 10 years. She is involved in the preclinical development of enzyme loaded-red blood cells as therapeutics for inborn errors of metabolism.

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The Economics and Sustainability of Orphan Drugs

Carina Schulmann Schey
University of Groningen, Netherlands

Orphan drugs are increasingly under scrutiny by reimbursement bodies in Europe. This is due in part to the unexpected rise in the number of orphan drugs that received marketing authorization since 2000. The high prices of some orphan drugs and the budget constraints, affordability and sustainability of access to orphan drugs further contribute to the sometimes- negative spotlight on orphan drugs. However, one of the limitations in the current reimbursement pathways is the use of cost-effectiveness analyses to assist in the decision-making process. Increasingly, payers and policy makers highlight the need for alternative methods of assessing the value of orphan drugs and demonstrating their ongoing accessibility. A novel approach, using multi-criteria decision analysis, was developed to review orphan drugs. The framework has been tested with useful results. The strength and versatility of multi-criteria decision analysis is that it permits the different criteria to be assigned different weight based on their relevance to the hypothesis being tested. But one of the limitations is the lack of experience in the weighting of the criteria. In pursuance of in-depth insights on the weight that should be allocated to each criterion, an interactive web-based tool was developed that allowed respondents to complete by allocating the weights they thought suitable for each criterion. This presentation will provide the economic background in the provision of treatments for rare diseases, share some of the key economic and financial hurdles and provide the outcomes of the web-based tool and the perspectives gathered therefrom as well as suggest actions going forward in a bid to improve access to rare disease treatments while ensuring that they remain affordable and therefore ensuring sustainability in the future.

Recent Publications

1. Schey C, Milanova T and Hutchings A (2011) Estimating the budget impact of orphan medicines in Europe: 2010-2020. Orphanet Journal of Rare Diseases. 6(1):62.
2. Oliva E N, Schey C and Hutchings A S (2011) A review of anemia as a cardiovascular risk factor in patients with myelodysplastic syndromes. American Journal of Blood Research. 1(2):160-166.
3. Hutchings A, Schey C, Dutton R, Achana F and Antonov K (2014) Estimating the budget impact of orphan drugs in Sweden and France 2013-2020. Orphanet Journal of Rare Diseases., 9(1):22
4. Schey C, Krabbe P F M, Postma M J and Connolly M P (2017) Multi-criteria decision analysis (MCDA): testing a proposed MCDA framework for orphan drugs. Orphanet journal of rare diseases. 12:10.
5. M P Connolly, E Goodwin, C Schey and J Zummo (2017) Toxoplasmic encephalitis relapse rates with pyrimethamine-based therapy: systematic review and meta-analysis. Pathogens and Global Health., 111(1):31-44.

Biography

Carina Schulmann Schey is pursuing her PhD in the economics of orphan drugs and assessing alternative ways to adjudicate their value-add in the management of rare diseases. With a background as a Clinical Pharmacist with a special interest in rare diseases, she has published several peer-reviewed articles and abstracts in rare diseases. She sits on the expert judges' panel for the MassChallenge and on the scientific advisory panels for several charities, and as a Non-Executive Director for healthcare organizations.

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New therapies in genetic skeletal diseases achieved through drug repurposing

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Genetic skeletal diseases (GSDs) are an extremely diverse and complex group of diseases that primarily affect the development and homeostasis of the skeleton. There are more than 450 unique and well-characterised phenotypes that range in severity from relatively mild to severe and lethal forms and although individually rare, as a group of related orphan diseases, GSDs have an overall prevalence of at least 1 per 4,000 children, which represents a large unmet medical need. Our studies have focussed on a group of clinically-related GSDs that present with disproportionate short stature and early onset OA and result from dominant-negative mutations in a range of cartilage structural proteins including cartilage oligomeric matrix protein (COMP), matrilin-3, aggrecan and types II, IX and X collagens. We have unequivocally established that endoplasmic reticulum (ER) stress, induced in chondrocytes as a result of accumulated misfolded mutant proteins, is the primary cause of growth plate dysplasia and reduced bone growth in a broad group of GSDs. Moreover, we have recently demonstrated that reducing ER-stress, through the administration of a repurposed anti-epileptic drug carbamazepine (cbz), in both cell and mouse models, restores cell homeostasis and bone growth in metaphyseal chondrodysplasia, type Schmid (MCDS) resulting from collagen X mutations.

Recent Publications

1. Bell P A, Dennis E P, Hartley C L, Jackson R M, Porter A, Boot-Handford R P, Pirog K A and Briggs M D (2019) Mesencephalic astrocyte-derived neurotropic factor is an important factor in chondrocyte ER homeostasis. Cell Stress Chaperones. 24(1):159-173.
2. Mullan L A, Mularczyk E J, Kung L H, Forouhan M, Wragg J M, Goodacre R, Bateman J F, Swanton E, Briggs M D and Boot-Handford R P (2017) Increased intracellular proteolysis reduces disease severity in an ER stress-associated dwarfism. J Clin Invest. 127(10):3861-3865.
3. Gibson B G and Briggs M D (2016) The aggrecanopathies; an evolving phenotypic spectrum of human genetic skeletal diseases. Orphanet J Rare Dis. 11(1):86.
4. Briggs M D, Bell P A and Pirog K A (2014) The utility of mouse models to provide information regarding the pathomolecular mechanisms in human genetic skeletal diseases: The emerging role of endoplasmic reticulum stress (Review). Int J Mol Med. 35(6):1483-92.
5. Cameron T L, Gresshoff I L, Bell K M, Piróg K A, Sampurno L, Hartley C L, Sanford E M, Wilson R, Ermann J, Boot-Handford R P, Glimcher L H, Briggs M D and Bateman J F (2015) Cartilage-specific ablation of XBP1 signaling in mouse results in a chondrodysplasia characterized by reduced chondrocyte proliferation and delayed cartilage maturation and mineralization. Osteoarthritis Cartilage. 23(4):661-70.

Biography

Michael Darren Briggs has obtained his PhD in Molecular Genetics at the MRC-Clinical Research Centre in Harrow and undertook a Genetics Fellowship at Cedars-Sinai Medical Center in Los Angeles. In 1996 he moved to the University of Manchester and in 2012 he was appointed as a Professor of Skeletal Genetics at Newcastle University. Over the last 15 years he has been instrumental in establishing four Pan-European consortia for the clinical diagnosis and research of genetic skeletal diseases. His primary research interested is focused on refining diseases mechanisms in genetic bone diseases to identify new therapies for future clinical trials.

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Nitisinone in the treatment of alkaptonuria

Lakshminarayan Ranganath
Royal Liverpool University Hospital, UK

Alkaptonuria (AKU) is an iconic autosomal recessive severe multisystem disorder of the tyrosine degradation pathway due to lack of homogentisate dioxygenase resulting in increased circulating and urinary homogentisic acid. Morbidity includes lithiasis (renal, salivary, prostate, gall bladder), osteopenia, fractures, ruptures of ligaments/muscle/tendons, spine and joint disease. An approach to treating AKU by inhibiting the production of HGA by using nitisinone has been recently recognized. Nitisinone has been used in a related tyrosine disorder, hereditary tyrosinaemia 1 (fatal in early childhood) as the standard of care for more than 20 years. This presentation discusses the efforts of our group in developing nitisinone for AKU, an approach consistent with repurposing. Nitisinone is being developed as a licensed therapy in DevelopAKUre, a European Union funded clinical programme. In parallel, nitisinone is also being used off license in a centre (NAC) commissioned by NHS England Highly Specialised Services since 2012. Data collected from the NAC shows a beneficial effect of nitisinone in AKU.

Biography

Lakshminarayan Ranganath is a Consultant in Clinical Biochemistry and Metabolic Medicine at the Royal Liverpool Hospital. He has completed his Graduation in Medicine from Madras before moving to UK. He has completed a Clinical and Research Training in Surrey before moving to Liverpool in 1999 where he presently works. He has established the AKU theme of clinical and basic science research in 2003. He is now a leader in this field. He has published over 100 papers. He is the Chief Investigator and Coordinating Investigator of SONIA clinical trials. He is the inaugural Clinical Director of the Robert Gregory National AKU Centre in Liverpool.

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Change in gonadotropins in postmenopausal women: Effects of parity

Ekhator C N[1], Egbon P O[2], Ukponahiunsi C A[2], Okoeguale V E[2] and **Koko K[1]**

[1]Ambrose Alli University, Nigeria

[2]St Philomena Catholic Hospital, Nigeria

Introduction: This report assessed the effect of parity on gonadotropins pattern in postmenopausal women. We studied 280 post menopausal women (40 each grouped into nulliparous to para 6). Although there was no significant different in their ages, serum follicle stimulating hormone (FSH) and luteinizing hormone (LH) appeared to correlate negatively with parity. Thus, the levels of gonadotropins may vary with parity in postmenopausal women. Endocrinologically, female aging caused a progressive increase and decrease in FSH and estrogen levels respectively. However, reports showed that FSH secretion varies with individual's characteristics and only a few studies have investigated the effect of age, body mass index, lifestyle factors and ethnic differences. This report was to assess the effect of parity on gonadotropins changes in postmenopausal women.

Materials & Methods: The study was conducted among 280 postmenopausal women attending clinic at Saint Philomena Catholic Hospital in Benin City, Nigeria. They consisted of 40 subjects each with natural menopause transition, devoid of medical, surgical or pathological influence and classified from nulliparous to para 6. After inform consent and approval was given, medical history and blood sample were obtained for serum FSH and luteinizing hormone levels.

Results: The mean age of the women ranges from 56.05±6.91 to 59.25±5.45 years. Nulliparous postmenopausal women had higher FSH ($p>0.05$) but lower LH ($p<0.05$) levels compared to porous postmenopausal women. Parity seems to negatively correlate with FSH and LH levels in postmenopausal women.

Discussion: Based on the results, serum gonadotropin levels may vary with parity as with age, BMI, lifestyle and ethnicity.

Parity	FSH (IU/ml)	LH (IU/ml)
Nulliparous	49.79±1.54	28.58±1.02
Parous	47.16±4.12	33.72±7.01*

Values are mean ± SEM; * significant at $p<0.05$

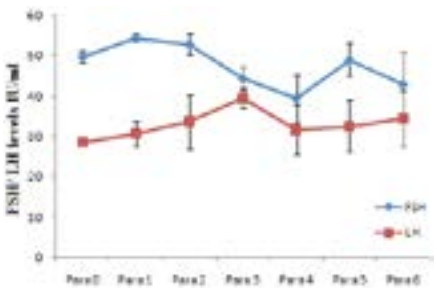

Fig: FSH and LH levels at different parity in postmenopausal women.

Recent Publications

1. Burger H, Dudley E, Hopper J, Groome N, Guthrie J, Green A and Dennerstein L (1999) Prospectively measured levels of serum follicle-stimulating hormone, estradiol and the dimeric inhibins during the menopausal transition in a population based cohort of women. J Clin Endocrinol Metab. 84(11):4025-4030.

2. Manson J M, Sammel M D, Freeman E W and Grisso J A (2001) Racial differences in sex hormone levels in women approaching the transition to menopause. Fertil Steril. 75(2):297-304.
3. Randolph Jr J F, Sowers M F, Gold E B, Mohr B A, Luborsky J, Santoro N, McConnell D S, Finkelstein J S, Korenman S G, Matthews K A, Sternfeld B and Lasley B L (2003) Reproductive hormones in the early menopausal transition: relationship to ethnicity, body size, and menopausal status. J Clin Endocrinol Metab. 88(4):1516-1522.

Biography

Ekhator C N is working as an Associate Professor in the department of Physiology in Ambrose Alli University, Nigeria. He published several articles in many journals. He completed his graduation from University of Ibadan.

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Clinical case of congenital hyperinsulinism in infant born by mother with type 2 diabetes

N B Belykh, A Yu Philimonova and **A D Bazhenova**
Omsk State Medical University, Russian Federation

Relevance: Congenital hyperinsulinism (CHI) is a rare hereditary disease characterized by insulin hypersecretion and severe persistent hypoglycemia in children.

Aim: The aim of the study is to present a clinical case of CHI in a child born of mother with type 2 diabetes.

Patients & Methods: Analysis of the clinical case and medical documentation.

Results: The girl from the 3rd pregnancy proceeding against the background of type 2 diabetes, 3 preterm births (35-36 weeks), weigh is 3410 g. After birth, the glycaemia was 0.1 mmol/l and then stabilized (5.0-4.3 mmol/l). In the first year of life glycaemia was in the range of 3.0-4.0 mmol/l, the neurodevelopment corresponded to the age. At 11 months of age, the level of insulin was 17.4 μE/ml. At the age of one year on the background of a long hungry pause glycaemia was 1.6 mmol/l; the child became lethargic, convulsions were noted. The girl was urgently hospitalized in the hospital with suspected CHI. The diagnosis was confirmed in the National Research Center for Endocrinology, where during the examination the glycaemia was 2.7 mmol/l, insulin-3.78 μE/ml, C-peptide-0.731 ng/ml. On the background of diazoxide intake in a dose of 5.6 mg/kg/day after a hungry period of 11.5 hours, glycaemia-2.9 mmol/l, ketonemia-1.1 mmol/l, insulin-1.56 μE/ml. To clarify the variant of the disease is carried out molecular genetic study. The child was prescribed diazoxide therapy (5.6 mg/kg/day), against which persistent euglycaemia and adequate insulin suppression are achieved. The girl is currently under the supervision of a pediatrician and endocrinologist at the place of residence. The tolerability of the therapy is satisfactory. Glycaemia rates correspond to the norm; the child does not lag behind his peers in neurodevelopment.

Conclusion: The disease manifested itself as a hypoglycemic state on the 2nd day, but later, due to the absence of signs of hypoglycemia, the condition was regarded as transient. The manifestation at the age of one year required an in-depth examination of the child, during which the CHI was diagnosed.

Biography

N. B Belykh is a pediatrician. She is working as an Associate Professor in Department of Pediatrics at State Pediatric Medical University, Russia. She published several articles in many journals.

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Video Presentation

Day 1

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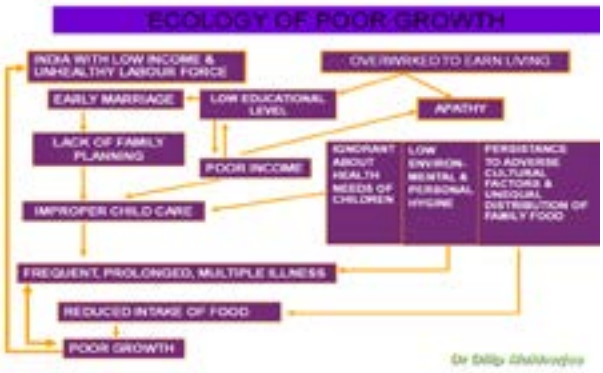
Breast-milk deprivation and its effect in early infancy in rural coastal West Bengal

Dilip Kumar Mukherjee

Vivekananda Institute of Medical Sciences under West Bengal Health University, India

This study was conducted in a Pediatric Clinic at Kakdwip, the southernmost part of south west coastal Sundarbans, near Bay of Bengal. The main source of income is from agriculture. Majority are day-laborers while the sizeable portion of people in general among the working class is poor. Environmental sanitation is not satisfactory. The 65% are Hindus & 35% are Muslim. While conducting the clinic, it was observed that some infants often came with florid case of malnutrition-quite early in age. On enquiry it was revealed that in most of these cases, the infant were denied of breast milk and was fed with candy water instead. This evoked us to study and investigate the cases and this forms the bases of this present presentation. Frank PEM can occur in early infancy (a majority occurred within 4-12 weeks of age). This is due to denying the breast milk to the newborn and resulting in poor performance of breast milk by the mother. The reasons for not giving breast milk were-inadequate breast milk, acidity of the mother, death of the previous child in early infancy and having 'breast milk diarrhea'. The majority incidences were on primi-para mother (53.33%) and in mothers whose age is less than 20. This is a very significant and alarming observation. These mothers who have no knowledge about infant feeding can be easily swayed and dictated by the advice of people around who advise them to stop breast milk and to start candy water, sago or very diluted formula feeds instead and thus gradually all these ultimately resulted in PEM. Thus the teenaged mothers who are physically, mentally, socially and psychologically are not competent to take individual charge of the baby are the victims. Does it signal us to raise the marriage age to 21 years at least so that the mothers become more mature, independent and capable? This study reflects the vital importance of breast milk in the feeding of newborn and early infancy and also the lack of health education of the poor teenaged mothers in rural setup.



Recent Publications

1. Ashok K Patwari, Sanjay Kumar and Jennifer Beard (2015) Undernutrition among infants less than 6 months of age: an underestimated public health problem in India. Maternal and Child Nutrition 11(1):119-126.
2. M M Islam, Y Arafat, N Connell, et.al., (2018) Severe malnutrition in infants aged <6 months-Outcomes and risk factors in Bangladesh: A prospective cohort study. Maternal and Child Nutrition. e12642.

3. Marko Kerac, H Blencowe, et.al., (2011) Prevalence of wasting among under 6-month-old infants in developing countries and implications of new case definitions using WHO growth standards: a secondary data analysis. Archives Diseases in Childhood. 96(11):1008-1013.
4. M Mwangome, M Ngari, et. al., (2017) Diagnostic criteria for severe acute malnutrition among infants aged under 6 months. American Journal of Clinical Nutrition. 105(6):1415-1423.
5. Y Arafat, M M Islam, et.al., (2018) Perceptions of acute malnutrition and its management in infants under six months of age: a qualitative study in rural Bangladesh. Clinical Medicine Insights: Pediatrics.12:1-10.

Biography

Dilip Kumar Mukherjee has his expertise in growth and development from birth till maturity in longitudinal study especially in low socioeconomic group of Children in West Bengal, India. He is a Postgraduate Teacher in pediatrics with special reference in growth and development and nutrition.

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Notes: