Re: Letter in support of the application to include misoprostol on the WHO Model List of Essential Medicines for treatment of post-partum haemorrhage

29 January 2013

Dear Committee Members,

We, the undersigned, are writing in support of the application to include misoprostol on the World Health Organization’s (WHO) Model List of Essential Medicines (EML) for treatment of post-partum haemorrhage (PPH) submitted by Gynuity Health Projects. We support the listing of misoprostol (800mcg sublingual) for its PPH treatment indication in section 22.01.00.00 “Oxytocics”.

Post-partum haemorrhage is the most significant direct cause of maternal death and disability globally. It continues to contribute disproportionately to negative health outcomes for women, particularly in low resource settings, who often do not have immediate access to obstetric services, trained personnel, or standard uterotonic therapy. Oxytocin, the widely recommended agent for preventing and treating PPH due to uterine atony, requires parenteral administration, and, therefore, skills to give intramuscular injection or intravenous infusion, as well as sterile equipment, and refrigeration.

In settings where standard uterotonics are not available or their administration is not feasible, misoprostol, a synthetic E1 prostaglandin analogue, may be the only technology available to control PPH. Its tablet form and its stability at room temperature facilitate its use at all levels of the health care system. Misoprostol’s proven ability to induce uterine contractions, and its low-cost, wide availability and ease of use, make it an ideal medicine to add to the package of interventions available to providers to treat PPH. Misoprostol has been shown to control active post-partum bleeding from haemorrhages suspected to be due to uterine atony.\textsuperscript{1-2} The addition of misoprostol to the EML for its PPH treatment indication could potentially contribute to efforts to achieve Millennium Development Goal #5 to reduce maternal mortality by three-quarters by the year 2015.

In 2012, international organisations, including WHO and the International Federation of Gynecology and Obstetrics (FIGO), updated their guidelines\textsuperscript{3-4-5} to reflect the emerging scientific data on the use of misoprostol for the treatment of PPH.
In its 2012 Recommendations for the Prevention and Treatment of Postpartum Haemorrhage\(^3\), WHO states that “If intravenous oxytocin is unavailable, or if the bleeding does not respond to oxytocin, the use of intravenous ergometrine, oxytocin-ergometrine fixed dose, or a prostaglandin drug (including sublingual misoprostol, 800 μg), is recommended.”

In its 2012 guidance on PPH\(^4\), FIGO recommends that all birth attendants have the necessary training – appropriate to the settings where they work – to administer uterotonics drugs safely and to ensure that uterotonics are available in sufficient quantity to meet the need. To this end, FIGO calls upon national regulatory agencies and policy makers to approve misoprostol for PPH prevention and treatment and to ensure that current best-evidence regimens are adopted. For PPH treatment, FIGO recommends a single dose of 800 μg misoprostol administered sublingually immediately after PPH is diagnosed and if 40 IU IV oxytocin is not immediately available (irrespective of the prophylactic measures).\(^5\)

We thank you for considering the addition of misoprostol to the WHO’s EML for the treatment of PPH.

Yours respectfully,

Professor Sir Sabaratnam Arulkumaran
President
International Federation of Gynecology and Obstetrics (FIGO)

Agneta S Bridges
Secretary General
International Confederation of Midwives (ICM)

Ana Alfrevic, MD, PhD
Senior Lecturer
The Wolfson Centre for Personalised Medicine
Department of Molecular and Clinical Pharmacology
Institute of Translational Medicine
University of Liverpool

Ann M. Starrs
President
Family Care International

André B. Lalonde MD, FRCSC
Professor of Obstetrics and Gynecology
University of Ottawa
McGill University (Canada)
Andrew Weeks
Professor of International Maternal Health
Sanyu Research Unit
University of Liverpool
Liverpool Women’s Hospital (UK)

Dr Anibal Faúndes
Emeritus Professor, State University of Campinas (Brazil)
General Coordinator, Working Group on the Prevention of Unsafe Abortion (FIGO)

Anthony Falconer
President
Royal College of Obstetricians and Gynaecologists (RCOG)

Associate Professor Berna Dilbaz
General Secretary
Turkish Association of Reproductive Health and Family Planning (Turkey)

Dr B.S. Kodkany
Professor of Obstetrics and Gynaecology
Principal Investigator
JNMC Women’s & Children’s Health Research Unit
Director, KLEUs Research Foundation
J.N. Medical College (India)

Dr Carlos Füchtner
Bolivia
Past President
Latin American Federation of Obstetrics and Gynaecology Societies (FLASOG)

Christopher B Lynch
Emeritus Professor
Milton Keynes General Hospital NHS Trust (UK)

Professor C.N. Purandare
Consultant Obstetrician & Gynecologist (India)
President Elect
International Federation of Gynecology and Obstetrics (FIGO)

Cynthia K. Stanton, PhD
Associate Professor
Department of Population, Family and Reproductive Health
The Johns Hopkins Bloomberg School of Public Health (USA)
Dr Dorothy Shaw, MBChB, FRCSC
Vice President, Medical Affairs
British Columbia Women’s Hospital and Health Centre (Canada)

Elizabeth S. Maguire
President and CEO
Ipas

Emad Darwish
Professor of Obstetrics and Gynecology
Faculty of Medicine, Alexandria University (Egypt)

Fran Jaeger, AM, MPH, DrPH
Sr. Clinical Researcher & Manager, Special Projects-Women’s Health
Women’s & Children’s Health Research Center
Christana Care Health Services, Inc. (USA)

Frances Day-Stirk
President
International Confederation of Midwives (ICM)

Professor Hamid Rushwan, MD, FRCOG
Chief Executive Officer
International Federation of Gynecology and Obstetrics (FIGO)

Julia Bunting
Director, Programme and Technical Division
International Planned Parenthood Federation

Kristina Gemzell Danielsson
Professor, MD, PhD
Head of Obstetrics and Gynaecology
Department of Women’s and Children’s Health
Karolinska Institutet (Sweden)

Dr Magfera Begum
Director
Family Planning Association of Bangladesh

Nancy L. Sloan, DrPH
Sr. Clinical Researcher & Epidemiologist
Christana Care Health Services, Inc. (USA)
Ndola Prata, MD, MSc
Associate Professor in Residence, Maternal and Child Health
Scientific Director, Bixby Center for Population, Health and Sustainability
School of Public Health
University of California, Berkeley

Professor Nguma Aloïs
President
Société Africaine de Gynécologie et d’Obstétrique (SAFO)

Nguyen Thi Nhu Ngoc
Director
Center for Research and Consultancy in Reproductive Health (Vietnam)

Pam Norick
President and CEO
Venture Strategies Innovations

Pamela W. Barnes
President and CEO
EngenderHealth

Paul D. Blumenthal, MD, MPH
Professor of Obstetrics and Gynecology
Director, The Stanford Gynecology Service
Director, Stanford Program for International Reproductive Education and Services (SPIRES)
Stanford University School of Medicine

Dr Paula Franklin
Global Medical Director
Marie Stopes International

Richard J. Derman, MD, MPH
Marie E. Pinizzotto, MD Endowed Chair of Obstetrics & Gynecology
Director, Center for Women’s & Children’s Health Research
Christian Care Health Services, Inc. (USA)

Prof. Émérite Robert J. I. LEKE
MD, DES, CES, FRCS(c), FWACS
Gynécologue/Obstétricien
Hôpital Central Yaoundé (Cameroon)
Sally G. Cowal  
Senior Vice President and Chief Liaison Officer  
Population Services International

Shafiq Mirzazada, M.D., M.P.H.  
Country Director  
Aga Khan Health Service, Afghanistan

Sharon L. Camp  
President and CEO  
Guttmacher Institute

Dr Shivaprasad S Goudar, MD, MHPE  
Professor of Physiology & Research Coordinator  
Women’s and Children’s Health Research Unit  
KLE University’s J N Medical College, Belgaum (India)

Suellen Miller  
Professor, Director, Safe Motherhood Program  
Bixby Center for Global Reproductive Health  
Department of Obstetrics, Gynecology, and Reproductive Sciences  
School of Medicine  
University of California, San Francisco

Dr Swaraj Rajbhandari  
Sr. Obstetrician/Gynecologies & Maternal and Newborn Health Specialist (Nepal)  
Past President & Founding Member, Nepal Society of Obstetricians and Gynecologists (NESOG)

Tori Sutherland, MPH  
University of Texas, Southwestern

Dr Wilfrido León  
Universidad Central del Ecuador  
Universidad Católica del Ecuador  
Sociedad Ecuatoriana de Ginecología y Obstetricia

Professor William Stones, MD, FRCOG  
Chair, FIGO Committee for Safe Motherhood and Newborn Health  
The Puribai Kanji Jamal Professor  
Chair, Department of Obstetrics and Gynaecology  
Aga Khan University, Nairobi (Kenya)
Zarko Alfirevic, MD, FRCOG
Professor of Fetal and Maternal Medicine
Head of Department of Women's and Children's Health
Institute of Translational Medicine
University of Liverpool (UK)

References


