Antepartum Administration of Lactoferrin for Prevention of Neonatal *E. Coli* Sepsis

Inventors: Susana Chavez-Bueno, Rachel Chevalier

The Innovation:

Prenatal maternal vaginal administration of lactoferrin (LF) significantly decreases vaginal bacterial loads of a clinically significant neonatal invasive *E. coli* isolate. Placental bacterial loads, and burden of infection in the offspring were also significantly decreased. Prenatal lactoferrin is a potential preventative intervention against neonatal sepsis.

Background:

Escherichia coli is the most common cause of early-onset newborn sepsis. Affected infants have a nearly 40% chance of dying. Newborns become infected with *E. coli* that normally reside in the intestine and genital tract of pregnant women. Pathogens ascend from the birth canal infecting the newborn and producing neonatal septicemia. Physicians currently have no methods to prevent newborn *E. coli* infection. Current approaches are limited to treatment of the newborn after they present with signs of infection and often are not effective.

Lactoferrin (LF) is a human antibacterial and immunomodulatory glycoprotein secreted in breastmilk, tears, saliva, and vaginal fluid. LF has a long history of safety and has been given to preterm newborns to prevent late-onset sepsis and in the first-trimester of pregnancy to prevent pre-term labor.

The Innovation:

The Innovation comprises a vaginal formulation of LF for maternal administration during the mid to late stages of pregnancy to effectively prevent, or reduce the severity of, neonatal *E. coli* sepsis.

Children's Mercy KANSAS CITY

Contact: Marcia Molina | Director of Technology Transfer
mimolina@cmh.edu |TechTransfer@cmh.edu

- *In vivo* animal studies (mice) were conducted with clinically significant *E.coli* isolates using human (hLF) and bovine (bLF) lactoferrin, each of which were found to be effective in reducing *E.coli* levels compared to placebo-treated dams
- Vaginal bacterial loads were significantly lower in hLF pre-treated dams compared to placebo
- Placental bacterial loads were significantly lower in hLF and bLF treated dams compared to placebo
- Bacterial loads in blood, liver, spleen and brains of embryos of hLF and bLF pre-treated dams were significantly lower compared to placebo

Advantages and Potential Applications:

- A vaginal formulation of LF for administration during pregnancy in an inpatient or outpatient setting to effectively prevent or reduce the severity of neonatal *E. Coli* sepsis.
- LF is not an antibiotic, this approach would not contribute to the worsening problem of antimicrobial resistance which is a concern with methods used to prevent other sources of newborn infection.

Market Size:

Greater than 2000 cases of newborn sepsis in the US and over five million cases worldwide are reported annually. The WHO estimates that 340,000 newborns die of sepsis annually. LF can be delivered prophylactically as part of routine pre-natal care.

Status: Provisional Patent Application filed March 14, 2022. PCT Application filed March 14, 2023.

Licensing: Children's Mercy, Kansas City seeks to have discussions with companies that are interested in licensing and/or research collaborations.

Children's Mercy KANSAS CITY

Contact: Marcia Molina | Director of Technology Transfer
(785) 341-8112 (mobile) | mimolina@cmh.edu | TechTransfer@cmh.edu