Budget Submission: $5million

A $1.5M investment from the Australian Government would enable Lifeblood to scale up production of an Australian made fortifier and an initial safety trial.

A further $3.5M, would also enable a world first full-scale clinical trial to be undertaken, developing an impactful new Australian product that meets clinical demand, improves health outcomes for our most vulnerable babies and saves the health system money.

Context

Premature babies need extra nutrients to support their rapid growth. Cow milk proteins are difficult for them to digest and can increase their risk of complications.

A fortifier made from human milk could give up to 26,000 premature babies the extra nutrients they need, but no such product is currently available in Australia.

Lifeblood to manufacture an Australian made breast milk fortifier to meet clinical demand. SAHMRI to perform safety and clinical trials as an essential next step in the fortifier's development.

Background

Mother's own milk is the best nutrition, but babies born prematurely, or low birthweight often need more nutrient-dense milk than is possible for a mother (or donor) to produce. These babies need extra nutrients to support their rapid growth during an important period for brain and gut development. Inadequate nutrition at this critical time can cause lifelong health and developmental problems.

Cow's milk-based supplements called fortifiers are routinely added to mother's own and donor milk to provide additional nutrients (especially protein) to vulnerable babies, but cow's milk proteins are difficult for preterm babies' immature guts to digest. Research has shown that the use of cow's milk fortifiers – even when the only other nutrition that infants are consuming is mother's own milk – can increase the risk of complications, including the risk of necrotising enterocolitis, a potentially fatal gut disease.

A fortifier made from human milk could give these vulnerable babies the extra nutrients they need without exposing them to cow's milk products, but no such product is currently available in Australia.

Opportunity

With the establishment of Lifeblood Milk, for the first time in Australia there is a national, safe supply of donated human milk ("donor milk"). Thanks to our many generous donors, Lifeblood now has the capability to investigate new ways that we can improve care for vulnerable babies while still ensuring that we can supply donor milk to babies who need it. As a result, Lifeblood has established a research program in collaboration with several world class research institutes including CSIRO for the manufacture of novel products, and the South Australian Health and Medical Research Institute (SAHMRI) for the management of associated clinical trials. This program adds value to Lifeblood's current donor milk service by leveraging existing infrastructure to develop new products with nutritional and therapeutic benefits to help even more babies get the best start in life.

Australian clinicians want a fortifier made from human milk. Lifeblood's Milk Clinical Advisory Board has previously and recently (Sept 2021) endorsed developing a fortifier derived from human milk as a key priority.

Lifeblood has contracted CSIRO to trial production of Australia's first fortifier made from donated breast milk. Lifeblood has sought feedback on results of trial production runs from SAHMRI and are currently finalising the production process and identifying a scaled manufacturing location.

What still needs to be done

• Scale-up production of fortifier made from donor milk to support clinical trials.

• The first in-human trial will be a safety trial in well babies born moderate-late preterm (n= 40). This trial is necessary to proceed to trials that demonstrate the efficacy and benefits of this product.

• SAHMRI to conduct a world-first clinical trial, to investigate if the fortifier made from donor milk demonstrates the expected benefits in supporting growth, while reducing rates of complications associated with current cow's milk derived products.

Reach

We will focus our efforts on initially producing fortifier for babies born at or before 28 weeks, who are at highest risk of the most serious complications and where a fortifier made from human milk is likely to have the greatest benefits and return-on-investment – initially approximately 1500 babies per year. However, the potential impact once production is established is the preterm population of approximately 26,000 babies.

About SAHMRI & Australian Red Cross Lifeblood

The South Australian Health and Medical Research Institute (SAHMRI) is an independent health and medical research institute housing more than 700 medical researchers working together to tackle the biggest health challenges in society today. This includes world-leading researchers in the development and translation of infant nutrition interventions, with particular interest in reducing the consequences of prematurity on lifelong health.

Australian Red Cross Lifeblood (Lifeblood) provides services to the health sector in Australia and is responsible for the collection, processing and distribution of life-giving blood, plasma, transplantation, human milk and other biological products for world-leading health outcomes to the Australian community. Lifeblood is guided by the fundamental principles of the Red Cross: humanity, impartiality, neutrality, independence, voluntary service, unity and universality.

Together, SAHMRI and Lifeblood are leading a consortium to revolutionise the way human milk, and novel products made from human milk, are used as nutritional and medical interventions to improve health outcomes in vulnerable infants, but with potential application for a diverse range of medical indications.

Therapeutic potential

Human milk is a highly sophisticated human origin biological with unique components that have demonstrated therapeutic impact in some settings, and significant therapeutic potential in many others.

Human milk has evolved to provide the sole source of nourishment during a critical developmental window when our brain, organs, physiology and metabolism are being fine-tuned for health across life. This ability demonstrates the profound significance of human milk as a model to investigate novel therapeutic agents. Yet until recently the complexity of human milk has been under-appreciated. New discoveries reveal that human milk is an intricate and dynamic fluid with a unique composition of proteins, lipids, carbohydrates, immune factors, prebiotics, digestive enzymes, growth factors and hormones, healthy bacteria, stem cells and other cells. Critically, human milk contains an array of specialised bioactive compounds that are not found in any other sources of milk (e.g. cow's milk). Many of these compounds have significant therapeutic potential.

In its simplest form, donated human milk, used instead of infant formula (which is made from cow's milk), has been shown to decrease the risk of necrotising enterocolitis, a life-threatening bowel disease, in infants born very premature (before 32 weeks of pregnancy).

Mother's own milk is the best source of nutrition for babies, and any collection of human milk and associated clinical use must occur in a way that supports and enhances maternal breastfeeding. Large quantities of human milk are needed to purify and concentrate its key components, and to date ethically accessing the required volumes of milk to enable the development of this industry has proven extremely difficult. In Australia, we are uniquely poised to overcome this major challenge with

the recent launch of Lifeblood's donor milk service. This is the only donor milk service globally with national reach, and has sufficient donor reach to ethically collect enough milk annually to support novel activities in this space.

Preterm infants need specialised nutritional support to grow and develop optimally, and these needs have not and are unlikely to be met by advances in cow's milk-derived nutritional products. Innovation in the use of donated human milk represents the most promising avenue for improving preterm infant nutrition, but a lack of investment into the development and evaluation of novel biologicals and lack of clarity regarding regulatory pathways is hindering progress in this area.

Over the past two decades there have been significant improvements in the survival of preterm infants. However, improvements in serious morbidity have plateaued. This is thought to be due to prolonged inadequate early nutrition, which remains a fundamental challenge for neonatal care. Mother's own milk is the best source of nutrition for these infants, yet many preterm babies miss out on the protective effects of human milk, as they have difficulties breastfeeding and often need more milk and nutrients than their mothers can supply. To elaborate, preterm infants have very high nutrient requirements to achieve the rapid brain, bone and organ growth that would normally occur in the womb, but they can only ingest small volumes of milk due to their small size and immaturity.

Globally, nutritional supplements made from concentrating cow's milk are routinely given to preterm infants, but current products are inadequate and can cause harm. Due to their significant gut immaturity, preterm infants often have difficulties digesting the foreign cow's milk proteins resulting in gut irritation and poor digestion of nutrients. Improving neonatal nutrition in now recognised as the most pressing priority for research and innovation in the care of preterm infants.

Preterm birth has a profound impact on infants, their families and wider society. In the newborn period, preterm infants have an increased risk of death and major morbidities including sepsis, respiratory distress, retinopathy of prematurity and necrotising enterocolitis. Many of these infants require a prolonged hospital stay after birth, and readmission throughout the early years of life.

The increased risk of morbidity persists across childhood. Preterm infants are more likely to have stunted growth, cognitive impairment, blindness, deafness, and chronic respiratory disease than term born infants. These complications have lifelong consequences for health and wellbeing, resulting in increased risks of chronic diseases in adult life including diabetes and heart disease.

More than 26,000 infants are born preterm (<37 weeks gestation) in Australia every year. Rates of preterm birth have not improved over the past two decades and worryingly, in many countries have increased. Advancements in nutritional care for preterm infants is critical to improving health and well-being throughout life for thousands of Australians.