

# ***AHRQ Healthcare Horizon Scanning System – Potential High-Impact Interventions Report***

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## **Priority Area 12: Pregnancy, Including Preterm Birth**

**Prepared for:**

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## **Statement of Funding and Purpose**

This report incorporates data collected during implementation of the Agency for Healthcare Research and Quality (AHRQ) Healthcare Horizon Scanning System by ECRI Institute under contract to AHRQ, Rockville, MD (Contract No. HHSA290201000006C). The findings and conclusions in this document are those of the authors, who are responsible for its content, and do not necessarily represent the views of AHRQ. No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

This report's content should not be construed as either endorsements or rejections of specific interventions. As topics are entered into the System, individual topic profiles are developed for technologies and programs that appear to be close to diffusion into practice in the United States. Those reports are sent to various experts with clinical, health systems, health administration, and/or research backgrounds for comment and opinions about potential for impact. The comments and opinions received are then considered and synthesized by ECRI Institute to identify interventions that experts deemed, through the comment process, to have potential for high impact. Please see the methods section for more details about this process. This report is produced twice annually and topics included may change depending on expert comments received on interventions issued for comment during the preceding 6 months.

A representative from AHRQ served as a Contracting Officer's Technical Representative and provided input during the implementation of the horizon scanning system. AHRQ did not directly participate in horizon scanning, assessing the leads for topics, or providing opinions regarding potential impact of interventions.

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## **Financial Disclosure Statement**

None of the individuals compiling this information has any affiliations or financial involvement that conflicts with the material presented in this report.

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## Preface

The purpose of the AHRQ Healthcare Horizon Scanning System is to conduct horizon scanning of emerging health care technologies and innovations to better inform patient-centered outcomes research investments at AHRQ through the Effective Health Care Program. The Healthcare Horizon Scanning System provides AHRQ a systematic process to identify and monitor emerging technologies and innovations in health care and to create an inventory of interventions that have the highest potential for impact on clinical care, the health care system, patient outcomes, and costs. It will also be a tool for the public to identify and find information on new health care technologies and interventions. Any investigator or funder of research will be able to use the AHRQ Healthcare Horizon Scanning System to select potential topics for research.

The health care technologies and innovations of interest for horizon scanning are those that have yet to diffuse into or become part of established health care practice. These health care interventions are still in the early stages of development or adoption, except in the case of new applications of already-diffused technologies. Consistent with the definitions of health care interventions provided by the Institute of Medicine and the Federal Coordinating Council for Comparative Effectiveness Research, AHRQ is interested in innovations in drugs and biologics, medical devices, screening and diagnostic tests, procedures, services and programs, and care delivery.

Horizon scanning involves two processes. The first is identifying and monitoring new and evolving health care interventions that are purported to or may hold potential to diagnose, treat, or otherwise manage a particular condition or to improve care delivery for a variety of conditions. The second is analyzing the relevant health care context in which these new and evolving interventions exist to understand their potential impact on clinical care, the health care system, patient outcomes, and costs. It is NOT the goal of the AHRQ Healthcare Horizon Scanning System to make predictions on the future use and costs of any health care technology. Rather, the reports will help to inform and guide the planning and prioritization of research resources.

We welcome comments on this Potential High Impact report. Send comments by mail to the Task Order Officer named in this report to: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to: [effectivehealthcare@ahrq.hhs.gov](mailto:effectivehealthcare@ahrq.hhs.gov).

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# Executive Summary

## Background

Horizon scanning is an activity undertaken to identify technological and system innovations that could have important impacts or bring about paradigm shifts. In the health care sector, horizon scanning pertains to identifying new (and new uses of existing) pharmaceuticals, medical devices, diagnostic tests and procedures, therapeutic interventions, rehabilitative interventions, behavioral health interventions, and public health and health promotion activities. In early 2010, the Agency for Healthcare Research and Quality (AHRQ) identified the need to establish a national Healthcare Horizon Scanning System to generate information to inform comparative-effectiveness research investments by AHRQ and other interested entities. AHRQ makes those investments in 14 priority areas. For purposes of horizon scanning, AHRQ's interests are broad and encompass drugs, devices, procedures, treatments, screening and diagnostics, therapeutics, surgery, programs, and care delivery innovations that address unmet needs. Thus, we refer to topics identified and tracked in the AHRQ Healthcare Horizon Scanning System generically as "interventions." The AHRQ Healthcare Horizon Scanning System implementation of a systematic horizon scanning protocol (developed between September 1 and November 30, 2010) began on December 1, 2010. The system is intended to identify interventions that purport to address an unmet need and are up to 7 years out on the horizon and then to follow them for up to 2 years after initial entry into the health care system. Since that implementation, review of more than 15,000 leads about potential topics has resulted in identification and tracking of about 1,600 topics across the 14 AHRQ priority areas and 1 cross-cutting area; about 950 topics are being actively tracked in the system.

## Methods

As part of the Healthcare Horizon Scanning System activity, a report on interventions deemed as having potential for high impact on some aspect of health care or the health care system (e.g., patient outcomes, utilization, infrastructure, costs) is aggregated twice annually. Topics eligible for inclusion are those interventions expected to be within 0–4 years of potential diffusion (e.g., in phase III trials or for which some preliminary efficacy data in the target population are available) in the United States or that have just begun diffusing and that have completed an expert feedback loop.

The determination of impact is made using a systematic process that involves compiling information on topics and issuing topic drafts to a small group of various experts (selected topic by topic) to gather their opinions and impressions about potential impact. Those impressions are used to determine potential impact. Information is compiled for expert comment on topics at a granular level (i.e., similar drugs in the same class are read separately), and then topics in the same class of a device, drug, or biologic are aggregated for discussion and impact assessment at a class level for this report. The process uses a topic-specific structured form with text boxes for comments and a scoring system (1 minimal to 4 high) for potential impact in seven parameters. Participants are required to respond to all parameters.

The scores and opinions are then synthesized to discern those topics deemed by experts to have potential for high impact in one or more of the parameters. Experts are drawn from an expanding database ECRI Institute maintains of approximately 350 experts nationwide who were invited and agreed to participate. The experts comprise a range of generalists and specialists in the health care sector whose experience reflects clinical practice, clinical research, health care delivery, health business, health technology assessment, or health facility administration perspectives. Each expert uses the structured form to also disclose any potential intellectual or financial conflicts of interest

(COIs). Perspectives of an expert with a COI are balanced by perspectives of experts without COIs. No more than two experts with a possible COI are considered out of a total of the seven or eight experts who are sought to provide comment for each topic. Experts are identified in the system by the perspective they bring (e.g., clinical, research, health systems, health business, health administration, health policy).

The topics included in this report had scores *and/or* supporting rationales at or above the overall average for all topics in this priority area that received comments by experts. Of key importance is that topic scores alone are not the sole criterion for inclusion—experts’ rationales are the main drivers for the designation of potentially high impact. We then associated topics that emerged as having potentially high impact with a further subcategorization of “lower,” “moderate,” or “higher” within the potential high-impact range. As the Healthcare Horizon Scanning System grows in number of topics on which expert opinions are received, and as the development status of the interventions changes, the list of topics designated as having potentially high impact is expected to change over time. This report is being generated twice a year.

For additional details on methods, please refer to the full AHRQ Healthcare Horizon Scanning System Protocol and Operations Manual published on AHRQ’s Effective Health Care Web site.

## Results

The table below lists the three topics for which (1) preliminary phase III data were available for drugs, phase II or III data were available for devices and procedures, or some human data were available for off-label uses or programs; (2) information was compiled by September 21, 2012, in this priority area; *and* (3) we received six to nine sets of comments from experts between August 2011 and October 19, 2012 (Eighteen topics in this priority area were being tracked in the system as of October 26, 2012). We present one summary on a single topic (indicated below by an asterisk) that emerged as potential high impact on the basis of experts’ comments and their assessment of potential impact. The material on interventions in this Executive Summary and report is organized alphabetically by intervention. Readers are encouraged to read the detailed information on each intervention that follows the Executive Summary.

### Priority Area 12: Pregnancy and Preterm Birth

Topic	High-Impact Potential
1. * Donor human milk program for very-low-birthweight infants	High
2. Endoglin urine screening test for preeclampsia screening	No high-impact potential at this time
3. Ulipristal acetate (CDB-2914) for uterine fibroids	No high-impact potential at this time

## Discussion

Relatively few new developments in interventions or programs and services in the area of pregnancy and preterm birth have been identified as meeting criteria of the Healthcare Horizon Scanning System. Of the topics identified that have received expert comments, one program, donor human milk programs for very-low-birthweight (VLBW) infants, emerged as having a potentially high impact for this updated report. Although the donor milk program that emerged as potentially high impact does not employ novel technology, it leverages a scarce resource, excess breast milk from unrelated donors to support VLBW infants.

## Donor Human Milk Program for Very-Low-Birthweight Infants

- **Key Facts:** VLBW is defined as a newborn weight of less than 1,500 grams (3 lb, 5 oz) at birth. Data from the U.S. Centers for Disease Control and Prevention indicate VLBW and extreme prematurity (infants born before 32 weeks' gestation) are factors predicting a higher risk of death during the first month of life if an infant is not born at a level III hospital. Child Health USA reports that infants born at such low birthweights are about 100 times as likely to die in the first year of life as infants of normal birth weight (>5 lb, 8 oz). VLBW infants who survive are at significantly increased risk of severe cognitive impairment and pulmonary and vision problems, requiring increased levels of medical, educational, and parental care. Many mothers who give birth to premature VLBW infants are unable to provide breast milk at all or in sufficient quantities. Donor milk from other lactating mothers might provide an option to improve neonatal health outcomes. Lactating women pump and donate their milk to milk banks. Similar to standard practice at blood banks, lactating donors are screened for communicable diseases, alcohol consumption within a specified period, medication use, and vitamin supplement use, and donors must be nonsmokers. Milk is frozen and transported to the milk bank, where it is pasteurized, cultured for bacteria, and shipped overnight to hospitals and homes. A prescription is needed for the milk to be dispensed. The U.S. Food and Drug Administration (FDA) does not regulate human milk banking but offers guidelines and provisions if mothers choose to feed infants with donor human milk. FDA's advisory panel on this topic strongly recommended against using donated breast milk not acquired from an accredited milk bank. Costs for donated breast milk are reported to be between \$3 and \$5 per ounce with additional costs for shipping. In contrast, infant formula costs between 71 and 83 cents per ounce and may be provided free to hospitals. The National Association of Neonatal Nurses recently asserted that every dollar expended on providing donor human milk saves \$11 in medical costs associated with health conditions, including septicemia and lifelong developmental disorders. Diffusion has been limited in large part by lack of awareness of the need and inconsistent reimbursement mechanisms and coverage policies. Hospitals may consider donor human milk part of the room and meal charge, include it in pharmaceutical costs, pay for it out of their unit's budget, or seek financial support from private foundations. Payment often depends on the diagnostic code assigned to the infant and on prescribing-practitioner documentation. The U.S. Centers for Medicare & Medicaid Services has no national coverage determination on donor breast milk for premature infants and only one State has mandated coverage.
- **Key Expert Comments:** Experts thought that human donor milk programs have potential to reduce rates of disease and infection in neonates, and they were eager to see additional studies to determine this intervention's impact on neurodevelopment. Experts agreed that this intervention has potential to reduce health disparities as well and thought that increasing accessibility of donor human milk programs to African-American and socioeconomically disadvantaged babies might significantly improve infant health outcomes.
- **Potential for High Impact:** High

## **Pregnancy, Including Preterm Birth, Intervention**



## Donor Human Milk Program for Very-Low-Birthweight Infants

Very low birthweight (VLBW) is defined as a newborn weight of less than 1,500 grams (3 lb, 5 oz) at birth. Data from the U.S. Centers for Disease Control and Prevention indicate VLBW and extreme prematurity (infants born before 32 weeks' gestation) are factors predicting a higher risk of death during the first month of life if an infant is not born at a level III hospital.<sup>1</sup> Child Health USA reports that infants born at such low birthweights are about 100 times as likely to die in the first year of life as infants of normal birthweight (>5 lb, 8 oz). VLBW infants who survive are at significantly increased risk of significant cognitive impairment and pulmonary and vision problems, requiring increased levels of medical, educational, and parental care.<sup>2</sup> Many mothers who give birth to a premature infant are unable to provide breast milk at all or in sufficient quantities. This signals the need for an intervention aimed at improving physical and neurodevelopmental outcomes in these infants.

Donor milk from other lactating mothers is a potential intervention for mothers facing challenges to breastfeeding their VLBW children, such as lingering complications from pregnancy, anxiety regarding the infant's health, lack of privacy that curtails initiation of milk expression, dislike of breast pumps, and daily travel to the neonatal intensive care unit from home or work after delivery.<sup>3</sup> In human milk donation, lactating women pump breast milk and donate it to milk banks. Similar to standard practices at blood banks, lactating donors are screened for communicable diseases, alcohol consumption within a specified period, and medication and vitamin supplement use; they must be nonsmokers. Human donor milk processing involves multiple steps, commencing with pasteurization (PST) team members scrubbing their hands before applying gloves required to handle donated milk. They transfer milk from the donation container to a glass flask, mixing samples from about three to five donors and distributing evenly. PST workers then distribute the milk evenly into smaller glass bottles and prepare the samples for PST. The smaller milk bottles are gently pasteurized to kill bacteria while preserving most of the milk's nutritional components, including digestive enzymes, immunologic factors, growth factors, and hormones.<sup>4</sup> Once the PST process is completed, workers check for bacterial contamination and discard the milk if bacteria are detected. Milk samples that have passed inspection are frozen and stored until delivered to a recipient's hospital or home.<sup>5</sup> Research indicates breast milk may reduce risk of necrotizing enterocolitis, urinary tract infections, and retinopathy of prematurity while improving IQ and visual development.<sup>4</sup>

In 2012, Colaizy and colleagues presented data from a study evaluating the efficacy of human milk—maternal, donor, or mixed—as measured by growth of 171 hospitalized VLBW infants. Authors reported the following:<sup>6</sup>

[Sixteen percent] of infants were small-for-gestational age (SGA, < 10th percentile) at birth, and 34% of infants were SGA at discharge. Infants fed >75% human milk had a greater negative change in weight z-score from birth to discharge compared to infants receiving < 75% (-0.6 vs, -0.4,  $p = 0.03$ ). Protein and caloric supplementation beyond standard human milk fortifier was related to human milk intake ( $p = 0.04$ ). Among infants receiving > 75% human milk, there was no significant difference in change in weight z-score by milk type (donor - 0.84, maternal -0.56, mixed -0.45,  $p = 0.54$ ). Infants receiving >75% donor milk had higher rates of SGA status at discharge than those fed maternal or mixed milk (56% vs. 35% (maternal), 21% (mixed),  $p = 0.08$ ).

In 2010, Sullivan and colleagues presented data from a study evaluating the efficacy of an exclusively human-milk-based diet (at 2 intake levels) compared with a diet of both human and

bovine milk-based products in extremely premature infants. The authors concluded, “The 3 groups (total n=207 infants) had similar baseline demographic variables, duration of parenteral nutrition, rates of late-onset sepsis, and growth. The groups receiving an exclusively human milk diet had significantly lower rates of necrotizing enterocolitis (NEC),  $p=0.02$ , and NEC requiring surgical intervention ( $p=0.007$ ).”<sup>7</sup>

FDA does not regulate human milk banking.<sup>8</sup> FDA, however, recommends against feeding with breast milk acquired directly from individuals or through the Internet and recommends that if, after consultation with a health care provider, a mother decides to feed an infant with human milk from a source other than her own, only milk from a source that has been screened to ensure its safety should be used.<sup>9</sup>

Costs for donated breast milk are reported to be between \$3 and \$5 per ounce with additional costs for shipping.<sup>10</sup> In contrast, infant formula costs between 71 and 83 cents per ounce and may be provided free to hospitals.<sup>10</sup> The National Association of Neonatal Nurses recently reported that every dollar expended on providing donor human milk saves \$11 in medical costs associated with health conditions including septicemia and lifelong developmental disorders.<sup>11</sup>

Despite potential cost barriers, this service has been steadily diffusing over the past few years. The first official human milk bank in the United States was established in 1919.<sup>10</sup> The Human Milk Banking Association of North America (HMBANA, Fort Worth, TX), established in 1985, published the standards used by all North American milk banks in 1990.<sup>10</sup>

As of October 2012, 13 accredited milk banks were listed on the HMBANA Web site. They are in the following cities: Austin, TX; Calgary, Alberta, Canada; Coralville, IA; Columbus, OH; Denver, CO; Fort Worth, TX; Indianapolis, IN; Kalamazoo, MI; Kansas City, MO; Newtonville, MA; Raleigh, NC; San Jose, CA; and Vancouver, British Columbia, Canada.

The HMBANA Web site listed the following cities as home for four additional, “developing” milk banks: Madison, MS; Orlando, FL; Portland, OR; and Toronto, Ontario, Canada.<sup>12</sup>

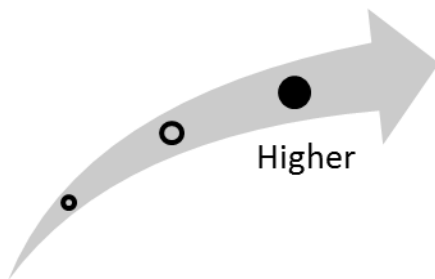
Reimbursement for donor human milk differs by State and institution. The U.S. Centers for Medicare & Medicaid Services has no national coverage determination on donor breast milk for premature infants and only one State has mandated coverage.

Hospitals may consider donor human milk part of the room and meal charge, include it in pharmaceutical costs, pay for it out of their unit’s budget, or seek financial support from private foundations. Payment often depends on the diagnostic code assigned to the infant and on prescribing-practitioner documentation.<sup>13</sup>

## **Clinical Pathway at Point of This Intervention**

Premature VLBW infants require specific management of fluids, electrolytes, and nutrition. Information from the prenatal and neonatal history may assist neonatologists in identifying conditions affecting neonatal fluid and electrolyte balance. Nutrition needs may include parenteral and or enteral modalities. The decision to use enteral feeding depends on the infant’s ability to coordinate sucking, swallowing, and breathing. In general, human milk is preferred for infant enteral nutrition, but mothers of premature VLBW infants are sometimes unable to provide breast milk.<sup>14</sup> Using human milk donated by other mothers and prepared for VLBW neonates is being investigated to support VLBW nutrition when the infant’s mother is unable to provide any or sufficient breast milk.

**Figure 1. Overall high-impact potential: donor human milk program for very-low-birthweight infants**



Overall, experts commenting on this intervention viewed donor human milk as having high potential to meet a significant unmet need of supplying breast milk to VLBW infants. Although experts agreed that providing human donor milk might result in reduced rates of disease and infection, they thought that additional studies are needed to determine this intervention's impact on neurodevelopment. Experts generally agreed on this intervention's potential to positively affect health disparities and that increasing the accessibility of donor human milk to African-American and socioeconomically disadvantaged babies may significantly improve patient health outcomes. Overall, experts believe this intervention might highly affect health outcomes for this patient population. Based on this input, our overall assessment is that this intervention is in the high end of the high-potential-impact range.

## **Results and Discussion of Comments**

Seven experts, with clinical, research, health systems, and health administration backgrounds, provided perspectives on this intervention.<sup>15-21</sup> All experts saw a significant unmet need for more innovative ways to supply VLBW patients with the nutrients needed to avoid potential health complications, and they agreed donor human milk could be a sound intervention aimed at mitigating these complications. One research expert opined that if a mother is unable or unwilling to breastfeed her infant, donor human milk banks would provide a viable alternative to meet the needs of VLBW infants. One expert said that although this intervention might fulfill an unmet need, a question arises as to the number of mothers unwilling or unable to breastfeed their infants.

All experts agreed that donor human milk has the potential to significantly improve patient health outcomes, pointing to its potential impact on reducing rates of asthma, diarrhea, ear infections, necrotizing enterocolitis, pneumonia, and sepsis in VLBW infants. Although some experts believe long-term studies are needed to properly evaluate this intervention's impact on neurodevelopment, one research expert stated that randomized control trials or other direct comparison controlled studies "seem unnecessary though payers will likely demand them."<sup>16</sup> This research expert continues, "What is the effect of pasteurization on survival of immunoglobulins etc? This seems like the greatest threat to the health benefits."<sup>16</sup>

Most experts agreed that donor human milk banks have the potential to significantly affect health disparities, with one research expert stating that "African Americans and socioeconomically disadvantaged babies are most likely to be born prematurely. Not having access to the health benefits of breast milk when their mothers cannot provide it (whether for health or economic reasons) will put the babies at further long-term disadvantage if their development is impaired."<sup>16</sup> Another research expert stated, "With the use of banked [human donor] milk, babies born to mothers with HIV, drug addiction, or health problems who are unable to provide breast milk for their infant will be able to receive the health benefits, therefore reducing disparity."<sup>17</sup> But one research expert did not believe in this intervention's ability to reduce health disparities, citing the

fact that health insurance does not currently extend coverage for human donor milk, therefore widening the barrier for the economically disadvantaged.

Experts generally agreed that this intervention's potential to disrupt the current health care delivery infrastructure and this patient population's management would be low. A research expert mentioned that special facilities may need to be in place to process and store donor milk for distribution. Experts also agreed that both clinician and patient acceptance of this intervention would be significantly high, given the awareness of the health benefits of breast milk for infants, particularly VLBW infants. One clinical expert stated, "While there will be concern over infectious transfer I think this will be countered by the perceived benefits to the infant."<sup>19</sup> A research expert listed potential costs and "convenience of use" as a barrier to clinician acceptance.<sup>17</sup> The same expert also cited the education of the health care team responsible for screening and storing the donor milk and administering the programs as critical to the acceptance of this intervention. Many experts believe there may be an initial increase in costs, but the reduction in costs stemming from long-term complications of health issues for VLBW infants might ultimately significantly lower costs for this patient population.

Overall, experts agreed that although more safety and efficacy studies must be performed to determine its effect on neurodevelopment outcomes, donor human milk has potential for high impact among this patient population, providing an efficacious and safe alternative to maternal breast feeding for VLBW infants. One clinical expert stated, "This is an important intervention with large potential to improve the health and development of VLBW infants as well as reduce the costs to the health care system and society. Additional research in this area should be of high priority."<sup>19</sup> Another expert believes providing another nutrition option for VLBW infants could be critical to improving long-term development in this patient population.

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