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

Priority Area 12: Pregnancy, Including Preterm Birth

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U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

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Prepared by:
ECRI Institute
5200 Butler Pike
Plymouth Meeting, PA 19462

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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.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Elise Berliner, Ph.D.
Task Order Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

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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 4 years out on the horizon and then to follow them up to 2 years after initial entry into the health care system. Since that implementation, review of more than 16,000 leads about potential topics has resulted in identification and tracking of about 1,800 topics across the 14 AHRQ priority areas and 1 cross-cutting area; about 600 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 high-impact-potential 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 two topics for which (1) some human data were available for programs (no drug, device, or procedure topics in the system were ready for consideration for this report); (2) information was compiled by May 16, 2013, in this priority area; *and* (3) we received five to nine sets of comments from experts between October 25, 2011, and May 18, 2013. (Nine topics in this priority area were being tracked in the system as of May 18, 2013). We present one summary on a single topic (indicated below by an asterisk) that emerged as having higher-impact potential on the basis of experts' comments and their assessment of potential impact. The material on interventions appears in this Executive Summary. Readers are encouraged to read the detailed information on the 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	No potential for high impact at this time
2. *Vending machine dispensers for emergency oral contraceptive (Plan B One-Step) to prevent pregnancy	Lower end of the high-impact-potential range

Discussion

Relatively few new developments in interventions or programs and services in the pregnancy and preterm birth priority area have been identified for the Healthcare Horizon Scanning System despite extensive scanning. Several topics previously in the system for this priority area have timed out of the system and/or shown no potential for high impact after at least 2 years of tracking. For programs, we often extend the timeframe over which we track those topics because programs can take longer to demonstrate their potential. Of the topics identified on which we received expert comments, only one program emerged for this report as having a potentially high impact: vending machine dispensers for emergency oral contraceptive (Plan B One-Step) to prevent pregnancy. The donor human milk program topic was previously designated as having potential for high impact, but after 2.5 years of tracking has not yet fulfilled that potential and will be archived in the system. Although the vending machine dispenser for emergency oral contraceptive program does not

employ novel technology, it increases access to emergency contraceptives to prevent unwanted pregnancy and the associated health impacts and costs.

Vending Machine Dispensers for Emergency Oral Contraceptive (Plan B One-Step) To Prevent Pregnancy

- **Key Facts**: Statistics from the U.S. Centers for Disease Control and Prevention (CDC) show nearly half of U.S. pregnancies are unplanned, with statistics from CDC's National Survey of Family Growth indicating about 37% of U.S. births result from unexpected pregnancies. Despite the safety and efficacy of emergency contraception (EC), its use remains low. Barriers to EC use include lack of knowledge or awareness, lack of access, negative attitudes toward EC, and high costs. An EC-pill vending machine located in a health center could increase access to ECs and health care services and reduce costs for women of childbearing age. Shippensburg University in Pennsylvania incorporated an EC-pill vending machine into its student health center in 2010, charging $25 for each dose of Plan B One-Step® for students 17 years of age or older. Student survey respondents gave the EC vending machine an 85% approval rating in 2010, citing ease of access, convenience, reasonable cost, and student comfort with familiar health care practitioners as advantages of this intervention that could significantly reduce unintended pregnancies and improve quality of life. The U.S. Food and Drug Administration (FDA) ruled recently that this intervention is not subject to FDA approval; Shippensburg University is the only location we could identify that has announced availability of this program.
- **Key Expert Comments**: Experts commenting on this intervention viewed it as having potential to address a significant unmet need of access to EC to prevent unwanted pregnancy. Experts noted potential political and societal barriers to widespread acceptance and adoption of this intervention but noted that based on current acceptance of EC, it might still be widely adopted. Overwhelmingly, experts suggested a potential for expanding this intervention into other settings and that it could have an impact on health disparities by further increasing access to EC to those at highest risk of unwanted pregnancy. Basing our opinion on this input, our overall assessment is that this intervention is in the lower end of the high-impact-potential range.
- **Potential for High Impact**: Lower end of the high-impact-potential range

Pregnancy, Including Preterm Birth, Intervention

Vending Machine Dispensers for Emergency Oral Contraceptive (Plan B One-Step) To Prevent Pregnancy

Unmet need: Accessible birth-control methods are important for reducing the risk of unintended pregnancy.[1] Postcoital pregnancy prevention (emergency contraception [EC]) is used after unprotected intercourse or when precoital birth control methods may have failed (e.g., a ruptured condom or interrupted birth pill cycle) and a woman is at risk of pregnancy.[1] Despite the availability of effective contraceptive methods, unintended pregnancies continue to occur. Statistics from the U.S. Centers for Disease Control and Prevention show nearly half of U.S. pregnancies are unplanned, with statistics from its National Survey of Family Growth indicating about 37% of U.S. births result from unexpected pregnancies.[2,3] A study conducted in 2000 and 2001 reported that emergency contraception could potentially prevent 51,000 abortions annually in the United States. The study further estimated that EC could have led to the 43% decline in total U.S. abortions seen between 1994 and 2000.

Despite the safety and efficacy of EC, its use remains low.[4] Barriers to EC use include lack of knowledge or awareness, lack of access, negative attitudes toward EC, and high costs. An EC-pill vending-machine dispenser located in a health center could increase access to ECs and health care services and reduce costs for women of childbearing age.

Intervention: Upon request from the student government association, Shippensburg University in Pennsylvania incorporated an EC-pill vending machine into its student health center in 2010, charging $25 for each dose of Plan B One-Step® (levonorgestrel) for students 17 years of age or older.[5] At the program site, students are not required to have a physician's prescription to obtain ECs from the vending machine.[5] The vending machine also includes other reproductive health products, including condoms and pregnancy test kits.[5]

Clinical trials: Although we identified no completed trial results, student survey respondents at the university where this intervention was installed gave the EC vending machine an 85% approval rating in 2010.[5] University students cited access, convenience, cost, and comfortableness with familiar health care practitioners as advantages of this intervention that could significantly reduce unintended pregnancies and improve quality of life.[5]

Program developers and funding: Shippensburg University's vending machine dispenses the EC pills at $25 per dose and charges students only what the pharmaceutical company charges the school for the pills, which is lower than published retail costs of the drug acquired from a pharmacy; the university does not cover or subsidize cost of the drug.[6]

Teva Pharmaceutical Industries, Ltd., Petah-Tikva, Israel, makes Plan B One-Step.

Diffusion: Shippensburg University is the only college campus we identified that has announced availability of EC pill dispensing by an on-campus vending machine. In January 2013, the Obama administration agreed to allow the university to continue dispensing EC through the vending machine; the U. S. Food and Drug Administration stated it would not intervene to require regulation of the machine.[7] On June 11, 2013, the Obama administration dropped its appeal of a court ruling that expanded access to Plan B to consumers of all ages without a prescription.[8] Please note that this change was announced after expert comments were gathered on this topic.

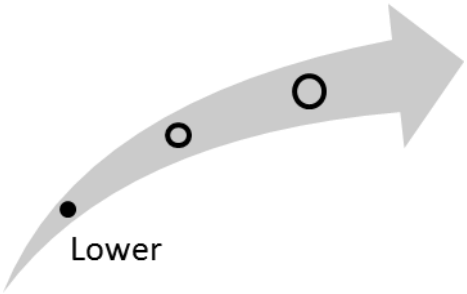
No provider or training is required to access or use the intervention; however, a vending machine would need to be purchased to implement this intervention.

Clinical Pathway at Point of This Intervention

EC can be obtained at a pharmacy, physician office, or hospital emergency room. Pharmacies may require physician's prescription to obtain ECs, depending on a woman's age or local regulations. This intervention negates the need for these methods of obtaining EC and instead may increase access and convenience and reduce the stigma associated with obtaining EC. No provider or training is required to access or use the intervention. However, to prevent misuse that could pose a risk of adverse events and to improve EC knowledge, health care practitioners in the health center should be available to field questions regarding EC use (e.g., contraindications, adverse events) and sex education.[5]

Complementary programs to this intervention could include behavior- and lifestyle-modification programs (i.e., sexual education programs, associated health materials). EC vending machines could diffuse rapidly at other college campuses as a more convenient, discreet, and affordable means of accessing EC to prevent pregnancy.

Figure 1. Overall high-impact potential: vending machine dispensers for emergency oral contraceptive (Plan B One-Step) to prevent pregnancy



Overall, the majority of experts commenting on this intervention viewed vending machine dispensers for EC as having potential to address a significant unmet need of access to EC to prevent unwanted pregnancy. Experts noted the potential political barriers to widespread acceptance and adoption of this intervention, but basing their opinions on current acceptance of EC thought it may still be widely adopted. Opinions on the potential for this intervention to disrupt the current health care infrastructure varied, although experts noted it has potential to reduce demand for services, such as abortions and prenatal and obstetrical care, as well as their associated costs. Overwhelmingly, the experts noted the potential for easily expanding this intervention into other settings to increase access, which might then reduce health disparities related to unwanted pregnancy. Based on this input, our overall assessment is that this intervention is in the lower end of the high-impact-potential range.

Results and Discussion of Comments

Six experts, with clinical, research, health systems, and health administration backgrounds, provided perspectives on this intervention.[9-14]We organized the following discussion of expert comments by the parameters on which experts commented.

Unmet need and health outcomes: Unintended pregnancy is very common in the United States, and access to EC represents an unmet need, the majority of experts concurred. However, two experts noted that this program could have a more significant impact on unmet need if expanded into other settings, such as rural areas. Experts identified a need for a more appealing way to increase knowledge and access to EC, a need they believe this intervention appears to meet. One expert with a clinical background noted, "the potential to reduce unintended pregnancy has not been

realized plausibly because of obstacles to access" and indicated, "this intervention could reduce this obstacle."

Experts agreed this intervention targets a population that is at increased risk of unintended pregnancy and offers a large potential to decrease this risk. However, experts also noted that the population this intervention targets could also potentially access EC by other traditional means such as a pharmacy, although the cost might be higher. This intervention has potential to increase access and awareness in this population, thereby possibly addressing an unmet need and preventing unwanted pregnancy, the experts thought.

Acceptance and adoption: Experts' perceptions varied about the potential acceptance of this intervention. Some suggested that physicians might oppose having EC so readily available without physician oversight and followup with the patient. Conversely, other experts noted that current physician acceptance of EC suggests minimal resistance to use of a vending machine access point.

Most of the experts thought that patient acceptance of this intervention might be controversial, depending on people's social, religious, and political perspectives about contraception. Views of people who oppose contraception and premarital sexual activity pose potential barriers to diffusion of this intervention, according to the experts. Privacy concerns and stigmatization surrounding accessing EC in public setting were also noted as possible barriers to acceptance. Overall, experts concluded that despite these obstacles, the potential for adoption by both patients and providers would be large.

Health care delivery infrastructure and patient management: Views by experts diverged on the potential for this intervention to disrupt care processes and patient management. Some experts indicated this invention would have little impact on the overall delivery of care because EC is available over the counter and without a prescription at pharmacies in some states. However, other experts viewed this intervention as having potential to reduce the burden on the health care system and health care costs by preventing unwanted pregnancy, reducing the number of women seeking abortions or obstetrical and birthing services.

Health disparities: The ability of this intervention to address health disparities would be substantial if it is expanded beyond the current college campus setting, experts concluded. In a college setting, experts agreed, the impact on health disparities would be limited because college students may be able to afford EC accessed through other means. The majority of experts suggested this intervention is well suited to use in settings with limited access to EC such as rural communities and underserved populations.

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