

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

Priority Area 12: Pregnancy, Including Preterm Birth

Prepared for:

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Rockville, MD 20850
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Contract No. HHSA290201000006C

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December 2013

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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Suggested citation: ECRI Institute. AHRQ Healthcare Horizon Scanning System Potential High-Impact Interventions: Priority Area 12: Pregnancy, Including Preterm Birth. (Prepared by ECRI Institute under Contract No. HHSA290201000006C.) Rockville, MD: Agency for Healthcare Research and Quality. December 2013. <http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program/1/ahrq-horizon-scanning-system/>

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.

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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 identification of 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 3 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 16,200 leads about potential topics has resulted in identification and tracking of about 1,900 topics across the 14 AHRQ priority areas and 1 cross-cutting area; about 500 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 a year. Topics eligible for inclusion are those interventions expected to be within 0–3 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 the two topics for which data were available; for which information was compiled and sent for expert comment before October 27, 2013, in this priority area; and for which we received six to eight sets of comments from experts between April 9, 2012, and October 29, 2013. (Seven topics in this priority area were being tracked in the system as of October 29, 2013.) We present one summary of a single topic (indicated below by an asterisk) that emerged as having high-impact potential on the basis of experts’ comments and their assessment of potential impact. 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. Preconception Care System (Gabby) for improving health outcomes in pregnancy	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. Of the topics identified on which we received expert comments, only one program emerged as having a high impact potential: vending machine dispensers for emergency oral contraceptive (Plan B One-Step) to prevent pregnancy. Although this program does not employ novel technology, it increases access to emergency contraceptives to prevent unplanned pregnancy and the associated health impacts and costs.

The other topic considered, but ultimately deemed to have no potential for high impact at this time, was Preconception Care System, also known as Gabby. It is intended to improve health outcomes in pregnancy. In 2011, the Gabby system was featured in the Final Action Contract Report, “Communication-focused Technologies for Improving the Health of Young African-American Women” produced by AHRQ. The Gabby Preconception Care System was designed to

help women (particularly women of health-disparate populations) have healthy pregnancies and to improve infant health outcomes. It uses a computerized avatar to deliver educational information to the user. “Gabby” replicates the conversational behavior of an empathetic health care provider seeing a patient face-to-face and delivers culturally appropriate messages tailored to the individual patient. The system allows the user to educate herself on identified preconception risks to purportedly help mitigate risk and improve mother and child health outcomes. Experts providing comments were hesitant that the System could meet the unmet need in preconception care. They were especially concerned about patient motivation to use this system and thought the patients who could potentially benefit most from this system would be least likely to be motivated to access it. Thus, experts deemed the intervention to have no potential for high impact at this time.

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’s National Survey of Family Growth indicate that about 37% of U.S. births result from unexpected pregnancies. Despite the safety and efficacy of emergency contraception (EC), its use remains low. EC prevents pregnancy by inhibiting ovulation. 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 is intended to increase access to ECs 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 EC in this context.
- **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 and unplanned 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 thought it could have an impact on health disparities by expanding EC access to those at higher risk (e.g., those not wishing to become pregnant who also engage in sexual intercourse without practicing birth control) of unwanted pregnancy. Based 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 becoming pregnant.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, and statistics from its National Survey of Family Growth indicate about 37% of U.S. births result from unexpected pregnancies.^{2,3} A study conducted in 2000 and 2001 reported that EC could potentially prevent 51,000 abortions annually in the U.S. The study further estimated that EC could have led to the 43% decline in total U.S. abortions seen between 1994 and 2000. Despite its safety and efficacy, EC use remains low.⁴ Barriers to use include lack of knowledge or awareness, lack of access, negative attitudes toward EC, and cost. An EC-pill vending machine located in a student health center is intended to increase access to EC and health care services and reduce costs for women of childbearing age.

Intervention: Upon request from the student government association, Shippensburg University in Shippensburg, PA, 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. At the program site, students are not required to have a physician's prescription to obtain ECs from the vending machine. 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. 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: In January 2013, the Obama administration agreed to allow Shippensburg 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 nationwide without a prescription.⁸ Please note that this change was announced after expert comments were gathered on this topic.

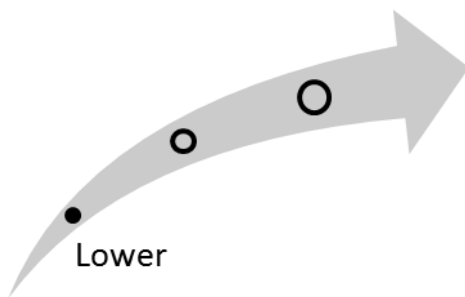
Although several universities across the United States have indicated they considered the idea of installing a Plan B One-Step dispensing machine in 2013 (after the FDA decision), Shippensburg University is the only college campus we could identify as having installed an EC-pill dispensing vending machine on campus. 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 department. Pharmacies may require a physician's prescription to obtain EC, depending on a woman's age or local regulations. This intervention negates the need for these methods of obtaining EC and instead could increase access and convenience and reduce the stigma associated with obtaining EC. No provider and no 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 include behavior- and lifestyle-modification programs (i.e., sex education programs, associated health materials). EC vending machines could diffuse rapidly at other college campuses as a convenient, discreet, and affordable means of accessing EC to prevent unwanted 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 for access to EC to prevent unwanted pregnancy. Experts noted the potential political barriers to widespread acceptance and adoption, but thought it might 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, experts noted the potential for easily expanding this intervention to 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 have organized the following discussion of expert comments by the parameters on which experts commented.

Unmet need and health outcomes: Unintended pregnancy is 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 clinical expert 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 (i.e., college women of childbearing age) could also potentially access EC by other 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 making EC so readily available without physician oversight and patient followup. 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 controversy might surround patient acceptance, 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 experts. Privacy concerns and stigmatization surrounding access to EC in a 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: Experts' views 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 pregnancies, thereby 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 were 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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