The Iowa HPV Vaccination Project: Using a Patient Assistance Program as a Safety Net
Special Thanks

Many thanks to those who contributed to creation of this template, especially:

Jodi Tomlonovic, Executive Director at the Family Planning Council of Iowa
Denise Wheeler, Iowa Department of Public Health Family Planning Coordinator

Staff & Leadership at the following family planning clinics:

Central Iowa Family Planning
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New Opportunities
Northeast Iowa Community Action Family Planning
Planned Parenthood of the Heartland
Planned Parenthood of Southeast Iowa
St. Luke’s Women’s Health
Southern Iowa Family Planning
Unity Healthcare
Women’s Health Services

Contributing HPV Advisory Group Members:

Jane Andrew, Wanda Besco, Valerie Campbell,
Robyn Davis, Kathy Dooley, Lori Egan, Kele Harris,
Lori Hoffmann, Karith Humpal, Sandy Kahler, Cherry Klein,
Syl Manlove, Dinny Nielson, Mary Odell, Vicki Palm,
Suzie Ruiter, Ann Short, Lori Sorden, Sherri Sperlich

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# Table of Contents

<table>
<thead>
<tr>
<th>Item</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview of Need &amp; Patient Assistance Program</td>
<td>-4-</td>
</tr>
<tr>
<td>Patient Assistance Eligibility</td>
<td>-5-</td>
</tr>
<tr>
<td>Steps to Implementation, Part I</td>
<td>-6-9-</td>
</tr>
<tr>
<td>Pricing &amp; Billing Example</td>
<td>-6-</td>
</tr>
<tr>
<td>Funding Needs Formula</td>
<td>-7-</td>
</tr>
<tr>
<td>PAP Ordering Management Overview</td>
<td>-8-</td>
</tr>
<tr>
<td>PAP Ordering Management Example</td>
<td>-9-</td>
</tr>
<tr>
<td>Vaccine Log/Tracking Template</td>
<td>-10-</td>
</tr>
<tr>
<td>Steps to Implementation, Part II</td>
<td>-11-12-</td>
</tr>
<tr>
<td>Staff Training</td>
<td>-11-</td>
</tr>
<tr>
<td>Patient Education</td>
<td>-12-</td>
</tr>
<tr>
<td>Vaccine Storage &amp; Handling</td>
<td>-13-</td>
</tr>
<tr>
<td>FAQ: Help from Peers</td>
<td>-14-</td>
</tr>
<tr>
<td>Additional Resources</td>
<td>-15-</td>
</tr>
</tbody>
</table>
Iowa HPV Vaccination Project Template: The PAP as a Safety Net

Using Merck & Co., Inc.’s Patient Assistance Program to Provide the HPV Vaccine to Uninsured or Underinsured Patients, 19-26

57.7% of women*, age 19-26 utilizing family planning services in Iowa, are uninsured, but 93.8%* of those still want to receive the HPV vaccine, Gardasil. Gardasil costs approximately $130 per shot and there are 3 shots to complete the series, making it one of the most expensive vaccine series on the market. Furthermore, office visit costs at family planning clinics around Iowa average $15-20.00. Low-income and uninsured patients are often unable to pay for such preventative measures.

In research recently completed by the Family Planning Council of Iowa as part of the HPV Project, data was gathered to determine if, in a family planning clinic setting, Merck & Co., Inc.’s Patient Assistance Program (PAP) is a viable safety net measure. After utilizing this program during a 6-month time period at Planned Parenthood of Southeast Iowa clinics and providing more than 120 female patients (At the time of this pilot project Gardasil had only been approved for women) Gardasil shots through the program, it has been determined that the PAP is a recommended option for helping uninsured patients receive the HPV vaccine.

However, this program does not come without some pitfalls. First, there is the issue of building Gardasil inventory to begin the program. Small clinics and/or clinics with small budgets will likely find this a stumbling block, limiting the number of patients who can utilize the program. Second, the assistance program is provided, as a philanthropic outreach by Merck & Co., Inc. Consequently, Merck can stop the program at any time and without reason and has set up strict enrollment options for clinics. For example, Merck & Co. does not allow clinics to use federal or government money to purchase Gardasil vials for use with the Patient Assistance Program. The Patient Assistant Program is an option, but should not be the only means addressed for provision of the HPV vaccine to vulnerable populations in Iowa and around the nation.

In order to assist family planning clinic leadership’s ability to fully utilize Merck & Co., Inc.’s Patient Assistance Program, a template has been created for use. The template is made up of several pieces and has been put together in this booklet with tabs to facilitate easy access. Leadership should “walk through” the template to set up a system in their clinic for using the Patient Assistance Program (PAP), making changes to fit the needs of clinics and patients as necessary. Please remember, this template is a general guide – you may find it necessary to make revisions for your own use.

* At the time of this pilot project Gardasil was only approved for women. Therefore, any numbers indicated in this template are representative only of the female clients served during the time of this pilot project.
Iowa HPV Vaccination Project Template: Patient Assistance Eligibility

There are several types (strains) of HPV – the Gardasil vaccine helps protects against 4 types (strains) of HPV. Two (2) types cause 70% of Cervical Cancer and two (2) types cause 90% of Genital Warts.

Three (3) shots over 6 months:
- Dose 1 - Now
- Dose 2 - 30-60 days after 1st dose
- Dose 3 - 6 months after 1st dose (unless it hasn’t been 12 weeks between Dose 2 and Dose 3)

- Female or Male
- Age 19 – 26
- Patient DOES NOT have public or private insurance
- Income
  - $43,320 for individuals
  - $58,280 for couples
  - $88,200 for a family of four...These guidelines are set at 400% of the Federal Poverty Guidelines.
  - If the patient has insurance they may still be eligible if they do not have HPV vaccination coverage, have a high deductible to meet, or cannot make their co-payment. Contact Merck with “Extenuating Circumstances”.

- Does not have to be a resident of Iowa or a US citizen
- Merck Patient Assistance is open until 7:00 pm CST and can be contacted by dialing 1-800-293-3881.

Need to Know: NDC # and Lot # for Patient Application
Iowa HPV Vaccination Project Template: Pricing & Billing Example

Each vial of Gardasil vaccine is $130.00. Pre-filled syringes cost more. Discounts are offered for purchasing items in bulk. Vaccine administration and office visit fees are not covered under the PAP program.

You will need to determine how those fees will be handled at your clinic(s).

Examples:

An established patient (19-26) does not have insurance and is Level 4 - wants Gardasil. They will be eligible for the Patient Assistance Program (PAP) which pays for the vaccine only.

The patient will need to pay for the office visit and injection fee (administration). Their cost would be $14.00 and needs to be paid the same day. If the patient was new, their cost would be $21.00 and also needs to be paid the same day.

An established patient (19-26) has insurance that does not cover immunizations, and is a Level 4 – wants Gardasil. They may still be eligible to receive Patient Assistance Benefits. Contact Merck & Co., Inc. directly to determine patient eligibility.

**Prices vary by clinic. Use this example as a guide when setting up your own system.

<table>
<thead>
<tr>
<th>Level</th>
<th>New Patient</th>
<th>Established Patient</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>$15.00</td>
<td>$8.00</td>
<td>$6.00</td>
</tr>
<tr>
<td>5</td>
<td>$23.00</td>
<td>$12.00</td>
<td>$9.00</td>
</tr>
<tr>
<td>6</td>
<td>$30.00</td>
<td>$15.00</td>
<td>$12.00</td>
</tr>
<tr>
<td>7</td>
<td>$38.00</td>
<td>$19.00</td>
<td>$16.00</td>
</tr>
</tbody>
</table>
Iowa HPV Vaccination Project Template: Steps to Implementation  PART I

FUNDING NEEDS FORMULA

1. Determine the number of patients, 19-26, who currently use clinic services without health insurance who REQUEST the HPV vaccine and are eligible for the Patient Assistance Program. Follow the formulas below to help you estimate the number of vials you will need to purchase and how much money you will need. NOTE: At the time of the pilot project Gardasil was only approved for women, therefore any numbers indicated are only representative of female patients. Clinics will need to add more at the end of the formula to account for male patients:

71.5% of family planning female clients 19-26 would be eligible to participate in the Patient Assistance Program around the state based on their uninsured status.

- Number of women, 19-26, who currently using clinic services without health insurance:

  (a)____________________
  (.715 X Total Female Clinic Population, 19-26)

92% of the total number of women 19-26 currently using family planning clinic services in Iowa would be eligible because they meet the income guidelines of the Patient Assistance Program.

- Number of women, 19-26, without health insurance who meet the income guidelines of the Patient Assistance Program:

  (b)____________________
  (Number from (a) X .92)

41.7% of the total number of women 19-26 currently using family planning clinic services in Iowa are eligible to get Gardasil free through the Patient Assistance Program.

- Potential number of women, 19-26, without health insurance who meet the income guidelines of the Patient Assistance Program and who REQUEST the HPV Vaccine:

  (c)____________________
  (Number from (b) X .417)

- Potential number of women, 19-26, without health insurance who meet the income guidelines of the Patient Assistance Program, and who REQUEST the HPV vaccine, and who will visit the clinic within the FIRST 6 MONTHS of the Patient Assistance Program:

  (d)____________________
  (Number from (c) X 6= Anticipated Number of Vials for Initial Order)

- Potential total funding needed to secure appropriate number of Gardasil vials for initial order:

  (e)____________________
  (Number from (d) X $130)
Iowa HPV Vaccination Project: PAP Ordering Management

Merck replaces Gardasil vials based on number of eligible patients enrolled in the PAP. They replace vials quarterly, so there is some lag time between use and receipt of another vial. You will need to have Gardasil inventory to provide the first and second shots in the series for the quarter. As noted, the vials are replaced, which means that if you provide a client the first shot in the series, you will be provided a replacement first shot in the series. You will need to use the replacement shot for another patient. You are not provided the second shot in the series until you have provided the second shot in the series to an eligible patient. Once you have provided a series of shots for eligible patients, you will be able to provide Gardasil free of charge. However, you will need some money up front to build an inventory. The amount of money you need depends entirely upon the number of patients, 19-26, utilizing your clinic’s services that are uninsured and want the HPV vaccine. Each of the vials costs approximately $130.00 (summer, 2009).

For example, during one month you see about 50* female patients, 19-26. Of those, 68%* are uninsured or 34 female patients. Based on Iowa HPV Project data, it is fair to assume that approximately 94%*, or 30* female patients, will come into your clinic and want to receive the HPV vaccine and be eligible for this assistance program. *Adjust number to include some male patients. You can increase or decrease depending on how many men decide to get the vaccine at your particular clinic.

Remember, Gardasil is given in a 3-shot series. The first shot is given, the second shot is given 2 months from the first does and the third shot is given 6 months from first dose. That means you will give the same number of shots during month 1 and 3, but then have to wait until month 6 to provide the final shot in the series. Please see the PAP Ordering Management example in the tabbed section of this template titled accordingly.

Based on data collected as part of a pilot project through the Iowa HPV Vaccination Program, it is recommended that a clinic be prepared to order at least 6 months worth of Gardasil vaccine. However, since some small clinics may not have funds available to support this kind of upfront purchase, clinics should begin building their inventory with whatever dollars are available. Tracking PAP ordering, administration and reimbursement is vital to maintaining a consistent flow of vaccine that is readily available for patients.

Furthermore, you will need to have a system in place to track your PAP orders, doses administered, and reimbursements received. Most clinics who utilize the PAP combine this process with their billing, enabling them to code procedures specifically for the PAP. However, if you do not have a system that can be tailored to meet this need, another option is to just set up an Excel spreadsheet to track ordering, doses administered, and reimbursements received. This is rather simplistic, but will get the job done. Used in conjunction with the PAP Ordering Management example available as part of this template, you will have a clear picture of order flow.

Please Note: It is essential to make contact with your Merck representative early in this process if you do not already have a relationship with them. You will need their assistance throughout the process to ensure seamless training opportunities, shipments, deliveries, storage and payments.

*At the time of this pilot project Gardasil was only approved for women. Therefore, any numbers indicated in this template are representative only of the female patients served in the pilot project clinics during the time of the pilot project.
**PAP = Patient Assistance Program

### Example: PAP Ordering Management

<table>
<thead>
<tr>
<th></th>
<th>Month 1</th>
<th>Month 2</th>
<th>Month 3</th>
<th>Month 4</th>
<th>Month 5</th>
<th>Month 6</th>
<th>Month 7</th>
<th>Month 8</th>
<th>Month 9</th>
<th>Month 10</th>
<th>Month 11</th>
<th>Month 12</th>
</tr>
</thead>
<tbody>
<tr>
<td># Administered</td>
<td>30 PAP</td>
<td>30 PAP</td>
<td>60 PAP</td>
<td>60 PAP</td>
<td>90 PAP</td>
<td>90 PAP</td>
<td>90 PAP</td>
<td>90 PAP</td>
<td>90 PAP</td>
<td>90 PAP</td>
<td>90 PAP</td>
<td>90 PAP</td>
</tr>
<tr>
<td>New</td>
<td>New</td>
<td>Month 1 &amp; New</td>
<td>Month 2 &amp; New</td>
<td>Month 3 &amp; New</td>
<td>Month 1 &amp; New</td>
<td>Month 2 &amp; New</td>
<td>Month 3 &amp; New</td>
<td>Month 4 &amp; New</td>
<td>Month 5 &amp; New</td>
<td>Month 6 &amp; New</td>
<td>Month 7 &amp; New</td>
<td>Month 8 &amp; New</td>
</tr>
<tr>
<td>Quarterly Reimbursment</td>
<td>Q 1 PAP Reimbursement: 90 Vials #1, 30 Vials #2 (120)</td>
<td>Q 2 PAP Reimbursement: 90 Vials #1, 90 Vials #2, 30 Vials #3 (210)</td>
<td>Q 3 PAP Reimbursement: 90 Vials #1, 90 Vials #2, 90 Vials #3 (270)</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>ORDER</td>
<td>120 Vials $15,600</td>
<td>90 Vials $11,700</td>
<td>60 Vials $7,800</td>
<td>0 Vials</td>
<td></td>
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<tr>
<td>10% Order</td>
<td>12 Vials $1,560</td>
<td>9 Vials $1,170</td>
<td>6 Vials $780</td>
<td>0 Vials</td>
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<tr>
<td>5% Order (approx.)</td>
<td>6 Vials $780</td>
<td>4 Vials $520</td>
<td>2 Vials $260</td>
<td>0 Vials</td>
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## Patient Assistance Program (PAP)

### PAP Ordering Management

<table>
<thead>
<tr>
<th>Number of Vials Received</th>
<th>Vials Administered Dose #1</th>
<th>Vials Administered Dose #2</th>
<th>Vials Administered Dose #3</th>
<th>Vials Expected</th>
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2. If necessary, offer appropriate staff training for Gardasil administration & PAP Enrollment Guidelines. Utilize the Association of Reproductive Healthcare Association’s Managing HPV: A New Era in Patient Care clinician handbook for guidance. See the PAP Patient Enrollment Guidelines or visit Merck’s website http://www.merck.com/merckhelps/vaccines/home.html.

3. Make note of storage/refrigerator space and instruct staff about appropriate vaccine storage and inventory management. Any comprehensive inventory management system should include the following components:
   - **Order Information** (dates of orders/dates of delivery/check-in)
     - i. See the “Ordering Management” tabbed section of this template.
   - **Storage Information** (dates of storage/dates of use/dates of rotation/dates of expiration/daily monitoring of temperature)
     - ii. See the Centers for Disease Control’s Vaccine Storage and Handling Toolkit online at http://www2.cdc.gov/nip/isd/immtoolkit/content/vacadmin/techniques.htm for easy-to-use vaccine storage and handling resources. For quick reference, please see the “Vaccine Storage & Handling” section of this template.

4. Order HPV-related patient education materials & display as appropriate. This will include materials from the pharmaceutical company, but should also include materials from the CDC, Association of Reproductive Healthcare Professionals (ARHP), and other reputable sources. Make these available to clients, members of the community, and others as necessary. Web site addresses for these organizations can be found in the “Additional Resources” tabbed section of this template.

5. Determine a “start date” for Gardasil administration using Merck’s PAP. Prepare materials for patient enrollment, including Applications, Fax Machine, Insurance Information, etc. Double-check materials for vial storage, including refrigerator, PAP Inventory Management logs, etc. Also, order bulk copies of client applications and display items at (800) 293-3881 8:00am–8:00pm EST Monday–Friday.

6. Based on template provided and other clinic factors, order the appropriate number of vaccines to begin administration. Call (800) 293-3881 8:00am–8:00pm EST Monday–Friday. Note: Orders only ship Monday-Wednesday. Orders placed on Thursday or Friday will not ship until the following Monday. It is best to order before noon on Wednesday to ensure same week delivery. Be sure to order only what you need, as Merck does not offer refunds. Pay attention to clinic hours of operation & communicate those clearly to Merck when ordering. It is best to have vials delivered to clinics that are open M-F all day and then deliver or make available for pick up, vials for part-time clinics. Communicate expectations about delivery to all staff so everyone is clear about how to deal with deliveries from Merck. See the “Vaccine Storage & Handling” section of this template for forms to track deliveries.
Iowa HPV Vaccination Project Template: Steps to Implementation (Cont.)

7. Set up a system in your clinic for identifying & enrolling patients in Merck & Co., Inc.’s PAP. This works well if it can be completed prior to a patient’s scheduled appointment and if the same staff member can complete this for each patient. It works well if the book keeper or insurance verification person can take on this responsibility, since enrollment for this assistance hinges on patient insurance coverage. Post patient eligibility information in a prominent place and remind staff to work through the process step-by-step. See the tabbed section of this template titled “PAP Eligibility” for sample postings.

8. Make revisions. Ask for help – use your Merck representative, they know or can find the answers. Talk to your peers in other family planning settings to gain insight and get feedback about what works and what doesn’t.

If you have questions or concerns about this template, please do not hesitate to contact the Family Planning Council of Iowa’s HPV Project Coordinator, Lori Sorden, at 515-288-9028 ext. 16. If you have questions or concerns about the Patient Assistance Program, please contact Merck & Co., Inc. directly at (800) 293-3881 8:00am–8:00pm EST Monday–Friday.
In addition to the checklist on this page, please visit the Centers for Disease Control’s website for access to their Vaccine Storage & Handling Toolkit at http://www2.cdc.gov/nip/isd/immtoolkit/content/vacadmin/techniques.htm

Here are the 20 most important things you can do to safeguard your vaccine supply. Are you doing them all? Reviewing this list can help you improve your clinic’s vaccine management practices.

1. We have a designated person in charge of the handling and storage of our vaccines.

2. We have a back-up person in charge of the handling and storage of our vaccines.

3. A vaccine inventory log is maintained that documents:
   - Vaccine name and number of doses received
   - Date the vaccine was received
   - Arrival condition of vaccine
   - Vaccine manufacturer and lot number
   - Vaccine expiration date

4. Our refrigerator for vaccines is either household-style or commercial-style, NOT dormitory-style. The freezer compartment has a separate exterior door. Alternatively, we use two storage units: a free-standing refrigerator and a separate, free-standing freezer.

5. We do NOT store any food or drink in the refrigerator or freezer.

6. We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.

7. We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date.

8. We check vaccine expiration dates and we first use those that will expire soonest.

9. We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.

10. We always keep a thermometer in the refrigerator.

11. The temperature in the refrigerator is maintained at 35–46°F (2–8°C).

12. We keep extra containers of water in the refrigerator to help maintain cold temperatures.

13. We always keep a thermometer in the freezer.

14. The temperature in the freezer is maintained at +5°F (-15°C) or colder.

15. We keep ice packs and other ice-filled containers in the freezer to help maintain cold temperatures.

16. We post a temperature log on the refrigerator door on which we record the refrigerator and freezer temperatures twice a day—first thing in the morning and at clinic closing time—and we know whom to call if the temperature goes out of range.

17. We have a “Do Not Unplug” sign next to the refrigerator’s electrical outlet.

18. In the event of a refrigerator failure, we take the following steps:
   - We assure that the vaccines are placed in a location with adequate refrigeration.
   - We mark exposed vaccines and separate them from undamaged vaccines.
   - We note the refrigerator or freezer temperature and contact the vaccine manufacturer or state health department to determine how to handle the affected vaccines.
   - We follow the vaccine manufacturer’s or health department’s instructions as to whether the affected vaccines can be used, and, if so, we mark the vials with the revised expiration date provided by the manufacturer or health department.

19. We have obtained a detailed written policy for general and emergency vaccine management from our local or state health department.

20. If all above answers are “yes,” we are patting ourselves on the back. If not, we have assigned someone to implement needed changes!
**Iowa HPV Vaccination Project Template: FAQ’s**

**Q:** What if our clinic cannot afford to buy 20 or 30 vaccines to start the Patient Assistance Program? Can we just buy a few to get started?

**A:** It is difficult to find extra money for Gardasil vials, so be creative and use whatever dollars are available – even if you are only buying 2 or 3 doses of Gardasil. You may find that applying for a grant, asking for donations, or holding a fundraiser could get you well on your way to providing the HPV vaccine to vulnerable populations at your clinic.

**Q:** Can we choose syringes or pre-filled vials when we order Gardasil for use with the Patient Assistance Program?

**A:** No. Merck retains the right to select either pre-filled syringes or vials for replacement doses, which may or may not be the same as what was administered to eligible clients.

**Q:** Where do I get patient applications?

**A:** Patient applications are available from Merck & Co., Inc. either by calling them at 1-800-994-2111 from 8:00 AM–8:00 PM ET, Monday through Friday, excluding holidays or by visiting their website and preordering a supply, complete with a brochure explaining the program -- [http://www.merck.com/merckhelps/patientassistance/request_application_healthcare.html](http://www.merck.com/merckhelps/patientassistance/request_application_healthcare.html)

**Q:** Are patient applications available in other languages?

**A:** Yes, they are available in Spanish.

**Q:** What if my patient is covered by insurance, but doesn’t have immunization coverage? Is there any way they can still apply for the Patient Assistance Program?

**A:** Yes, they may still apply for the Patient Assistance Program. Merck will likely deny their eligibility. However, you have the opportunity to refute that decision by documenting their inability to get the HPV vaccine without the help of the Patient Assistance Program.

**Q:** What if my patient is not a citizen of the United States? Can they still get the vaccine through the Patient Assistance Program?

**A:** Yes. No documentation of citizenship is needed for eligibility. The United States Resident “box” needs to be marked “yes” on the Patient Assistance Client Application.

**Q:** When a patient returns for a subsequent dose in their Gardasil series, will they need to re-apply for the Patient Assistance Program or will their previously completed application be valid for all shots in the series?

**A:** A new application will need to be completed and submitted to the Merck Vaccine Patient Assistance Program for eligibility assessment prior to a patient receiving a subsequent dose in a multi-dose series or for another Merck vaccine.
Iowa HPV Vaccination Project Template: Additional Resources

Here are some links to websites that may provide additional information for successful implementation of the Patient Assistance Program:

Family Planning Council of Iowa:
http://www.fpcouncil.com

Iowa Department of Public Health Bureau of Family Health:
http://www.idph.state.ia.us/hpcdp/family_health.asp

Merck & Co., Inc.’s Patient Assistance Program:
http://www.merck.com/pap/pap/consumer/

Association of Reproductive Health Professionals:
http://www.arhp.org/Publications-and-Resources/Clinical-Proceedings/Managing-HPV

Planned Parenthood of Southeast Iowa (PPSI) worked through a pilot project during 2007 & 2008 in which they evaluated the effectiveness of utilizing Merck & Co., Inc.’s Patient Assistance Program. Because of their involvement, they have wonderful insights into how to work through set up and implementation of the PAP. They have volunteered to field your questions about the Patient Assistance Program, as necessary. NOTE: At the time of this pilot project Gardasil was only approved for women.

Cherry Klein, CEO:
Phone: (319) 753-6209
Email: cherry.klein@ppfa.org

Kele Harris, Income Verification Specialist & Patient Assistance:
Phone: (319) 753-6209
Email: kele.harris@ppfa.org

Additionally, other organizations around Iowa are using Merck & Co., Inc.’s Patient Assistance Program. They also have insights into how to get things up and running.

Northeast Iowa Community Action: (563) 382-8436

Planned Parenthood of the Heartland: (515) 235-0456

Southern Iowa Family Planning: (641) 682-9955

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