Centers for Disease Control and Prevention

Pregnancy and Vaccination

Guidelines for Vaccinating Pregnant Women

On This Page

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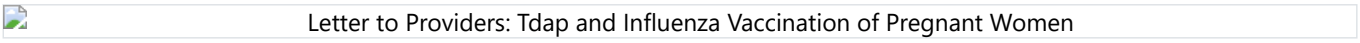
ACIP Guidelines

ACIP: Guidance for Vaccine Recommendations in Pregnant and Breastfeeding Women

Risk to a developing fetus from vaccination of the mother during pregnancy is theoretical. No evidence exists of risk to the fetus from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids. Live vaccines administered to a pregnant woman pose a theoretical risk to the fetus; therefore, live, attenuated virus and live bacterial vaccines generally are contraindicated during pregnancy.

Tdap and Influenza Vaccination of Pregnant Women



Letter to Providers: Tdap and Influenza Vaccination of Pregnant Women [2 pages] **October 9, 2014**

"Benefits of vaccinating pregnant women usually outweigh potential risks when the likelihood of disease exposure is high, when infection would pose a risk to the mother or fetus, and when the vaccine is unlikely to cause harm."
CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011; 60 (No. 2): 26.

- The following table may be used to find a "general" recommendation for vaccinating a pregnant woman with a particular vaccine.
- The third column of the table refers the reader to more detailed information from the appropriate ACIP recommendations.
- Each quotation from an ACIP recommendation in turn references the entire document, where the quotation(s) can be found in context.

Vaccine		**General Recommendation for Use in Pregnant Women**	**For More Information See text**
Routine	Hepatitis A	Base decision on risk vs. benefit.	See Hepatitis A text
	Hepatitis B	Recommended in some circumstances.	See Hepatitis B text
	Human Papillomavirus (HPV)	Not recommended.	See HPV text

Vaccine		General Recommendation for Use in Pregnant Women	For More Information See text
	Influenza (LAIV)	Contraindicated.	See Influenza(LAIV) text

>General Vaccine Recommendation for Use in Pregnant Women

Routine Vaccines:

- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Influenza (inactivated)
- Influenza (LAIV)
- Measles, Mumps, Rubella (MMR)
- Meningococcal (MenACWY or MPSV4)
- Meningococcal (MenB)
- Pneumococcal Conjugate (PCV13)
- Pneumococcal Polysaccharide (PPSV23)
- Polio (IPV)
- Tetanus, Diphtheria, and Pertussis (Tdap); & Tetanus and Diphtheria (Td)
- Varicella
- Zoster

Hepatitis A

- The safety of hepatitis A vaccination during pregnancy has not been determined; however, because hepatitis A vaccine is produced from inactivated HAV, the theoretic risk to the developing fetus is expected to be low. The risk associated with vaccination should be weighed against the risk for hepatitis A in pregnant women who might be at high risk for exposure to HAV. 1

Hepatitis B

- Pregnancy is not a contraindication to vaccination. Limited data suggest that developing fetuses are not at risk for adverse events when hepatitis B vaccine is administered to pregnant women. Available vaccines contain noninfectious HBsAg and should cause no risk of infection to the fetus. 2
- **Pregnant women who are identified as being at risk for HBV infection during pregnancy** (e.g., having more than one sex partner during the previous 6 months, been evaluated or treated for an STD, recent or current injection drug use, or having had an HBsAg-positive sex partner) **should be vaccinated**. 3

Human Papillomavirus (HPV)

- **HPV vaccines are not recommended for use in pregnant women**. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose series should be delayed until completion of pregnancy. Pregnancy testing is not needed before vaccination. If a vaccine dose has been administered during pregnancy, no intervention is needed. 4
- A new pregnancy registry has been established for 9vHPV. Pregnancy registries for 4vHPV and 2vHPV have been closed with concurrence from FDA. 4

Influenza (Inactivated)

- Pregnant and postpartum women are at higher risk for severe illness and complications from influenza than women who are not pregnant because of changes in the immune system, heart, and lungs during pregnancy…. Influenza vaccination can be administered at any time during pregnancy, before and during the influenza season. **Women who are or will be pregnant during influenza season should receive IIV**. 5

Influenza (LAIV)

- **Live attenuated influenza vaccine (LAIV) is not recommended for use during pregnancy.** 5

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Measles, Mumps, Rubella (MMR)

- **MMR vaccines should not be administered to women known to be pregnant or attempting to become pregnant**. Because of the theoretical risk to the fetus when the mother receives a live virus vaccine, women should be counseled to avoid becoming pregnant for 28 days after receipt of MMR vaccine. If the vaccine is inadvertently administered to a pregnant woman or a pregnancy occurs within 28 days of vaccination, she should be counseled about the theoretical risk to the fetus. 6
- Routine pregnancy testing of women of childbearing age before administering a live-virus vaccine is not recommended. MMR or varicella vaccination during pregnancy should not be considered a reason to terminate pregnancy. 7
- Rubella-susceptible women who are not vaccinated because they state they are or may be pregnant should be counseled about the potential risk for CRS and the importance of being vaccinated as soon as they are no longer pregnant. 8

Meningococcal (MenACWY or MPSV4)

- **Pregnancy should not preclude vaccination with MenACWY or MPSV4, if indicated**. Women of childbearing age who become aware that they were pregnant at the time of MenACWY vaccination should contact their health-care provider or the vaccine manufacturer so that their experience might be captured in the vaccine manufacturer's registry of vaccination during pregnancy. 9

Meningococcal (MenB)

- No randomized controlled clinical trials have been conducted to evaluate use of MenB vaccines in pregnant or lactating women. Vaccination should be deferred in pregnant and lac¬tating women unless the woman is at increased risk, and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks. 10

Pneumococcal Conjugate (PCV13)

- ACIP has not published pregnancy recommendations for PCV13 at this time.

Pneumococcal Polysaccharide (PPSV23)

- The safety of pneumococcal polysaccharide vaccine during the first trimester of pregnancy has not been evaluated, although no adverse consequences have been reported among newborns whose mothers were inadvertently vaccinated during pregnancy. 11

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Polio (IPV)

- Although no adverse effects of IPV have been documented among pregnant women or their fetuses, vaccination of pregnant women should be avoided on theoretical grounds. However, if a pregnant woman is at increased risk for infection and requires immediate protection against polio, IPV can be administered in accordance with the recommended schedules for adults. 12

Tetanus, Diphtheria, and Pertussis (Tdap); & Tetanus and Diphtheria (Td)

- **Health-care personnel should administer a dose of Tdap during each pregnancy irrespective of the patient's prior history of receiving Tdap**. To maximize the maternal antibody response and passive antibody transfer to the infant, optimal timing for Tdap administration is between 27 and 36 weeks of gestation although Tdap may be given at any time during pregnancy. 13
- Currently available data suggest that vaccinating earlier in the 27 through 36–week period will maximize passive antibody transfer to the infant. 27
- For women not previously vaccinated with Tdap, if Tdap is not administered during pregnancy, Tdap should be administered immediately postpartum. 13
- Available data from… studies do not suggest any elevated frequency or unusual patterns of adverse events in pregnant women who received Tdap and that the few serious adverse events reported were unlikely to have been caused by the vaccine. 14
- *Wound Management:* If a Td booster is indicated for a pregnant woman, health-care providers should administer Tdap. 13
- *Unknown or Incomplete Tetanus Vaccination:* To ensure protection against maternal and neonatal tetanus, pregnant women who never have been vaccinated against tetanus should receive three vaccinations containing tetanus and reduced diphtheria toxoids. The recommended schedule is 0, 4 weeks and 6 through 12 months. Tdap should replace 1 dose of Td, preferably between 27 and 36 weeks gestation… 13
- Providers are encouraged to report administration of Tdap to a pregnant woman, regardless of trimester, to the appropriate manufacturer's pregnancy registry: for Adacel® to sanofi pasteur, telephone 1-800-822-2463 and for Boostrix® to GlaxoSmithKline Biologicals, telephone 1-888-452-9622. 15

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Varicella

- Because the effects of the varicella virus on the fetus are unknown, **pregnant women should not be vaccinated**. Nonpregnant women who are vaccinated should avoid becoming pregnant for 1 month after each injection. For persons without evidence of immunity, having a pregnant household member is not a contraindication for vaccination. 16
- Wild-type varicella poses a low risk to the fetus…. Because the virulence of the attenuated virus used in the vaccine is less than that of the wild-type virus, the risk to the fetus, if any, should be even lower. 16
- Routine pregnancy testing of women of childbearing age before administering a live-virus vaccine is not recommended. If a pregnant woman is inadvertently vaccinated or becomes pregnant within 4 weeks after MMR or varicella vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, MMR or varicella vaccination during pregnancy should not be considered a reason to terminate pregnancy. 7
- To monitor the pregnancy outcomes of women inadvertently vaccinated with VZV-containing vaccines immediately before or during pregnancy, Merck and CDC established the Merck/CDC Pregnancy Registry for VZV-Containing Vaccines in 1995. The low rate of exposure of varicella-susceptible women of childbearing age to VZV-containing vaccines, in addition to the rarity of the outcome, contribute to the low feasibility that the registry will provide more robust data on the risk for congenital varicella syndrome within a reasonable timeframe. New patient enrollment was discontinued as of October 16, 2013. Merck will continue to monitor pregnancy outcomes after inadvertent exposures to VZV-containing vaccines during pregnancy or within 3 months before conception. CDC and the Food and Drug Administration will continue to monitor adverse events after vaccination with VZV-containing vaccines through the Vaccine Adverse Event Reporting System (VAERS). New cases of exposure immediately before or during pregnancy or other adverse events after vaccination with Varivax, ProQuad, or Zostavax, should be reported to Merck (telephone, 1-877-888-4231) and to VAERS . 17

Zoster

- **Zoster vaccine (Zostavax®) should not be administered to pregnant women**. Additionally, Zostavax is not licensed for the age groups that include women of traditional childbearing ages. 18
- In most circumstances, the decision to terminate a pregnancy should not be based on whether zoster vaccine was administered during pregnancy. 18
- To monitor the pregnancy outcomes of women inadvertently vaccinated with VZV-containing vaccines immediately before or during pregnancy, Merck and CDC established the Merck/CDC Pregnancy Registry for VZV-Containing Vaccines in 1995. The low rate of exposure of varicella-susceptible women of childbearing age to VZV-containing vaccines, in addition to the rarity of the outcome, contribute to the low feasibility that the registry will provide more robust data on the risk for congenital varicella syndrome within a reasonable timeframe. New patient enrollment was discontinued as of October 16, 2013. Merck will continue to monitor pregnancy outcomes after inadvertent exposures to VZV-containing vaccines during pregnancy or

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Travel & Other Vaccines

Prenatal Screening for Vaccine-Preventable Diseases

Travel and Other:

- Anthrax
- BCG
- Japanese Encephalitis
- Rabies
- Typhoid
- Vaccinia (Smallpox)
- Yellow Fever

Anthrax

- **In a pre-event setting**, in which the risk for exposure to aerosolized *B. anthracis* spores is presumably low, **vaccination of pregnant women is not recommended** and should be deferred until after pregnancy. 19
- **In a post-event setting** that poses a high risk for exposure to aerosolized *B. anthracis* spores, **pregnancy is neither a precaution nor a contraindication** to PEP. Pregnant women at risk for inhalation anthrax should receive AVA and 60 days of antimicrobial therapy as described. 19

BCG

- **BCG vaccination should not be given during pregnancy**. Even though no harmful effects of BCG vaccination on the fetus have been observed, further studies are needed to prove its safety. 20

Japanese Encephalitis (JE)

- No controlled studies have assessed the safety, immunogenicity, or efficacy of [Ixiaro] in pregnant women. Preclinical studies of [Ixiaro] in pregnant rats did not show evidence of harm to the mother or fetus. 21

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Rabies

- Because of the potential consequences of inadequately managed rabies exposure, **pregnancy is not considered a contraindication to postexposure prophylaxis**. Certain studies have indicated no increased incidence of abortion, premature births, or fetal abnormalities associated with rabies vaccination. **If the risk of exposure to rabies is substantial, pre-exposure prophylaxis also might be indicated during pregnancy**. Rabies exposure or the diagnosis of rabies in the mother should not be regarded as reasons to terminate the pregnancy. 22

Typhoid

- No data have been reported on the use of either typhoid vaccine in pregnant women. In general, live vaccines like Ty21a are contraindicated in pregnancy. Vi polysaccharide vaccine should be given to pregnant women only if clearly needed. 23

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Vaccinia (Smallpox)

- Because of the limited risk but severe consequences of fetal infection, **smallpox vaccine should not be administered in a pre-event setting to pregnant women or to women who are trying to become pregnant.** 24
- If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after smallpox vaccination, she should be counseled regarding concern for the fetus. Smallpox vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy. CDC has established a pregnancy registry to prospectively follow the outcome of such pregnancies and facilitate the investigation of any adverse pregnancy outcome among pregnant women who were inadvertently vaccinated. For enrollment in the registry, contact CDC at 404-639-8253. 24
- **Pregnant women who have had a definite exposure to smallpox virus** (i.e., face-to-face, household, or close-proximity contact with a smallpox patient) and are, therefore, at high risk for contracting the disease, **should… be vaccinated**. Smallpox infection among pregnant women has been reported to result in a more severe infection than among nonpregnant women. Therefore the risks to the mother and fetus from experiencing clinical smallpox substantially outweigh any potential risks regarding vaccination. In addition, vaccinia virus has not been documented to be teratogenic, and the incidence of fetal vaccinia is low. 24
- When the level of exposure risk is undetermined, the decision to vaccinate should be made after assessment by the clinician and the patient of the potential risks versus the benefits of smallpox vaccination. 25

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Yellow Fever

- **Pregnancy is a precaution for YF vaccine administration**, compared with most other live vaccines, which are contraindicated in pregnancy. If travel is unavoidable, and the risks for YFV exposure are felt to outweigh the vaccination risks, a pregnant woman should be vaccinated. If the risks for vaccination are felt to outweigh the risks for YFV exposure, pregnant women should be issued a medical waiver to fulfill health regulations. 26
- Because pregnancy might affect immunologic function, serologic testing to document an immune response to the vaccine should be considered. 26
- Although no specific data are available, a woman should wait 4 weeks after receiving YF vaccine before conceiving. 26

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Prenatal Screening

"Pregnant women should be evaluated for immunity to rubella and varicella and be tested for the presence of HBsAg during every pregnancy. Women susceptible to rubella and varicella should be vaccinated immediately after delivery. A woman found to be HBsAg positive should be monitored carefully to ensure that the infant receives HBIG and begins the hepatitis B vaccine series no later than 12 hours after birth and that the infant completes the recommended hepatitis B vaccine series on schedule." 7

Passive Immunization during Pregnancy

"No known risk exists for the fetus from passive immunization of pregnant women with immune globulin preparations." 7

Breastfeeding and Vaccination

"**Neither inactivated nor live-virus vaccines administered to a lactating woman affect the safety of breastfeeding for women or their infants**. Although live viruses in vaccines can replicate in vaccine recipients (i.e., the mother), the majority of live viruses in vaccines have been demonstrated not to be excreted in human milk. Varicella vaccine virus has not been found in human milk. Although rubella vaccine virus might be excreted in human milk, the virus usually does not infect the infant. If infection does occur, it is well tolerated because the virus is attenuated. Inactivated, recombinant, subunit, polysaccharide, and conjugate vaccines, as well as toxoids, pose no risk for mothers who are breastfeeding or for their infants." 7

"**Breastfeeding is a contraindication for smallpox vaccination of the mother** because of the theoretical risk for contact transmission from mother to infant. **Yellow fever vaccine should be avoided in breastfeeding women**. However, when nursing mothers cannot avoid or postpone travel to areas endemic for yellow fever in which risk for acquisition is high, these women

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Principles for Developing Pregnancy Recommendations

Formulating policy to guide vaccination of women during pregnancy and breastfeeding is challenging because the evidence-base to guide decisions is extremely limited. In 2008, CDC published *Guiding Principles for Developing ACIP Recommendations for Vaccination During Pregnancy and Breastfeeding* to "provide guidance to help standardize both the process of policy formulation and the format and language of recommendations for pregnant and breastfeeding women" to CDC workgroups or subject matter experts developing vaccine statements subsequent to that date.

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FDA Pregnancy Categories

Regulation traditionally required that each product be classified under one of five pregnancy categories (A, B, C, D, or X, as described below), on the basis of risk of reproductive and developmental adverse effects or, for certain categories, on the basis of such risk weighted against potential benefits.

These FDA pregnancy letter categories are:

Pregnancy Category A. Adequate and well controlled studies in women fail to demonstrate a risk to the fetus in the first trimester (and there is no evidence of a risk in later trimester), and the possibility of fetal harm appears remote.

Pregnancy Category B. Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester (and there is no evidence of risk in later trimesters).

Pregnancy Category C. Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks OR Animal reproduction studies have not been conducted and there are no adequate and well-controlled studies in humans.

Pregnancy Category D. There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Pregnancy Category X. Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in the use of the drug in pregnant women clearly outweigh potential benefits.

Recently, FDA determined that these letter categories were often confusing and did not accurately or consistently communicate differences in degrees of fetal risk. Because risk-benefit decisions regarding use of a drug during pregnancy are more complex than the category designations suggest, reliance on the categories by health care providers may often be misplaced and could result in poorly informed clinical decision making.

In December of 2014, the FDA published the *Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling*, referred to as the "Pregnancy and Lactation Labeling Rule" (PLLR or final rule). **The PLLR removes pregnancy letter categories – A, B, C, D and X**. Instead, under the final rule, narrative summaries of the risks of a drug during pregnancy and discussions of the data supporting those summaries are required in labeling to provide more meaningful information for clinicians.

These labeling changes went into effect on June 30, 2015. Prescription drugs and biologic products submitted after June 30, 2015, will use the new format immediately, while labeling for prescription drugs approved on or after June 30, 2001, will be phased in gradually.

As of August 2016, most vaccines have not yet converted from the FDA letter categories, and are rated in manufacturers' package inserts as follows:

- **Pregnancy Category B**: Human Papillomavirus, Influenza (Fluarix, FluLaval, Afluria, Flublok, Flucelvax, Fluzone, Fluzone Intradermal, Fluvirin, Fluad, FluMist), Japanese Encephalitis (Ixiaro), Meningococcal (Menveo), Tdap (Boostrix), Meningococcal B.
- **Pregnancy Category C**: Hepatitis A, Hepatitis B, Influenza (Fluzone High Dose, FluMist), MMR, Meningococcal ACWY (Menactra, Menomune), Pneumococcal (Pneumovax23), Td, Tdap (Adacel), BCG, Japanese Encephalitis (JE-VAX), Rabies, Typhoid.
- **Pregnancy Category D**: Anthrax, Vaccinia.

Vaccines that have converted from the letter categories as of August 2016 are:

Pneumococcal (Prevnar13) – "Available data on Prevnar 13 administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy."

Polio – "Animal reproduction studies have not been conducted with IPOL vaccine. It is also not known whether IPOL vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. IPOL vaccine should be given to a pregnant woman only if clearly needed."

Varicella: Contraindication. Varivax should not be administered to pregnant females since wild-type varicella can sometimes cause congenital varicella infection. Pregnancy should be avoided for three months following vaccination with Varivax.

Yellow Fever: "It is also not known whether YF-195 VAX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 196 YF-VAX should be given to a pregnant woman only if clearly needed."

Zoster: "Contraindication. Zostavax should not be administered to pregnant females since wild-type varicella can sometimes cause congenital varicella infection. Pregnancy should be avoided for three months following vaccination with Zostavax."

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Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (DHHS)

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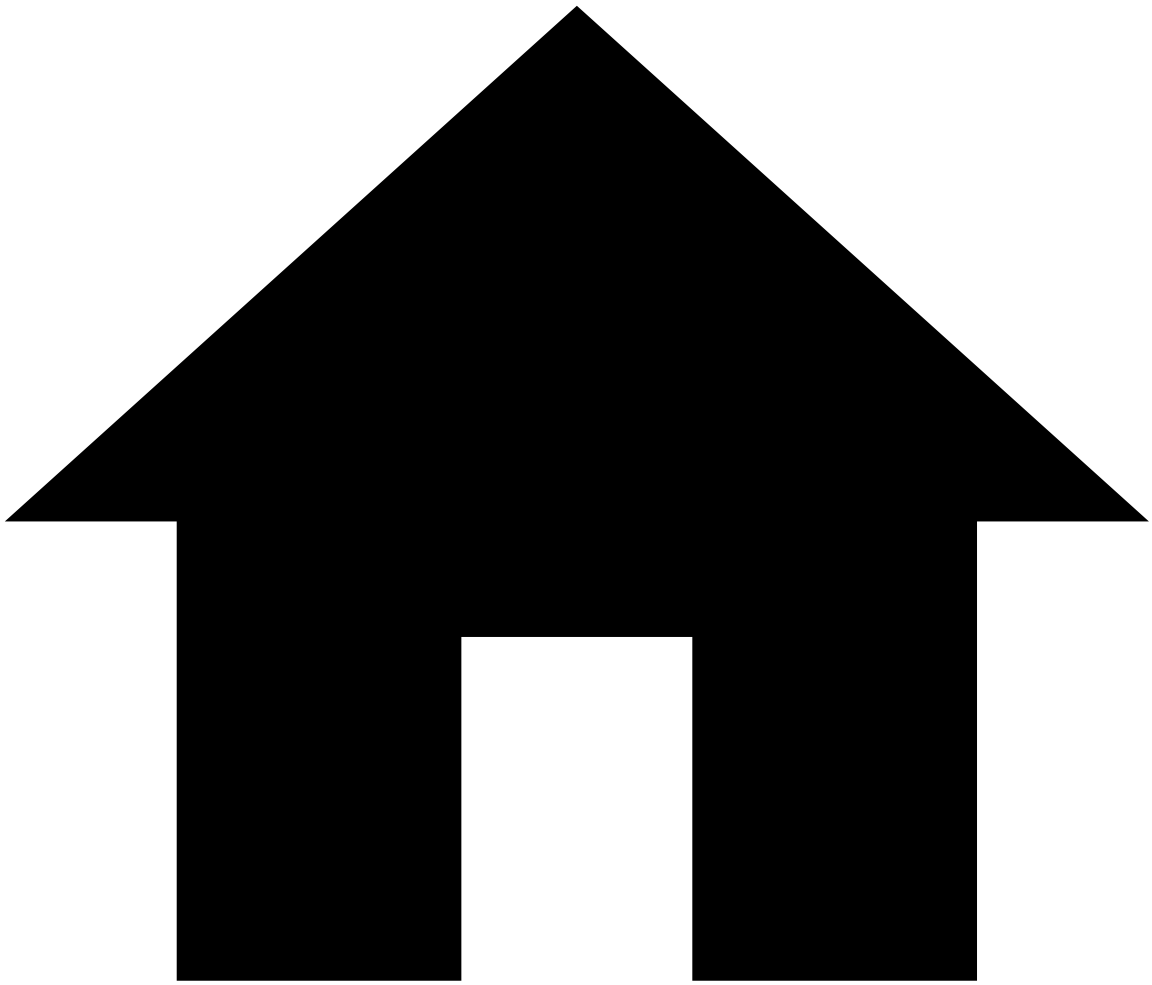

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