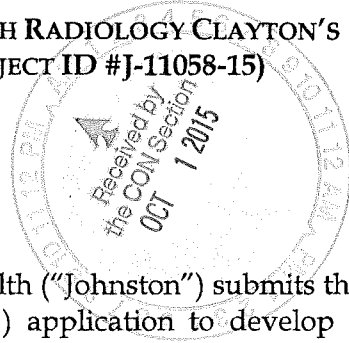


COMMENTS ON PINNACLE HEALTH SERVICES D/B/A RALEIGH RADIOLOGY CLAYTON'S  
CON APPLICATION FOR A DIAGNOSTIC CENTER (PROJECT ID #J-11058-15)

submitted by

JOHNSTON HEALTH



In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Johnston Health ("Johnston") submits the following comments related to Pinnacle Health Services' ("PHS") application to develop a diagnostic center in Clayton, North Carolina. Johnston's comments include *"discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards."* See N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's review of these comments, Johnston has organized its discussion by issue, noting the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue.

PHS's application should not be approved as proposed. Johnston has identified the following specific issues, each of which contributes to PHS's non-conformity:

1. Need for the proposed project;
2. Project not the least costly or most effective alternative;
3. Unnecessary duplication of existing health services; and,
4. Unreasonable project schedule.

Each of the issues listed above are discussed in turn below. Please note that relative to each issue, Johnston has identified the statutory or regulatory review criteria creating the non-conformity.

#### NEED FOR THE PROPOSED PROJECT

PHS proposes to replace its existing 2D mammography unit with a 3D unit. Although PHS cites the benefits of 3D mammography, it fails to demonstrate the need of the population it proposes to serve has for additional 3D mammography capacity in Johnston County, based on at least the following reasons.

According to its application, PHS initiated service on its existing 2D unit late in CY 2012. Thus, the current unit, which has a useful life of seven years, has been operating for no more than three years. PHS has not yet even fully depreciated the existing unit; in fact, the existing equipment has more than 50 percent of its useful life remaining. On page 52 of the application, PHS acknowledges this early replacement, but states that a "great need to replace the existing 2D" remains because of its anticipation that 3D will become the standard of care in the future and to offer the same caliber of services at RRC that it does at Raleigh Radiology Cedarhurst. However, PHS fails to consider the following three factors that counter the "great need" that it cites.

### 3D Capacity Available in Service Area

PHS fails to appropriately recognize that Johnston Health has acquired two 3D mammography units to replace its existing 2D equipment. On page 37 of the application, PHS states: *"In a letter to DHSR dated August 13, 2015, Johnston Health claims that next year they intend to replace two of their 2D mammography units with 3D mammography units. The potential 3D mammography equipment have [sic] not yet been acquired and were not operational in the previous 12 months."* PHS is incorrect in its evaluation of Johnston Health's replacement. According to the CON statute, an *"obligation for a capital expenditure is incurred when: (1) An enforceable contract, excepting contracts which are expressly contingent upon issuance of a certificate of need, is entered into by a person for the construction, acquisition, lease or financing of a capital asset."* See N.C. GEN. STAT. § 131E-178(c)1. As indicated in its letter to DHSR on August 13, 2015, Johnston Health issued purchase orders for the equipment in July 2015 and thus has incurred the obligation for the capital expenditure associated with the replacement of its mammography equipment.

As noted in its August letter to DHSR, Johnston Health's mammography units (the two used for screening and diagnostic mammograms) have a total annual capacity of 16,848 procedures. A corrected mammography screening rate calculation (see explanation below) applied to the age 40+ service area female population and using PHS' assumption that, on average over the next three years, 37 percent of mammograms will be 3D results in a demand for 9,132 3D mammograms. (24,682 corrected annual mammography demand × 37% = 9,132 3D mammography exams per year.) Johnston has sufficient capacity to accommodate all 9,132 3D mammograms each year, even assuming that 3D volume is all incremental to its current volume (16,848 Johnston capacity - 6,909 Johnston current volume = 9,939 Johnston available capacity.) Thus, Johnston's two 3D units have more than sufficient capacity to meet the 3D mammography demand as calculated based on PHS' corrected assumptions for the next three years. At the very least, Johnston's 3D units have the capacity to accommodate the 4,245 3D procedures PHS projects for the first three project years. Moreover, as indicated in its letter to DHSR, the capacity of Johnston's mammography equipment can be expanded by extending hours of operation. (Of note: Johnston Health's mammography hours of operation are already more extensive than those offered by PHS, as it offers Saturday hours at its Smithfield location.)

### Mammography Capacity Available in Service Area

Notwithstanding the benefits of 3D mammography, PHS projects that over the course of the first three project years, only 37 percent of mammography procedures will be 3D (4,245 total 3D procedures for project years / 11,401 total mammography procedures for project years = 37%). Thus, the majority of its volume over the first three project years will be 2D mammography, for which it could use its existing equipment acquired only in 2012 and for which there are numerous other existing providers within the service area that PHS fails to account for in its attempt to demonstrate need.

Specifically, PHS fails to demonstrate compliance with 10A NCAC 14C .1804(1) and (2), which state in part:

*.1804(1): "documentation that all existing health service facilities providing similar medical diagnostic equipment and services as proposed in the CON application in the*

*defined diagnostic center service area were operating at 80% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application."*

*.1804(2): "documentation that all existing and approved medical diagnostic equipment and services of the type proposed in the CON application are projected to be utilize at 80% of the maximum number of procedures..."*

PHS attempts to circumvent these regulatory requirements by arguing first that 3D breast tomosynthesis mammography is not similar medical diagnostic equipment to 2D mammography and second that Johnston's acquired 3D mammography equipment is "prospective" and not approved equipment.

To the latter point, as noted above, Johnston has incurred an obligation for a capital expenditure for its 3D mammography equipment. Although the replacement at Johnston does not require any formal approval by the Agency because the dollar value of the replacement does not exceed \$2 million, Johnston nonetheless put the Agency on notice of its acquisition of 3D mammography units via its August 13, 2015 letter. This is the equivalent of approved equipment if such a replacement had required CON approval. Given the historical existence and operation of Johnston's two existing mammography units, the obligation of a capital expenditure to replace these units with 3D units, and notification of such to the Agency, the analyst must consider these new units in development as being the functional equivalent of "existing or approved" 3D mammography units within the service area proposed in the PHS application under 10A NCAC 14C .1804(2).

To the former point, PHS is inconsistent in its representations throughout the application regarding "similar medical diagnostic equipment." As noted above, in response to the rules, PHS attempts to circumvent by alleging that its proposed 3D equipment is not similar to the existing 2D equipment. However, as noted previously, PHS proposes to use this 3D equipment to perform more than 50 percent of procedures as 2D over the course of the first three project years. Moreover, PHS makes the following statements in the application that indicate the similarity of the 3D equipment to its existing 2D equipment.

- Letter of intent: *"Acquisition of this enhanced technology...."*
- Page 13: *"It is important to note that the proposed Hologic replacement equipment can perform both 2D digital mammography procedures and 3D breast tomosynthesis mammography procedures; therefore, RRC patients who do not elect 3D mammography will continue to have access to the same 2D digital mammography services currently provided at RRC."*
- Page 92: *"The proposed project is simply a mammography equipment replacement. Therefore, the projected mammography payor mix is based on the historical digital mammography service payor mix."*
- Page 95: *"The proposed digital mammography equipment replacement project will result in no change to the total facility staffing at RRC."*

- Page 98: *“As previously described, PHS proposes to upgrade its 2D digital mammography system at RRC. Patients will continue to be referred by physicians to RRC for mammography screenings and diagnostic needs.”*
- Page 109: *“This proposed project is not for a new service, but for replacement of RRC’s existing digital mammography system. Therefore, RRC will not have any startup or initial operating expenses.”*

Thus, with the exception of its responses to the regulatory criteria, PHS references this project as a simple replacement of its existing mammography equipment. Of note, the regulatory definition of replacement equipment specifically states that replacement equipment is comparable to existing equipment if *“(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service....”* See 10A NCAC 14C .0303(d). Although the proposed 3D equipment may possess expanded capabilities, or “enhanced technology” as referenced in PHS’ letter of intent, it is clearly functionally similar and used for the same diagnostic purposes as 2D mammography equipment.

Therefore, PHS fails to demonstrate conformity with the regulatory criteria noted above. Specifically, PHS fails to demonstrate that Johnston Health’s and WakeMed Clayton’s existing mammography units operated at 80 percent of maximum utilization within the past 12 months. According to 2015 Hospital License Renewal Applications (“HLRA”), none of these existing mammography units were operating at 80 percent of maximum utilization during the last 12 months.

Facility	Mammography Units <sup>1</sup>	Capacity <sup>2</sup>	2015 HLRA Volume <sup>3</sup>	% Utilization
Johnston-Smithfield	1	8,528	4,892	57.4%
Johnston-Clayton	1	8,320	2,017	24.2%
WakeMed-Clayton	1	4,560	1,312	28.7%

<sup>1</sup>Although Johnston reports 3 mammography units on its HLRA, as noted in its August 2015 letter to DHSR one of those units is used solely for needle-guided biopsies; as such, Johnston has not included that unit in its capacity calculations. <sup>2</sup>For the Johnston units, Johnston has used the capacity as outlined in its August 2015 letter to DHSR, subtracting all of the hours required for stereotactic biopsies from the Smithfield unit. To be conservative in its estimate of the WakeMed Clayton capacity, Johnston has used the definition in the PHS application. <sup>3</sup>Johnston has included volume by site as referenced in its August 2015 letter to DHSR, which matches the total volume shown on its 2015 HLRA.

Likewise, PHS fails to demonstrate that these units will be at 80 percent of maximum utilization by the third year of the proposed project. In addition to these units located in health service facilities, PHS fails to demonstrate that mammography units operated by non-health service facilities will be utilized at 80 percent of maximum utilization in year three of the project, including units operated by Eastern Carolina Medical Center, Wake Radiology Garner, Wake Radiology Smithfield, and Horizon Family Medicine.

On page 68 of the application, PHS estimates service area mammography demand at 45,684 per year, based on the assumption that approximately two-thirds of the female population age 40+ receive a mammogram annually. The screening rate used by PHS is reported as the American Cancer Society's 2005-2010 screening rate, 67 percent. According to Johnston's research, such screening rates are based on the percentage of women who have had a mammography within the last two years, which does not equate to annual demand. (See Attachment 1, Table 1.) This is particularly relevant as various research and medical organizations differ on recommendation for the most efficacious use of screening mammography (e.g., ACS continues to recommend annual mammograms starting at age 40, while the US Preventive Services Task Force ["USPSTF"] recommends bi-annual mammograms starting at age 50). In fact, USPSTF indicates that bi-annual screening maximizes the benefits of screening in decreasing breast cancer mortality, while also reducing the harm stemming from annual screening.<sup>1</sup> As such, estimated demand in the proposed service area based on actual screening rates is more likely to be only 24,682 procedures per year. (68,185 women age 40+ x 72.4% screening rate [see Attachment 1, Table 1] / 2 years = 24,682 per year.)

Regardless of the specific recommendation, it is clear that lack of capacity is not a factor in mammography demand in the service area, given the known utilization and available capacity of existing health service facility mammography units, not to mention to the considerable number of other existing mammography units in the service area for whom utilization is not known publically. Based on the inventory listed on page 62 of the PHS application (excluding the Johnston Community College unit and the third and fourth units attributed to Johnston Health), there are a total of 8 mammography units operating in the service area.

Provider	# of Mammography Units	Capacity at 4,560 per Unit	Capacity at 6,129 per Unit
Eastern Carolina Medical Center	1	4,560	6,129
WakeMed Clayton	1	4,560	6,129
Raleigh Radiology Clayton	1	4,560	6,129
Wake Radiology Garner	1	4,560	6,129
Johnston Health	2	9,120	12,258
Wake Radiology - Smithfield	1	4,560	6,129
Horizon Family Medicine	1	4,560	6,129
Total	8	36,480	49,032

As the table above demonstrates, applying PHS' capacity as defined in the RRC application (4,560) to the 8 existing units results in capacity for 36,480 mammography procedures per year. Using the RRWF application capacity of 6,129 (see discussion below) applied to the 8 existing units results in capacity for 49,032 mammography procedures per year. (Of note, the capacity definitions in both the RRC application and the RRWF application are lower than the capacity of the two Johnston Health units.) Regardless of capacity definition, there is significant availability of mammography capacity in the service area and significant available capacity of 3D mammography available at Johnston.

<sup>1</sup><http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening#clinical-considerations>

Finally, as noted in the discussion that follows, PHS fails to demonstrate that its own proposed mammography equipment will be at 80 percent of maximum utilization based upon reasonable assumptions.

Underutilization of Proposed Equipment

The assumptions PHS utilizes in the RRC application result in almost 89 percent utilization of the proposed equipment in year three. However, those assumptions appear to be arbitrary, despite PHS' attempts to explain away differences from its assumptions in previous applications. PHS filed an application in June 2015 to replace its existing 2D mammography equipment at the Raleigh Radiology Wake Forest location with 3D mammography equipment (Project ID #J-11048-15). The chart below compares various statistics within the two applications that influence capacity according to PHS.

Statistic	RRWF Assumption	RRC Assumption
Hours of operation	M-F, 8am-5pm	M-F, 8am-5pm
Average hours per week	43	40
Mammography technologist FTEs	1.22	1.18
Total allocated FTEs	2.91	3.23
Mammography technologist year 2 salary (CY 2017)	\$62,917	\$57,134

PHS notes the differences in capacity its RRC application, but states that *“the RRWF mammography service is available, on average, 43 hours each week. The RRC mammography service is available, on average, up to 40 hours each week. Additionally, the patient turnover time for mammography procedures at RRWF is 20 minutes compared to 25 minutes at RRC. The difference between the patient turnover times for mammography procedures is due to the presence of greater radiologic technologists staffing for RRWF’s mammography services compared to RRC’s mammography service. This creates the opportunity at RRWF to more quickly turn over the room between patients compared to RRC. In summary, these two material variances result in different mammography service capacity at RRC compared to RRWF.”* See RRC application page 29. However, an analysis of the actual statistics shown above does not support the materiality of these variances such that it is reasonable to assume a significantly lower capacity on the RRC mammography unit than the RRWF unit. First, the hours of operation are the same, yet PHS claims that the RRC unit is only operational 40 hours a week compared to 43 at RRWF. Second, PHS claims that the difference in technologist availability allows RRWF to turn over the room more quickly and serve 3 patients per hour versus 2.4 at RRC. As noted above, however, the difference in mammography technologist FTEs is only 0.04 between the two sites, which equates to 83 hours per year (0.04 x 2080 = 83) or 1.6 hours per week for 50 weeks a year. It is not reasonable to assume that the additional availability of mammography technologist for 1.6 hours per week would be the reason that RRWF can provide three additional hours of capacity per week (43 versus 40) given the same operating hours (M-F, 8am-5pm) and a reduction in turnover time/additional capacity of 6.6 hours per week (10 minutes per hour x 40 hours = 400 minutes/60 minutes per hour = 6.6 hours per week). Moreover, as shown in the table above, RRC has a higher number of overall FTEs allocated to mammography than RRWF. Thus, more reasonable assumptions would indicate a capacity of 6,129 procedures per year (same as RRWF), which would leave RRC

operating at only 66 percent maximum utilization in year three of the project (4,048 / 6,129 = 66 percent).

Notwithstanding the comment above, an approval of the RRWF application by the Agency would not mandate approval of this application for RRC. Although it is reasonable to make comparisons of capacity availability using the statistics above, other market-based factors could make a material difference in the conformity of the RRWF and RRC applications. For example, the RRWF application includes a narrowly defined service area such that it excludes any health service facility provider that reported existing mammography utilization. In contrast, the RRC application covers a defined service area that includes health service facilities who have reported mammography utilization, namely Johnston Health and WakeMed Clayton. Furthermore, Johnston Health provided notification, prior to PHS' August 17, 2015 CON submission, to both the Agency and PHS that it had acquired 3D mammography equipment. As demonstrated in these comments, the Johnston mammography units have available capacity to meet the needs of the service area as identified by the PHS application. In its review of a Scotland County diagnostic center application in 2006, the Agency relied on information provided during the review period to determine that existing providers within the service area were not operating at required thresholds and therefore that the applicant failed to demonstrate the inability of existing providers to meet the need. See SMH Urgent Care and Imaging Center Findings, Project ID # N-7772-06.

Moreover, the RRWF application is more conservative in its projected utilization than the RRC application. The RRWF application shows historical mammography volume grew at a compound annual rate of 8 percent from CY 2011 to CY 2015. The RRWF application was more conservative in projecting future volume at a rate of 2.7 percent per year, based on the growth rate of the service area population of women age 40+. In contrast, the RRC application projects mammography volume based on one-half of the prior year's growth rate, which equates to an annual growth rate of 9 percent during the first three years of the project, while the service area population of women age 40+ is expected to grow by only 2.4 percent annually. As noted in the PHS application, RRC has only offered mammography services since fall 2012. Thus, CY 2015 represents only the third year of mammography service at RRC and one would expect a higher growth rate during the start-up years of service—a growth rate that is unlikely to be sustained. Thus, not only is the RRC mammography unit projected to be underutilized based on similar operating hours/service as RRWF, but the projected utilization at RRC is based on significantly more aggressive assumptions, which if not achieved would result in even greater underutilization.

For these reasons, the PHS application has failed to demonstrate need for the proposed project, and failed to demonstrate conformity with regulatory criteria and standards. Thus, the application should be found non-conforming with Criterion 3 and 10A NCAC 14C .1804(1) and (2).

#### **PROJECT NOT LEAST COSTLY/MOST EFFECTIVE ALTERNATIVE**

As discussed previously, given the availability of both 3D and 2D mammography capacity in the service area, PHS fails to demonstrate the need to replace its fairly new 2D mammography

equipment—equipment that was installed no more than three years ago and with more than half of its useful life remaining.

On page 20 of the application, PHS states: *“RRC is a cost effective provider of diagnostic imaging services which generally are more cost effective than hospital-based services. Third-party payors often exert pressures on their subscribers to choose low-cost options for outpatient care. This pressure comes in the form of higher out-of-pocket expenses for patients who choose hospital-based outpatient providers. Therefore, RRC is a cost effective alternative in the local service area.”* Although payors may enact policies that encourage utilization of non-hospital-based facilities for some services, that is virtually a moot point with regard to mammography services. The Affordable Care Act requires Medicare and private insurers to cover screening mammography services with no cost-sharing by the patient<sup>2</sup>. Thus, differences between freestanding and hospital-based facilities are irrelevant to most mammography patients, with the exception of the self-insured and indigent. For the latter groups, PHS proposes to provide approximately 27 mammography procedures to charity care patients in year three (\$8,833 in charity care / \$329 charge per scan = 27) and to write-down charges for another 65 patients (\$21,487 / \$329 = 65), which represents just over 2 percent of PHS’ projected mammography procedures in year three.

For these reasons, the PHS application has failed to demonstrate its project is the least costly/most effective alternative. Thus, the application should be found non-conforming with Criterion 4.

#### UNNECESSARY DUPLICATION

PHS fails to demonstrate that its proposed project will not result in unnecessary duplication of existing health resources. First, PHS fails to demonstrate that the need for 3D mammography in the proposed service area surpasses the capacity of the 3D mammography equipment that Johnston Health has acquired. Second, PHS fails to demonstrate that existing health service facilities’ mammography equipment has been operating at 80 percent maximum utilization during the last year or that existing mammography units are expected to be operating at 80 percent maximum utilization by the end of the third project year. Third, and of particular relevance given the availability of both 3D and 2D capacity in the service area, PHS fails to demonstrate the need to replace its fairly new 2D mammography equipment—equipment that was installed no more than three years ago and with more than half of its useful life remaining.

For these reasons, the PHS application should be found non-conforming with Criterion 6.

#### UNREASONABLE PROJECT SCHEDULE

The PHS application and financial statements assume a start date of January 1, 2016. As noted on the project schedule on page 121 of the application, the CON is not likely to be issued until December 28, 2015, assuming an expedited review is granted by a decision date of November 27, 2015. In fact, the project schedule shows that PHS intends to order the equipment on December 1, 2015 prior to receipt of the CON on December 28, 2015, which it cannot do by statute: *“No person shall offer or develop a new institutional health service without first obtaining a*

---

<sup>2</sup> [http://www.cdc.gov/pcd/issues/2012/12\\_0069.htm](http://www.cdc.gov/pcd/issues/2012/12_0069.htm)



*certificate of need from the Department....No person shall incur an obligation for a capital expenditure which is a new institutional health service without first obtaining a certificate of need from the Department."* See N.C. GEN. STAT. § 131E-178(a) and (c). Thus, PHS' utilization projections and financial statements are based upon unreasonable assumptions regarding implementation of the proposed project.

# ATTACHMENT 1

## Cancer Screening — United States, 2010

Each year, approximately 350,000 persons are diagnosed with breast, cervical, or colorectal cancer in the United States, and nearly 100,000 die from these diseases (1). The U.S. Preventive Services Task Force (USPSTF) recommends screening tests for each of these cancers to reduce morbidity and mortality (2). *Healthy People 2020* sets national objectives for use of the recommended cancer screening tests and identifies the National Health Interview Survey (NHIS) as the means to measure progress. Data from the 2010 NHIS were analyzed to assess use of the recommended tests by age, race, ethnicity, education, length of U.S. residence, and source and financing of health care to identify groups not receiving the full benefits of screening and to target specific interventions to increase screening rates. Overall, the breast cancer screening rate was 72.4% (below the *Healthy People 2020* target of 81.1%), cervical cancer screening was 83.0% (below the target of 93.0%), and colorectal cancer screening was 58.6% (below the target of 70.5%). Screening rates for all three cancer screening tests were significantly lower among Asians than among whites and blacks. Hispanics were less likely to be screened for cervical and colorectal cancer. Higher screening rates were positively associated with education, availability and use of health care, and length of U.S. residence. Continued monitoring of screening rates helps to assess progress toward meeting *Healthy People 2020* targets and to develop strategies to reach those targets.

NHIS is a periodic, nationwide, household survey of a representative sample of the U.S. civilian noninstitutionalized population; it includes cancer screening questions on the adult questionnaire. Respondents are asked whether they have been screened with specific tests for cancer, and if they have, when the tests were performed last. For this analysis, because the questionnaire did not distinguish between tests for screening and those performed for other reasons, any report of testing for cancer was categorized as a screening test. Reports of screening were used to determine the portion of the population up-to-date for screenings recommended by USPSTF (2).

Since 2006, NHIS has oversampled Hispanic and Asian populations (3), increasing the ability to examine screening

use among specific racial and ethnic subgroups. Asians were categorized as Chinese, Filipino, or other Asian. Hispanics were categorized as Puerto Rican, Mexican, Mexican-American, Central or South American, or other Hispanic. Sampling weights were applied to account for the probability of selection. Screening percentages and 95% confidence intervals (CIs) were calculated using statistical software to account for complex sample design. Linear trends during 2000–2010 were tested for men and women separately using unadjusted logistic regression models. The conditional response rate for the 2010 NHIS adult sample was 77.3%, and the final response rate was 60.8% (3).

### Breast Cancer Screening

USPSTF recommends that women aged 50–74 years be screened for breast cancer by mammography every 2 years (2). Based on responses to the 2010 NHIS, 72.4% (CI = 70.7%–74.0%) of women overall followed this recommendation, significantly less than the *Healthy People 2020* target of 81.1% (4), with whites and blacks more frequently screened than Asians (Table 1). Considerably lower mammography use was reported by those reporting no usual source of health care (36.2%) or no health insurance (38.2%). Immigrant women who had been in the United States for ≥10 years were almost as likely as U.S.-born women to report having had a mammogram within the past 2 years (70.3% and 73.1%, respectively), whereas only 46.6% of immigrants in the United States for <10 years reported being screened in the past 2 years. Education level also was associated positively with

#### INSIDE

- 46 Gang Homicides — Five U.S. Cities, 2003–2008
- 52 Nodding Syndrome — South Sudan, 2011
- 55 Notes from the Field: Use of Tetanus, Diphtheria, and Pertussis Vaccine (Tdap) in an Emergency Department — Arizona, 2009–2010
- 58 QuickStats



screening. Overall, the proportion of women aged 50–74 years who reported having had a mammogram in the past 2 years remained stable during 2000–2010 (Figure).

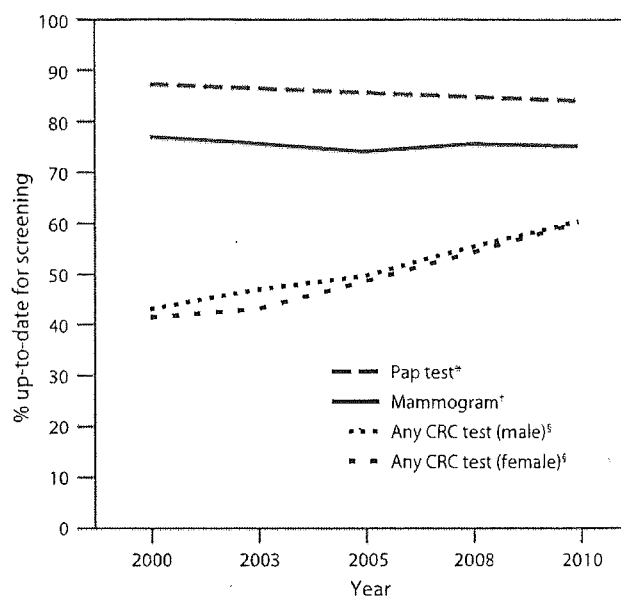
### Cervical Cancer Screening

USPSTF recommends that women aged 21–65 years with a cervix be screened for cervical cancer and precancerous lesions by Papanicolaou (Pap) smear testing every 3 years (2). Overall, 83.0% (CI = 82.0%–84.0%) of women with no hysterectomy reported having a Pap test within the past 3 years (Table 1), significantly less than the *Healthy People 2020* target of 93.0% (4). Rates were significantly lower among Asians (75.4% [CI = 71.1%–79.3%]). Among Asians, Filipinas were more likely to have been screened (86.9% [CI = 80.2%–91.6%]) than other Asians. Those without access to health care were less likely to receive testing; 64.9% of women with no usual source of care and 63.8% of uninsured women were up-to-date. From 2000 to 2010, a small but significant downward trend was observed in the number of women who reported having had a Pap test within the past 3 years.

### Colorectal Cancer Screening

The USPSTF guidelines call for regular screening of both men and women for colorectal cancer, starting at age 50 years and continuing until age 75 years, by any of the following three regimens: 1) annual high-sensitivity fecal occult blood testing, 2) sigmoidoscopy every 5 years combined with

FIGURE. Percentage of men and women up-to-date on screening for breast, cervical, or colorectal cancer, by type of test, sex, and year — United States, 2000–2010



Abbreviations: CRC = colorectal cancer; Pap = Papanicolaou.  
 \* Among women aged 21–65 years with no hysterectomy.  
 † Among women aged 50–74 years.  
 ‡ Among persons aged 50–75 years.

high-sensitivity fecal occult blood testing every 3 years, or 3) screening colonoscopy at intervals of 10 years (2). Overall,

The *MMWR* series of publications is published by the Office of Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30333.

**Suggested citation:** Centers for Disease Control and Prevention. [Article title]. *MMWR* 2012;61:[inclusive page numbers].

#### Centers for Disease Control and Prevention

Thomas R. Frieden, MD, MPH, *Director*  
 Harold W. Jaffe, MD, MA, *Associate Director for Science*  
 James W. Stephens, PhD, *Director, Office of Science Quality*  
 Stephen B. Thacker, MD, MSc, *Deputy Director for Surveillance, Epidemiology, and Laboratory Services*  
 Stephanie Zaza, MD, MPH, *Director, Epidemiology and Analysis Program Office*

#### MMWR Editorial and Production Staff

Ronald L. Moolenaar, MD, MPH, *Editor, MMWR Series*  
 John S. Moran, MD, MPH, *Deputy Editor, MMWR Series*  
 Teresa F. Rutledge, *Managing Editor, MMWR Series*  
 Douglas W. Weatherwax, *Lead Technical Writer-Editor*  
 Donald G. Meadows, MA, Jude C. Rutledge, *Writer-Editors*  
 Martha F. Boyd, *Lead Visual Information Specialist*  
 Maureen A. Leahy, Julia C. Martinroe,  
 Stephen R. Spriggs, Terraye M. Starr  
*Visual Information Specialists*  
 Quang M. Doan, MBA, Phyllis H. King  
*Information Technology Specialist*

#### MMWR Editorial Board

William L. Roper, MD, MPH, Chapel Hill, NC, *Chairman*  
 Matthew L. Boulton, MD, MPH, Ann Arbor, MI  
 Virginia A. Caine, MD, Indianapolis, IN  
 Jonathan E. Fielding, MD, MPH, MBA, Los Angeles, CA  
 David W. Fleming, MD, Seattle, WA  
 William E. Halperin, MD, DrPH, MPH, Newark, NJ  
 King K. Holmes, MD, PhD, Seattle, WA  
 Deborah Holtzman, PhD, Atlanta, GA  
 Timothy F. Jones, MD, Nashville, TN  
 Dennis G. Maki, MD, Madison, WI  
 Patricia Quinlisk, MD, MPH, Des Moines, IA  
 Patrick L. Remington, MD, MPH, Madison, WI  
 John V. Rullan, MD, MPH, San Juan, PR  
 William Schaffner, MD, Nashville, TN  
 Dixie E. Snider, MD, MPH, Atlanta, GA  
 John W. Ward, MD, Atlanta, GA

TABLE 1. Breast and cervical cancer screening percentages, by demographic and access to care characteristics — National Health Interview Survey, United States, 2010

Characteristic	Breast cancer			Cervical cancer		
	Mammogram within 2 yrs*			Pap test within 3 yrs*		
	No.	%	(95% CI)	No.	%	(95% CI)
Overall†	4,869	72.4	(70.7–74.0)	8,999	83.0	(82.0–84.0)
<b>Race</b>						
White	3,690	72.8	(70.9–74.6)	6,543	83.4	(82.3–84.5)
Black/African American	852	73.2	(69.7–76.3)	1,626	85.0	(82.8–87.0)
American Indian/Alaska Native	54	69.4	(53.4–81.7)	97	78.7	(65.9–87.5)
Asian	258	64.1	(57.6–70.0)	685	75.4	(71.1–79.3)
Chinese	54	68.1	(53.4–80.0)	144	71.6	(62.2–79.5)
Filipino	72	62.1	(48.9–73.7)	175	86.9	(80.2–91.6)
Other Asian	132	63.5	(53.4–72.5)	366	70.6	(65.1–75.6)
<b>Ethnicity</b>						
Non-Hispanic	4,200	72.7	(70.9–74.4)	7,021	83.8	(82.6–84.9)
Hispanic	669	69.7	(65.5–73.6)	1,978	78.7	(76.3–80.8)
Puerto Rican	86	74.3	(62.7–83.2)	216	85.5	(77.3–91.1)
Mexican	212	66.4	(59.0–73.1)	794	75.0	(70.9–78.6)
Mexican American	144	66.1	(55.1–75.6)	418	80.1	(74.6–84.6)
Central or South American	105	71.4	(60.7–80.2)	327	79.8	(74.4–84.3)
Other Hispanic	122	76.5	(69.5–82.3)	223	81.5	(75.1–86.4)
<b>Age group (yrs)</b>						
21–30				2,392	84.1	(82.2–85.9)
31–40				2,309	84.7	(82.7–86.4)
41–50				2,018	82.5	(80.2–84.6)
51–65				2,280	80.8	(78.8–82.6)
50–64	3,386	72.7	(70.7–74.5)			
65–74	1,483	71.9	(69.0–74.7)			
<b>Length of U.S. residence</b>						
U.S.-born	4,007	73.1	(71.3–74.8)	6,833	85.0	(83.9–86.0)
In United States <10 yrs	61	46.6	(33.5–60.2)	577	67.1	(62.3–71.5)
In United States ≥10 yrs	794	70.3	(66.6–73.8)	1,572	77.8	(74.6–80.7)
<b>Education</b>						
Less than high school	809	58.3	(53.8–62.7)	1,244	69.4	(66.1–72.5)
High school graduate	1,375	69.5	(66.5–72.4)	2,010	77.7	(75.4–79.9)
Some college or associate degree	1,443	73.9	(71.1–76.4)	2,906	85.3	(83.6–86.8)
College graduate	1,229	80.8	(78.0–83.3)	2,818	89.0	(87.5–90.3)
<b>Usual source of care</b>						
None or hospital emergency department	402	36.2	(30.3–42.4)	1,562	64.9	(61.7–67.9)
Has usual source	4,467	75.4	(73.7–77.0)	7,436	86.4	(85.4–87.4)
<b>Health insurance</b>						
Private/Military	3,121	79.8	(77.9–81.5)	5,612	88.7	(87.7–89.7)
Public only	1,192	63.4	(59.8–66.9)	1,422	81.9	(79.1–84.4)
Uninsured	542	38.2	(33.5–43.2)	1,907	63.8	(61.1–66.4)

Abbreviations: CI = confidence interval; Pap = Papanicolaou.

\* The U.S. Preventive Services Task Force recommends that women aged 50–74 years be screened for breast cancer by mammography every 2 years and that women aged 21–65 years be screened for cervical cancer and precancerous lesions by Pap smear testing every 3 years.

† Overall percentages were age-standardized to the 2000 U.S. standard population.

58.6% (CI = 57.3%–59.9%) of adults reported being up-to-date with colorectal cancer screening (Table 2). This is significantly lower than the *Healthy People 2020* target of 70.5%. Nearly identical proportions of men (58.5%) and women (58.8%) reported being up-to-date. Whites were significantly more likely to report being up-to-date than blacks or Asians. Hispanics were less likely to report being up-to-date (46.5% [CI = 42.9%–50.2%]) than non-Hispanics. Among respondents who 1) had been in the United States for <10

years; 2) did not have a usual, nonemergency department source of care; or 3) did not have health insurance, less than a quarter reported having been screened within the recommended interval. Respondents aged 65–75 years were more likely to be up-to-date than those aged 50–64 years. Significant upward trends were seen in the proportion of adults up-to-date with colorectal cancer screening from 2000 to 2010 using any colorectal cancer screening regimen (Figure).

**TABLE 2. Colorectal cancer screening percentages, by demographic and access to care characteristics — National Health Interview Survey, United States, 2010**

Characteristic	Colorectal cancer*		
	No.	%	(95% CI)
Overall†	8,914	58.6	(57.3–59.9)
<b>Sex</b>			
Male	3,929	58.5	(56.6–60.4)
Female	4,985	58.8	(57.1–60.5)
<b>Race</b>			
White	6,813	59.8	(58.4–61.2)
Black/African American	1,524	55.0	(51.7–58.2)
American Indian/Alaska Native	82	49.5	(35.3–63.8)
Asian	472	46.9	(41.7–52.2)
Chinese	92	41.3	(28.8–55.0)
Filipino	138	54.5	(44.2–64.3)
Other Asian	242	44.3	(36.5–52.4)
<b>Ethnicity</b>			
Non-Hispanic	7,745	59.9	(58.5–61.3)
Hispanic	1,169	46.5	(42.9–50.2)
Puerto Rican	147	55.3	(45.2–65.0)
Mexican	389	37.8	(31.9–44.1)
Mexican American	242	54.9	(47.2–62.3)
Central or South American	198	47.3	(39.3–55.5)
Other Hispanic	193	46.0	(36.7–55.5)
<b>Age group (yrs)</b>			
50–64	6,091	55.0	(53.4–56.6)
65–75	2,823	67.9	(65.9–69.8)
<b>Length of U.S. residence</b>			
U.S.-born	7,369	60.5	(59.1–61.8)
In United States <10 yrs	111	21.3	(14.0–31.0)
In United States ≥10 yrs	1,424	49.5	(46.2–52.8)
<b>Education</b>			
Less than high school	1,521	44.6	(41.5–47.7)
High school graduate	2,472	53.6	(51.4–55.9)
Some college or associate degree	2,513	62.0	(59.8–64.1)
College graduate	2,376	67.3	(65.0–69.5)
<b>Usual source of care</b>			
None or hospital emergency department	871	20.8	(17.4–24.6)
Has usual source	8,042	62.4	(61.1–63.7)
<b>Health insurance</b>			
Private/Military	8,891	58.7	(57.4–60.0)
Public only	5,780	65.0	(63.4–66.5)
Uninsured	2,092	55.3	(52.5–58.1)
	1,019	20.7	(17.9–23.8)

Abbreviation: CI = confidence interval.

\* The U.S. Preventive Services Task Force recommends regular screening for colorectal cancer by men and women aged 50–75 years by 1) annual high-sensitivity fecal occult blood testing, 2) sigmoidoscopy every 5 years combined with high-sensitivity fecal occult blood testing every 3 years, or 3) screening colonoscopy at intervals of 10 years.

† Overall percentages were age-standardized to the 2000 U.S. standard population.

### Reported by

Carrie N. Klabunde, PhD, Martin Brown, PhD, Rachel Ballard-Barbash, MD, National Cancer Institute. Mary C. White, ScD, Trevor Thompson, Marcus Plescia, MD, Div of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion; Sallyann Coleman King, MD, EIS Officer, CDC. **Corresponding contributor:** Sallyann Coleman King, scolemanking@cdc.gov, 770-488-5892.

### Editorial Note

Measuring use of recommended cancer screening regimens and changes in use over time is important to identify groups that might not be receiving the full benefits of screening. The population-based estimates in this report show a slight downward trend in the proportion of women up-to-date with screening for cervical cancer but no change over time in breast cancer screening rates. Screening rates for colorectal cancer increased markedly for men and women, with the rate for women increasing slightly faster, so that rates among men and women were the same in 2010. Breast cancer and colorectal cancer screening rates for persons living in the United States <10 years have declined since 2008 (5,6), and many of those known to face health disparities, such as those without a source of health care and those who are uninsured, continue to be screened less often than recommended. The proportions of women being screened for breast cancer (72.4%) and cervical cancers (83.0%) are below the respective *Healthy People 2020* targets of 81.1% and 93.0%. Screening for colorectal cancer has increased over time, reaching 58.6%, according to the 2010 NHIS data, and 65.4%, according to 2010 Behavioral Risk Factor Surveillance Survey (BRFSS) data (7). Both estimates are considerably lower than the *Healthy People 2020* target of 70.5% (4). Differences between BRFSS and NHIS estimates of cancer screening rates are likely the result of differences in the methods used for the surveys (8).

Financial barriers to screening might explain some of the observed disparities in cancer screening rates. The National Breast and Cervical Cancer Early Detection Program provides free or low-cost screening and diagnostic breast and cervical cancer services to low-income, underinsured, and uninsured women, and access to state Medicaid programs for treatment if breast or cervical cancer are diagnosed.\* The Affordable Care Act is expected to reduce financial barriers to screening by expanding insurance coverage. Breast, cervical, and colorectal cancer screening are now covered free in Medicare and in newly offered private insurance plans. State Medicaid programs that provide these services free will receive an enhanced federal match rate. Other efforts are needed, such as developing systems that identify persons eligible for cancer screening tests, actively encouraging the use of screening tests, and monitoring participation to improve screening rates.

Previous studies have shown that racial and ethnic subgroups differ in cancer screening use (9,10). Large variations were seen between some subgroups. Subgroups that were more likely to receive one type of cancer screening were not necessarily more likely to receive all types. This study further illustrates

\* Additional information is available at <http://www.cdc.gov/cancer/nbccedp>.

**What is already known on this topic?**

Screening at certain ages detects breast, cervical, and colorectal cancer early and reduces morbidity and mortality. The *Healthy People 2020* targets for breast, cervical, and colorectal cancer screening are 81.1%, 93.0%, and 70.5% of the targeted age groups.

**What is added by this report?**

Analysis of data from the 2010 National Health Interview Survey shows that the proportion of the U.S. population screened for cancer according to current recommendations remains below target levels. The proportions screened are 72.4% for breast cancer, 83.0% for cervical cancer, and 58.6% for colorectal cancer. Screening rates for breast cancer have changed little in the past 10 years, whereas rates for cervical cancer have decreased slightly, and rates for colorectal cancer have increased. Screening use varies with age group, race, ethnicity, education, access to health care, and length of U.S. residence.

**What are the implications for public health practice?**

Efforts should be made to improve screening rates in all population groups (including targeting populations with particularly low levels of cancer screening) to increase population screening levels to meet *Healthy People 2020* targets and reduce cancer morbidity and mortality.

the importance of identifying and tracking differences among racial and ethnic subgroups and provides guidance for future targeted interventions.

The age ranges examined in this report correspond to the specifications in *Healthy People 2020* objectives, based on current guidelines from USPSTF (2,3), but some persons younger or older than those ages also might benefit from screening. For cervical cancer screening, USPSTF recommends screening women aged >65 years who previously have not been screened or for whom information about previous screening is not available. For adults aged 75–85 years who previously have not been screened for colorectal cancer, USPSTF recommends that screening decisions be made considering the person's health status and competing risks. For mammography screening, USPSTF states that evidence is insufficient to assess the additional benefits and harms of screening in women aged ≥75 years.

The findings in this report are subject to at least four limitations. First, NHIS data are self-reported, and any report of testing for cancer was classified as a screening test; therefore, these data are subject to inaccuracies. Second, screening recommendations have changed over time. Third, before 2005, the NHIS survey allowed incomplete responses to questions about the date of the test, often requiring assumptions to recode screening measures. To facilitate comparisons over time, this analysis imposed the 2000 method, which allows use of data defined consistently across all years. As a result, the description

of screening rates might be less accurate, so that the percentages shown for 2010 in the trend analysis differ slightly from those reported in the tables (5). Finally, the 2003 NHIS did not include questions on prior hysterectomy; consequently, 2003 data for Pap smears in the trend analysis were excluded to allow for exclusion of women who had undergone hysterectomy.

Although progress toward achieving the *Healthy People 2020* objective for colorectal cancer screening is being made, screening for breast cancer and cervical cancer has not increased over the past decade, and screening use remains low for many groups. This study shows the disparity in subgroup screening rates. Monitoring of these groups is important to assess progress toward reaching *Healthy People 2020* cancer screening targets. Efforts should be made to improve screening rates in all population groups (including targeted efforts for populations with particularly low levels of cancer screening).

**References**

1. Taplin S. Breast cancer screening improvement means considering the entire process. Testimony before the Subcommittee on Health, Committee on Energy and Commerce, US House of Representatives; October 7, 2009. Washington, DC: US Department of Health and Human Services; 2011. Available at <http://www.hhs.gov/asl/testify/2009/10/t20091007a.html>. Accessed January 17, 2012.
2. US Preventive Services Task Force. Recommendations for adults: cancer. Rockville, MD: US Preventive Services Task Force; 2011. Available at <http://www.uspreventiveservicestaskforce.org/adultrec.htm>. Accessed January 17, 2012.
3. National Center for Health Statistics. 2010 National Health Interview Survey (NHIS) public use data release: NHIS survey description. Hyattsville, MD: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2011. Available at [ftp://ftp.cdc.gov/pub/health\\_statistics/nchs/dataset\\_documentation/nhis/2010/srydesc.pdf](ftp://ftp.cdc.gov/pub/health_statistics/nchs/dataset_documentation/nhis/2010/srydesc.pdf). Accessed January 19, 2012.
4. US Department of Health and Human Services. *Healthy People 2020* topics and objectives: cancer. Washington, DC: US Department of Health and Human Services; 2011. Available at <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=5>. Accessed January 17, 2012.
5. Breen N, Gentleman JF, Schiller JS. Update on mammography trends: comparisons of rates in 2000, 2005, and 2008. *Cancer* 2011;117:2209–18.
6. Klabunde CN, Cronin KA, Breen N, Waldron WR, Ambros AH, Nadel MR. Trends in colorectal cancer test use among vulnerable populations in the United States. *Cancer Epidemiol Biomarkers Prev* 2011;20:1611–21.
7. CDC. Vital signs: colorectal cancer screening, incidence, and mortality—United States, 2002–2010. *MMWR* 2011;60:884–9.
8. Raghunathan T, Xie D, Schenker N, et al. Combining information from two surveys to estimate country-level prevalence rates of cancer risk factors and screening. *J Am Stat Assoc* 2007;102:474–86.
9. Miller BA, Chu KC, Hankey BF, Ries IA. Cancer incidence and mortality patterns among specific Asian and Pacific Islander populations in the U.S. *Cancer Causes Control* 2008;19:227–56.
10. Gorin SS, Heck JE. Cancer screening among Latino subgroups in the United States. *Prev Med* 2005;40:515–26.