UPDATE ON ZIKA VIRUS INFECTION

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IMPORTANCE

WHO declared Zika a Public Health Emergency of International Concern on February 1, 2016
Since its initial advisory release on January 15, 2016, CDC has released > 140 updates/advisories (through September 20, 2016)
Potential for local transmission in the U.S. was recognized several months before it was documented in Miami FL on August 1, 2016
Early August 2016 was first time CDC has advised a group of individuals (pregnant women) to not travel to an area in the U.S. where transmission of an infectious agent was occurring

HISTORY

Zika virus first isolated from blood of a rhesus macaque in the Zika forest of Uganda in 1947
Virus isolated from *Aedes africanus* mosquitos after its discovery, but was initially not thought to cause human disease
Though serosurvey published in 1953 of residents of multiple areas of Uganda revealed a 6.1% seroprevalance rate
Later serosurveys indicated a much broader geographic distribution, including Asia

HISTORY

Human illness first recognized in Nigeria in 1953
But despite recognition that it could produce a mild, febrile illness, only 13 cases were reported over the next 57 years
Came as a surprise when 2007 outbreak occurred on several islands in the state of Yap, Federated States of Micronesia, infecting ~5,000

HISTORY

Later outbreak in French Polynesia in 2013 and 2014 estimated to have involved ~32,000 people
Similar to those seen in Yap, but cases of Guillain-Barre syndrome were noted
Early in 2016, French Polynesian investigators retrospectively identified an increased # of fetal anomalies, including microcephaly, with the 2013-2014 outbreak

HISTORY

First identified in the Americas in March 2015, when an outbreak occurred in Bahia, Brazil
By October 2015, the outbreak had spread to at least 14 states in Brazil
In December 2015, Brazilian Ministry of Health estimated up to 1.3 million persons had been infected
HISTORY
In September 2015, Brazil reported an increase in the number of infants born with microcephaly in the same areas where Zika infection was first reported. By mid-February 2016, over 4300 cases of microcephaly were reported, though misdiagnosis and over-reporting likely inflated the number. Later, confirmation of microcephaly was seen in 1/3 of the first 1300 infants evaluated.

By October 2015, Zika was reported outside of Brazil in Columbia. By March 2016, the virus had spread to at least 33 countries and territories in the Americas, including some U.S. territories. Local Zika transmission was first reported in the U.S. in a neighborhood in Miami, FL on August 1, 2016; later, locally transmitted cases were reported in the Miami Beach area.

ETIOLOGY
ZIKA VIRUS
Single-stranded RNA virus in the genus Flavivirus, family Flaviviridae
Closely related to dengue, yellow fever, Japanese encephalitis, and West Nile viruses
Likely originated in East Africa, then spread to West Africa and then to Asia, resulting in distinct lineages (Nigerian cluster, MR766 cluster, Asian genotype)

All strains currently associated with the outbreak in the Americas are most closely related to strains from the Far East. Strains from the Americas examined to date are genetically very similar to each other, with ~99% nucleotide homology.

All Zika strains worldwide are similar to each other with < 12% nucleotide divergence. Has been important for the development of diagnostic assays. Close genetic similarity between all strains suggests that a vaccine developed against any strain will likely be protective against all strains.

RESERVOIRS/ VECTORS
Humans and non-human primates are the principal vertebrate reservoirs/hosts for Zika virus. Vectors are infected Aedes species mosquitoes:
- Aedes aegypti: most common, but rare in KY
- Aedes albopictus: can survive in more temperate climates, extending the range where outbreaks can occur; more common in KY
Culex mosquitoes are NOT vectors.
VECTORS

Both species are aggressive daytime biters and feed both indoors and outdoors near dwellings. *A. aegypti* has high vectorial capability because it feeds primarily on humans, often bites multiple people in a single blood meal, has an almost imperceptible bite, and lives in close association with human habitation. Breed in containers having water in them, as small as the cap of a water bottle.

EPIDEMIOLOGY

Current incidence in the Americas is difficult to gauge.
- Symptoms are non-specific and usually mild.
- Laboratory diagnosis is not uniformly available.
- Flavivirus antibody cross-reactivity complicates serologic assessment in areas where dengue is endemic.

Zika virus disease cases reported to ArboNET as of October 26, 2016:
- US States and DC: 4,091 (26 in KY - none acquired in the US)
- US Territories: 28,723
- Pregnant women with any laboratory evidence of Zika infection as of October 20, 2016:
  - US States and DC: 953 (2 in KY)
  - US Territories: 2,027
Pregnancy outcomes among women with lab evidence of possible Zika infection as of Oct 20, ’16

- Live born infants with birth defects consistent with Zika infection
  - US States and DC: 23 (none in KY)
  - US Territories: 1

- Pregnancy losses with birth defects consistent with Zika infection
  - US States and DC: 5 (none in KY)
  - US Territories: 1

Reasons for the marked emergence of Zika infection in past decade are unknown, but concomitant increased incidence and spread of dengue and chikungunya transmitted by the same vectors suggests common mechanisms:

- Globalization and urbanization
- Viral introduction into previously unexposed populations
- Viral mutations affecting transmission and/or virulence

Reason for the previous lack of recorded cases of adverse pregnancy outcomes and Guillain-Barre syndrome in areas of Africa and Asia where the virus is endemic is unknown:

May reflect:
- The increased incidence of infection seen in the past decade
- Changes in viral virulence

Bite from an infected Aedes species mosquito - primary mode

- Virus infects the mosquito from the mosquito’s contact with a non-human primate (sylvatic transmission cycle) or another human (anthroponotic urban-suburban transmission cycle)

Maternal fetal/neonatal transmission

- Prenatal (congenital infection)
- Intrapartum/perinatal

Sexual transmission

- Initially only reported from male to female; later reported from female to male and between same sex partners
- May occur from symptomatic or asymptomatic individual
- Can occur via any form of sexual contact

Blood transfusion

Laboratory exposure

Theoretical:

- Breast feeding - has not yet been documented, though the virus has been found in the breast milk of mothers who became symptomatic near the day of delivery
- Organ and tissue transplantation

Virus has been found in urine and saliva, but no clear evidence that it is transmitted via these routes.
CLINICAL FEATURES

Incubation period 3-14 days (similar to that of other flaviviruses)
Duration of viremia 2-7 days in most, but occasionally up to 14 days
Duration of viruria usually longer (14 days) than viremia; recent report of even longer (~2 months) duration in a congenitally infected infant
Virus remains in semen for >3 months

Most (~80%) infections are asymptomatic
Children more often asymptomatic than adults
Symptomatic illness is usually mild and self-limited, lasting from a few days up to ~ a week
Severe illness requiring hospitalization unusual
Fatalities are very rare

Most common:
Fever
Maculopapular rash - less common in children; usually starts on trunk then spreads to face and extremities; often somewhat pruritic
Arthralgias
Non-exudative conjunctivitis

Less common:
Headache
Myalgias
Vomiting - more common in children
Retro-orbital pain
Edema

Neurologic (non-fetal):
Guillain-Barre syndrome (GBS)
Temporal and geographical relationship with the outbreaks in the Far Pacific and the Americas
Case control study in French Polynesia revealed strong association (odds ratio > 34) with Zika infection
Meningoencephalitis/ ADEM
Myelitis
CLINICAL FEATURES
ADVERSE FETAL OUTCOMES

Rarely seen with other flavivirus infections

Microcephaly

CDC definition: head circumference <3rd percentile for gestational age and sex

Baseline prevalence in a population
~6 cases (range 2-12) per 10,000 live births (0.06%)

Zika virus primarily targets neural progenitor cells

CLINICAL FEATURES
ADVERSE FETAL OUTCOMES

Microcephaly

In French Polynesian outbreak, estimated risk of microcephaly due to maternal Zika infection was 0.95%

Recently published (NEJM, July 2016) analysis from Brazil estimates risk due to infection in the first trimester to likely be in the range of 0.88% to 13.2%

CLINICAL FEATURES
ADVERSE FETAL OUTCOMES

Microcephaly

Some data suggest highest risk if maternal Zika infection is acquired in the first trimester, but risk persists into the second trimester

In case reports of microcephaly, maternal Zika infection most commonly occurred between 7 and 13 weeks’ gestation, but occurred in some as late as 18 weeks

But recent study suggests peak risk is at gestational age 14-17 weeks

CLINICAL FEATURES
ADVERSE FETAL OUTCOMES

Limitations of current estimates of risk of microcephaly include:

Lack of consistent and standardized definition of microcephaly in areas where the complication has mainly been reported

Limited data from areas where infection rates are not fully known and cases of suspected microcephaly still being evaluated and reported

CLINICAL FEATURES
ADVERSE FETAL OUTCOMES

Intracranial calcifications

Excessive/redundant skin of the scalp

Suggests interruption of cerebral growth occurring after initial formation of brain structures followed by partial collapse of the skull (fetal brain disruption sequence)

Ocular abnormalities- wide range have been seen

Hearing loss- unsure if it can be progressive
CLINICAL FEATURES
ADVERSE FETAL OUTCOMES
Intrauterine growth retardation
May be associated with placental calcifications and low placental: fetal weight ratio
Hydrops fetalis
Arthrogryposis/ club foot
Fetal death
But no evidence exists that Zika infection during pregnancy affects future pregnancies

CLINICAL FEATURES
Outcome of neonatal infection acquired perinatally (in peripartum period)
Little is known
One infant reported whose mom developed fever, rash, and myalgias 3 days before delivery developed thrombocytopenia and a transient rash 4 days after birth but fully recovered

DIFFERENTIAL DIAGNOSIS
Other flavivirus infections
Dengue
Chikungunya
Enterovirus infection
Adenovirus infection
Parvovirus infection
Malaria
Rickettsial infection
Leptospirosis

ZIKA VS DENGUE VS CHIKUNGUNYA
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DIAGNOSIS
Consideration should be given to the possibility of Zika infection based on the patient’s clinical manifestations, places and dates of travel, and activities
Manifestations overlap with those dengue and chikungunya so may need to evaluate for these in addition to Zika

LABORATORY DIAGNOSIS
REVERSE TRANSCRIPTASE PCR (rRT-PCR)
Can perform for Zika on serum, urine, CSF, amniotic fluid, placental and fetal tissue
Only serum can be tested for dengue, chikungunya
The available Triplex PCR assays for all 3 viruses
Indications for sending on serum and urine:
(1) Patient presenting < 14 days after onset of symptoms (to detect viremia and viruria)
LAB DIAGNOSIS

rRT-PCR

Indications (continued):
(2) Infant born to mother with laboratory evidence of Zika infection during pregnancy or, unless maternal Zika testing is negative, who was born to mother who traveled to or resided in an area with active Zika virus transmission during their pregnancy or had unprotected sexual contact with a partner residing or traveling to those areas
(3) Asymptomatic pregnant woman < 14 days of the date of last exposure if they have traveled to areas with active Zika transmission or have had unprotected sexual contact with a partner traveling to or residing in area with active Zika transmission

LABORATORY DIAGNOSIS

rRT-PCR

Indications (continued):
(4) Symptomatic pregnant woman who presents for care \( \geq 2 \) weeks after exposure and is found to be Zika IgM positive
(5) Asymptomatic pregnant woman who has positive or equivocal Zika IgM-ELISA that was collected 2-12 weeks after returning from travel or exposure

LABORATORY DIAGNOSIS

rRT-PCR

Indication of Interpretation
Positive test on any sample confirms Zika infection; no additional testing needed
Negative test does NOT exclude Zika infection and serum should be sent for IgM-ELISA antibody assay

LABORATORY DIAGNOSIS

IgM ANTIBODY CAPTURE ELISA (IgM-ELISA)

IgM antibodies appear 4-5 days from onset of symptoms and persist for at least 12 weeks
Perform on serum; if clinically indicated, could also do on CSF if symptomatic \( \geq 1 \) week
IgM-ELISA assays also available for dengue, chikungunya
Limitation:
False positives due to cross-reactivity with other flaviviruses (dengue, chikungunya) and possible non-specific cross-reactivity

LABORATORY DIAGNOSIS

IgM-ELISA

Indications:
(1) Patient \( \geq 2 \) weeks after onset of symptoms and no earlier sample collected; can also send also for dengue, chikungunya IgM testing
(2) Patient with negative rRT-PCR on serum and urine; can also send also for dengue, chikungunya IgM testing

LABORATORY DIAGNOSIS

IgM-ELISA

Indications (continued)
(3) Infant born to mother with laboratory evidence of Zika infection during pregnancy or, unless maternal Zika testing is negative, who was born to mother who traveled to or resided in an area with active Zika virus transmission during their pregnancy or who had unprotected sexual contact with a partner residing in or traveling to those areas
LABORATORY DIAGNOSIS
IgM-ELISA

Indications (continued)

(4) Asymptomatic pregnant woman 2-12 weeks after
the last date of possible exposure if they have
traveled to areas with active Zika transmission or
have had unprotected sex with a partner traveling to
or residing in area with active Zika transmission

(5) Pregnant woman continuing to reside in areas of
active Zika transmission (done periodically as part of
routine obstetric care in the 1st and 2nd trimester)

Interpretation

If negative, no further testing is needed
Exception: asymptomatic pregnant
women potentially exposed to Zika who
are undergoing sequential testing during
the 1st and 2nd trimesters

LABORATORY DIAGNOSIS
IgM-ELISA

Interpretation

If positive, equivocal, or inconclusive,
specimen should be sent to CDC or CDC-
designated laboratory for plaque-
reduction neutralization test (PRNT) to
confirm status

However, if Zika IgM-ELISA is positive
and dengue IgM-ELISA is negative, can
consider patient to be presumptively infected
with Zika

Interpretation

If positive, equivocal, or inconclusive,
specimen should be sent to CDC or CDC-
designated laboratory for plaque-
reduction neutralization test (PRNT) to
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Other Tests

Plaque-reduction neutralization test (PRNT)
Labor intensive, costly, requires use of
live virus and specialized reagents; only
done at CDC or CDC-designated labs
Only used to confirm positive, equivocal, or
inconclusive IgM-ELISA tests

IgG antibody tests
Even less specific than IgM assays, so
not recommended

Specimens for Zika (and dengue, chikungunya) testing are
preferentially sent to the State Lab (though can be sent to
Quest)

Requires clearance by Epidemiology there (502-564-
3261, ext 4246)

rRT-PCR (for all 3 viruses) and IgM-ELISA
(for Zika and chikungunya) testing done there
(dengue IgM must be sent to commercial lab);
PCR results back in 1-2 days; positive IgM ELISA test
results not finalized and reported until
confirmed by PRNT (but could call for
preliminary result)
EVALUATION OF INFANTS WITH POSSIBLE CONGENITAL ZIKA VIRUS INFECTION

Revised interim guidelines from the CDC released on August 19, 2016

Testing recommended for:

1. Infants born to mothers with laboratory evidence of Zika infection during pregnancy
   - Those with + rRT-PCR on any maternal specimen
   - Those with + Zika IgM and with confirmatory neutralizing antibody (by PRNT) for Zika or flavivirus, not otherwise specified

2. Infants who were born to mothers with risk factors for Zika infection (traveled to or resided in an area with Zika transmission or had unprotected sexual contact with a partner traveling or residing in such an area) but were not tested or were tested outside of the appropriate window

Zika rRT-PCR and Zika IgM-ELISA
- Perform on infant’s serum, urine (only rRT-PCR), and possibly CSF
- Should NOT be obtained from cord blood
- Should be obtained within 2 days of birth
- If testing done later, distinguishing between congenital, perinatal, and postnatal infection can be difficult
- If timing of infection uncertain, manage infant as if has possible congenital Zika infection
**INTERPRETATION OF LABORATORY TESTING OF INFANT BLOOD, URINE, AND/OR CSF FOR EVIDENCE OF CONGENITAL ZIKA VIRUS INFECTION**

Those with – rRT-PCR but + IgM testing
- Considered to have probable infection
- Unless PRNT was done on mom, PRNT needs to be done on infant sample
- But PRNT cannot distinguish between maternal and infant antibodies, so congenital infection might not be confirmed until infant ≥ 18 months old
- PRNT should be done on infant ≥ 18 months of age whose initial serum was IgM positive if Zika-specific neutralizing antibodies were detected by PRNT on either the infant’s or mother’s blood sample

**CLINICAL EVALUATION OF INFANTS INFANTS BORN TO MOTHERS WITH LABORATORY EVIDENCE OF ZIKA INFECTION**

Before hospital discharge
- Comprehensive PE
  - Assess Ht, Wt, HC, gestational age, neuro abnormalities, dysmorphic features
- Head ultrasound
- Standard newborn hearing screen
- Infant Zika virus testing

**INTERPRETATION OF LABORATORY TESTING OF INFANT BLOOD, URINE, AND/OR CSF FOR EVIDENCE OF CONGENITAL ZIKA VIRUS INFECTION**

Those with –rRT-PCR and –IgM- ELISA testing
- Usually considered to not have Zika infection
- However, if clinical concerns remain (microcephaly with negative evaluation for other known causes), PRNT at age 18 months can be considered
  - If PRNT negative, infant does not have congenital Zika infection
  - If positive, congenital Zika infection is presumed, but postnatal infection cannot be excluded (especially if live in area with Zika transmission)

**CLINICAL EVALUATION OF INFANTS INFANTS BORN TO MOTHERS WITH LABORATORY EVIDENCE OF ZIKA INFECTION**

No evidence of abnormalities on PE
- Infant testing negative for Zika infection
  - Routine care- especially growth, development
- Infant testing positive for Zika infection
  - Routine care- especially growth, development
  - Ophthalmology evaluation and BAER- before 1 month of age
  - Consider repeat BAER at 4-6 months
  - Behavioral audiology at 9-12 months if BAER not done at 4-6 months

Abnormalities consistent with congenital Zika syndrome
- Consider transfer to facility with subspecialty care
- CBC, CMP
- BAER, ophthalmology evaluation- before 1 month of age
- Consider advanced neuroimaging (in consultation with neurology)- CT more sensitive than MRI for intracranial calcifications

Abnormalities consistent with congenital Zika syndrome (continued)
- Infant testing negative for Zika infection
  - Evaluate for other infectious or non-infectious causes of microcephaly and/or other anomalies
  - Consider ID, genetics consultation (could be obtained earlier)
- Routine preventive health care
- Routine and congenital infection-specific anticipatory guidance
- Further management as indicated
Abnormalities consistent with congenital Zika syndrome (continued)

Infant testing positive for Zika infection
- Neuro exam at 1 and 2 months; refer to neurology, if not done earlier, if any abnormalities or for provider/parental concerns
- Thyroid function (T4, TSH)- repeat testing at 2 wks & 3 mo.
- Ophthalmology evaluation- repeat at 3 months
- Repeat BAER- at 4-6 months and probably at 9-12 months
- Routine care- especially monitor growth and feeding- and anticipatory guidance

Abnormalities consistent with congenital Zika syndrome (continued)

Infant testing negative for Zika infection
- Evaluate for other infectious and non-infectious causes of congenital anomalies (consider ID, genetics consultation)
- Further management as indicated

Infant lab testing positive for Zika infection
- Evaluate for other infectious and non-infectious causes of congenital anomalies (consider ID, genetics consultation)
- Further management as indicated

Infant lab testing negative for Zika infection
- No evidence of abnormalities on PE (cont’d)
- If infant follow-up can be assured, can defer additional infant assessment until the results of the maternal Zika lab testing are back
- If any of the maternal testing is +, infant will need Zika lab testing, head US, ophthalmology exam
- However, if the maternal testing was done >12 weeks after her exposure, unless rRT-PCR on placental tissue was sent and it is negative, should do the infant Zika lab testing, head US, eye exam
- Outpatient management as appropriate for test results
OTHER ASPECTS OF OUTPATIENT MANAGEMENT OF INFANTS WITH LAB EVIDENCE OF ZIKA INFECTION

Infant has abnormalities consistent with congenital Zika syndrome

Establish a medical home for routine and preventive care and to facilitate coordination of care

Ideally, should be the PCP

CDC recommends monthly visits with PCP for 1st 6 months

Encourage breast feeding

Infant has no evidence of abnormalities

Close monitoring recommended until further info available because some sequelae could be subtle or delayed in onset

Establish medical home (PCP) for routine and preventive care and anticipatory guidance

Close attention to growth, development; use standardized, validated developmental screening tool at 9 mo or earlier if there are concerns

OTHER ASPECTS OF OUTPATIENT MANAGEMENT OF INFANTS WITH LAB EVIDENCE OF ZIKA INFECTION

Infant has no evidence of abnormalities (cont’d)

BAER- within 1 month, consider at 4-6 months

Behavioral audiometry at 9-12 months if BAER not done at 4-6 months; refer to audiology if needed

Eye exam- within 1 mo; assess visual regard, vision screening at well child visits afterwards; refer back to ophthalmology if concerns arise

Provide family and supportive services
OTHER ASPECTS OF MANAGEMENT

Report information on pregnant women with laboratory evidence of Zika infection and their infants (regardless of infant test results) to state health departments for inclusion in the U.S. Zika Pregnancy Registry.

Limited data is available regarding Zika intrapartum/perinatal transmission; CDC will release guidelines regarding evaluation and management of these infants as more information is available.

THERAPY

Supportive care only
No antiviral therapy yet available

PREVENTION

Immunization
No vaccine is yet available
Phase 1 trials likely to begin soon
Prevention efforts center on:
Avoiding mosquito bites
Controlling the mosquito vector
Reducing sexual transmission
Prevention of infection during pregnancy
Laboratory screening of blood and blood product donors for Zika virus (FDA recommendation)

PREVENTION

AVOIDING MOSQUITO BITES
Use of insect repellants on exposed skin
Products containing 30-50% DEET
Not for children < 2 mo
Max recommended concentration in infants and children is 30% per CDC
Picaridin
Oil of lemon eucalyptus (para methane diol)
Not for kids < age 3
If use sunscreen, apply sunscreen 1st; don’t use combination sunscreen/insect repellant products
Permethrin can be used to treat clothing

PREVENTION

AVOIDING MOSQUITO BITES
Wear long sleeve shirts and pants
Mosquito nets
Can use to protect infants < age 2 mo
Stay in dwellings with window screens and/or air conditioning
Travelers to areas with active Zika transmission should use mosquito repellants during travel and for 3 weeks after return from travel
PREVENTION CONTROLLING THE MOSQUITO VECTOR
Requires integrated approach
- Elimination of mosquito breeding sites
- Application of larvicides
- Application of insecticides to kill adult mosquitoes
But variable effectiveness due to inconsistent participation among a population and presence of hidden breeding sites in urban settings

PREVENTION REDUCING SEXUAL TRANSMISSION
Couples in which one or both partners have traveled to or resided in an area with active Zika transmission and who are not pregnant and are not planning to become pregnant
- If one or both partners have had confirmed or clinically suspected Zika infection:
  - Consistently use barrier methods or abstain from sex
    - Women: for at least 8 weeks after onset of illness
    - Men: for at least 6 months after onset of illness

PREVENTION REDUCING SEXUAL TRANSMISSION
If one or both partners have not had confirmed or clinically suspected Zika infection but have traveled to but do not currently reside in an area with active Zika transmission
- Consider using barrier methods or abstain from sex for at least 8 weeks for women and 6 months for men after that partner’s last possible Zika exposure

PREVENTION REDUCING SEXUAL TRANSMISSION
For couples trying to conceive in which one or both partners has had possible Zika exposure through travel or unprotected sexual contact but do not currently live in areas with active Zika transmission
- Women should postpone such attempts for 8 weeks and men should postpone attempts for 6 months after symptom onset or last possible exposure

PREVENTION REDUCING SEXUAL TRANSMISSION
If one or both partners have not had confirmed or clinically suspected Zika infection but the couple continues to reside in an area of active Zika transmission
- Consider use of barrier methods or abstaining from sex while active transmission is occurring in that area

PREVENTION PREVENTION OF INFECTION DURING PREGNANCY
Avoid non-essential travel to areas with active Zika transmission
If travel or reside in such areas, undertake steps to avoid mosquito bites and prevent sexual transmission
PREVENTION
PREVENTION OF INFECTION DURING PREGNANCY

Women and men who live in or travel to areas with active Zika transmission and have a pregnant sexual partner should use barrier methods to prevent infection any time they have sex or abstain from sex during the pregnancy.

PREVENTION
PREVENTION OF INFECTION DURING PREGNANCY

All pregnant women should be assessed for possible Zika exposure and signs or symptoms of Zika infection at each prenatal visit. Test pregnant women for Zika who live in or have traveled to areas with active Zika transmission, who have signs or symptoms suggestive of Zika infection, or who have had unprotected sex with a partner who traveled to or lived in those areas.