Public Health
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Cattaraugus County
Health Department
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CATTARAUGUS COUNTY
BOARD OF HEALTH

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Joseph Bohan, MD, *President*

James Lapey, *Vice-President*

Giles Hamlin, MD
Zahid Chohan, MD
Sondra Fox, RN
Richard Haberer
Theresa Raftis
James Snyder

MINUTES

August 5, 2015

The 838th meeting of the Cattaraugus County Board of Health was held at The Point Restaurant, 800 East State Street, Olean, New York on August 5, 2015.

The following members were present:

Dr. Joseph Bohan
Dr. Zahid Chohan
Sondra Fox, RN
Richard Haberer
Theresa Raftis

Also present were:

Kevin D. Watkins, MD, MPH, Public Health Director
Mark Howden, County Attorney
Linda Edstrom, County Legislator
John Padlo, County Legislator
Paula Stockman, County Legislator
Donna Vickman, County Legislator
Gilbert Witte, MD, Medical Director
Dave Porter, Hearing Officer
Susan Andrews, Director of Patient Services
Raymond Jordan, Sr. Public Health Sanitarian
Debra Lacher, Secretary to Public Health Director
Eric Wohlers, Director of Environmental Health
Rick Miller, Olean Times Herald

The meeting was called to order by Dr. Bohan. The roll was called and a quorum declared.

Mr. Haberer made a motion to approve the minutes of the Board of Health (BOH) meeting held on June 2, 2015, it was seconded by Ms. Raftis, and unanimously approved.

Dr. Bohan read a letter of resignation from Georgina Paul, FNP dated June 18th, 2015, which was written to the members of the Cattaraugus County Board of Health. Mrs. Paul stated that she was grateful for the chance to serve the community in the capacity as a Board member but due to personal reasons, she regrettably needs to resign. Mrs. Paul has offered to assist the Board with any matters that would concern the local Amish community as she still has close ties in working with this group. Dr. Bohan informed the Board that Mrs. Paul has been on the Board since January 6, 2011 and that she will be sent a certificate of appreciation for her services.

Dr. Watkins has identified a couple of possible candidates who would be interested in filling this open seat on the Board. The first is Mr. David Smith; he is currently a principal at the Gowanda Middle School, and also an advocate for the Healthy Livable Community Consortium. The second candidate who was contacted was Larry Himelein, who expressed that he would consider serving on the board if we could not find another candidate from the northwestern part of the county. Dr. Bohan asked if there was any discussion on the proposed candidates, after hearing none, the Board voted unanimously to accept the names of these two nominees and to submit their names to Mr. Marsh who will choose one of the nominees for legislature appointment to the Board.

Dr. Bohan recognized and welcomed Mr. Padlo, county legislator, to the Board of Health meeting.

DIRECTORS REPORT: Dr. Watkins reported that the Health Department was in its final stages for submitting all requested material to the Public Health Accreditation Board for review and stated that after reviewing the standards and measures of the submission process the department realized that the accreditation board requires the Board of Health approval on a number of departmental documents.

In April 2015 the Health Department underwent a consolidated survey by New York State Department of Health. The surveyors reviewed almost all the departments programs: environmental health, community health, lead, immunization, communicable disease, epidemiology, TB, public health emergency preparedness, children with special health care needs, fiscal and the administration division of the department's programs. The review went very well with lots of positive feedback for the department but the surveyors identified areas that could be strengthened. They requested that the department present to the Board of Health for approval, all departmental policies and procedures. This would require an annual or biennial approval. Dr. Watkins stated that all policies and procedures have been standardized for the department as part of a requirement from both the consolidated review and accreditation process. He reminded the board that a copy of all the departments' policies and procedures were sent to each Board member on a flash drive, for their review. Dr. Watkins iterated that each division's policies and procedures must have a separate adoption by the Board, as opposed to one blanket approval for all policies.

Dr. Watkins asked the Chairman to entertain a motion to adopt the Nursing policies and procedures. Dr. Bohan asked for a motion to approve the Nursing policies and procedures. Mr. Haberer made a motion to adopt the policies and procedures for the nursing division, the motion was seconded by Ms. Raftis and the motion was unanimously approved by the Board.

Dr. Watkins asked the Chairman to entertain a motion to adopt the Children with Special Health Care Needs policies and procedures. Dr. Bohan asked for a motion to approve the Children with Special Health Care Needs policies and procedures. A motion to adopt was made by Mrs. Fox, seconded by Ms. Raftis and the motion received a unanimous approval.

Dr. Watkins asked the Chairman to entertain a motion to adopt the Early Intervention Program policies and procedures. Dr. Bohan asked for a motion to approve the Early Intervention Program policies and procedures. Mr. Haberer made a motion to adopt the policies and procedures for the Early Intervention Program; the motion was seconded by Ms. Raftis and unanimously approved by the Board.

Dr. Watkins asked the Chairman to entertain a motion to adopt the Environmental Health policies and procedures. Dr. Bohan asked for a motion to approve the Environmental Health policies and procedures. A motion to adopt was made by Ms. Raftis, seconded by Dr. Chohan and the motion was unanimously approved by the Board.

Dr. Watkins asked the Chairman to entertain a motion to adopt the Public Health Emergency Preparedness policy and procedures. Dr. Bohan asked for a motion to approve the Public Health Emergency Preparedness policy and procedures. A motion to adopt was made by Dr. Chohan, seconded by Mr. Haberer and unanimously approved by the Board.

Dr. Watkins asked the Chairman to entertain a motion to adopt the Laboratory's policies and procedures. Dr. Bohan asked for a motion to approve the Laboratory's policies and procedures. A motion to adopt the Laboratory's policies and procedures was made by Ms. Raftis, seconded by Dr. Chohan and unanimously approved by the Board.

Dr. Watkins asked the Chairman to entertain a motion to adopt the Administrative Operational Manual policies and procedures. Dr. Bohan asked for a motion to approve the Administrative Operational Manual policies and procedures. A motion to adopt was made by Mr. Haberer, seconded by Ms. Raftis and unanimously approved by the Board.

Dr. Watkins asked the Chairman to entertain a motion to adopt the Health Insurance Portability and Accountability Act (HIPAA) policies and procedures, forms and self-assessment tools. Dr. Bohan asked for a motion to approve the Health Insurance Portability and Accountability Act (HIPAA) policies and procedures, forms and self-assessment tools. A motion to adopt was made by Dr. Chohan; the motion was seconded by Ms. Raftis and unanimously approved by the Board.

Dr. Watkins updated the Board on the accreditation process. He stated that the first part of the accreditation process required the submission of a strategic plan. This plan was created by the Health Department's Accreditation team along with the management team of the department. He went on to say that, because it is a document that is used to communicate with the department and its governing body about the department's goal and the actions needed to achieve those goals, the strategic plan needs approval by the Governing Board. Dr. Watkins reiterated that a copy of the strategic plan was sent to each Board member on the flash drive. A strategic plan tracking sheet which outlines the objectives and goals for the Health Department alone with a copy of the dashboard of remaining standards and measures to complete was handed out to those in attendance. He explained that the tracking sheet is used monthly to review the progress of the department's goals and objectives.

Dr. Watkins asked the Chairman to entertain a motion to adopt the strategic plan for 2014-2017. Dr. Bohan asked for a motion to approve the strategic plan for 2014-2017. A motion to approve was made by Mr. Haberer, was seconded by Mrs. Fox and unanimously approved by the Board.

Dr. Watkins expounded upon the duties and responsibilities of the Board. He stated that the Board of Health (BOH) is empowered by New York State Public Health Law to formulate, to promulgate, to adopt, and to publish rules, regulations, orders, and directions for the security of life and health for the Cattaraugus County District. He went on to say that the BOH has been given the power to enforce provisions of both the State and County Sanitary Codes. In addition to these activities, the Board provides information and direction to the Cattaraugus County Legislators regarding Public Health issues. Dr. Watkins stated that part of the accreditation process requires the BOH to review and approve their bylaws. Dr. Watkins reiterated that a copy of the BOH bylaws was sent to each Board member on their flash drive and a copy of the bylaws were distributed to those in attendance. Dr. Watkins asked the Chairman to entertain a motion to adopt the BOH bylaws. Dr. Bohan asked for a motion to approve the BOH bylaws. A motion was made by Dr. Chohan, seconded by Mr. Haberer, and unanimously approved by the Board.

Dr. Watkins reiterated that the BOH duties and responsibilities and stated that the Board is empowered by the New York State Public Health Law to formulate, adopt, and publish rules, regulations, orders, and directions for the security of life and health for Cattaraugus County Health District. Such published rules and regulations shall be called the Sanitary Code. Dr. Watkins stated part of the accreditation process requires that the BOH review, and approve the Cattaraugus County Sanitary Code at least every (5) years. Dr. Watkins stated that the department has worked with both County Attorneys and NYSDOH on the revisions of the County's Sanitary Code. He stated that the department has provided a summation sheet of the major revisions of the County's Sanitary Code for their review; a copy of the summation sheet was distributed to those in attendance, and reminded the Board that a copy of the County's Sanitary Code was provided on their flash drive. Dr. Watkins went on to say that the Sanitary Code is the standards or the laws that the residents of Cattaraugus County will have to abide by, once the Sanitary Code is adopted by the Board.

Mr. Haberer asked if now that tattoo shops are being required to be permitted by the Health Department if that would help prohibit unlawful tattooing, as has happened in the past. Dr. Watkins stated that tattoo shops are already under permit by the department, but the new change is requiring the tattoo artist to be under permit and to complete an annual blood borne pathogen training course. Ms. Raftis inquired whether nail salons were under the jurisdiction of being monitored by the Health Department. It was the consensus that they were regulated by the State but Dr. Watkins informed the Board that he would provide information on what State agency actually regulates the nail salons. Paula Stockman asked for clarification on the extending separation distance requirements for public water systems. Mr. Wohlers explained that public water supplies need to be 200 feet away from any potential source of contamination. He stated that New York State standards have not changed but left a gap between regulating private water supplies, and public water supplies. Small commercial systems that were falling through the cracks of these two definitions will now be addressed. Rick Miller questioned whether these new regulations applied to private wells. Mr. Wohlers informed him that this would include private wells. Once all questions were addressed, Ms. Raftis made a motion to adopt the revised Cattaraugus County Sanitary Code, seconded by Mrs. Fox, and unanimously approved by the Board.

Dr. Watkins continued and reminded the Board that the Cattaraugus County Health Department (CCHD) provides certain core public health services. These basic services include family health, communicable disease control, chronic disease prevention, community health assessment, environmental health, and emergency preparedness and response. He went on to say, that in addition to the core programs being administered at CCHD all other programmatic services provided by the department can be found in the department's 2014 annual report. Dr. Watkins reminded the Board that the annual report must be presented to the governing body as it is a requirement of the accreditation process. He also stated that a copy of the annual report was provided on the Board's flash drives and a hard copy was distributed to those in attendance. Dr. Watkins presented a power point presentation of the 2014 annual report.

Dr. Watkins updated the Board of a new Ebola vaccine breakthrough. He stated that there has been over 27,000 confirmed cases of Ebola and over 11,000 deaths due to Ebola. He added that in 2014, there were no vaccines or antiviral medications available to protect a person from the Ebola virus, but as recently as last week, The Lancet, published an article revealing that a new vaccine for Ebola has potentially been identified, the vaccine is called VSV-EBOV and it has been shown to have a 100% efficacy. A copy of the article was distributed to those in attendance. He stated that this was a remarkable Public Health achievement.

NURSING DIVISION REPORT: Mrs. Andrews reported that there have been eight (8) confirmed cases of Lyme disease this year. She added that is more than what we have seen since 2009 and it is only the first half of the year.

Mrs. Andrews informed the Board that the rabies post exposure vaccines year to date total is twelve (12), most were bat exposures, but there has also been an increase in dog bites.

She reported that the lead program point of care testing and education continues to take place at the WIC clinics. This has included Olean, Salamanca, and Delevan sites which reached (56) families. She reported that out of the (56) families tested, (1) child was identified to have an elevated blood lead level.

Dr. Bohan asked if the number of children with elevated blood lead levels due to lead exposure seem to be higher or lower than what has been reported in the past. Mrs. Andrews replied that due to the higher rate of testing for lead in children and the removal of lead out of paint, fewer elevated blood lead levels are being reported.

Mrs. Andrews reported that the homecare census for this year is showing a 13% decrease compared to this time last year. She stated that the referring source having the greatest impact on this decline is the Kaleida Health system which has shown a 25% decrease in the number of referrals we use to receive.

ENVIRONMENTAL DIVISION REPORT: Mr. Wohlers reported on the mosquito surveillance program and stated that the number of mosquitoes being collected have been real low. He stated that there are no plans to spray in the immediate future as the larvae numbers have been consistently low.

Mr. Wohlers reported that the Community Development Block Grant (CDBG) received by the department in 2014, which is a state funded grant program to support low income families to assist with the repair or replacement of their wells, or septic systems, is within its 2 year cycle and the department must spend the balance of what we have left in the grant by April 2016, therefore the department is trying to do as much as we can this last month of summer. He stated that there are 4-5 septic projects currently out to bid right now, and there are 2-3 more water projects going out to bid.

Mr. Wohlers informed the board that the department finally received (8) new electronic tablets from the State, and the tablets will be used to transition from doing restaurant inspections, and facility inspections on carbon paper to direct data entry. He stated that within the next two weeks staff will have in-service training to get accustomed to the new software. He added that the goal is to perform all inspections electronically within the next month.

Mr. Wohlers stated that the Cattaraugus County Fair is this week and that staff is busy inspecting multiple temporary food events, and festivals.

Mr. Wohlers informed the board that there is a new board of directors and kennel manager for the SPCA and that the department met with them last week. He stated that every time there is a turnover in the SPCA administration we need to meet with them to explain all the procedures of maintaining their septic system and the process of getting rabies vaccines for their animals.

Mr. Wohlers stated that now is the prime time for bats to move into living spaces within homes due to the heat. He added that the department is fielding several calls with questions on what to do with bats found in the home and residents are bringing bats in for testing.

Mr. Wohlers updated the Board on public water system project. He stated they the department is working with the village of Cattaraugus, to monitor the water quality daily as they have gone through some personnel changes. He added that the department has been working with the town of West Valley as they have purchased the rights to make West Valley a municipal water district. The environmental health division is sponsoring training for the water system operators within the county which will take place early September.

Dr. Bohan inquired about the adulticide spraying that was performed by the Seneca Nation of Indians. Mr. Wohlers explained that the county does not conduct surveillance on the reservation and that they conduct their own program. He added that they have a nuisance program and conduct annual adulticide spraying.

Hearing Officer, David Porter reported on the following enforcement cases from a hearing held on July 14, 2015.

DOCKET 15-015 (REVISED 7-21-15)

George and Elizabeth May, 5447 Ashford Hollow Road, West Valley, NY 14171
Violations: Sanitary Code of the Cattaraugus County Health District, Article II, Sec. 16.6.1. After investigating a complaint, inadequately treated sewage was found to be discharging onto the surface of the ground in the respondent's front yard. Property was to be vacated by 6-5-2015.

Administrative Hearing: 7-14-2015

Public Health Sanitarian: Samuel Dayton appeared for CCHD and was sworn in.
Respondent: An agent on behalf of the respondent signed for certified letter and respondent did not appear.

Testimony of Mr. Dayton:	a.) Peoples Exhibit #1 Enf.-1 read and affirmed to be true. b.) Peoples Exhibit #2 Stipulation offered with a $75.00 civil compromise.
Summary of Events:	1) August 2014 site visit. Confirmed discharge, told respondent of grant opportunity for replacement. 2) December 2014 Respondent took name off from grant request. 3) Peoples Exhibit # 4. January 2015 Respondent would not speak with Mr. S. Dayton. Mr. S. Dayton sent letter dated 1-20-15 concerning need to fix discharge. 4) April 2015 Respondents attorney contacted Mr. S. Dayton about grant money and fixing the discharge. Attorney said respondent would vacate by 6-5-15. Peoples Exhibit #5 letter from respondent. 5) Respondent did not vacate the premise on 6-5-15 and enforcement was commenced. 6) Counsel for respondent called July 2015 and said respondent would vacate by 7-13-15. 7) 7-14-15 home is vacant.
Hearing Officer Findings:	The respondent is in violation of CCHD Sanitary Code, Article II, Section 16.6.1 inadequately treated sewage being discharged.
Recommendation:	Adjourn the docket for one month to allow respondents attorney and the CCHD to work out proper notification to the lending institution and possible placarding the residence. Pull the civil compromise.

A motion was made by Mrs. Fox to adjourn docket15-015 as recommended by Mr. Porter, seconded by Mr. Haberer, and unanimously approved.

DOCKET 15-016

The Birdwalk, Inc., 5816 Route 242 East, Ellicottville, NY 14731
Violations: 10NYCRR Sec. 5-1.72 (c) (1) Respondent failed to submit complete daily records
for the operation of the noncommunity water supply for the month of May 2015 to this office by the 10th day of the following month. A notice for the administrative hearing was mailed and signed for with a stipulation offer of civil compromise.

Previous Docket #'s: 14-021, 15-001

Administrative Hearing: 7-14-2015

Senior Public Health Sanitarian: Raymond Jordan appeared for CCHD and was sworn in.
Respondent: Properly served but did not appear.

Testimony of Mr. Jordan:	a.) P. Ex. #1 Enf.-1 read and affirmed to be true. b.) P. Ex. #3 a stipulation offering a $200.00 civil compromise. c.) P. Ex. #2 letter dated 3-20-09 to the respondent explaining compliance of reporting per Sec. 5-1.72 May's report has never been received.
Hearing Officer Findings:	The Respondent is in violation of 10NYCRR Sec. 5-1.72 (c) (1) failure to report by the 10th day of the month subsequent to the reporting period.
Recommendations:	That the respondent's civil compromise offer of $200.00 be changed to a fine of $400.00 for failure to report per section 5.172(c)(1) of the New York State Sanitary Code and also failure to appear for the administrative hearing. The fine must be paid by August 31, 2015 or a $10.00 per diem will be levied for every day not paid.

A motion was made by Ms. Raftis regarding docket 15-016 to accept the Mr. Porter's Recommendation, seconded by Mr. Haberer, and unanimously approved.

There being no further business to discuss, a motion to adjourn was made by Mr. Haberer, and seconded by Ms. Fox and unanimously approved.

Respectfully submitted,

Kevin D. Watkins, M.D.

Kevin D. Watkins, M.D., M.P.H.
Secretary to the Board of Health
KDW/dl

COUNTY OF CATTARAUGUS
STATE OF NEW YORK
ENFORCEMENT LIST

Hearing Officer: David Porter
August 18, 2015

DOCKET 15-005

Adam Hayes, P.O. Box 149, Killbuck, NY 14748
Violations: Sanitary Code of the Cattaraugus County Health District, Article II, Sec. 25.2.8 Respondent failed to provide proof of current vaccination for rabies following a human biting incident.

Administrative Hearing: 8-18-2015

Public Health Sanitarian: Mr. Eli Rust appeared for CCHD and was sworn in.
Respondent: No show, was properly served and offered a civil compromise.

Testimony of Mr. Rust:

a.) Peoples Exhibit #1 Enf.-1 read and affirmed to be true and correct.
b.) P.E. #2- Cattaraugus County bite report from sheriff.
c.) 4-20-15 visited dog owner - dog not restrained, no owner present identified as P.E. #2.
d.) 4-29-15 visited dog owner, checked on condition of dog, gave hand out for rabies clinic.
e.) Letter dated 4-22-15 explaining rabies, confinement requirement and possible enforcement identified as P.E. #3. Check of condition of child bite.
f.) Confinement report identified as P.E. #4 no further information/contact by respondent concerning vaccination of his dog. This is the second biting incident.

Hearing Officer Findings:

The respondent is in violation of Sanitary Code, Article II, Section 25.2.8 failure to provide proof of current vaccination.

Recommendation:

1. That the respondent pay $150.00 fine by 9-30-15.
2. The respondent provides proof of vaccination of his dog by 9-30-15.
3. Failure to pay and provide proof of vaccination for his dog will result in a $10.00 per day per diem after 9-30-15.

DOCKET 15-014

David Meller, 5 MKIN, LLC, 8765 Stahley Rd., East Amherst, NY 14051
Violation: Location 5651 Humphrey Rd., Great Valley, N.Y.

Previous Docket dated 12-3-14

Violations (2)
-Sanitary code of CCHD Part 11.7 respondent failed to comply with the stipulation agreement signed by the respondent on 12-3-14
-Sanitary code of CCHD Article 11 Section 16.6.1 discharge of inadequately treated sewage found on the ground during an inspection on 4-5-15.

Administrative Hearing: 8-18-2015

Public Health Sanitarian: Mr. Eli Rust appeared for CCHD and was sworn in.
Respondent: Phone conference with Health Department.

Testimony of Mr. Miller: Respondent gave testimony that the first contractor hired after permit and design by CCHD took the down payment and did not perform any work. The second contractor hired, known by CCHD performed the installation per design and will be ready for inspection by CCHD personnel on the afternoon of this date.

Mr. E. Rust visited the site in the afternoon of 8-18-15 and approved the system.

Hearing Officer Findings: The Respondent was in violation of the two violations stated.

Recommendations: That the CCHD consider docket 15-014 closed.

DOCKET 15-018

Respondent: Roseanne Hopkins, 115 S. 12th Street, Olean, N.Y. 14760

Violation: Sanitary code of CCHD Article 11 Part 25.2.8 Respondent failed to submit required rabies vaccination after a human biting incident.

Administrative Hearing: 8-18-2015

Public Health Sanitarian: Mr. Richard Dayton appeared for CCHD and was sworn in.
Respondent: No show, properly served, and was offered a civil compromise.

Testimony of Mr. Dayton:
a.) Peoples Exhibit #1 Enf. Read and affirmed to be true and correct.
b.) A copy of Article II identified as P.E. #2.
c.) CCHD animal exposure and bite form properly filled out identified as P.E. #3.
d.) Confinement form dog checked 4/28/15 and found dog to be okay identified as P.E. #4.

DOCKET 15-018 (Continued):

e.) Letter dated 6-8-15 discussing mandatory rabies vaccination for domestic dogs identified as P.E. #5.
f.) CCSC service certification identified as P.E. #6.

Hearing Officer Findings: The respondent is in violation of CCSC Section 25.2.8. Respondent did not submit evidence of rabies vaccination after a biting incident. CCHD personnel visited the respondent, checked on the well being of the person bitten (respondent), checked on the well being of the dog and explained the seriousness of compliance for animal vaccination.

Recommendations:
1. That the respondent pay a $150.00 fine by 9-30-15.
2. The respondent provide proof of vaccination of her dog, Dempsey, Bassett by 9-30-15.
3. Failure to pay and provide proof of vaccination for her dog will result in a $10.00 per day per diem after 9-30-15.

DOCKET 15-020

Randy G. Korkowicz, 44 East Main Street, Allegany, NY 14706, Randy's Up-The-River, 3767 S. Nine Mile Rd., Allegany, N.Y. 14706
Violations (3)

a.) 10NYCRR Part 14-1.10 (b) (2) at the time of inspection the potentially hazardous products in the sliding glass door cooler were found to be between 50 degrees- 51 degrees Fahrenheit.
b.) 10NYCRR Part 14-1.44 the sliding glass door cooler was not maintaining adequate refrigeration temperature at time of inspection. Reason-walk in cooler was found to be filled beyond capacity.
c.) 10NYCRR Part 14-1.83 at time of inspection a potentially hazardous product was being reheated by a method not capable of heating from refrigerated temperature to 165 degrees Fahrenheit within two hours.

Administrative Hearing: 8-18-2015

Public Health Sanitarian: Mr. Eli Rust appeared for CCHD and was sworn in.
Respondent: Mr. Randy G. Korkowicz appeared.

Testimony of Mr. Rust:
a.) Peoples Exhibit #1 Enf.-1 was read and affirmed to be true and correct.
b.) Food service establishment report dated 7-28-15 sliding glass door refrigerator found to be at 50-52 degrees Fahrenheit. Some items had to be discarded. Insufficient refrigerated storage therefore due to being overstocked cannot maintain adequate temperature. Reheat using steam tables, must reach 165 degrees F. in less than 2 hours from 45 degrees F., identified as P.E. #2.

DOCKET 15-020 (Continued):

c.) Food service establishment report dated 7-28-15 sliding glass door refrigeration found to be 50-52 degrees F. Items above 45 degrees F. were moved to walk in cooler. Sliding glass door cooler is not operating at an adequate temperature actual temperature 50-52 deg. F. (2) violations for same reason in back to back inspections means Referred to administrative hearing, and re-inspect, identified as P.E. #3.
d.) Memo to Ray Jordan from E. Rust on 8-5-15 respondent asked Mr. Rust to evaluate the sliding glass cooler at approximately 3:15 pm Mr. Rust and respondent measured the temperature in the cooler was 52-52 degrees F. caused by excessive ice buildup the unit was shut down and emptied for repair, memo identified as P.E. #4

Respondent's reply: 1. Invoice dated 8-11-15 for Magara Refrigeration for repair of a 2 door glass sliding cooler at Randy's Up-The-River. New timer installed, temperature cycle at 36-40 degrees F., identified as R#1.

Mr. Rust's wrap up:
- Mr. Rust is not telling the respondent, Randy Korkowicz, how to run his restaurant but rather measure and evaluate equipment and procedures that are in use at the food service establishment.
- Mr. Rust reported to the respondent that his cooling/refrigeration systems are over capacity for the throughput.
- Mr. Rust made a strong recommendation to the respondent to move all draft beer kegs to a new piece of equipment therefore freeing up capacity for the rest of the products.

Respondent agreed.

Re-inspection on 8-20-15 showed repaired 2 door glass sliding cooler to be holding correct temperature.

Hearing Officer Findings: The respondent is in violation of the findings (3) found at the time of the food service establishment inspection dated 7-21-15.
1.) Sliding glass door cooler had products at 50-51 degrees F.
2.) Sliding glass door cooler is being used past capacity.
3.) Re heat method not meeting state sanitary code effective 1-8-97

Recommendations: 1.) Respondent expand cooling/ cold storage facilities to meet the state sanitary code date 1-8-97 by moving the draft beer kegs from the present cooling system to a new cooling system. Identify, obtain and implement by 11-3-15, a new draft beer cooling system.
2.) The respondent be fined for (3) violations, all category two, and 1st offenses.
(3) Violations x $50.00 per violation = $150.00. The fine should be paid by 9-30-15. A $10.00 per day per diem will be levied for every day after 9-30-15 that the fine is not paid.

DOCKET 15-021

Randy G. Korkowicz, 44 East Main St., Allegany, NY 14206, Randy's Up-The River catering. Violations (2)

a.) 10NYCRR Part 14-1.40 (a) during routine inspection at the respondents catering operation, potentially hazardous food was found stored in hot holding units between 45-140 degrees F.

b.) 10NYCRR Part 14-1.143 (a) respondent failed to provide adequate hand washing facilities for his employees during an off-site catering operation.

Administrative Hearing: 8-18-2015

Public Health Sanitarian: Mr. Richard Dayton appeared for CCHD and was sworn in.
Respondent: Mr. Randy G. Korkowicz appeared.

Testimony of Mr. Dayton: Enf.-1 was read and affirmed to be true and correct identified as P.E. #1.

Mr. R. Dayton supplied (9) individual food service establishment inspection reports for Randy's Up-The-River catering service they are as follows:

DATE	ACTIVITY	RED VIOL.	BLUE VIOL.
7-26-15	Taste of Olean	1	1
8-23-14	Rally in the Valley	2	1
7-27-14	Taste of Olean	1	0
9-28-13	Bonagany	0	4
7-28-13	Taste of Olean	0	1
7-29-12	Taste of Olean	2	1
9-22-12	Bonagany	1	0
8-25-12	Rally in the Valley	0	1
6-09-12	St. Mary's Festival	0	3

7 Critical
12 Non-critical

-Five other catering dates revealed (9) more non-critical violations. All non-critical violations 12+9=21 total are for the same violation not having hot/ cold water hand washing facilities for employees during off site catering operations. The (7) critical violations are for potentially hazardous foods found stored in hot holding units between 45-140 degrees F.

-Letter dated 3-11-05 to respondent from R. Jordan, Sr. Health Sanitarian requesting information on source of water for employees and disposal. Return date 4-8-05 identified as P.E. #12

-An observation that a different inspector wrote up the same non-critical violation (21) times in (14) different inspections.

-Respondent and Mr. R. Dayton had an excellent discussion.

-Mr. Dayton stated CCHD position "compliance is not optional" food service establishments will follow the State Sanitary Code Sub Part 14-1 effective 1-8-97.

DOCKET 15-021 (Continued):

-Mr. Korkowicz stated he is fixing his catering service vehicles for hot/cold water for employees during off-site catering operations. If not fixed he will not cater per respondent.

Hearing Officer Findings: The respondent is in violation of

1. Potentially hazardous food found stored in hot holding units between 45-140 degrees F.
2. Absence of adequate hand washing facilities for employees during off-site catering operations.

Recommendations: Fine (2) categories (2) violations, each violation is $50.00 for 1st offense.

Two violations x $50.00/violation=$100.00 to be paid on or before 9-30-15. A $10.00 per day per diem will be levied for every day not paid after 9-30-15.

Fix catering vehicles to provide hot/old adequate hand washing facilities for employees during off-site catering. Complete prior to next catering job per Randy Korkowicz.

DOCKET 15-022

Darel Tingue, Corner Sports Bar & Grill Inc., 8383 Kingsbury Hill Rd., Franklinville, NY 14737. Violations (4)

1. **10NYCRR Part 14-1.120 during routine water monitoring on 11-18-14 it was found that the permanent disinfection equipment was not operational. A boil water notice was instituted and still in effect.**
2. **10NYCRR Part 14-1.195 respondent has not granted access to a Health Department Representative since 5/16/15. To date the respondent has not allowed routine inspection and collection of the required re-check bacteriological water samples.**
3. **10NYCRR Part 5-1.71 (b) respondent has failed to exercise care and due diligence in the operation and maintenance of the public water supply system by failing to repair the equipment and make necessary steps to ensure an adequate and safe supply.**
4. **10NYCRR Part 5-1.72 (c) (1) respondent failed to submit complete daily records for the operation of the non community water supply for the month of June 2015 to the office by the 10th day of the following month.**

Administrative Hearing: 8-18-2015

Public Health Sanitarian: Mr. E. Rust appeared for the CCHD and was sworn in.
Respondent: No show, properly served.

DOCKET 15-022 (Continued):

Testimony of Mr. Rust: The respondent is only accountable for violations after 3-24-15 when he took over the ownership and operations.

a.) Enf.-1 was read and affirmed to be true and correct identified as P.E. #1.
b.) Water system field compliance report identified as P.E. #2 dated 12-9-14. Serious, boil water in effect as of 11-18-14.
c.) Letter dated 11-18-14 from Chris Covert notice of violation identified as P.E. #3.
d.) Letter dated 3-31-15 to respondent concerning violations and boil water in effect identified as P.E. #4.
e.) Water system operation report from respondent dated 5-1-15 having difficulty getting the disinfection equipment operational identified as P.E. #5.
f.) Water system operational report dated 6-10-15 from respondent saying system is now functional, incomplete report identified as P.E. #6.
g.) Water system operations report dated 3-31-15 from respondent saying he took over on 3-16-15 as Owner and President.
h.) Letter dated 7-14-15 hand delivered to respondent purpose of letter was that the boil water notice posted 11-18-14 is only a short term/temporary measure until the equipment is operational. The Health Department needs access to inspect the repairs and collect water samples necessary to eliminate the boil water status. A dead line was offered, identified as P.E. #8.
i.) Proof of service to respondent identified as P.E. #9.

Operating permit for the Corner Sports Bar and Grill Inc. expires 9-30-15.

Hearing Officer Findings: The respondent under Docket 15-022 is in violation of (4) serious charges.

1.) Permanent disinfection equipment not operational creating an on-going boil water notice.
2.) Not granted access to the Health Department Representative to conduct a routine inspection and collect samples.
3.) Respondent has failed to exercise care and due diligence to keep public water supply system in repair and take necessary steps to ensure an adequate and safe supply.
4.) Fail to submit complete daily records for the operation of the non-community water system for the month of June 2015.

Recommendations: Fines recommended:

a.) Violation #1 Category 2 $100.00
b.) Violation #2 $ 0.00
c.) Violation #3 Category 2 $100.00
d.) Violation #4 Category 2 $100.00

Total $300.00 Must be pd. on or before 9-30-15

DOCKET 15-022 (Continued):

1.) Equipment- Have permanent disinfection equipment operational by 9-28-15.
2.) Testing- Two consecutive water samples must be taken 24 hours apart before noon 9-30-15.
3.) With the respondent complying with all the recommendations prior to 9-30-15 then The Sports Bar and Grill permit to operate will be considered with an application permit.
4.) A $10.00 per day per diem will be levied for every day after 9-30-15, that the fine, equipment and testing are not complete.

DOCKET 15-023

Timothy Farina, 10110 Rt. 242, Little Valley, NY 14755
Violations: CCSC Sec. 25.2.8 respondent's dog was involved in a human biting incident. Respondent did not submit evidence of a rabies vaccination certificate by the prescribed deadline.

Administrative Hearing: 8-18-2015

Public Health Sanitarian: Mike Hastings appeared for CCHD and was sworn in.
Respondent: No show properly served and was offered a civil compromise.

Testimony of Mr. Hastings:
a.) P.E. #1 Enf.-1 read and affirmed to be true and correct.
b.) Olean General Hospital animal bite report dated 6-24-15 identified as P.E. #2.
c.) Health Department bite report, (4) attempts to have compliance identified as P.E. #3.
d.) Letter to respondent explaining rabies; confinement, current vaccination identified as P.E. #4.
e.) Final letter to respondent dated 6-23-15 explaining importance of vaccination identified as P.E. #5.
f.) Animal confinement form- respondent supplied CHD with confinement form but no vaccination record or proof identified as P.E. #6.

Hearing Officer Findings:
The respondent is in violation of CCSC Sec. 25.2.8 respondent did not submit evidence of rabies vaccination after a biting incident. CCHD personnel visited the respondent, check on the well being of person bitten, check on the well being of the dog and explained the seriousness of compliance for animal vaccination

Recommendations:
1. That the respondent pay a $150.00 fine by 9-30-15.
2. The respondent provide proof of vaccination of his dog Eli, Pit-bull, by 9-30-15.

DOCKET 15-023 (Continued):

3. Failure to pay and provide proof of vaccination for his dog will result in a $10.00 per day, per diem after 9-30-15.

DOCKET 15-024

Nicole Ellis, 5437 Kyler Hill Rd., Little Valley, NY 14755
Violation: CCSC Sec. 25.2.8 respondent did not submit evidence of rabies vaccination by a prescribed deadline, after a human biting incident.

Administrative Hearing: 8-18-2015

Public Health Sanitarian: Mr. Mike Hastings appeared for CCHD and was sworn in.
Respondent: No show, properly served, and was offered a civil compromise.

Testimony of Mr. Hastings:
a.) P.E. #1 Enf-1 read and affirmed to be true and correct.
b.) P.E. #2 Bite report from CCHD.
c.) OGH animal bite report identified as P.E. #3.
d.) Letter to respondent 6-23-15 explaining rabies, confinement, current vaccination identified as P.E. #4.
e.) Confinement form identified as P.E. #5.

Hearing Officer Findings:
The respondent is in violation of CCSC 25.2.8 respondent did not submit evidence of rabies vaccination after a human biting incident. CCHD personnel visited the respondent, checking on the well being of the person bitten, checking on the well being of the dog and explained the seriousness of compliance for animal vaccination.

Recommendation:
1. That the respondent pay a $150.00 fine by 9-30-15.
2. The respondent provides proof of vaccination of her dog, Si, Pit-bull, by 9-30-15.
3. Failure to pay and provide proof of vaccination for her dog will result in a $10.00 per day per diem after 9-30-15.

Sanitary Code of the Cattaraugus County Health District

Summary of Significant Changes

Introduction:

In general, past revisions of the county sanitary code were minor and addressed specific issues arising from historic practice. The 2015 proposed revisions to the "SANITARY CODE OF THE CATTARAUGUS COUNTY HEALTH DISTRICT" (county sanitary code) are a culmination of hundreds of hours of discussion among Cattaraugus County Health Department management, staff as well as external partner agencies and customers. These revisions aim to be proactive, addressing the following goals;

- *clarify legal authority forcurrent environmental health divisional practices and procedures,*
- *simplify and modernize language,*
- *update definitions to align with current practices and procedures,*
- *where appropriate, minimize opportunity for interpretation,*
- *to provide legal authority for addressing existing environmental / public health issues through additional mechanisms,*
- *ensure consistency with relevant sections of 10 NYCRR.*

To this end, environmental health division management, and when needed technical staff, conducted a line-by-line review of the current sanitary code, often resulting in significant discussion surrounding 'what-if' scenarios, implementation logistics and procedures, regulatory burden, public health benefits and legal exposure.

Upon completion, these proposed revisions were submitted to the NYSDOH Center for Environmental Health for review and comment with regard to consistency with 10 NYCRR. Five general comments were received and addressed in the current proposed revisions.

Listed below is a summary of 'major' changes to the current sanitary code.

Formatting	-	Provides for consistent format, numbering and citation
Definitions	-	New definitions were added where needed elsewhere in the county sanitary code. Some definitions were changed in an effort to make them more readable and / or to modify their meaning to reflect current environmental health practice and procedure. Finally, some definitions were eliminated if they were not present in the code or were replaced by other definitions.
Misinform-ation	-	Added section SCCCHD 11.6 strictly forbidding any person from providing false or misleading information.

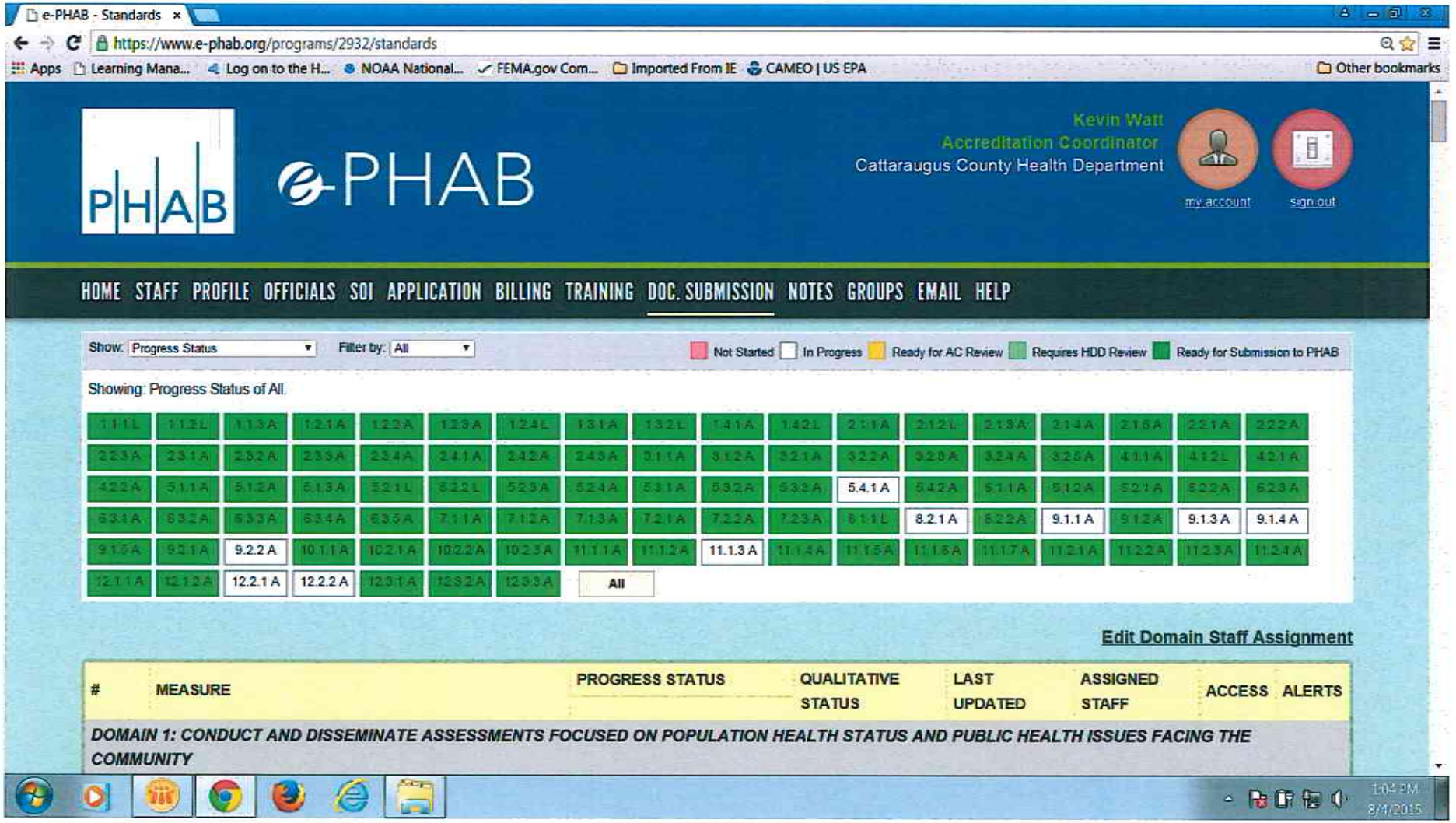
Body Art - Proposed revisions include a new Part 29 regulating the practice of body art and design of body art facilities. Tattooing is included as part of the definition of body art and is regulated in this part. Under this part, body art establishments and body art practitioners will be required to obtain a permit and follow all the requirements put forth in this part with regard to the design of body art facilities and the practice of body.

Public Health Hazards and Nuisances - Changes policy from one of "abating all complaints" to "accepting all complaints" of alleged public health hazards and nuisances. Revisions also attempt to minimally define the terms of Public Health Hazard and Public Health Nuisance.

Water Systems - Significant changes were made with regard to public water system regulation including:

- provision of a regulatory basis for historic environmental healthdivision policies and procedures with regard to small community public water systems (5-14 service connections),
- establishes a policy whereby no new disinfection waivers will be given,
- establishes an affirmative duty for the supplier of water to demonstrate a public water system is making daily operational and maintenance decisions regarding the system,
- extends separation distance requirements for public water system supply wells to existing as well as new and replacement wells,
- provides instances of *prima facie* lack of due diligence with regard to established best management practices and standards
- provides limited regulatory tools for addressing individual and commercial water systems not otherwise regulated.

Real Property Transfers - Empowers the department to require a visual inspection of water and wastewater systemcomponents, water / wastewater sampling,


e-PHAB - Standards
https://www.e-phab.org/programs/2932/standards
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PHAB
e-PHAB
Kevin Watt
Accreditation Coordinator
Cattaraugus County Health Department
my account
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HOME STAFF PROFILE OFFICIALS SOI APPLICATION BILLING TRAINING DOC. SUBMISSION NOTES GROUPS EMAIL HELP
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All
Edit Domain Staff Assignment
MEASURE PROGRESS STATUS QUALITATIVE STATUS LAST UPDATED ASSIGNED STAFF ACCESS ALERTS
DOMAIN 1: CONDUCT AND DISSEMINATE ASSESSMENTS FOCUSED ON POPULATION HEALTH STATUS AND PUBLIC HEALTH ISSUES FACING THE COMMUNITY
1:04 PM
8/4/2015

GOAL 1	Improve Electronic Infrastructure				
GOAL 1: Objective #1	Mobile capabilities for Environmental Health				
Baseline Data					
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Achieve 90% desktop to laptop conversion for field staff	Wohlers, Watkins, Ellis	IT, EH	December 2016	Completed	Received tablets from NYSDOH June 2015

GOAL 1: Objective #2	Mobile capabilities for Early Intervention				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Achieve 100% mobile internet capability	Watkins, Ellis,	IT, Verizon	December 2014	In-progress	The staff have the capability. The county's internet infastructure does not support this activity. New York State has set aside funding to improve and expand the availability of high speed internet. More information can been found on the following website: http://nysbroadband.ny.gov/state-funding

GOAL 1: Objective #3	Interoperability with Nursing Electronic Medical Records (EMR), Billing and Clinic				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
1. Feasability study with Nursing, Clinic, and Billing to assess current capabilities	Watkins, Ellis, Andrews, Spring, Williams	IT	March 2015	Completed	
2. Implement requested interoperabilities or begin investigation of new EMR	Ellis, Andrews, Spring, Williams	IT	December 2015	Completed	Scheduled product demos with vendors
3. Equipment and software updates in place for Nursing, Billing and Clinic	Watkins, Ellis, Andrews, Spring, Williams	IT	December 2017		

GOAL 1: Objective #4	Lifecycle management for Laboratory Equipment				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
1. Replace aging laboratory equipment with leased equipment	Ketchner, Watkins	IT, Lab, Admin	March 2015	Completed	Leased Hematology analyzer; Autoclave and Hood to consider in next plan review

GOAL 2	Increase Revenue and Improve Cost Control				
GOAL 2: Objective #1	Certify Home Care Nurses Assessment skills				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Improve OASIS training from 33% to 90% for Home Care Nurses	Andrews, Feldbauer, Grey		December 2016	In-progress	Securing funding to support OASIS training

GOAL 2: Objective #2	Increase the amount of clinical tests offered by HD laboratory & medical clinic				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description

Gather cost estimates to implement Drug screening program	Ketchner, Andrews, Williams, Dowdy		June 2015	In-Progress	Timeframe changed from December 2014 to June 2015, due to a Lab Supervisor staff change.
Gather cost estimates to implement EKG program	Andrews, Williams, Dowdy, Mallavarapu		December 2014	Completed	The cost of an EKG machine aas included in the 2014 budget.
Present to Legislators and Board of Health	Watkins		June 2015	In-Progress	laboratory personnel, implementation of new testing has been postponed until 2016.
Implement drug screening & EKG testing services	Andrews, Williams, Dowdy, Mallavarapu		December 2015		

GOAL 2: Objective #3	Identify increased opportunities for grant funding streams for core programs				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Seek grant writer to assist in funding opportunties	Ellis, Herrick		December 2015		
Look for additional funding opportunities	Wohlers, Andrews, Watt, Williams, Feldbauer, Grey		December 2016		

GOAL 3	Improve perception of Health Dept. and its visibility within the community				
GOAL 3: Objective #1	Educate the community about Health Department services				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Develop message	Parks, Leonard, Bennett, Nichols	HLCC, P2	December 2014	Completed	Updated HD Services brochure and website to be more user friendly
Create/Launch campaign	Parks, Leonard, Bennett, Nichols	Economic Development	June 2015	In-Progress	
Utilize print, radio and social media	Parks, Leonard, Bennett, Nichols	local radio, TV, youtube	December 2015		
Health educators to provide presentation to community groups	Parks, Leonard, Bennett, Nichols	HLCC, Community Action	December 2017		
Collaborate with organizations and agencies to disseminate information about various Health Department programs	Parks, Leonard, Bennett, Nichols	HLCC	December 2017		

GOAL 3: Objective #2	Standardize Intradepartmental Policies/Procedures				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Standardize Policy/Procedure Template	Division Managers		December 2017	In-Progress	Each department is standardizing their policies to the current template in place for Accreditation
Create Succession Plans for each division	Division Managers		December 2017		

GOAL 4	Reduce the incidence of Chronic Diseases				
GOAL 4: Objective #1	Identify Health Department clinic patients with chronic disease				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description

Collaborate with YMCA to provide a free one month membership/discount for membership	Watkins, Dowdy, Andrews, Mallavarapu	YMCA	January 2015	Completed	

GOAL 4: Objective #2	Educate the residents of Cattaraugus County on reducing the consumption of sugary sweetened beverages				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Encourage policy change in communities, schools, municipal office buildings	Parks, Leonard, Bennett, Nichols	HCA, CCE, local vendors	June 2015	In-Progress	CCE is giving presentation to organizations, schools and community groups about the negative health effects of SSB
PSA & Social Media Advertising	Parks, Watt		June 2015	In-Progress	Survey in progress for PSA campaign

GOAL 4: Objective #3	Create a web page for Healthy eating choices				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Create web page	Watt, Knabb, Parks, Bennett, Nichols	BOCES, CCA, R.D.	June 2016		
Create Videos	Parks, Leonard, Nichols	BOCES, CCA, R.D.	June 2016		
Create Recipe suggestions	Parks, Leonard, Bennett, Nichols	BOCES, CCA, R.D.	June 2016		

GOAL 4: Objective #4	Collaborate with Cattaraugus County Youth Development Coalition to create a video about making healthy lifestyle choices				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Recruit local school districts to participate in creation of PSA's (Tobacco, STD's, Teen Pregnancy)	Parks, Leonard	Local School Districts, Local Youth Bureaus	June 2016	In-Progress	In process of reaching out to school districts

GOAL 5	Reduce incidence of tobacco use in certain sectors of the community				
GOAL 5: Objective #1	Add tobacco education to existing Cattaraugus County Health education program to educate Middle High School/Senior High				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Develop lesson plan	Leonard, Nichols	Local School Districts	September 2015		
Recruit participation	Leonard, Nichols	Local School Districts	September 2015		

GOAL 5: Objective #2	Reduce the number of Cattaraugus County employees who use tobacco from 25% to 15%				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Increase awareness of NRT program	Andrews, Williams, Dowdy	Local Pharmacies, BigBox Retailers, STHCS, Tobacco Coalition, NYSDOH	December 2017	In-Progress	

GOAL 5: Objective #3	Seek funding for Nicotine replacement therapy				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description

olicit funding &/or donations for NRT	Nichols	BigBox Retailers, STHCS, Tobacco Coalition, NYSDOH	December 2016		

GOAL 6	Reduce Incidence of Sexually Transmitted Diseases in the community				
GOAL 6: Objective #1	Reduce the incidence of Hepatitis C in the community				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Conduct a feasability study on ntravenous drug use in Cattaraugus County	Andrews, Williams, Watt	Sheriff, CAReS, OGH	September 2016	In progress	
Use results from feasability study to letermine if a needle exchange rogram is necessary in the community	Andrews, Williams, Watt	Board of Health	October 2016		
Create Needle Exchange program if tudy determines necessary	Andrews, Williams	Board of Health, County Legislators	December 2017		

GOAL 6: Objective #2	Reduce the incidence of Chlamydia in the community				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
ncrease Reproductive Health outreach	Leonard, Dowdy	Local Colleges, Senior Groups	July 2015	In progress	
dentify agencies that would distribute lealth Department condoms	Leonard, Bennett, Andrews, Williams, Nichols	HLCC, Probation, Community Services, Social Services	September 2016		

GOAL 7	Performance Management				
GOAL 7: Objective #1	Reduce the incidence of Hepatitis C in the community				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Establish ad hoc committee to evaluate current assessment tool.	Watkins, Andrews, Ellis, Higley, Wohlers	Joseph Pillittere Public Works Commissioner	July 2015	Completed	
Evaluate other potential tools, techniques and processes used within or outside County government.	Watkins, Andrews, Ellis, Higley, Wohlers	Joseph Pillittere Public Works Commissioner	October 2015	In progress	
Bring findings to management.	Watkins, Andrews, Ellis, Higley, Wohlers	Joseph Pillittere Public Works Commissioner	October 2015		

GOAL 7: Objective #2	Add employee development to performance evaluation process.				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Have ad hoc committee determine how this goal should appear in review.	Watkins, Andrews, Ellis, Higley, Wohlers	n/a	October 2015	In progress	
Bring findings to management.	Watkins, Andrews, Ellis, Higley, Wohlers	n/a	October 2015		
Division managers will inform employees on this new initiative and get buy-in.	Watkins, Andrews, Ellis, Higley, Wohlers	n/a	November 2015		
Start process during next reviews.	Watkins, Andrews, Ellis, Higley, Wohlers	n/a	January 2015		

GOAL 7: Objective #3	Provide development opportunities for employees				
Activities	Lead Person	Partners	Timeframe	Progress towards goal	Description
Inform employees of Jamestown Community College (JCC) classes (use quarterly flyer and distribute).	Watkins, Andrews, Ellis, Higley, Wohlers	JCC	December 2017		
Have employees provide a list of their skills/expertise and develop an in-house training/mentoring program.	Watkins, Andrews, Ellis, Higley, Wohlers	NYSDOH Learning Management System	December 2016		
Bring outside experts from other departments or agencies on a quarterly basis that can provide additional staff development opportunities for staff.	Watkins, Andrews, Ellis, Higley, Wohlers	TBD	December 2017		

CATTARAUGUS COUNTY
BOARD OF HEALTH
BYLAWS

I. PREAMBLE

This Board, appointed by the County Legislature of Cattaraugus County, New York, as the Board of Health for the General Health District comprising the territory described in the resolution adopted January 10, 1923, and including the cities of Salamanca and Olean in accordance with the resolutions of consent adopted by the Mayors and Common Councils of those cities on January 15, 1923, and January 23, 1923, respectively, by authority of Chapter 509 of the Laws of 1921, and with the approval of the State Commissioner of Health, shall be known as the Cattaraugus County Board of Health.

II. STATUTORY COMPLIANCE

The operations and affairs of the Cattaraugus County Board of Health shall be conducted in accordance with the statutes of the State of New York.

III. MEMBERSHIP/ATTENDANCE

1. The Board of Health shall consist of seven members, one of whom shall be a member of the County Legislature, selected by the County Legislature, hereinafter referred to as Legislature, and at least three of whom shall be physicians licensed to practice in the State of New York, and in addition thereto, the City of Olean and the City of Salamanca shall be entitled to one additional representative member each, for a total of nine.

2. The members of the Board of Health shall be residents of Cattaraugus County.

3. (a) The members of the Board of Health shall be appointed by the County Legislature.

   (b) Upon the occurrence of a vacancy or vacancies, the County Medical Society may submit to the County Legislature, a list of three physicians from which the Legislature may choose the medical member or members of the Board.

   (c) The additional city representative members referred to in III (1), supra, shall be appointed by the Legislature from a list of three persons submitted by the Mayor of such city.

4. (a) The term of office of each appointive member shall be six years, with no more than two of such terms to expire annually. The term of the Legislative member shall be for such lesser period as may be required, in the event the member does not continue as a member of the legislature.

   (b) Vacancies shall be filled by appointment of the Legislature for the unexpired term.

5. In the event a Board of Health member fails to attend at least fifty percent (50%) of all meetings in any calendar year, and after 30 days written notice has been issued to such member, action may be taken at the next regular meeting by affirmative vote of a majority of the members of the Board, to recommend to the County Legislature that the member be replaced. A valid reason must be presented to the President of the Board verbally, or in writing, to be excused from a meeting. All requests to be excused will be reported to the secretary.

IV. OFFICERS

At the first meeting of each year, a President and Vice-President shall be elected. The Public Health Director shall act as Secretary.

V. MEETINGS

1. Meetings shall be held monthly at a time and place to be determined by the President.
2. Special meetings may be called by the President upon due notice to the members.
3. In the event of a public health emergency, a meeting may be called by the President, or the President's designee, at any time.

VI. RULES OF ORDER

Parliamentary procedure shall be determined by the latest edition of Robert's Rules of Order.

VII. AMENDMENT OF BYLAWS

These bylaws or any part thereof, may be rescinded, altered or amended at any regular meeting of the Board by affirmative vote of a majority of the members of the Board provided due notice of the proposed action is given the members with the notice of the meeting not less than seven (7) days before such meeting.

Adopted by Cattaraugus County Board of Health
08/05/2015

Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomised trial

Ana Maria Henao-Restrepo, Ira M Longini, Matthias Egger, Natalie E Dean, W John Edmunds, Anton Camacho, Miles W Carroll, Moussa Doumbia, Bertrand Draguez, Sophie Duraffour, Godwin Enwere, Rebecca Grais, Stephan Gunther, Stefanie Hossmann, Mandy Kader Kondé, Souleymane Kone, Eeva Kuisma, Myron M Levine, Sema Mandal, Gunnstein Norheim, Ximena Riveros, Aboubacar Soumah, Sven Trelle, Andrea S Vicari, Conall H Watson, Sakoba Kéïta, Marie Paule Kieny, John-Arne Røttingen**

Summary

Background A recombinant, replication-competent vesicular stomatitis virus-based vaccine expressing a surface glycoprotein of Zaire Ebolavirus (rVSV-ZEBOV) is a promising Ebola vaccine candidate. We report the results of an interim analysis of a trial of rVSV-ZEBOV in Guinea, west Africa.

Methods For this open-label, cluster-randomised ring vaccination trial, suspected cases of Ebola virus disease in Basse-Guinée (Guinea, west Africa) were independently ascertained by Ebola response teams as part of a national surveillance system. After laboratory confirmation of a new case, clusters of all contacts and contacts of contacts were defined and randomly allocated 1:1 to immediate vaccination or delayed (21 days later) vaccination with rVSV-ZEBOV (one dose of 2×10^7 plaque-forming units, administered intramuscularly in the deltoid muscle). Adults (age ≥18 years) who were not pregnant or breastfeeding were eligible for vaccination. Block randomisation was used, with randomly varying blocks, stratified by location (urban *vs* rural) and size of rings (≤20 *vs* >20 individuals). The study is open label and masking of participants and field teams to the time of vaccination is not possible, but Ebola response teams and laboratory workers were unaware of allocation to immediate or delayed vaccination. Taking into account the incubation period of the virus of about 10 days, the prespecified primary outcome was laboratory-confirmed Ebola virus disease with onset of symptoms at least 10 days after randomisation. The primary analysis was per protocol and compared the incidence of Ebola virus disease in eligible and vaccinated individuals in immediate vaccination clusters with the incidence in eligible individuals in delayed vaccination clusters. This trial is registered with the Pan African Clinical Trials Registry, number PACTR201503001057193.

Findings Between April 1, 2015, and July 20, 2015, 90 clusters, with a total population of 7651 people were included in the planned interim analysis. 48 of these clusters (4123 people) were randomly assigned to immediate vaccination with rVSV-ZEBOV, and 42 clusters (3528 people) were randomly assigned to delayed vaccination with rVSV-ZEBOV. In the immediate vaccination group, there were no cases of Ebola virus disease with symptom onset at least 10 days after randomisation, whereas in the delayed vaccination group there were 16 cases of Ebola virus disease from seven clusters, showing a vaccine efficacy of 100% (95% CI 74·7–100·0; p=0·0036). No new cases of Ebola virus disease were diagnosed in vaccinees from the immediate or delayed groups from 6 days post-vaccination. At the cluster level, with the inclusion of all eligible adults, vaccine effectiveness was 75·1% (95% CI −7·1 to 94·2; p=0·1791), and 76·3% (95% CI −15·5 to 95·1; p=0·3351) with the inclusion of everyone (eligible or not eligible for vaccination). 43 serious adverse events were reported; one serious adverse event was judged to be causally related to vaccination (a febrile episode in a vaccinated participant, which resolved without sequelae). Assessment of serious adverse events is ongoing.

Interpretation The results of this interim analysis indicate that rVSV-ZEBOV might be highly efficacious and safe in preventing Ebola virus disease, and is most likely effective at the population level when delivered during an Ebola virus disease outbreak via a ring vaccination strategy.

Funding WHO, with support from the Wellcome Trust (UK); Médecins Sans Frontières; the Norwegian Ministry of Foreign Affairs through the Research Council of Norway; and the Canadian Government through the Public Health Agency of Canada, Canadian Institutes of Health Research, International Development Research Centre, and Department of Foreign Affairs, Trade and Development.

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Published Online July 31, 2015 http://dx.doi.org/10.1016/S0140-6736(15)61117-5

See Online/Editorial http://dx.doi.org/10.1016/S0140-6736(15)61177-1

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For the protocol see http://www.bmj.com/content/bmj/suppl/2015/07/27/bmj.h3740.DC1/cama026973.w1_default.pdf

See Online for appendix

Introduction

Vaccines against Ebola virus disease are an urgent international priority.[1] However, at present, no licensed vaccines are available, despite promising results for several candidate vaccines in non-human primate studies and phase 1 trials.[2–9] The recombinant, replication-competent vesicular stomatitis virus-based candidate vaccine expressing the glycoprotein of a Zaire Ebolavirus (rVSV-ZEBOV) causes a transient systemic infection after a single injection, and produces a rapid immune response against the Ebola virus surface protein.[6,7]

The *Ebola ça Suffit* ("Ebola this is enough") cluster-randomised phase 3 trial is currently underway in Guinea to assess the efficacy of the rVSV-ZEBOV candidate vaccine for the prevention of Ebola virus disease. The trial uses a novel design for recruitment and estimation of vaccine efficacy,[10] modelled on the ring vaccination approach used for smallpox eradication in the 1970s.[11] Ring vaccination is defined as the vaccination of a cluster of individuals at high risk of infection, owing to their social or geographical connection to a confirmed index case.

The pilot phase of the trial began on March 23, 2015, with the immediate vaccination of three non-randomised clusters; randomisation of clusters started on April 1, 2015. Herein, we report the interim results of this trial, describe the characteristics of the clusters and individuals enrolled in the trial, report the incidence of Ebola virus disease in the rings up to July 20, 2015, and provide preliminary estimates of vaccine safety and effectiveness.

Research in context

Evidence before this study

The ongoing outbreak of Ebola virus disease in west Africa is the largest outbreak ever recorded. As of July 19, 2015, a total of 27 705 reported confirmed, probable, and suspected cases have been reported in Guinea, Liberia, and Sierra Leone, including 11 269 reported deaths. A meeting convened by WHO in September, 2014, in Geneva, Switzerland, concluded that an urgent need exists for efficacy and safety testing of the unlicensed vaccine candidates that are currently in development and that trials of candidate Ebola virus disease vaccines should be expedited. We searched Medline and Embase from January, 1990, to July 20, 2015, for phase 3 clinical trials assessing the efficacy of Ebola vaccines, without language restrictions, using the search terms "Ebola virus", "filovirus", "prophylaxis", "vaccine", and "clinical trials" to identify any published phase 3 trial results of Ebola vaccines. The rVSV-ZEBOV vaccine has been studied in phase 1 and 2 studies, which have documented its immunogenicity and safety profile. To our knowledge, ours is the only phase 3 trial of this vaccine in west Africa that has reported results, and no trial until now has used the ring vaccination cluster-randomised design. Therefore, we could not do a detailed systematic review at this point in time.

Added value of this study

Effective vaccines against Ebola virus disease could reduce morbidity and mortality and end the devastating Ebola epidemic, which is severely affecting the health system and the populations in west Africa. Our results provide the first evidence that the rVSV-ZEBOV vaccine is efficacious in a trial setting and might be effective in real-life scenarios. These results also document the feasibility and adequacy of ring vaccination cluster trial design in an outbreak situation in a resource-poor setting and when the incidence of Ebola virus disease is low in the general population.

Implications of all the available evidence

The results of this interim analysis suggest that rVSV-ZEBOV might be highly efficacious in preventing Ebola virus disease, and most likely effective at the population level when delivered during an outbreak using a ring vaccination strategy. These data can contribute to the ongoing assessment of this vaccine and help to inform policy and regulatory decisions with regard to the Ebola vaccination strategy.

Methods

Study design and participants

Described in detail elsewhere,[10] the ring vaccination trial is a novel cluster-randomised trial design to assess vaccine efficacy and effectiveness during outbreaks. We used an adaptive trial design with an α spending strategy to allow for interim analyses of the data. The full trial protocol can be accessed as a data supplement to a previous publication on this trial[10] and the original French version is available in the appendix.

The aim of the open-label *Ebola ça Suffit* trial is to assess whether or not one dose of rVSV-ZEBOV candidate vaccine administered by intramuscular injection to adult contacts and contacts of contacts of patients with confirmed Ebola virus disease can provide protection against the development of laboratory-confirmed Ebola virus disease. The trial is based in Basse-Guinée, a coastal area of Guinea, west Africa, that comprises the capital Conakry and eight other prefectures (for a map, see figure 1). This area was chosen because it was the only area of Guinea in which cases of Ebola virus disease were confirmed at the time of the start of the study. The Guinean national Ebola response teams report all newly confirmed cases of Ebola virus disease daily to the trial team. Suspected cases are ascertained by the national Ebola surveillance system based on reports from health-care facilities and the community, and confirmed in designated laboratories.[11] Within a few days of notification, a cluster of all contacts and contacts of contacts (including absent residents) is defined and randomly allocated to immediate or delayed vaccination.

Eligible consenting adults (aged ≥18 years) are vaccinated immediately or 21 days after randomisation. Participants in all clusters have access to free medical care at a private clinic in Conakry for any acute illness during the study period. The exception is suspected Ebola virus disease, for which the participants are transferred to the nearest Ebola treatment unit as per national guidelines.

For every index case included in the study, we define contacts as individuals who, within the last 21 days, lived in the same household, were visited by the index case after the onset of symptoms, or were in close physical contact with the patient's body or body fluids, linen, or clothes.[11] Contacts of contacts include neighbours, family or extended family members living within the nearest geographical boundary of all contacts, plus household members of any high-risk contacts.[11] Local social mobilisation experts visit the area of the index case's residence and seek participants' consent for the trial team to enumerate the cluster. A written information sheet and informed consent form were used to obtain consent from all participants. If the person was illiterate, these documents were read to him or her in one of the local languages in the presence of a valid witness. To document consent, a signature or fingerprint was obtained and a literate witness also signed the form. If a participant listed in a previously defined cluster develops Ebola virus disease, they are assessed as a potential new index case, as an outcome for the trial, or both. A new cluster is defined if at least 60% of the contacts and contacts of contacts live outside the original cluster.

All individuals aged 18 years or older who live in the defined cluster are eligible for vaccination. Exclusion criteria were any history of Ebola virus disease (self-reported or laboratory-confirmed disease), women who are breastfeeding, women with a self-reported or confirmed pregnancy (women are offered, but not required to take, a pregnancy test), self-report of clinically significant immunodeficiency, history of anaphylaxis to a vaccine or vaccine component, severe illness that makes the participant bed-bound or requires admission to hospital at the time of the vaccination. Eligible individuals might not receive the vaccination because they refuse or withdraw consent, or because they are away from home at the time of vaccination.

The trial was approved by the Guinean national medicines regulatory agency (Direction Nationale de la Pharmacie et du Laboratoire) and the national ethics committee (Comité National d'Ethique pour la Recherche en Santé), and by the WHO Ethical Research Commitee, and Norwegian Regional Committees for Medical and Health Research Ethics. All participants provided written informed consent, as described earlier.

Randomisation and masking

Randomisation was done in a 1:1 ratio at the cluster level. An independent statistician not otherwise involved in the trial generated the allocation sequence.

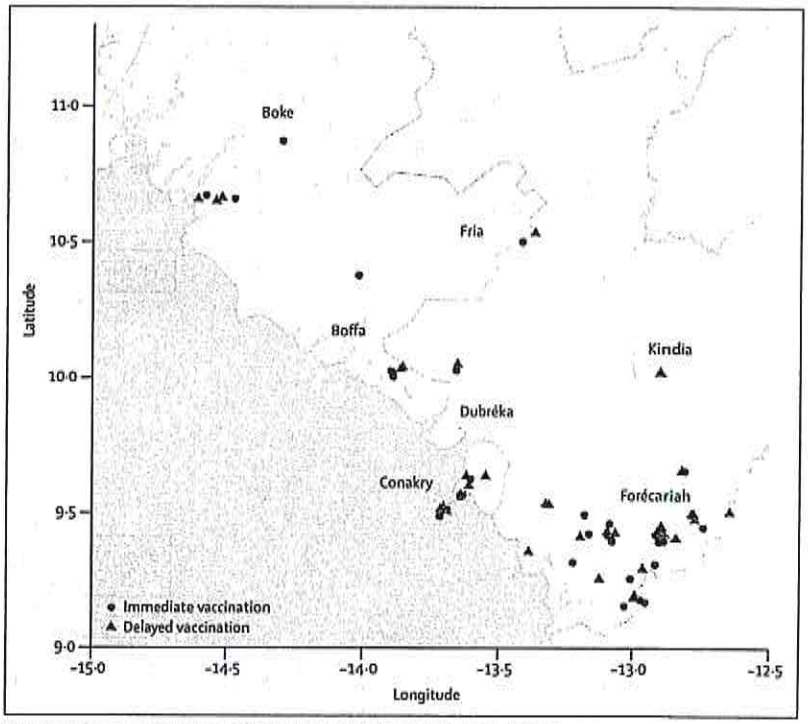

Figure 1: Study area of *Ebola ça Suffit* cluster vaccination trial in Basse-Guinée

Block randomisation was used with randomly varying blocks, stratified by location (urban *vs* rural) and size of rings (≤20 *vs* >20 individuals). The list of eligible participants and a preliminary eligibility assessment was done before randomisation. The randomisation list is stored in a data management system not accessible to anyone involved in the recruitment of trial participants. Allocation of a cluster was revealed only after registering the cluster in the system. Informed consent and assessment of eligibility were done after randomisation, but allocation was not disclosed to the participants until the end of the informed consent process. The study is open label, but Ebola response teams and laboratory workers are unaware of the allocation of clusters.

Procedures

One dose of 2×10^7 plaque-forming units (PFUs) of the rVSV-ZEBOV vaccine is administered intramuscularly in the deltoid muscle. It is recommended, but not required, that this injection should be administered into the non-dominant arm. To ensure that the participants in delayed clusters receive the vaccine on the designated date and, to improve compliance with follow-up, we contact the participants by telephone on the days before the scheduled visits. Merck Sharp & Dohme (Kenilworth, NJ, USA) provided the rVSV-ZEBOV vaccine used in the trial.

We observe the vaccinated volunteers for 30 min post-vaccination to record any adverse events, and visit them

at home on days 3, 14, 21, 42, 63, and 84 post-vaccination to document the potential occurrence of any serious adverse events. On days 3 and 14 post-vaccination, we obtain information about any type of adverse event from participants or next of kin, using a standardised questionnaire. We report all serious adverse events, including cases of Ebola virus disease in vaccinees to the trial's data and safety monitoring board as part of the serious adverse event reporting procedures.

The primary outcome—Ebola virus disease occurring at least 10 days after randomisation—is confirmed through detection of Ebola virus RNA by reverse-transcriptase PCR.[11] The Ebola response teams, which operate independently from the trial teams, investigate

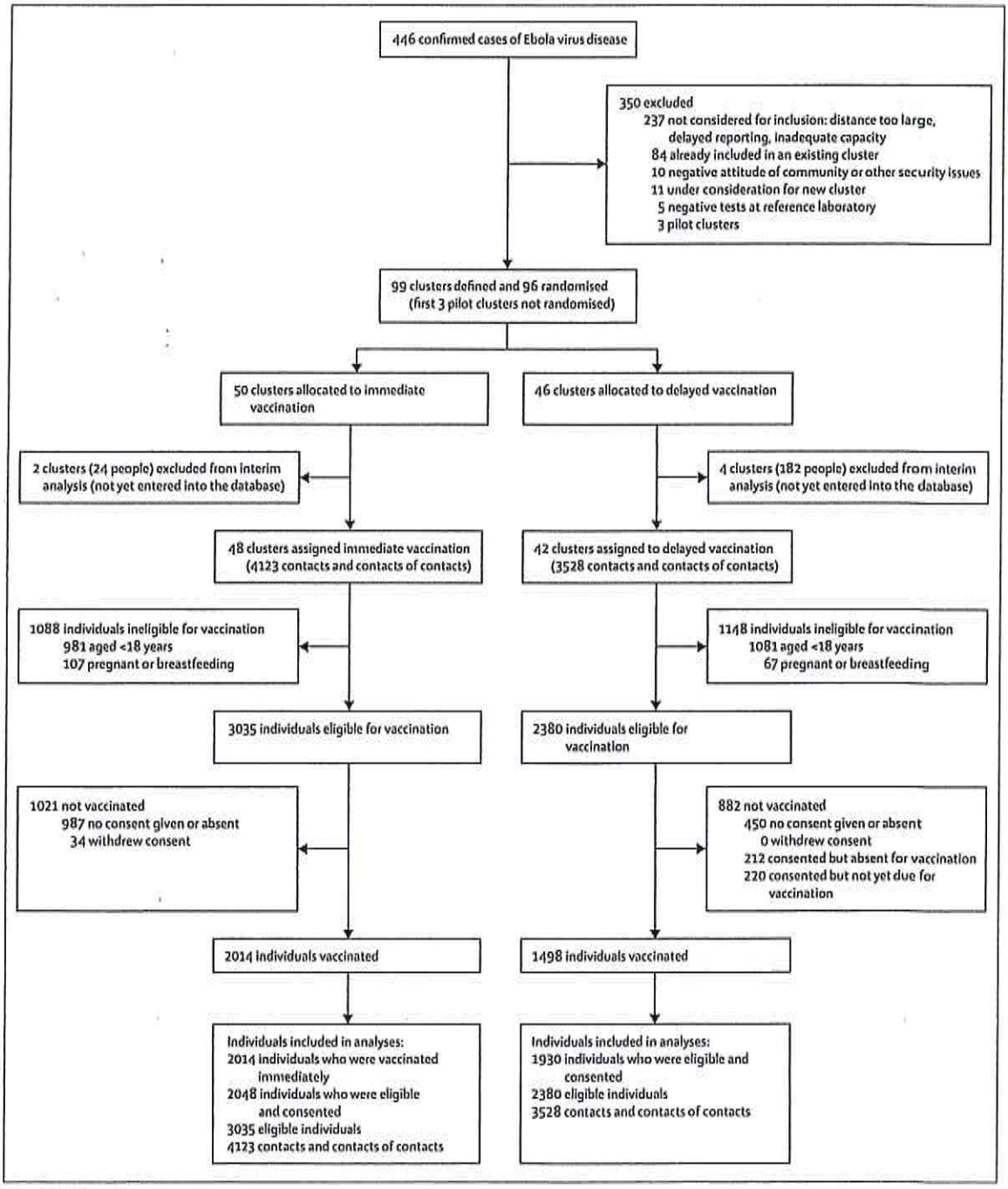

Figure 2: Trial profile

www.thelancet.com Published online July 31, 2015 http://dx.doi.org/10.1016/S0140-6736(15)61117-5

each suspected case and classify cases according to WHO definitions.[14] Whenever a suspected case is identified, the Ebola response team isolates and transfers the patient to the nearest Ebola treatment unit, and collects blood samples for laboratory tests in one of several designated laboratories. If the person has died, the response team collects specimens for laboratory confirmation and coordinates a safe and dignified burial. All contacts are monitored at home by members of the Ebola response team for 21 days following their last known exposure to the case, and are isolated if they become ill.[13]

Outcomes

The primary outcome is Ebola virus disease occurring at least 10 days after randomisation, confirmed through detection of Ebola virus RNA by reverse-transcriptase PCR, analysed per protocol as vaccine efficacy. Secondary outcomes were suspected and probable cases and serious adverse events occurring up to 84 days post-vaccination. Every day, the trial team reviews the data about confirmed new cases and searches the trial database, using surveillance and laboratory identification codes, name, last name, age, location, date of onset of symptoms, and date of notification to ascertain whether or not a new case qualifies as a primary outcome in a randomised cluster. We also review all available information about chains of transmission in the area of origin of the new Ebola virus disease case. The case is considered for inclusion as a new cluster.

Statistical analysis

The protocol and statistical analysis plan were approved and in place when the trial was started on April 1, 2015; amendments to the analysis plan made on May 15, 2015, modified the α spending rules to a more conservative function, and interim analysis timing (see appendix for the protocol, statistical analysis plan, and amended plan). The data and safety monitoring board reviewed interim analysis data on July 3, 2015.

Sample size calculations assumed that each cluster would contain an average of 50 consenting participants. We required 90% power to reject the null hypothesis of no vaccine efficacy, with the probability of a type I error (ie, α level) set at 5%, for a two-sided test of significance. To account for the clustering (ie, the design effect), we assumed an intra-class correlation coefficient of 0·05.[15,16] We calculated sample sizes by varying the percentage of contacts becoming infected and developing Ebola virus disease (ie, the illness rate) between 1% and 5%. We also varied the potential vaccine efficacy from 50% to 90%. For example, we found that if the vaccine efficacy was 70% and the infection rate 2%, then a total of 190 clusters would be needed. However, if the vaccine efficacy was 90%, with a 2% infection rate, then a total of 98 clusters would be needed. The trial is done in an adaptive manner, for which a two-sided, symmetric O'Brien-Fleming α spending strategy truncated at an absolute value of 3·00 is used (the O'Brien-Fleming threshold for this interim analysis was 0·0027).[17] We planned to do a single interim analysis at around 100 total clusters. No boundaries for futility were specified. The data and

	Immediate vaccination (n=48)	Delayed vaccination (n=42)
Index cases used to define clusters		
Age of index case, years	35·0 (20·1–40·0)	37·5 (25·0–50·0)
Women	26/48 (54%)	25/42 (60%)
Time from onset of symptoms to reporting of case by Ebola response team, days	3·9 (2·6)	4·3 (2·3)
Randomly allocated clusters		
Total number of people in cluster	80 (58–100)	74 (60–95)
Clusters located in rural areas	37/48 (77%)	32/42 (76%)
Clusters with ≥20 participants eligible and consenting in the clusters	44/48 (92%)	37/42 (88%)
Age of eligible participants, years	40·0 (26·5–50·0)	37·0 (29·0–55·0)
Compliance with follow-up visits for safety monitoring among eligible participants		
Day 3	1803/2014 (90%)	1384/1498 (92%)
Day 14	1657/1834 (90%)*	1326/1471 (90%)
Day 21	1562/1731 (90%)†	1306/1441 (91%)
Day 42	1212/1342 (90%)	930/1017 (91%)
Day 63	779/875 (89%)	308/397 (78%)
Day 84	313/345 (91%)	..

Data are median (IQR), n/N (%), or mean (SD). *The day 14 follow-up visit was not done in two clusters (121 vaccinees) because of public security issues. †The day 21 follow-up visit was not done in one cluster (31 vaccinees) because of public security issues.

Table 1: Characteristics of index cases, rings, and compliance with follow-up visits for safety monitoring

	All vaccinated in immediate versus all eligible in delayed (primary analysis)	All eligible and consented	All eligible (eligible adults, contacts and contacts of contacts)	All (all contacts and contacts of contacts)
Number of individuals (clusters)				
Immediate	2014 (48)	2048 (48)	3035 (48)	4123 (48)
Delayed	2380 (42)	1930 (42)	2380 (42)	3528 (42)
Number of cases at <10 days (affected clusters)				
Immediate	9 (4)	10 (5)	18 (9)	21 (9)
Delayed	16 (12)	6 (5)	16 (12)	25 (13)
Number of cases at ≥10 days (affected clusters)				
Immediate	0 (0)	0 (0)	6* (3)	8* (4)
Delayed	16† (7)	11† (5)	16† (7)	21† (7)
Vaccine efficacy/ effectiveness‡ (%; 95% CI)	100% (74·7 to 100)	100% (70·8 to 100)	75·1% (−7·1 to 94·2)	76·3% (−15·5 to 95·1)
p value§	0·0036	0·0194	0·1791	0·3351

*All cases occurred in unvaccinated individuals. †Four cases were vaccinated and developed symptoms on day 0, 2, 6, or 6 after vaccination. ‡From fitting a β-binomial distribution to the cluster-level numerators and denominators and using an inverted likelihood ratio test to identify the lower bound for vaccine efficacy (first two columns); from Cox proportional hazards model to estimate vaccine effectiveness (last two columns). §From Fisher's exact test (two-sided).

Table 2: Calculations of vaccine efficacy and vaccine effectiveness based on different study populations

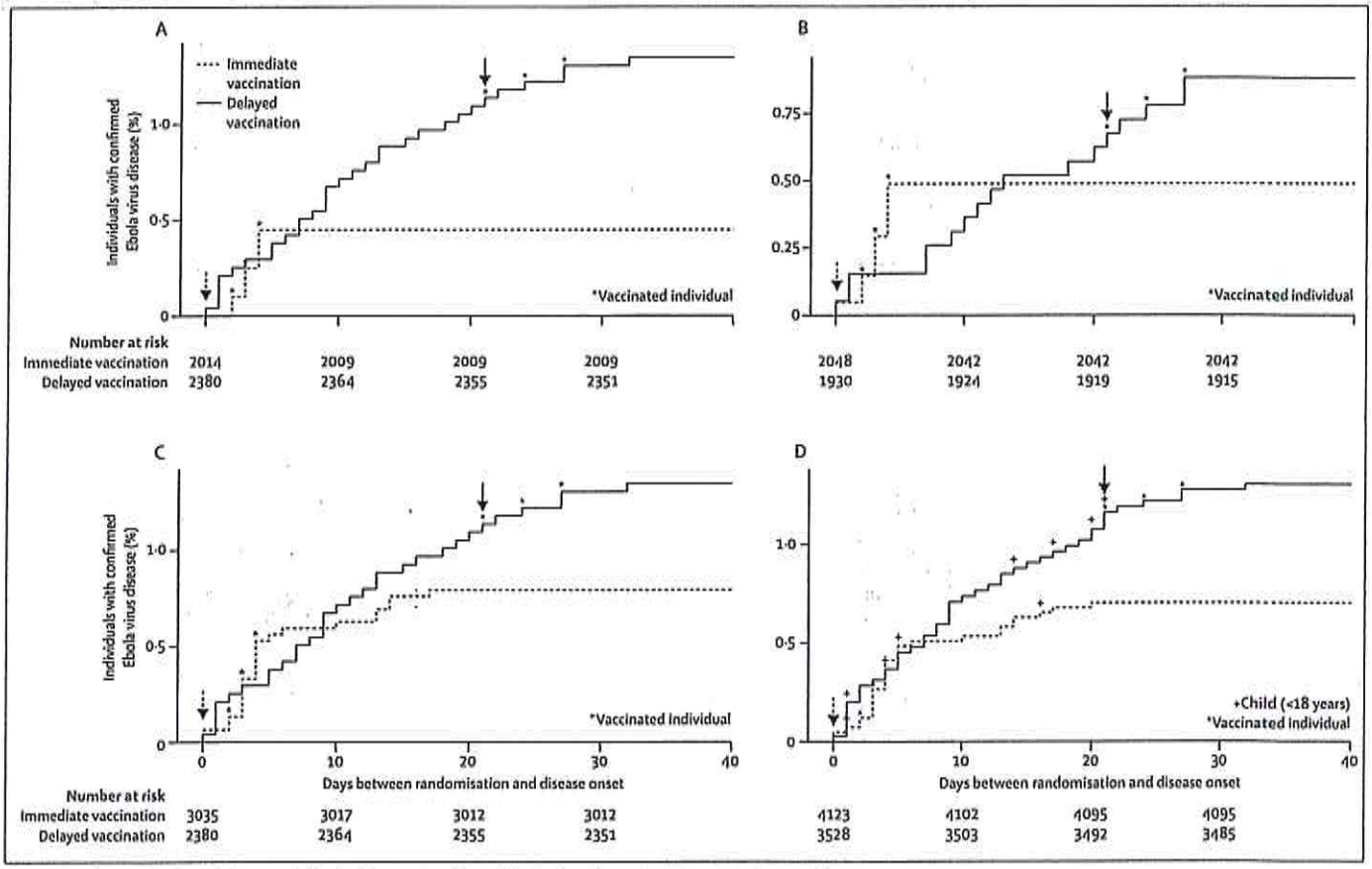

Figure 3: Kaplan-Meier plots of the cumulative incidence of confirmed Ebola virus disease in different study populations
(A) All vaccinated individuals assigned to immediate vaccination versus all eligible individuals assigned to delayed vaccination (primary analysis). (B) All eligible and consenting individuals. (C) All eligible individuals. (D) All individuals. Arrows indicate immediate (day 0) and delayed (day 21) vaccination. The shaded area shows the period excluded from analyses.

safety monitoring board can decide whether to continue or stop the trial, according to success, failure, or insufficient evidence.

A priori, we defined a delay of 10 days in the primary analysis to account for the incubation period of Ebola and the unknown time for the vaccine to develop protective immunity. Analyses of vaccine efficacy were therefore restricted to events occurring 10 days or more after randomisation. The primary analysis, as defined in a previous publication on this trial,[10] compared the incidence of Ebola virus disease in eligible and vaccinated individuals in immediate vaccination clusters with the incidence in eligible individuals in delayed vaccination clusters. Additional analyses compared the incidence in eligible and consenting individuals, eligible individuals, and all individuals. The first two analyses estimate vaccine efficacy, the latter two, vaccine effectiveness in different populations.[18]

In case of zero cases of Ebola virus disease occurring (ie, vaccine efficacy 100%) a 95% CI was derived by fitting a β-binomial distribution to the cluster-level numerators and denominators and using an inverted likelihood ratio test to identify the lower bound for vaccine efficacy. For comparisons in which events were reported in both groups, a Cox proportional hazards model was fitted using a cluster-level frailty term to adjust for clustering within rings.[10,19] We used a Fisher's exact test to compare the proportions of clusters with at least one event across the two trial groups. All analyses were done in R, version 3.2.0.[20]

This trial is registered with the Pan African Clinical Trials Registry, number PACTR201503001057193.

Role of the funding source

The funders had no role in the design of the study, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

This interim analysis includes clusters randomly assigned from April 1, 2015, up until July 20, 2015. Between these dates, 90 clusters were included, with a

total population of 7651 participants (figure 2). 48 clusters (4123 people) were randomly assigned to immediate vaccination with rVSV-ZEBOV, and 42 clusters (3528 people) were randomly assigned to delayed vaccination (21 days later). A total of 75 laboratory-confirmed cases of Ebola virus disease were identified in the 90 randomised clusters during the study period, of whom 33 patients died. The case-fatality rate was 52% (15/29) in the immediate vaccination rings and 39% (18/46) in the delayed vaccination rings.

At baseline, the two groups were similar in terms of characteristics of the index cases (age, sex, and delay between onset of symptoms and reporting of case by Ebola response teams) and the location and size of the clusters (table 1). The median age of the eligible and consenting adults was similar (table 1). The median number of people in each cluster was similar: 80 (IQR 58–100) in the immediate clusters and 74 (60–95) in the delayed clusters. Immediate and delayed clusters were similar in terms of the number of clusters with at least 20 participants and the mean age of the eligible and consenting participants (table 1). Rates of participant compliance to follow-up safety visits were roughly 90% for all visits in both immediate and delayed vaccination clusters.

In the 48 immediate vaccination clusters, 3035 (74%) of 4123 contacts and contacts of contacts were eligible for vaccination and 2014 (49%) were vaccinated. In the 42 delayed vaccination clusters 2380 (67%) of 3528 contacts and contacts of contacts were eligible for vaccination and 1498 (42%) were vaccinated (figure 2).

In our primary analysis, we compared the incidence of Ebola virus disease in all vaccinated individuals from the immediate vaccination group with all eligible individuals in the delayed vaccination group (table 2). At 10 days or more post-randomisation, no cases of Ebola virus disease occurred in the immediately vaccinated participants compared with 16 confirmed cases in eligible individuals in the delayed vaccination group. These 16 cases were from seven delayed vaccination rings, in three different prefectures. The estimated vaccine efficacy was 100% (95% CI 74·7–100·0). According to Fisher's exact test comparing the proportions of clusters with one or more eligible case, the p value was 0·0036 and did not cross the interim analysis threshold of p=0·0027. Figure 3A shows the cumulative incidence of Ebola virus disease in the two groups.

In a comparison of eligible and consenting individuals, the analysis of vaccine efficacy is based on zero cases of Ebola virus disease at 10 days or more post-randomisation in the immediate vaccination group and 11 confirmed cases in the delayed vaccination group, for an estimated vaccine efficacy of 100% (95% CI 70·8–100·0) and a p value of 0·0194 (table 2, figure 3B). When the analysis is expanded to all eligible people, six cases of Ebola virus disease occurred in three clusters in the immediate vaccination group versus 16 cases in seven clusters in the delayed vaccination group (table 2, figure 3C). Notably, all the cases in the immediate vaccination group occurred in unvaccinated individuals. The estimate of vaccine effectiveness in eligible people is 75·1% (95% CI –7·1 to 94·2; p=0·1791). Finally, if we include all contacts and contacts of contacts, the comparison is between eight confirmed cases of Ebola virus disease from four clusters (all in unvaccinated individuals) in the immediate vaccination group and 21 cases from seven clusters in the delayed group. The estimated vaccine efficacy in all members of the 90 clusters is 76·3% (95% CI –15·5 to 95·1, p=0·3351; table 2, figure 3D).

	Eligible adults allocated immediate vaccination		All eligible adults allocated to delayed vaccination (n=2380)	Ineligible (not vaccinated; age <18 years, pregnant, or lactating)	
	Vaccinated immediately (n=2014)	Never vaccinated (n=1021)		Allocated to immediate vaccination (n=1088)	Allocated to delayed vaccination (n=1148)
Allocated delay (42 clusters)					
Cluster D1	..	..	6	..	1
Cluster D2	..	..	3	..	4
Cluster D3	..	..	2	..	0
Cluster D4	..	..	2	..	0
Cluster D5	..	..	1	..	0
Cluster D6	..	..	1	..	0
Cluster D7	..	..	1	..	0
35 clusters with 0 cases	..	..	..	..	..
Allocated immediate (48 clusters)					
Cluster I1	0	3	..	1	..
Cluster I2	0	2	..	0	..
Cluster I3	0	1	..	0	..
Cluster I4	0	0	..	1	..
44 clusters with 0 cases	..	..	..	..	..
Total	0/2014 (0·0%)	6/1021 (0·6%)	16/2380 (0·7%)	2/1088 (0·2%)	5/1148 (0·4%)

Table 3: Distribution of confirmed Ebola virus disease cases in vaccinated and unvaccinated individuals in immediate and delayed clusters

Table 3 provides additional information about the distribution of confirmed cases of Ebola virus disease in vaccinated and unvaccinated individuals in the immediate and delayed vaccination rings.

The data about the secondary outcomes for efficacy and effectiveness and safety are not included in this Article and will be part of a future report once follow-up is completed for all participants and analyses have been done. The information regarding serious adverse events reported so far is included in the appendix. As of July 20, 2015, a total of 43 serious adverse events had been documented among eligible and consenting trial participants, including 27 confirmed cases of Ebola virus disease (see appendix).

Apart from Ebola virus disease, the three most common serious adverse events were suspected, unconfirmed Ebola virus disease (three cases), episodes of febrile illness (three cases), and road traffic accidents (three cases). 16 deaths occurred: 15 from Ebola virus disease and one from cardiac arrest. The initial causality assessment indicated that only one serious adverse event, an episode of febrile illness, in a male participant who recovered without sequelae was related to vaccination. Assessment of serious adverse events is ongoing.

Discussion

The interim results of the *Ebola ça Suffit* ring vaccination trial suggest that the efficacy of a single injection of rVSV-ZEBOV to prevent Ebola virus disease might be high, that protection can be established quickly, and that the vaccine might be effective at the population level when delivered by ring vaccination. As expected, Ebola virus disease typically occurred in local outbreaks, based on close-contact, person-to-person transmission.

The primary analysis of vaccine efficacy compared adults who were eligible and vaccinated in the immediate vaccination group with eligible adults in the delayed vaccination group. Eligible adults allocated to the immediate group who declined vaccination were therefore excluded from the primary analysis, whereas those from the delayed group who refused vaccination were included. Selection bias could have been introduced but was unlikely because the risk of Ebola virus disease was similar in the two groups in the first days after randomisation, and similar from day 10 onwards in eligible adults not vaccinated in the immediate group and eligible adults in the delayed group (table 2). Furthermore, when we restrict the comparison to eligible and consenting individuals, the estimated vaccine efficacy was identical to the estimate from the primary analysis (100%).

Additional evidence supports the conclusion that the rVSV-ZEBOV vaccine is efficacious and effective. Although the primary analysis considered only events prevented in the vaccinated participants from the immediate vaccination group, we recorded the same preventive effect in those individuals who were vaccinated in the delayed clusters. Indeed, no vaccinee developed symptoms more than 6 days after vaccination, irrespective of whether vaccination was immediate or delayed. This finding was also the case for the three immediate vaccination rings enrolled in the pilot phase of the trial, which were not randomised and therefore not included in the analysis reported here. Vaccination can reduce the risk of disease not only in people who were vaccinated but also indirectly in the unvaccinated population of the cluster. Such an effect was also evident in this interim analysis, but it was not statistically significant.

The rVSV-ZEBOV vaccine has been assessed in eight phase 1 studies in Europe, Africa, and North America;[6,7] a large phase 2 study (the PREVAIL study, NCT02344407) in Liberia; and an ongoing phase 3 study in Sierra Leone (the STRIVE study, NCT02378753) and more than 9000 volunteers have received this vaccine so far (Feinberg M, Merck Sharp & Dohme [known as Merck in the USA], Kenilworth, NJ, USA, personal communication). The phase 1 trials in healthy volunteers were done to test the safety and immunogenicity of the rVSV-ZEBOV vaccine and to inform dose selection.[6,7] These studies showed that the vaccine was immunogenic, with higher titres of neutralising antibodies produced at higher vaccine doses,[7] but the glycoprotein antibody titres were measured only at baseline and at 28 days post-vaccination. Although no data are yet available for the time needed for the vaccine to induce protective immunity, our results suggest that this might happen quickly, within a few days or a week. In the phase 1 trials, viraemia was transiently recorded in nearly all volunteers at the dose used in Guinea, but it was no longer detectable by day 8 in most of these individuals.

We took several measures to reduce the risk of bias in the *Ebola ça Suffit* cluster-randomised trial.[21] The randomisation of rings is done by an investigator based at the data centre in Conakry who is not involved in the field implementation of the trial. Any selection bias caused by subversion of randomisation is therefore unlikely.[22] The list of contacts and contacts of contacts (including contacts who happen to be absent) is completed before randomisation, and informed consent from participants is obtained post-randomisation. Separate teams are responsible for defining the clusters, obtaining informed consent and assessing patient eligibility, and for the actual vaccination process. Participants are informed about their group allocation only after they have given informed consent. The stratified randomisation procedures produce well-balanced groups and it seems unlikely that important imbalances exist in unmeasured variables strongly related to the risk of Ebola virus infection. The study is open label and masking of participants and field teams to the time of vaccination is not possible. However, the Ebola response teams and laboratory staff responsible for case ascertainment and laboratory confirmation are unaware of study participation or allocation of cases. Therefore, differential bias in the ascertainment of the outcomes is unlikely. So far, no cluster attrition has occurred and differential attrition with respect to characteristics associated with the risk of Ebola virus disease is unlikely. Cluster attrition would only affect our efficacy estimates if participants who are lost to follow-up later go on to develop Ebola virus disease, and these cases are not included in analyses. Since reporting of cases is very complete, this situation is not thought to be a likely source of bias.[15] Finally, much care is taken to ensure that the communicable disease control measures other than immediate or deferred ring vaccination are identical in the two groups.

We believe that the results from the *Ebola ça Suffit* ring vaccination trial are also likely to be externally valid and applicable to other regions of Guinea and to Sierra Leone and Liberia, the other two countries in west Africa most severely affected by the ongoing epidemic. Indeed, the

www.thelancet.com Published online July 31, 2015 http://dx.doi.org/10.1016/S0140-6736(15)61117-5

epidemiology and risk factors for Ebola virus transmission are consistent across countries.[23,24]

Our trial serves as a proof of concept for a novel ring vaccination cluster-randomised trial design.[10] This trial design is logistically feasible, even in resource-poor settings and in a crisis situation. The approach is successful when the incidence of Ebola virus disease is low in the general population and new cases are concentrated in family and community contacts. We are collecting detailed epidemiological and phylogenetic information to study transmission within the trial clusters. Ring vaccination therefore also bears great promise as a strategy for Ebola virus disease containment and elimination.

In the past few weeks, the number of new clusters that could be defined according to the present trial protocol has been reduced, since the number of new Ebola virus disease cases diagnosed per week in Guinea has fallen[25] and many of the adult contacts of the new Ebola virus disease cases are already part of defined clusters. The data and safety monitoring board has advised that the trial should be continued to expand the evidence on vaccine effectiveness and safety, but that randomisation should be stopped and we should continue with immediate vaccination of new clusters. As of July 24, 2015, approval from the national regulatory authority of Guinea and from relevant ethics review committees has been granted to implement this recommendation. The continued enrolment, immediate vaccination, and follow-up of clusters will generate additional data about the effectiveness of ring vaccination to protect communities through herd immunity, and will hopefully help to stop Ebola virus disease transmission in Guinea.

Contributors

IML, ME, AMH-R, WJE, CHW, MPK, and J-AR conceived and designed the trial; ME, AMH-R, IML, CHW, J-AR, AC, WJE, SM, GE, XR, ASV, SH, ST, and GN contributed to the protocol and design of the study. J-AR, MPK, MKK, AMH-R, BD, RG, and GN provided management and oversight of the trial as members of the study steering group. AMH-R coordinated the study design process and implementation of the trial on behalf of the study steering group. MD, MKK, and AS were co-principal investigators of this trial. AMH-R, MPK, SKé, MML, MD, MKK and AS, ASV, XR, GE, SH, ST, SKo, CHW, SM, and GN contributed to the field implementation of the trial. MWC, SD, SG, and EK supported the laboratory testing and validation of endpoints. IML, NED, and ME wrote the statistical analysis plan. IML and NED did the statistical analyses. ME, IML, NED, AMH-R, WJE, J-AR, and MPK contributed to the preparation of the report. All authors critically reviewed and approved the final version.

Declaration of interests

ME, WJE, AC, and CHW have acted as unpaid advisors to WHO on Ebola vaccination and report travel and accommodation paid for by WHO to attend meetings. WJE is a co-investigator on the European Commission Innovative Medicines Initiative-funded EBOVAC trial of the Johnson & Johnson prime-boost Ebola vaccine candidate, for which he has received a grant from the European Commission Innovative Medicines Initiative, and his partner is an epidemiologist at GlaxoSmithKline, in a role unrelated to the company's development of an Ebola vaccine. AC and CHW have acted as unpaid advisors to the EBOVAC trial, for which CHW reports travel and accommodation paid for by the EBOVAC consortium to attend a meeting. AC has received non-financial support from Janssen outside the submitted work. SG has received grants from the European Commission during the conduct of the study. ST has received grants from Research Council of Norway, during the conduct of the study. The other authors declare no competing interests.

Acknowledgments

We thank the people in Basse-Guinée for their participation, and all the field, laboratory, and data management staff who worked extremely hard and under difficult conditions to successfully implement this study. Merck Sharp & Dohme provided the vaccine used in the trial. We would like to acknowledge the support of the following organisations: Wellcome Trust, UK Department of International Development, Guinean Ministry of Health, Norwegian Ministry of Foreign Affairs, US Department of Defense, Public Health Agency of Canada, Swiss Agency for Therapeutic Products, the Bill & Melinda Gates Foundation, Health Canada, and the European Commission. We also thank the following individuals who directly contributed to the study: Jeremy Farrar, D A Henderson, Richard Peto, David Hone, Tore Godal, Djilali Abdelghafour, Yap Boum, Mar Cabeza-Cabrerizo, Rokiatu Dembele, Ibrahima Diatta, Mamoudou Harouna Djingarey, Julia Djonova, Andres Garcia, Myriam Grubo, Pierre Gsell, Yper Hall, Raul Iraheta, Olivier Lapujade, Nicola Low, Murray Lumpkin, Thomas Mauget, Christine Maure, Corinne Merle, Nicholas Misso, Bjørg Dystvold Nilsson, Marie-Pierre Preziosi, Vasee Moorthy, Jean-Marie Okwo Bele, William Perea, Guenal Rodier, Martina Rothenbühler, Peter Smith, Samba Sow, Graciela Spizzamiglio, Milagritos Tapia, Guido Torelli, Sara Sofie Viksmoen Watle, and our colleagues at WHO for their support with implementation of the trial. We also thank all members of our scientific advisory group, our data and safety monitoring board, and the Guinea vaccine trial working group.

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