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New York Nursing Homes and the COVID-19 Vaccine: Get the Facts

THE END OF COVID-19: VACCINATION AND THE LAST MILE

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VACCINE HESITATION

- MOST IMPORTANT FACTORS FOR ACCEPTANCE (KREPS ET AL JAMA 2020;3(10):E2025594
  - EFFICACY
  - DURATION OF PROTECTION
  - LOWER INCIDENCE OF MAJOR SIDE EFFECTS
- OTHER FACTORS
  - EMERGENCY USE AUTHORIZATION
  - DEVELOPMENT OUTSIDE THE USA
- SPECIFIC CONCERNS OF LTC STAFF
  - BEING FIRST
  - SAFETY
  - NOT BEING REPRESENTED IN VACCINE TRIALS

EMERGENCY USE AUTHORIZATION

- HERCULEAN EFFORT IN DEVELOPMENT BY GOVERNMENT AND ACADEMIA
- FDA USED THE SAME STANDARDS THAT IT HAS USED FOR DECADES
- NO STEPS WERE SKIPPED IN THE APPROVAL PROCESS
- 30,000-50,000 INDIVIDUALS WERE STUDIED
- 95% EFFECTIVE IN PREVENTING COVID INFECTION
- SAFETY PROFILE COMPARABLE TO OTHER VACCINES ON THE MARKET
- VOLUNTARY

TRUST

NURSES CONSISTENTLY ON TOP 25 YEARS

84% VERY HIGH/HIGH

99% VERY HIGH/HIGH AND AVERAGE

MEDICAL DOCTORS

67% VERY HIGH/HIGH

89% VERY HIGH/HIGH AND AVERAGE

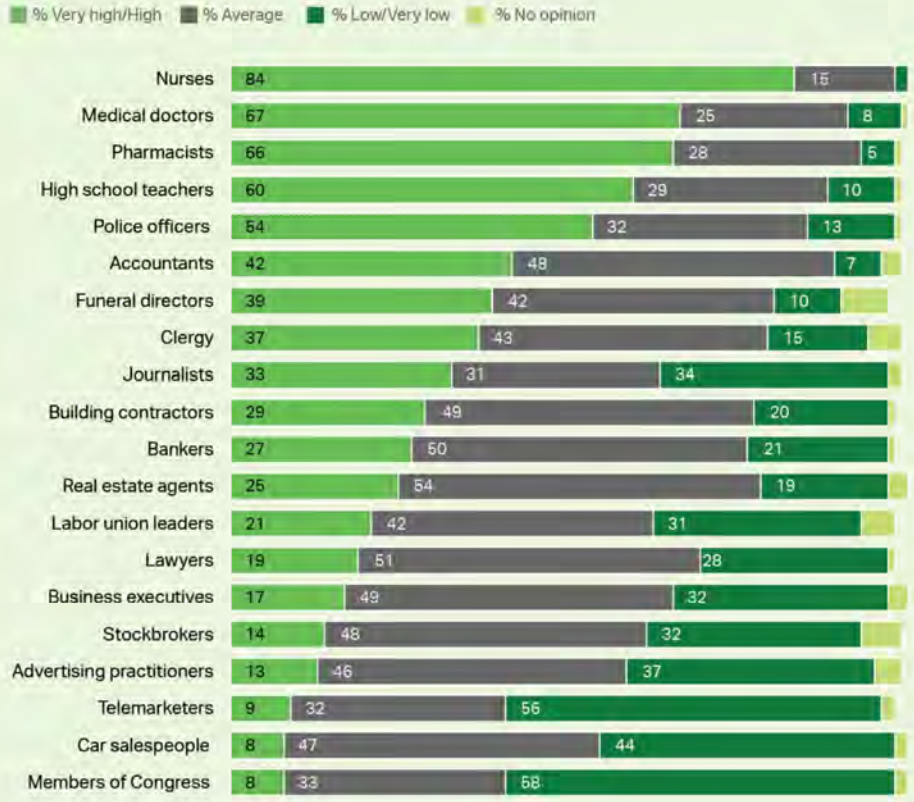
PHARMACISTS

66% VERY HIGH/HIGH

96% VERY HIGH/HIGH AND AVERAGE

GALLOP POLL DATA SINCE 1976

Please tell me how you would rate the honesty and ethical standards of people in these different fields -- very high, high, average, low or very low?



GALLUP, DEC. 3-12, 2018

Gallup has measured the public's views of the honesty and ethical standards of a variety of occupations since 1976. While the list changes from year to year, some professions have been included consistently over the past four decades.

EMPOWERMENT

LEADERSHIP BUY IN AND PROMOTION

- CHIEF NURSING OFFICER/DIRECTOR OF NURSING
- CHIEF MEDICAL OFFICER/MEDICAL DIRECTOR
- GOVERNING BODY/ADMINISTRATION

FRONT LINE STAFF AS ADVOCATES FOR VACCINATION

- CNA STAFF
- RN AND LPN STAFF
- PRIMARY CARE PHYSICIANS
- PHARMACISTS

PREPARATION FOR VACCINATION

- DESIGNATE VACCINE COORDINATOR(S) AND VERIFY CONTACT INFORMATION IN THE FACILITY AND AFTER HOURS
- SEND LETTER TO PATIENTS, SURROGATES AND STAFF WITH REGARD TO VACCINE
  - SAMPLE LETTER FROM AMDA CAN BE PROVIDED
  - SHOULD BE SIGNED BY CMO/MEDICAL DIRECTOR AND CNO/DIRECTOR OF NURSING
- IDENTIFY VACCINE CANDIDATES
    - AVOID IN SEVERE ALLERGIES AND ANAPHYLAXIS
    - AVOID IN CURRENT COVID INFECTION
    - SHOULD BE ADMINISTERED REGARDLESS OF RESOLVED COVID WITH OR WITHOUT ANTIBODIES
- DETERMINE DECISION MAKING CAPACITY OF THE PATIENTS

PREPARATION FOR VACCINATION

- DEVELOP AND IMPLEMENT POLICY AND PROCEDURE FOR:
  - PATIENTS
  - STAFF
- MANDATORY EDUCATION OF MEDICAL AND NURSING PERSONNEL (WEBEX AND RECORDED)
  - CONSENT FORMS WITH SIGNATURE
  - INDICATIONS AND EXCLUSIONS FOR VACCINATION
  - NECESSITY FOR REPEAT DOSE IN 21 DAYS (PFIZER) OR 28 DAYS (MODERNA)
  - POST VACCINE MONITORING PARAMETERS ESTABLISHED IN POLICY
  - ADVERSE REACTIONS
  - REPORTING AND DOCUMENTATION
    - TO MEDICAL PRACTITIONERS
    - TO NURSING ADMINISTRATION

PREPARATION FOR VACCINATION

- DEVELOP STAFF CONTINGENCY FOR POST VACCINATION SICK TIME
  - STAGGER STAFF VACCINATION ESPECIALLY BY DISCIPLINE
  - NO MORE THAN 1/3 OF STAFF SHOULD BE VACCINATED IN ONE DAY
- ANTICIPATE HOW MANY VACCINES WILL BE NEEDED FOR PATIENTS AND STAFF

VACCINE DAY

- POST VACCINE MONITORING SPACE: FOR 15-30 MINUTES
- SET UP AN EMERGENCY BOX IN THE CLINIC AREA
- FOR BEDBOUND/ROOM BOUND PATIENTS
  - WILL PHARMACY VACCINATORS GO FROM ROOM TO ROOM?
  - STAFF TO ACCOMPANY VACCINATOR DURING VACCINATION
  - WHO WILL MONITOR THE PATIENTS IN THE ROOM POST VACCINATION?

VACCINE DAY

- VACCINE CANDIDATES SHOULD BE ASKED ABOUT THE FOLLOWING HISTORY
  - ANY ALLERGIES
  - PRESENCE OF FEVER
  - PRESENCE OF BLEEDING DISORDER
  - TAKING BLOOD THINNING MEDICATIONS
  - CONDITION CAUSING IMMUNOCOMPROMISE
  - MEDICATIONS CAUSING IMMUNOCOMPROMISE
  - ARE PREGNANT OT PLANNING PREGNANCY
  - BREASTFEEDING
  - HAVE RECEIVED ANOTHER COVID VACCINE
    - THE VACCINES ARE NOT INTERCHANGEABLE
  - MUST BE 16 YEARS OF AGE OR OLDER

VACCINE-SIDE EFFECTS

Pfizer-BioNTech COVID-19 Vaccine
VRBPAC Briefing Document

Table 19. Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants in any Treatment Group from Dose 1 to 1-month After Dose 2, Phase 2/3 Safety Population*, 16 Years of Age and Older

System Organ Class Preferred Term	BNT162b2 N=18801 n (%)	Placebo N=18785 n (%)	Total N=37586 n (%)
General disorders and administration site conditions	3521 (18.7)	737 (3.9)	4258 (11.3)
Injection site pain	2125 (11.3)	286 (1.5)	2411 (6.4)
Fatigue	1029 (5.5)	260 (1.4)	1289 (3.4)
Pyrexia	1146 (6.1)	61 (0.3)	1207 (3.2)
Chills	999 (5.3)	87 (0.5)	1086 (2.9)
Pain	455 (2.4)	36 (0.2)	491 (1.3)
Musculoskeletal and connective tissue disorders	1387 (7.4)	401 (2.1)	1788 (4.8)
Myalgia	909 (4.8)	126 (0.7)	1035 (2.8)
Arthralgia	212 (1.1)	82 (0.4)	294 (0.8)
Nervous system disorders	1158 (6.2)	460 (2.4)	1618 (4.3)
Headache	973 (5.2)	304 (1.6)	1277 (3.4)
Gastrointestinal disorders	565 (3.0)	368 (2.0)	933 (2.5)
Diarrhoea	194 (1.0)	149 (0.8)	343 (0.9)
Nausea	216 (1.1)	63 (0.3)	279 (0.7)

Source: FDA analysis.
Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)
%: n/N. n = number of participants reporting at least 1 occurrence of the specified event.
of any event. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
* Participants ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.
Data analysis cutoff date: November 14, 2020.

Pfizer-BioNTech COVID-19 Vaccine
VRBPAC Briefing Document

Table 21. Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants in any Treatment Group from Dose 1 to 1 Month After Dose 2, Phase 2/3 Safety Population*, 65 Years and Older

System Organ Class Preferred Term	BNT162b2 (N=4058) n (%)	Placebo (N=4043) n (%)	Total (N=8101) n (%)
General disorders and administration site conditions	577 (14.2)	118 (2.9)	695 (8.6)
Injection site pain	361 (8.9)	39 (1.0)	400 (4.9)
Fatigue	175 (4.3)	44 (1.1)	219 (2.7)
Chills	143 (3.5)	19 (0.5)	162 (2.0)
Pyrexia	148 (3.6)	10 (0.2)	158 (2.0)
Pain	60 (1.5)	7 (0.2)	67 (0.8)
Musculoskeletal and connective tissue disorders	231 (5.7)	83 (2.1)	314 (3.9)
Myalgia	125 (3.1)	23 (0.6)	148 (1.8)
Arthralgia	42 (1.0)	21 (0.5)	63 (0.8)
Pain in extremity	33 (0.8)	10 (0.2)	43 (0.5)
Nervous system disorders	179 (4.4)	87 (2.2)	266 (3.3)
Headache	127 (3.1)	45 (1.1)	172 (2.1)
Gastrointestinal disorders	127 (3.1)	72 (1.8)	199 (2.5)
Diarrhea	49 (1.2)	26 (0.6)	75 (0.9)
Nausea	40 (1.0)	13 (0.3)	53 (0.7)

Source: FDA analysis.
Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)
%: n/N. n = number of participants reporting at least 1 occurrence of the specified event.
of any event. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
* Participants ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.
Data analysis cutoff date: November 14, 2020.

VACCINATION DAY

- SEVERE SIDE EFFECTS ARE RARE; THEY MAY INCLUDE
  - DIFFICULTY BREATHING
  - SWELLING OF FACE AND THROAT
  - FAST HEARTBEAT
  - WHOLE BODY RASH
  - DIZZINESS AND WEAKNESS

POST VACCINATION

- YOU CANNOT GET COVID-19 FROM THE VACCINE
- THE VACCINE DOES NOT CHANGE A PERSONS DNA

POST VACCINATION-SIDE EFFECTS

- REPORTING OF SIDE EFFECTS
  - FDA/CDC VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)
    - (800) 822-7967
    - HTTPS://VAERS.HHS.GOV/REPORTEVENT.HTML
- MONITORING
  - PRUDENT TO HAVE DAILY RN NOTES FOR 3 DAYS POST VACCINE
  - LOW THRESHOLD TO REACH OUT TO PRACTITIONERS CARING FOR PATIENTS ON CHANGES OF CONDITION
- DOCUMENT PATIENT SIDE EFFECTS IN MEDICAL RECORD
- STAFF SHOULD CONSULT WITH THEIR PERSONAL PHYSICIANS AND REPORT TO THEIR SUPERVISOR ANY SIDE EFFECTS

POST VACCINATION-COVID TESTS

- VIRAL TESTS
  - PRIOR RECEIPT OF PFIZER VACCINE WILL NOT AFFECT THE RESULTS OF COVID PCR OR ANTIGEN TESTS
- ANTIBODY TESTS
  - CURRENTLY AVAILABLE ANTIBODY TESTS FOR SARS-COV2 ASSESS IGM AND/OR IGG SPIKE OR NUCLEOCAPSIDE PROTEINS
  - PRIZER COVID-19 VACCINE CONTAINS MRNA THAT ENCODES THE SPIKE PROTEIN; THIS A POSITIVE TEST FOR SPIKE PROTEINS IGM/IGG COULD INDICATE PRIOR INFECTION OR VACCINATION
  - TO EVALUATE FOR EVIDENCE OF PRIOR INFECTION IN AN INDIVIDUAL WITH A HISTORY OF PFIZER COVID-19 VACCINE, A TEST SPECIFICALLY EVALUATING IGM/IGG TO THE NUCLEOCAPSID PROTEIN SHOULD BE USED

POST VACCINATION

- IMMUNITY IN ONLY ACHIEVED AFTER THE SECOND VACCINATION
- FACE MASKS AND SOCIAL DISTANCING WILL STILL BE REQUIRED FOR THE FORESEEABLE FUTURE
- AT THIS TIME IT IS UNKNOWN HOW LONG IMMUNITY IS CONFERRED FROM THE VACCINE