



Healthcare Quality Reporting Program

NURSING HOME SUBCOMMITTEE

3-4pm, 12/17/13

Healthcentric Advisors, 235 Promenade Street, Suite 500, Providence, RI 02908

Goals/Objectives

- To advise the Department on nursing home reporting and implement agreed-upon policies

Invitees

- | | | |
|--|---|--|
| <input checked="" type="checkbox"/> Rosa Baier, MPH | <input type="checkbox"/> Hugh Hall, MA | <input checked="" type="checkbox"/> Gail Patry, RN (Chair) |
| <input type="checkbox"/> Lonnie Bisbano | <input type="checkbox"/> Kathleen Nee, RN | <input type="checkbox"/> Arthur Pullano |
| <input checked="" type="checkbox"/> Emily Cooper, MPH | <input type="checkbox"/> Maureen Marsella, RN, BS | <input type="checkbox"/> Adele Renzulli |
| <input type="checkbox"/> John Gage, MBA, CNHA, CAS, FACHCA | <input checked="" type="checkbox"/> Ann Messier | <input type="checkbox"/> Janet Robinson, RN, MEd, CIC |
| <input checked="" type="checkbox"/> Diane Gallagher | <input type="checkbox"/> Jim Nyberg, MPA | <input checked="" type="checkbox"/> Samara Viner-Brown, MS |

Time

Topic/Notes

3:00pm

Welcome

Rosa Baier, MPH

Gail Patry, RN, CPHR

- Rosa welcomed participants and reviewed today's meeting objectives. Rosa then explained to the committee that the meetings in 2014 will be held at the Rhode Island Healthcare Association. Although the committee had expressed interest in moving the meetings to Healthcentric Advisors, the conference room here is not available during our scheduled meetings. She noted that the meeting dates for 2014 are included at the end of the agenda, and will be sent out again with the minutes. Rosa then discussed the previous meeting's action items:

- **Forward MIV reminder to Jim and Virginia (Rosa/Emily) – Complete**
MIV reminder was forwarded to Jim and Virginia.
- **Continue MIV follow-up with facilities (Emily/Ann) – Complete**
Ann and Emily continued follow-up with the facilities until the end of the survey period. More information about the survey, including some early results, will be discussed later in the meeting.
- **Finalize the consumer-friendly report template (Rosa/Emily) – Complete**
Emily and Rosa worked with the steering committee to finalize the consumer-friendly report template. This will be discussed later in the meeting.

- **Google analytics (handout)**

Emily went over the Google Analytics for the program's main page and the for the

Time	Topic/Notes
	<p>hospital reports page. She noted once again that these reports are not able to tell us whether the report pdfs are being opened. She pointed out that the information we have will allow us to track any major changes in program traffic; for example, if we increase consumer outreach to raise awareness about the available reports.</p> <p>Gail asked for an explanation of the % Exit and Bounce Rate columns. They are defined as follows:</p> <ul style="list-style-type: none"> • % Exit: is (number of exits) / (number of pageviews) for the page or set of pages. It indicates how often users exit from that page or set of pages when they view the page(s) • Bounce Rate: is the percentage of single-page visits (i.e. visits in which the person left your site from the entrance page without interacting with the page)
3:10pm	<p>Resident and Family Satisfaction Surveys <i>Rosa Baier, MPH</i> <i>Emily Cooper, MPH</i></p> <ul style="list-style-type: none"> - Process to date <p>At this point the survey has closed for the year and participating facilities should be able to view their results online through the MyInnerview portal.</p> <p>Emily asked if there were any major concerns from this year's survey process. She reminded the group that this year's process had included an increased number of reminders, including phone calls for key deadlines.</p> - Aggregate reports from MIV (handout): <p>Unfortunately the aggregate reports were not available in time for the meeting. This information will be shared with the committee when it becomes available. We will have the full results and data file by the middle of January.</p> - Next steps <p>We are planning to meet with Andrew Powers from Facility Regulations in March to discuss moving forward with citations for facilities that did not participate in the survey process.</p>
3:40pm	<p>Nursing Home Summary Report <i>Rosa Baier, MPH</i> <i>Emily Cooper, MPH</i></p> <ul style="list-style-type: none"> - Previous discussion and rationale <p>Rosa reminded the subcommittee that these reports are consumer focused and allow consumers to compare information from multiple reports across facilities. The creation of this report has been funded by CDC HAI funds. Our hope is to create a consumer-centric report without placing any additional reporting/data collection burden on the facilities.</p> - Progress since last meeting: <ul style="list-style-type: none"> • <u>Steering Committee</u> <p>Emily and Rosa brought the draft of the report to the steering committee. The steering committee provided input and reaffirmed their support of the report.</p> • <u>Hospital Subcommittee, including case managers</u> <p>Emily and Rosa brought the draft of the report to the hospital subcommittee. The</p>

Time	Topic/Notes
	<p>subcommittee provided input and communicated that this information would be helpful for case managers. Their input included suggestions to include information about the presence of a secure dementia unit and the number of skilled beds. They also suggested that we show whether a facility is Medicare and/or Medicaid certified rather than listing different types of insurance accepted. They felt that there are too many commercial insurance providers to include all of them, and that only including a subset would lead to confusion. They also mentioned a concern that providing quality and satisfaction information could complicate the discharge process, as all patients will only want the highly rated facilities. Although we understand their concern in this regard, we feel that is important information to provide to consumers.</p> <ul style="list-style-type: none"> ● <u>Primary data collection (handout) – survey content and goals</u> Rosa went over the goals of the primary data collection, explaining that this information would be used in the report, and will also be given to hospital case management departments. This will help these departments to have more complete and up to date information and will lessen the burden of their collecting this information themselves. Rosa reviewed the survey content and noted that to date we have received responses from 87 facilities, and are currently missing information from 3 facilities. ● <u>Partnership with the Safe Transitions project</u> Rosa explained that this data will also be used by the Healthcentric Advisors’ Safe Transitions project. They will be using this data to create a resource guide for Emergency Department (ED) case managers. This resource guide will also be available to other case managers. The Safe Transitions project was in the process of creating a similar survey; by partnering with them we were able to draw on their expertise in nursing home capabilities to best determine which questions to ask, and we were able to reduce the reporting burden for the facilities. This resource guide will be available to members of this subcommittee by request. <ul style="list-style-type: none"> – Discussion of updated report template (handout) Rosa and Emily went over the newest draft of the report template. Gail suggested adding in a column for facility inspections. Rosa explained that this information is available from Nursing Home Compare for the Medicare certified facilities, and we will look into adding it to the report. – Next steps Rosa told the group that once we have finished the primary data collection we will move forward with populating this report. The report will be updated each time one of the columns is updated.
3:50pm	<p>Healthcare Worker Influenza Vaccination Reporting <i>Rosa Baier, MPH</i></p> <ul style="list-style-type: none"> – Immunization Program’s process to date: <ul style="list-style-type: none"> ● <u>Facility notification</u> Rosa explained to the group that currently the facilities are notified of the reporting requirement through an email from HEALTH and a fax from facility regulations. ● <u>Data submission rate</u>

Time	Topic/Notes
	<p>We are currently seeing very low data submission rates, though the facilities who are reporting are showing high rates of vaccination.</p> <ul style="list-style-type: none"> - Discussion: <ul style="list-style-type: none"> • <u>How can we improve awareness of this requirement?</u> Rosa asked the group for ideas on how we can raise awareness of this requirement and raise submission rates. Gail suggested having the facility inspectors pass out notifications to the facilities during inspections. This will be discussed further during the meeting with Andrew Powers in March. Gail also offered to go to the facilities in the spring and discuss with them what reporting requirements they are aware of and why this information is not being submitted.
4:00pm	<p>Open Forum & Next Steps <i>Rosa Baier, MPH</i></p> <ul style="list-style-type: none"> - Action items <ul style="list-style-type: none"> • Share aggregate satisfaction reports with the subcommittee (Emily) • Meet with Andrew Powers in March(Rosa) • Populate summary report and share with committee (Emily/Rosa) • Outreach to facilities regarding reporting requirements in the spring (Gail) - Next meeting: 2/18 - Meeting dates for 2014: <ul style="list-style-type: none"> • 2/18 • 4/15 • 6/17 • 8/19 • 10/21 • 12/16 <p>Please note that the 2014 meetings will be held at the Rhode Island Healthcare Association (RIHCA), at 57 Kilvert St, Warwick, RI 02886 in the second floor conference room.</p>

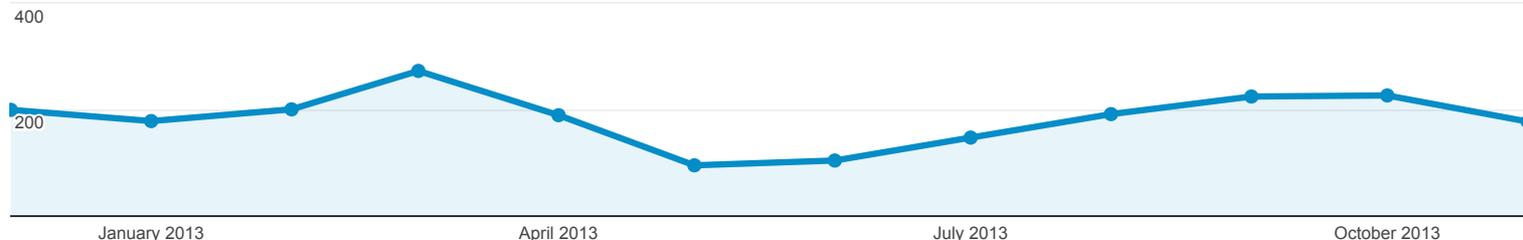
Main Page

Dec 1, 2012 - Nov 30, 2013

All Visits
0.06%

Report Tab

Pageviews



Month of Year	Pageviews	Unique Pageviews	Avg. Time on Page	% Exit	Bounce Rate
	2,202 % of Total: 0.06% (3,541,008)	1,436 % of Total: 0.06% (2,366,179)	00:00:47 Site Avg: 00:01:44 (-54.35%)	19.30% Site Avg: 35.94% (-46.29%)	43.40% Site Avg: 48.67% (-10.82%)
1. 201212	199	128	00:00:42	14.07%	38.89%
2. 201301	178	130	00:00:38	16.29%	29.03%
3. 201302	200	142	00:00:28	15.00%	42.86%
4. 201303	272	165	00:00:57	19.85%	40.58%
5. 201304	189	125	00:00:21	20.11%	51.43%
6. 201305	95	75	00:00:29	27.37%	54.55%
7. 201306	104	70	00:00:49	19.23%	33.33%
8. 201307	147	99	00:00:54	24.49%	66.67%
9. 201308	191	121	00:00:53	26.18%	56.25%
10. 201309	224	122	00:00:49	18.30%	38.64%
11. 201310	226	149	00:00:54	20.35%	36.17%
12. 201311	177	110	00:01:24	15.25%	31.03%

Rows 1 - 12 of 12

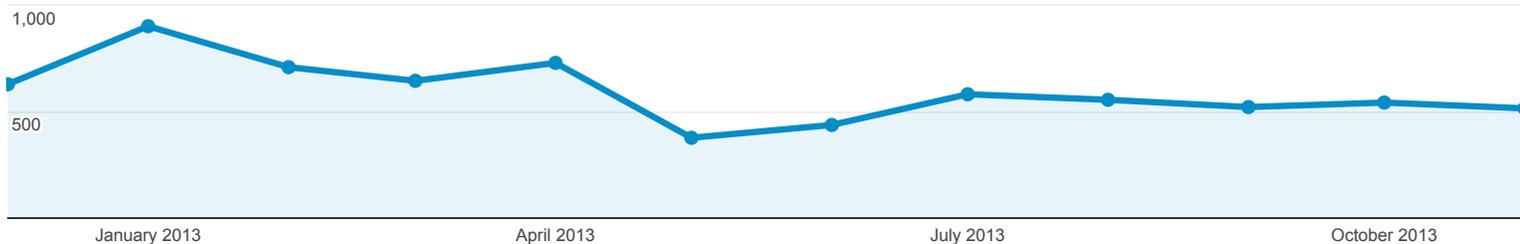
Nursing Home Quality

Dec 1, 2012 - Nov 30, 2013

All Visits
0.20%

Month

Pageviews



Month of Year	Pageviews	Unique Pageviews	Avg. Time on Page	% Exit	Bounce Rate
	7,124 % of Total: 0.20% (3,541,008)	4,094 % of Total: 0.17% (2,366,179)	00:02:00 Site Avg: 00:01:44 (16.22%)	39.54% Site Avg: 35.94% (10.04%)	52.72% Site Avg: 48.67% (8.33%)
1. 201212	627	303	00:01:51	30.14%	45.65%
2. 201301	899	473	00:01:57	34.93%	45.59%
3. 201302	707	373	00:02:07	34.94%	54.23%
4. 201303	643	377	00:01:38	41.21%	56.11%
5. 201304	727	400	00:01:31	37.55%	55.28%
6. 201305	376	222	00:01:51	42.02%	55.46%
7. 201306	436	272	00:02:01	40.60%	48.18%
8. 201307	580	366	00:02:16	44.14%	55.14%
9. 201308	554	358	00:02:25	45.31%	57.14%
10. 201309	520	312	00:02:00	40.58%	48.34%
11. 201310	541	319	00:02:16	43.81%	53.29%
12. 201311	514	319	00:02:35	46.50%	56.41%

Rows 1 - 12 of 12

RHODE ISLAND

2013

EXECUTIVE SUMMARY

Prepared by



NATIONAL RESEARCH
Corporation *Formerly My InnerView*

This report provides information needed to initiate quality improvement efforts, track referral sources, improve staff recruitment and retention, and evaluate outcomes of previous initiatives.

Includes:

RESIDENT SATISFACTION

FAMILY SATISFACTION

Published date: December 17, 2013

WHAT'S INSIDE

RESIDENT SATISFACTION

CHART
NUMBER:

GLOBAL SATISFACTION AND RATINGS BY DOMAIN FOR 2013	1
ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2013	2
QUADRANT ANALYSIS: STRENGTHS AND OPPORTUNITIES	3
ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2011, 2012 AND 2013	4
ITEMS RANKED WITHIN DOMAIN BY AVERAGE SCORES FOR 2013	5
AVERAGE SCORES BY ITEM BY LOCATION TYPE FOR 2013	6
DEMOGRAPHICS AND BACKGROUND INFORMATION FOR 2013	7
AVERAGE SCORES FOR "RECOMMENDATION TO OTHERS" BY DEMOGRAPHICS FOR 2013	8
DISTRIBUTION OF RESPONSE RATES FOR 2013	9

SKILLED NURSING RESIDENT SATISFACTION SURVEY REFERENCE

FAMILY SATISFACTION

CHART
NUMBER:

GLOBAL SATISFACTION AND RATINGS BY DOMAIN FOR 2013	1
ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2013	2
QUADRANT ANALYSIS: STRENGTHS AND OPPORTUNITIES	3
ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2011, 2012 AND 2013	4
ITEMS RANKED WITHIN DOMAIN BY AVERAGE SCORES FOR 2013	5
AVERAGE SCORES BY ITEM BY LOCATION TYPE FOR 2013	6
DEMOGRAPHICS AND BACKGROUND INFORMATION FOR 2013	7
AVERAGE SCORES FOR "RECOMMENDATION TO OTHERS" BY DEMOGRAPHICS FOR 2013	8
DISTRIBUTION OF RESPONSE RATES FOR 2013	9

SKILLED NURSING FAMILY SATISFACTION SURVEY REFERENCE

RHODE ISLAND

RESIDENT SATISFACTION

	2013	2012	2011
RESPONSE RATE	70%	62%	65%
FACILITIES SURVEYED	88	85	84
SURVEYS RECEIVED	2,345	2,223	2,040

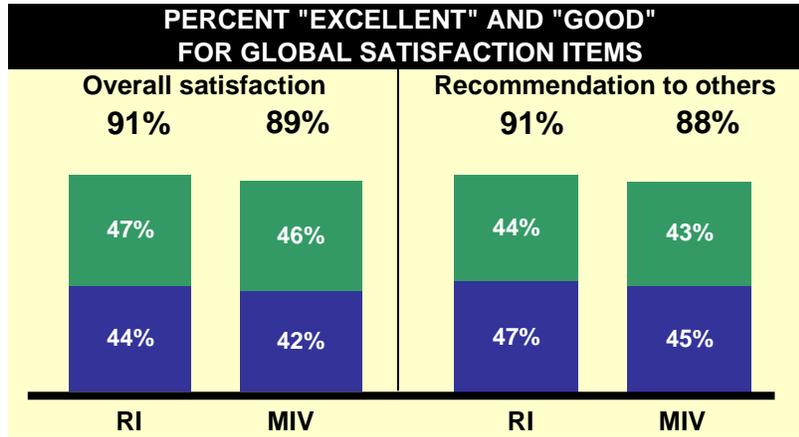


NATIONAL RESEARCH
Corporation Formerly My InnerView

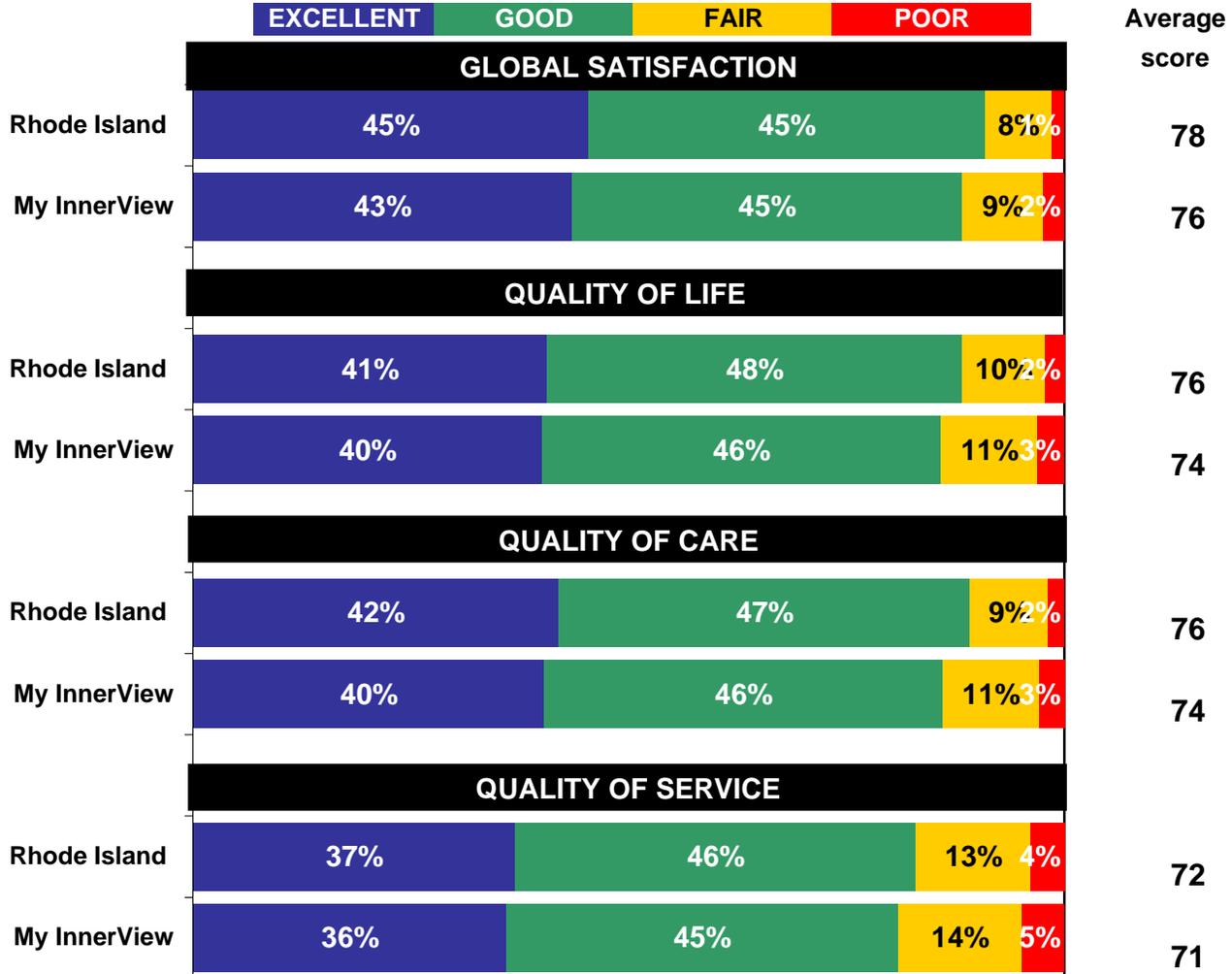
RHODE ISLAND

RESIDENT SATISFACTION

GLOBAL SATISFACTION AND RATINGS BY DOMAIN FOR 2013



(The total percentage listed may be higher or lower than individual rating totals due to rounding)



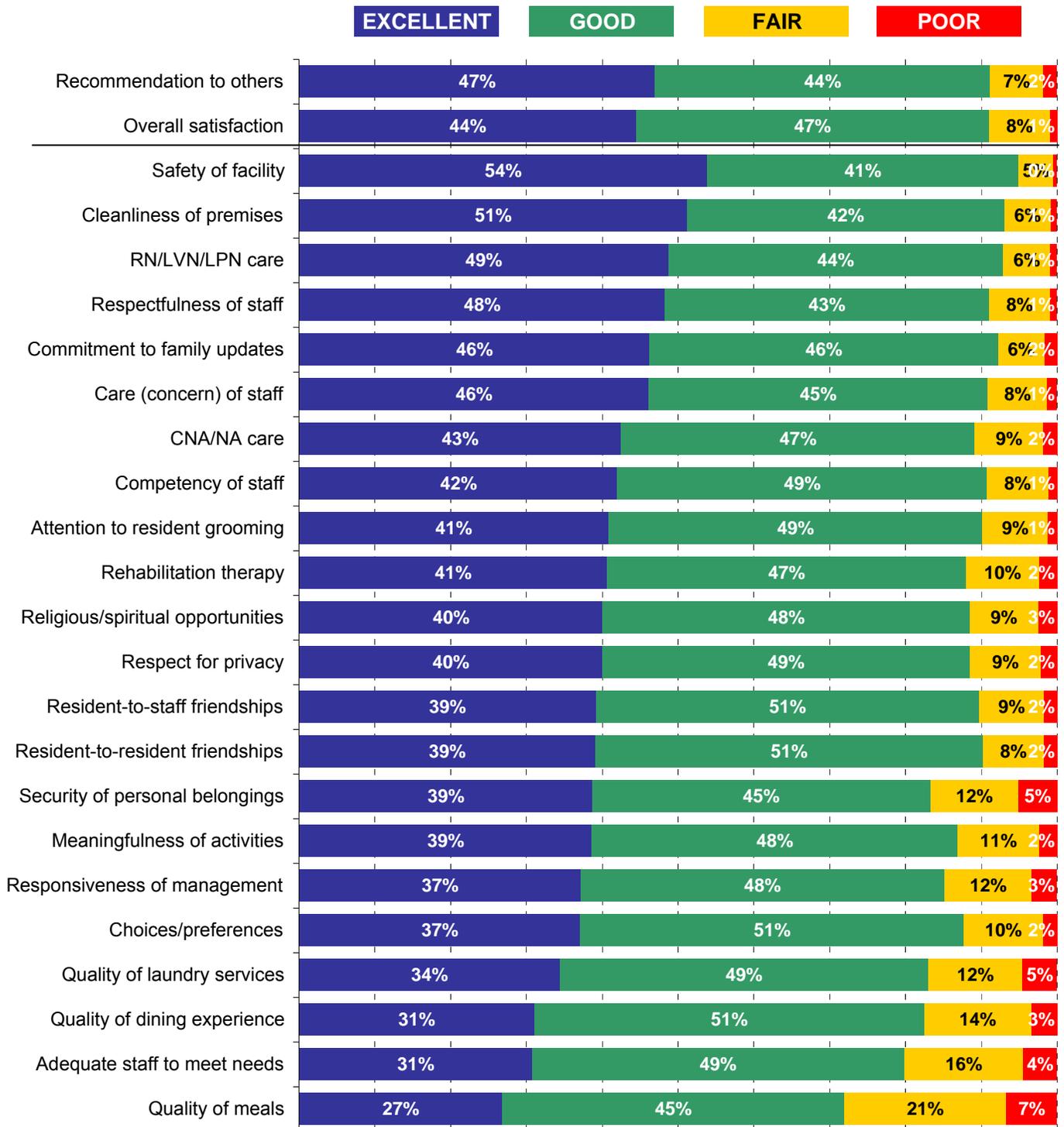
(May not total 100% due to rounding.)

RHODE ISLAND

RESIDENT SATISFACTION

ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2013

2



Items are ranked from highest to lowest on the percent of responses rated "Excellent." The percentages reflect averages survey respondents. (May not total 100% due to rounding.) See chart 4 for comparison to prior years.

RHODE ISLAND

RESIDENT SATISFACTION

QUADRANT ANALYSIS: STRENGTHS AND OPPORTUNITIES

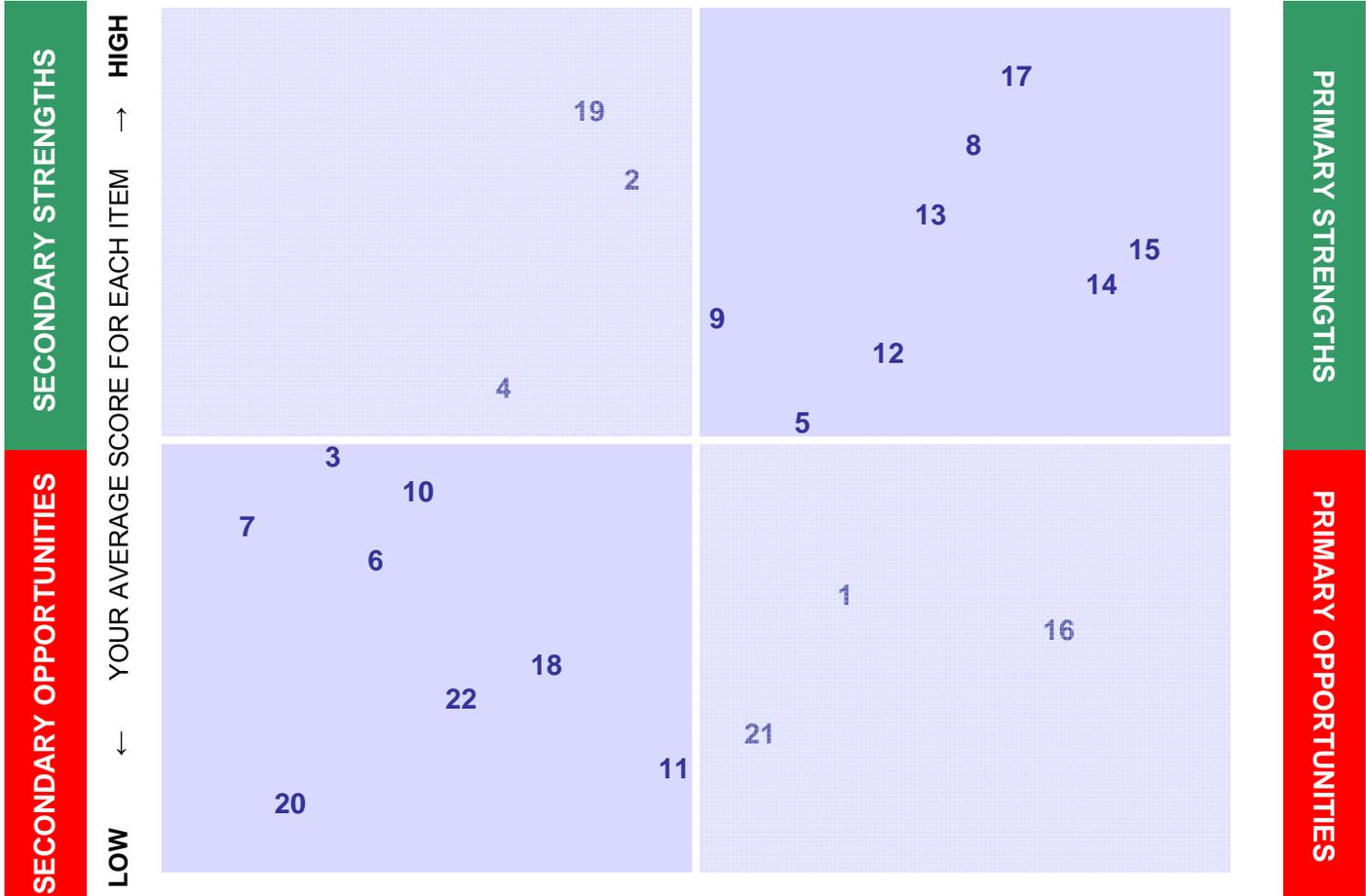
3

A

Quadrant A shows items of *lower* importance to "Recommendation" with a *higher* average score

Quadrant B shows items of *higher* importance to "Recommendation" with a *higher* average score

B



C

LOW ← IMPORTANCE TO RECOMMEND THIS FACILITY TO OTHERS → **HIGH**

D

Quadrant C shows items of *lower* importance to "Recommendation" with a *lower* average score

Quadrant D shows items of *higher* importance to "Recommendation" with a *lower* average score

The quadrant analysis plots the percentile rank of the average score on the satisfaction items against the percentile rank of the average "importance" score of each item and the question **What is your recommendation of this facility to others?** Items in the lower right quadrant are those that are most important to "Recommendation" but received the lowest scores.

See actual satisfaction items and report labels at end of section

RHODE ISLAND



SECONDARY STRENGTHS

Items with average scores above the midline but not as important to "Recommendation"

- 4 Resident-to-resident friendships
- 2 Respectfulness of staff
- 19 Cleanliness of premises



PRIMARY STRENGTHS

Items with average scores above the midline and more important to "Recommendation"

- 14 Competency of staff
- 15 Care (concern) of staff
- 5 Resident-to-staff friendships
- 12 Attention to resident grooming
- 13 Commitment to family updates
- 8 RN/LVN/LPN care
- 9 CNA/NA care
- 17 Safety of facility



SECONDARY OPPORTUNITIES

Items with average scores below the midline but not as important to "Recommendation"

- 11 Adequate staff to meet needs
- 18 Security of personal belongings
- 22 Quality of laundry services
- 20 Quality of meals
- 6 Meaningfulness of activities
- 10 Rehabilitation therapy
- 3 Respect for privacy
- 7 Religious/spiritual



PRIMARY OPPORTUNITIES

Items with average scores below the midline and more important to "Recommendation"

These are areas that represent a good opportunity for improvement.

PRIORITY ACTION AGENDA TM

The top FIVE items in Quadrant D (*Primary Opportunities*) comprise your Priority Action Agenda and provide a focus for improving willingness to recommend your facility to others.

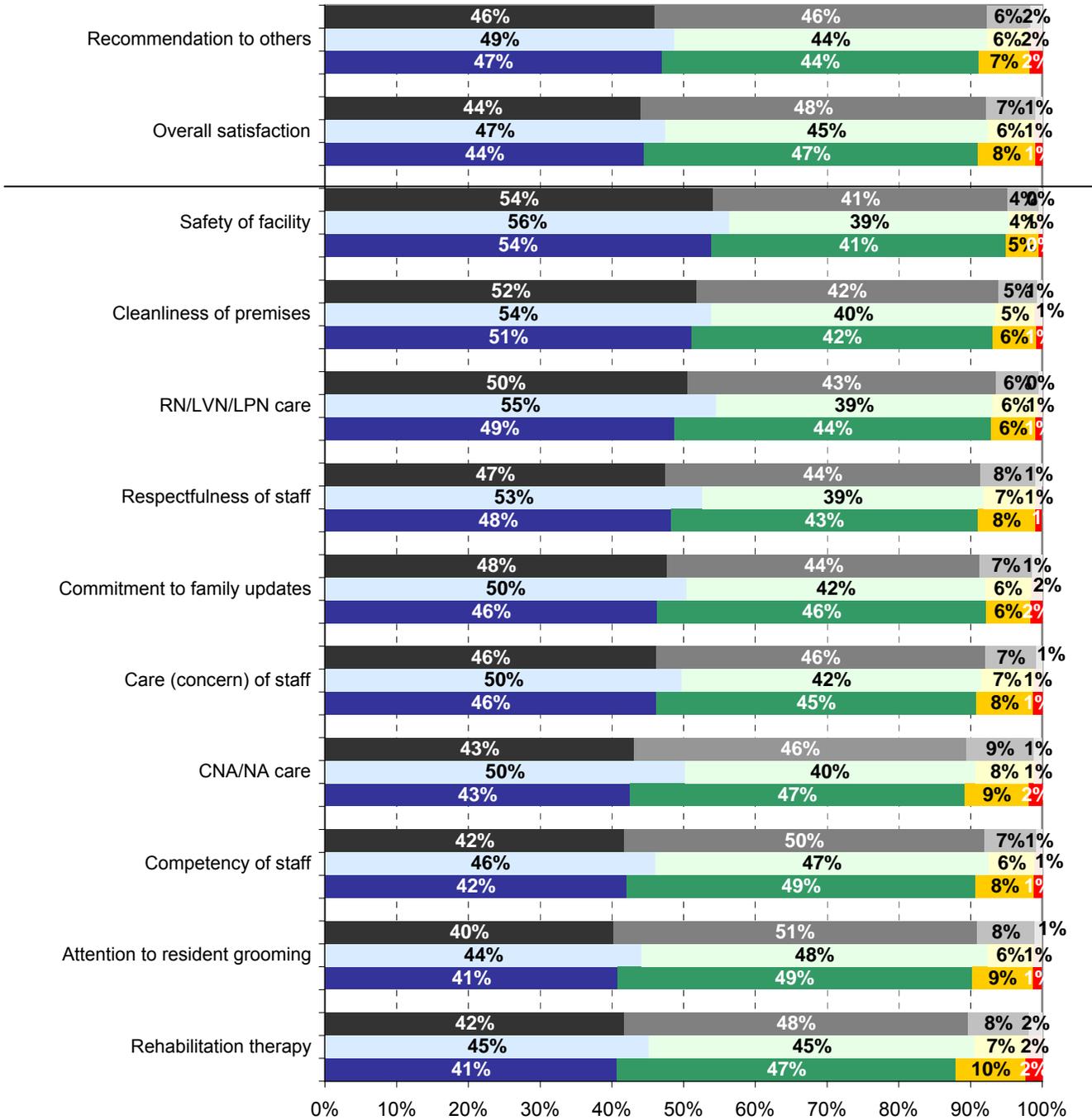
If Quadrant D has less than five items, the Priority Action Agenda will list only those items in the quadrant.

- 16 Responsiveness of management
- 21 Quality of dining experience
- 1 Choices/preferences

RESIDENT SATISFACTION

ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2011, 2012 AND 2013

Year	EXCELLENT	GOOD	FAIR	POOR
2011	EXCELLENT	GOOD	FAIR	POOR
2012	EXCELLENT	GOOD	FAIR	POOR
2013	EXCELLENT	GOOD	FAIR	POOR



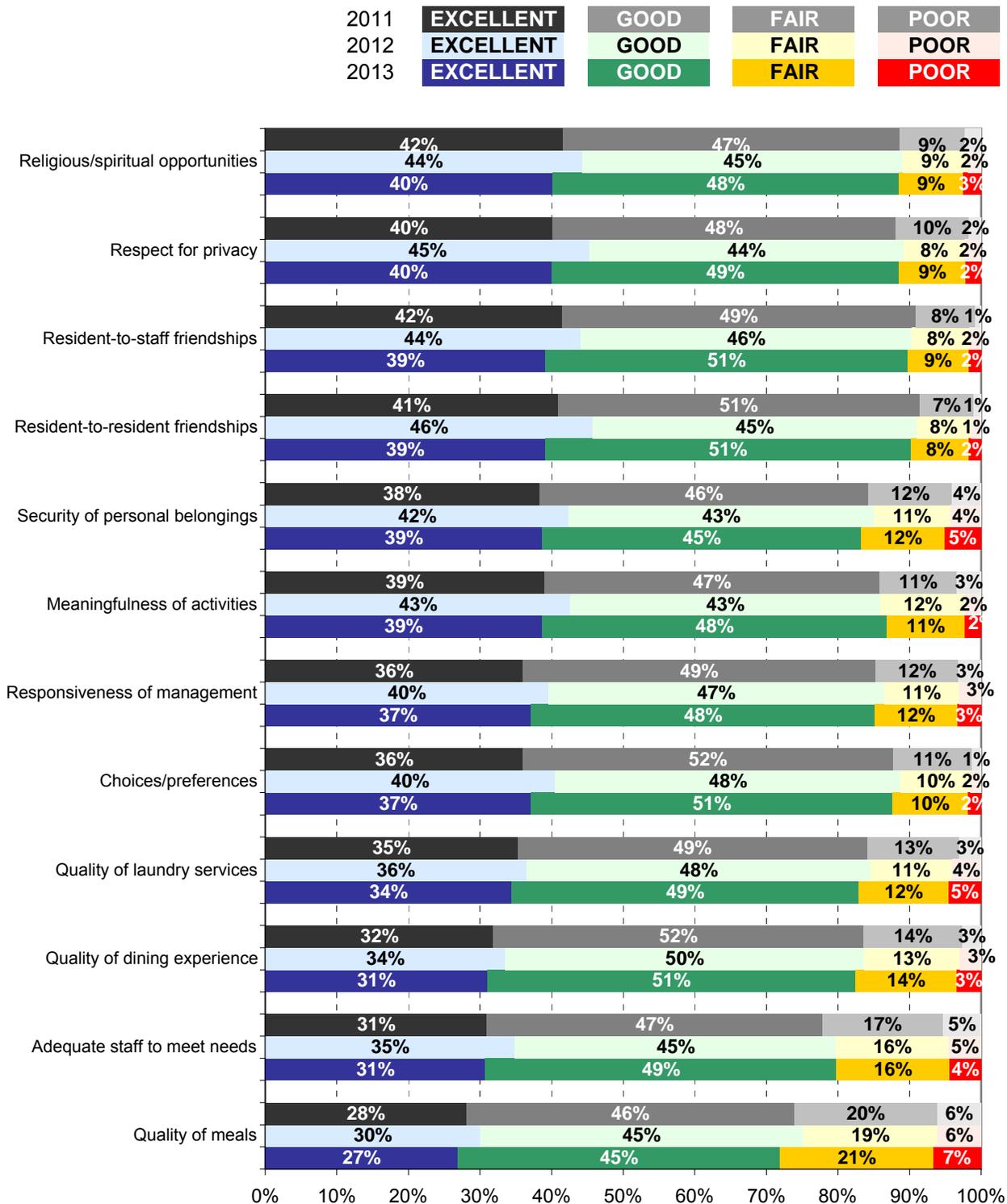
Items are ranked from highest to lowest on the percent of responses rated "Excellent" for the most recent year. (May not total 100% due to rounding.)

RHODE ISLAND

RESIDENT SATISFACTION

ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2011, 2012 AND 2013

CONTINUED



Items are ranked from highest to lowest on the percent of responses rated "Excellent" for the most recent year. (May not total 100% due to rounding.)

RHODE ISLAND

RESIDENT SATISFACTION

ITEMS RANKED WITHIN DOMAIN BY AVERAGE SCORES FOR 2013

5

		2012	2011	2013 MIV
Recommendation to others		80	79	77
Overall satisfaction		80	78	76
QUALITY OF LIFE	Safety of facility	84	83	81
	Respectfulness of staff	81	79	78
	Resident-to-resident friendships	78	77	76
	Resident-to-staff friendships	78	77	76
	Respect for privacy	77	75	75
	Religious/spiritual opportunities	77	76	75
	Meaningfulness of activities	75	74	73
	Choices/preferences	76	74	73
	Security of personal belongings	74	73	71
	Quality of dining experience	71	71	67
QUALITY OF CARE	RN/LVN/LPN care	82	81	79
	Commitment to family updates	80	79	77
	Care (concern) of staff	80	79	77
	Competency of staff	79	78	75
	CNA/NA care	80	77	75
	Attention to resident grooming	78	77	73
	Rehabilitation therapy	78	77	76
	Adequate staff to meet needs	70	68	65
QUALITY OF SERVICE	Cleanliness of premises	82	82	78
	Responsiveness of management	74	73	71
	Quality of laundry services	72	72	71
	Quality of meals	66	65	63

RHODE ISLAND

RESIDENT SATISFACTION

AVERAGE SCORES BY ITEM BY LOCATION TYPE FOR 2013

6

		Rhode Island	Rural	Suburban	Urban
QUALITY OF LIFE	Recommendation to others	79	76	81	79
	Overall satisfaction	78	76	80	77
	Safety of facility	83	81	85	82
	Respectfulness of staff	79	78	81	79
	Resident-to-resident friendships	76	75	77	76
	Resident-to-staff friendships	76	74	77	75
	Respect for privacy	75	74	76	76
	Religious/spiritual opportunities	75	76	76	74
	Choices/preferences	74	73	75	74
	Meaningfulness of activities	74	73	76	73
	Security of personal belongings	72	70	74	71
	Quality of dining experience	70	71	72	68
	QUALITY OF CARE	RN/LVN/LPN care	80	79	81
Commitment to family updates		79	77	81	78
Care (concern) of staff		79	77	80	78
CNA/NA care		77	76	78	76
Attention to resident grooming		77	74	78	76
Competency of staff		77	76	78	76
Rehabilitation therapy		75	73	78	74
Adequate staff to meet needs		69	63	70	70
QUALITY OF SERVICE	Cleanliness of premises	81	80	83	80
	Responsiveness of management	73	71	75	72
	Quality of laundry services	71	68	74	69
	Quality of meals	64	67	64	62

All scores represent average scores across survey respondents. Each item was measured on a four-point scale:

Poor = 0 Fair = 33.3 Good = 66.7 Excellent = 100

Items are listed by domain as they appear in the survey. The shading in the Rural, Suburban and Urban columns reflects a comparison to the state average: Green = higher than the state average; yellow = same as the state average; red = lower than the state average.

RHODE ISLAND

RESIDENT SATISFACTION

DEMOGRAPHICS AND BACKGROUND INFORMATION FOR 2013

7

RESIDENT

Gender of resident		Age of resident	
Female	71%	19 or under	0%
Male	29%	20 to 29	0%
		30 to 39	0%
		40 to 49	1%
		50 to 59	5%
		60 to 69	11%
		70 to 79	19%
		80 to 89	39%
		90 or older	25%

FACILITY CHOICE

Homes visited		Reason for choosing		Length of stay	
None	41%	Convenient location	22%	Less than 1 month	0%
Only this one	27%	Good reputation	28%	1 to 3 months	3%
Two	22%	Doctor or hospital	22%	3 to 6 months	5%
Three	6%	Relative or friend	15%	6 months to 1 year	16%
Four	2%	Insurance requirement	1%	1 to 3 years	42%
Five or more	2%	Other reason	11%	3 or more years	34%

VISITOR

Person visiting most		How often visited	
Spouse	7%	Less than once a year	1%
Child	53%	Once a year	2%
Brother or sister	14%	Once every 3 months	6%
Grandchild	2%	Once a month or more	20%
Friend	10%	Once a week or more	51%
Another person	14%	Almost daily	20%

Assistance with survey

By myself	20%
With facility staff	56%
With family or friend	16%
With another resident	0%
With another person	8%

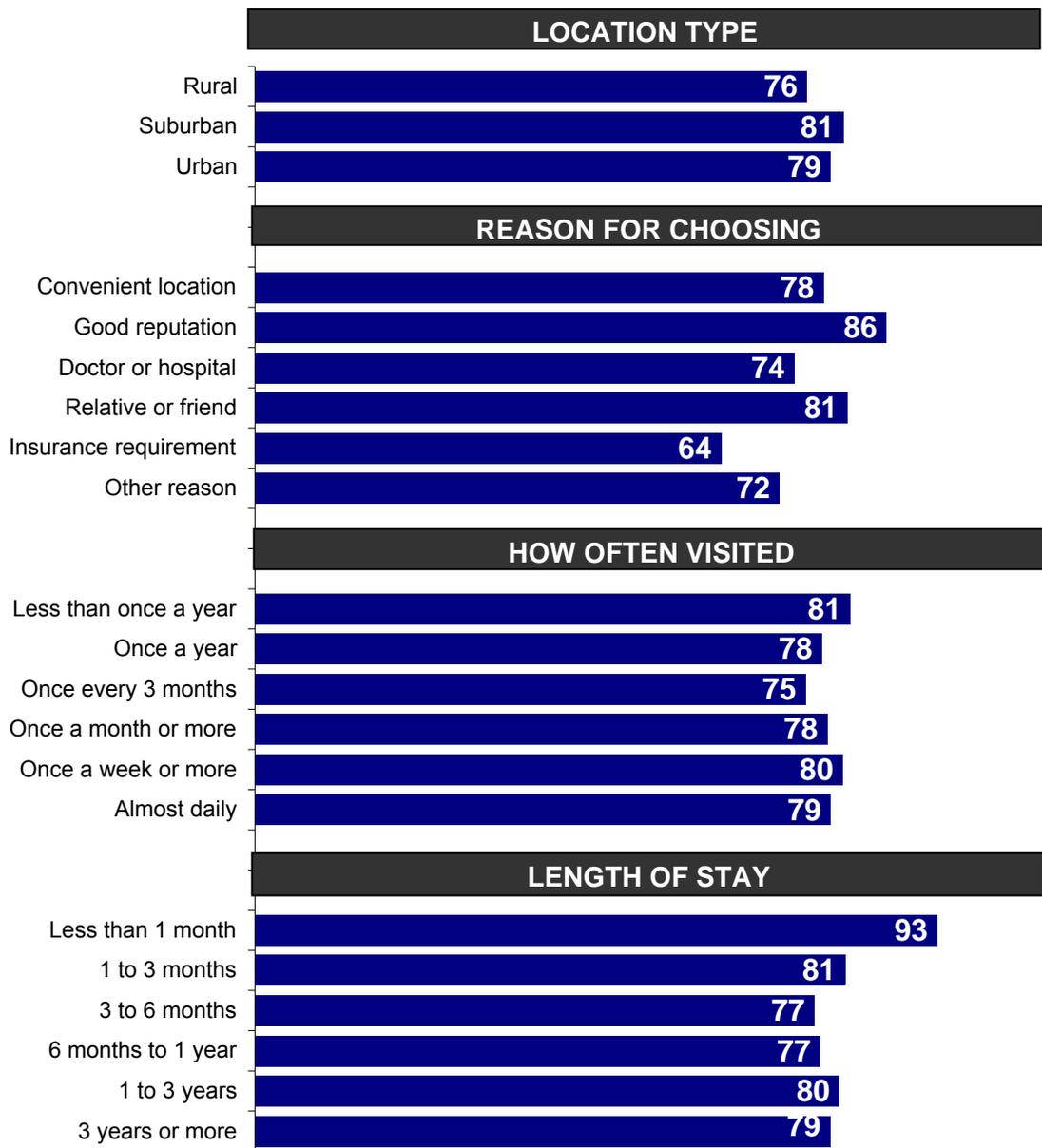
(May not total 100% due to rounding.)

RHODE ISLAND

RESIDENT SATISFACTION

AVERAGE SCORES FOR "RECOMMENDATION TO OTHERS" BY DEMOGRAPHICS FOR 2013

8



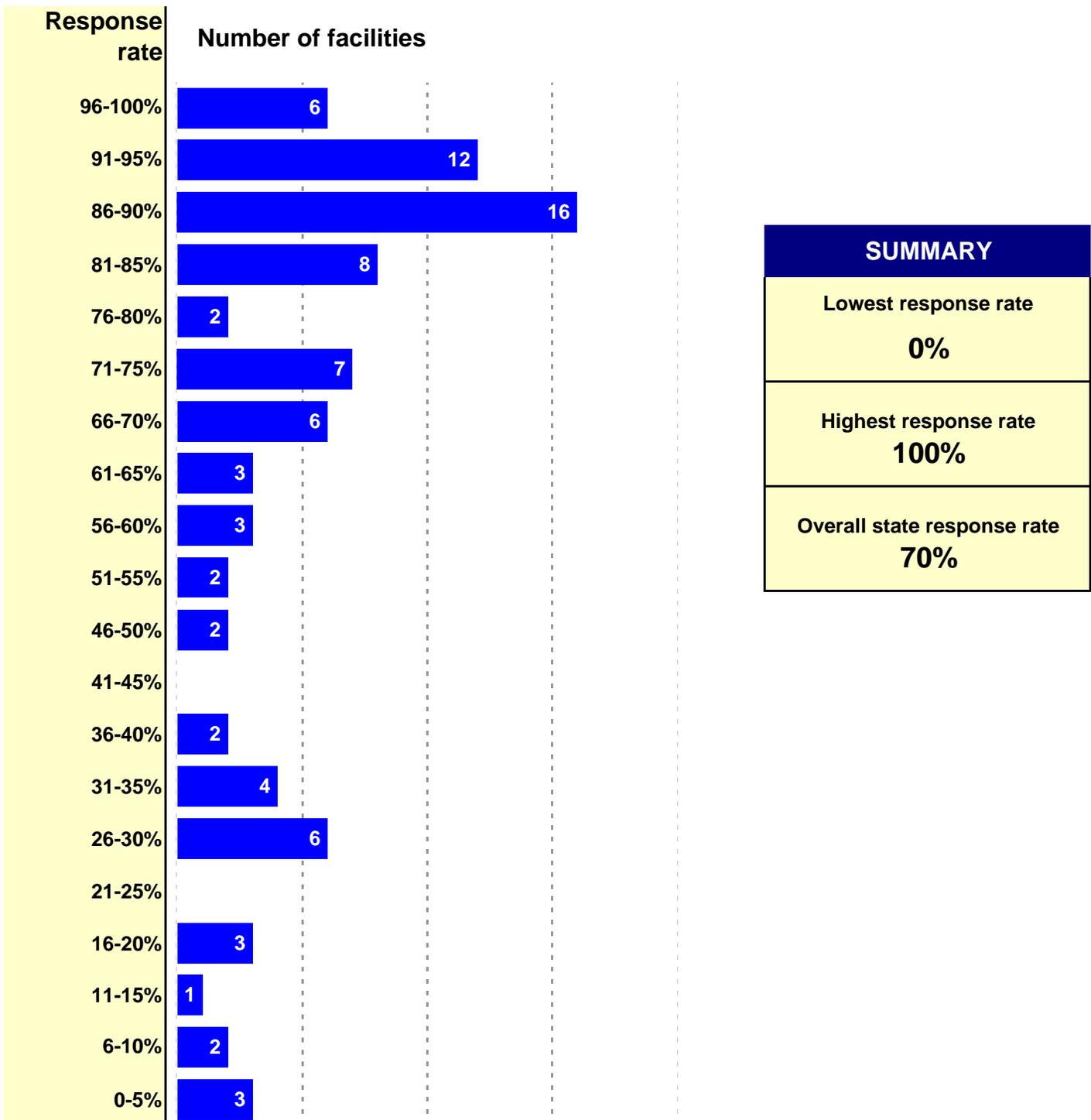
RHODE ISLAND

RESIDENT SATISFACTION

DISTRIBUTION OF RESPONSE RATES FOR 2013

9

Results are for 88 participating facilities.



RHODE ISLAND

RESIDENT SATISFACTION

SKILLED NURSING RESIDENT SATISFACTION SURVEY REFERENCE

ITEM NUMBER/LABEL	ORIGINAL SURVEY STATEMENT
GLOBAL SATISFACTION DOMAIN	
23 Overall satisfaction	How would you rate your overall satisfaction with this facility?
24 Recommendation to others	What is your recommendation of this facility to others?
QUALITY OF LIFE DOMAIN Rate this facility on ...	
1 Choices/preferences	Meeting your choices and preferences
2 Respectfulness of staff	The respect shown to you by staff
3 Respect for privacy	Meeting your need for privacy
4 Resident-to-resident friendships	Offering you opportunities for friendships with other residents
5 Resident-to-staff friendships	Offering you opportunities for friendships with staff
6 Meaningfulness of activities	Offering you meaningful activities
7 Religious/spiritual opportunities	Meeting your religious and spiritual needs
17 Safety of facility	How safe it is for you
18 Security of personal belongings	The security of your personal belongings
21 Quality of dining experience	How enjoyable your dining experience is
QUALITY OF CARE DOMAIN Rate this facility on ...	
8 RN/LVN/LPN care	The quality of care provided by the nurses (RNs/LVNs/LPNs)
9 CNA/NA care	The quality of care provided by the nursing assistants (CNAs/NAs)
10 Rehabilitation therapy	The quality of rehabilitation therapy (occupational, physical, speech)
11 Adequate staff to meet needs	Providing an adequate number of nursing staff to meet care needs
12 Attention to resident grooming	Meeting your grooming needs
13 Commitment to family updates	Keeping you and your family informed about you
14 Competency of staff	The competency of staff
15 Care (concern) of staff	The staff's care and concern for you
QUALITY OF SERVICE DOMAIN Rate this facility on ...	
16 Responsiveness of management	Management's responsiveness to your suggestions and concerns
19 Cleanliness of premises	The cleanliness of your room and surroundings
20 Quality of meals	The quality of the meals
22 Quality of laundry services	The quality of laundry services
DEMOGRAPHICS AND BACKGROUND INFORMATION	
25 Length of stay	How long have you lived at this facility?
26 Person visiting most	Who visits you most often?
27 How often visited	How often does this person visit the you?
28 Homes visited	How many nursing homes did you (or your family) visit before choosing this facility?
29 Reason for choosing	What is the most important reason you (or your family) chose this facility?
30 Gender of resident	What is your gender?
31 Age of resident	What is your age?
32 Assistance with survey	How is this survey being completed?

© 2009. Reproduction or duplication requires written permission from National Research Corporation.

FAMILY SATISFACTION

	2013	2012	2011
RESPONSE RATE	35%	36%	39%
FACILITIES SURVEYED	89	86	85
SURVEYS RECEIVED	1,913	1,900	1,948

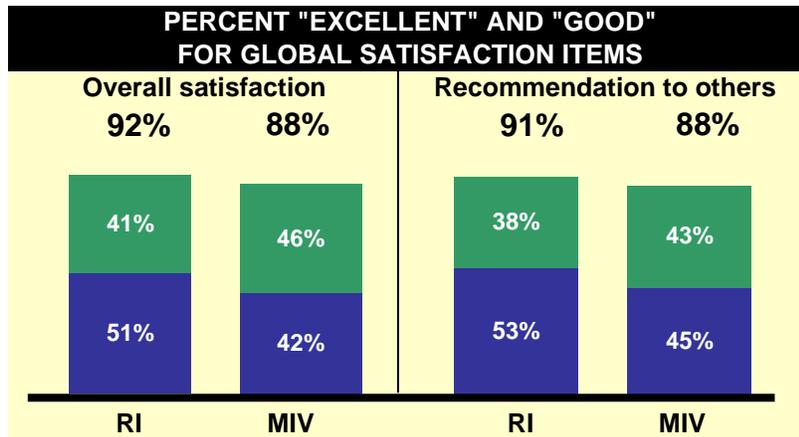


NATIONAL RESEARCH
Corporation Formerly My InnerView

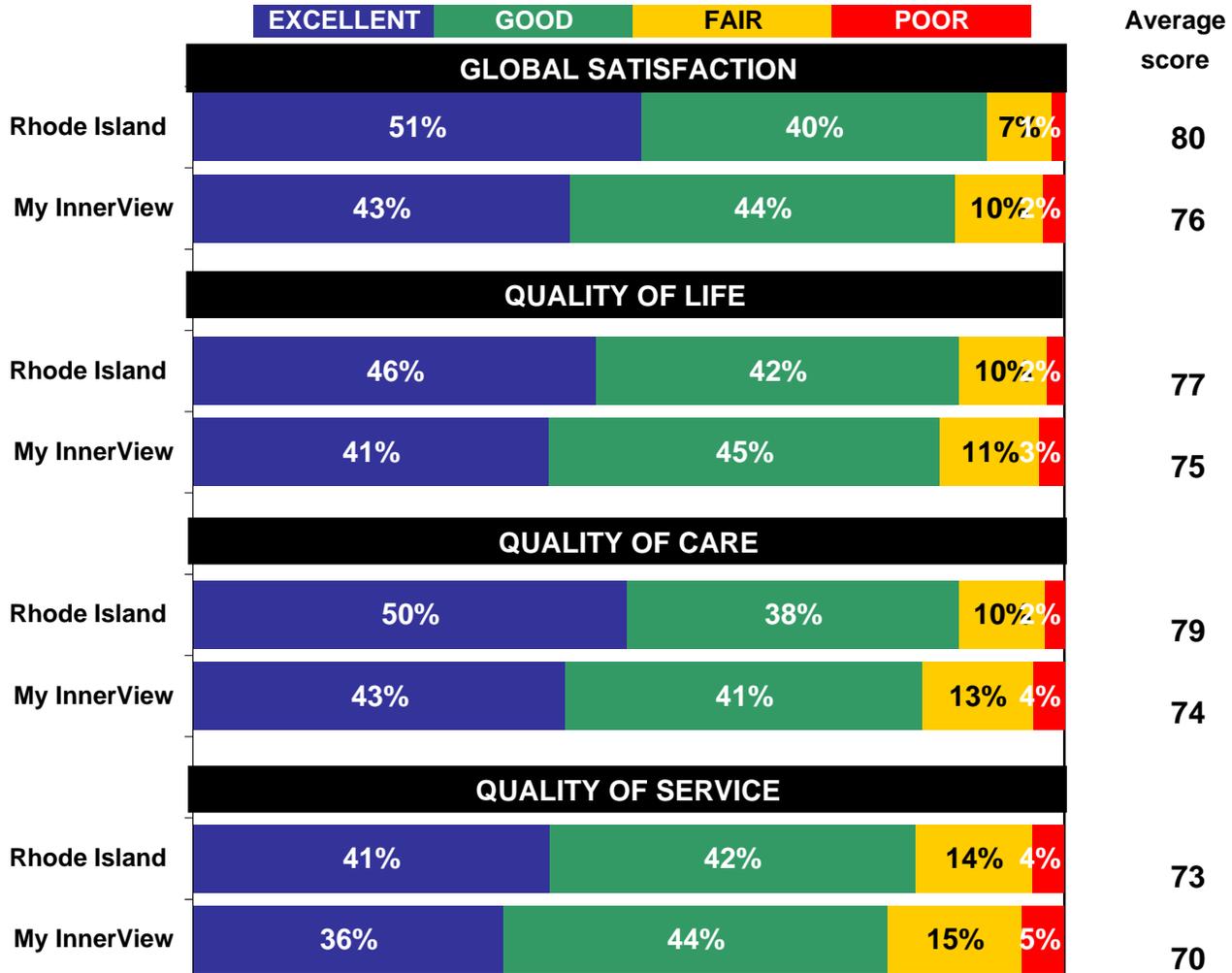
RHODE ISLAND

FAMILY SATISFACTION

GLOBAL SATISFACTION AND RATINGS BY DOMAIN FOR 2013



(The total percentage listed may be higher or lower than individual rating totals due to rounding.)



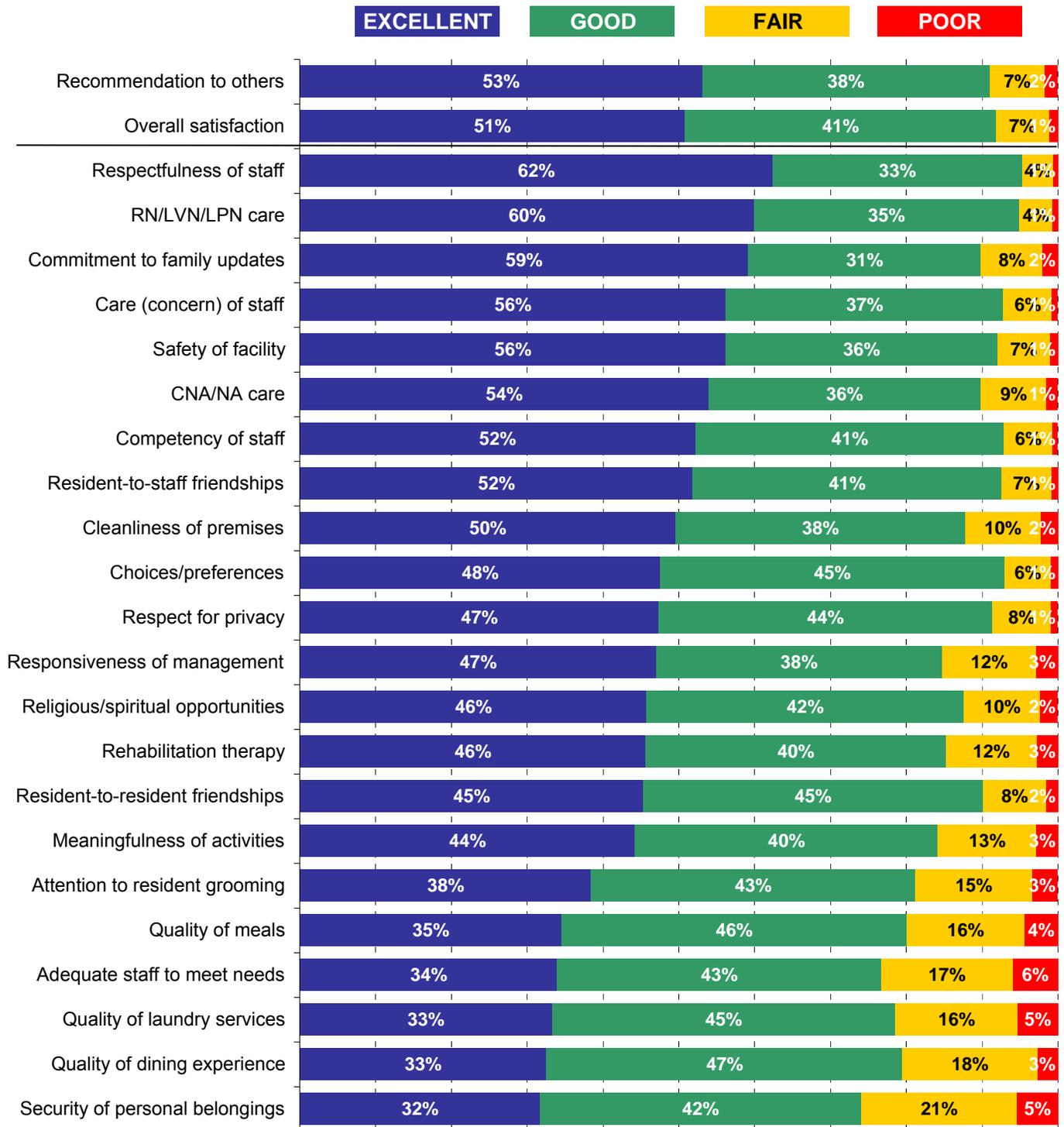
(May not total 100% due to rounding.)

RHODE ISLAND

FAMILY SATISFACTION

ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2013

2



Items are ranked from highest to lowest on the percent of responses rated "Excellent." The percentages reflect averages across survey respondents. (May not total 100% due to rounding.) See chart 4 for comparison to prior years.

RHODE ISLAND

FAMILY SATISFACTION

QUADRANT ANALYSIS: STRENGTHS AND OPPORTUNITIES

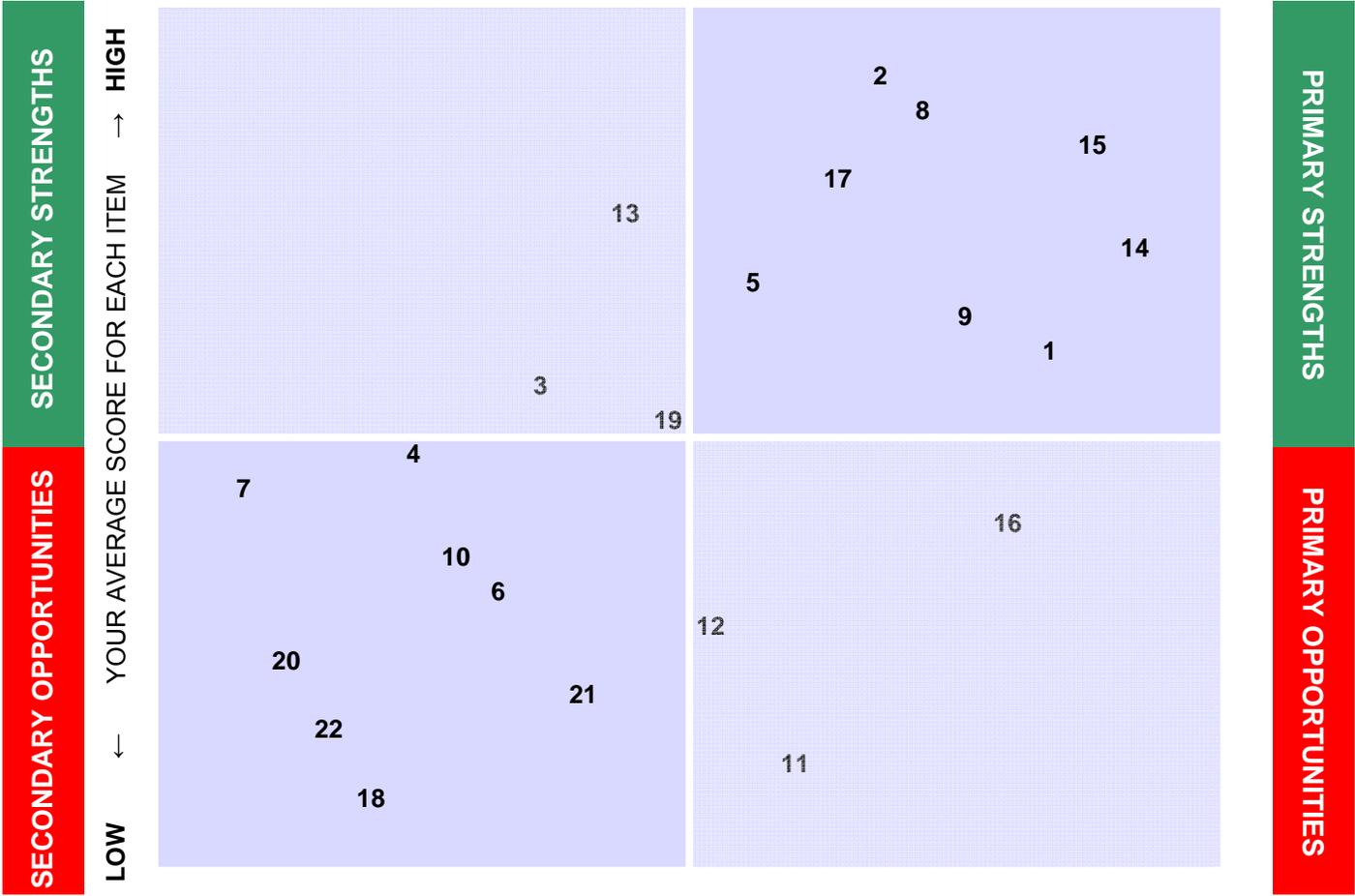
3

A

Quadrant A shows items of *lower* importance to "Recommendation" with a *higher* average score

Quadrant B shows items of *higher* importance to "Recommendation" with a *higher* average score

B



C

LOW ← IMPORTANCE TO RECOMMEND THIS FACILITY TO OTHERS → **HIGH**

Quadrant C shows items of *lower* importance to "Recommendation" with a *lower* average score

Quadrant D shows items of *higher* importance to "Recommendation" with a *lower* average score

D

The quadrant analysis plots the percentile rank of the average score on the satisfaction items against the percentile rank of the average "importance" score of each item and the question **What is your recommendation of this facility to others?** Items in the lower right quadrant are those that are most important to "Recommendation" but received the lowest scores.

See actual satisfaction items and report labels at end of section

RHODE ISLAND



SECONDARY STRENGTHS

Items with average scores above the midline but not as important to "Recommendation"

- 19 Cleanliness of premises
- 3 Respect for privacy
- 13 Commitment to family updates



PRIMARY STRENGTHS

Items with average scores above the midline and more important to "Recommendation"

- 1 Choices/preferences
- 14 Competency of staff
- 9 CNA/NA care
- 15 Care (concern) of staff
- 5 Resident-to-staff friendships
- 8 RN/LVN/LPN care
- 17 Safety of facility
- 2 Respectfulness of staff



SECONDARY OPPORTUNITIES

Items with average scores below the midline but not as important to "Recommendation"

- 21 Quality of dining experience
- 18 Security of personal belongings
- 6 Meaningfulness of activities
- 22 Quality of laundry services
- 10 Rehabilitation therapy
- 20 Quality of meals
- 4 Resident-to-resident friendships
- 7 Religious/spiritual opportunities



PRIMARY OPPORTUNITIES

Items with average scores below the midline and more important to "Recommendation"

These are areas that represent a good opportunity for improvement.

PRIORITY ACTION AGENDA™

The top FIVE items in Quadrant D (*Primary Opportunities*) comprise your Priority Action Agenda and provide a focus for improving willingness to recommend your facility to others.

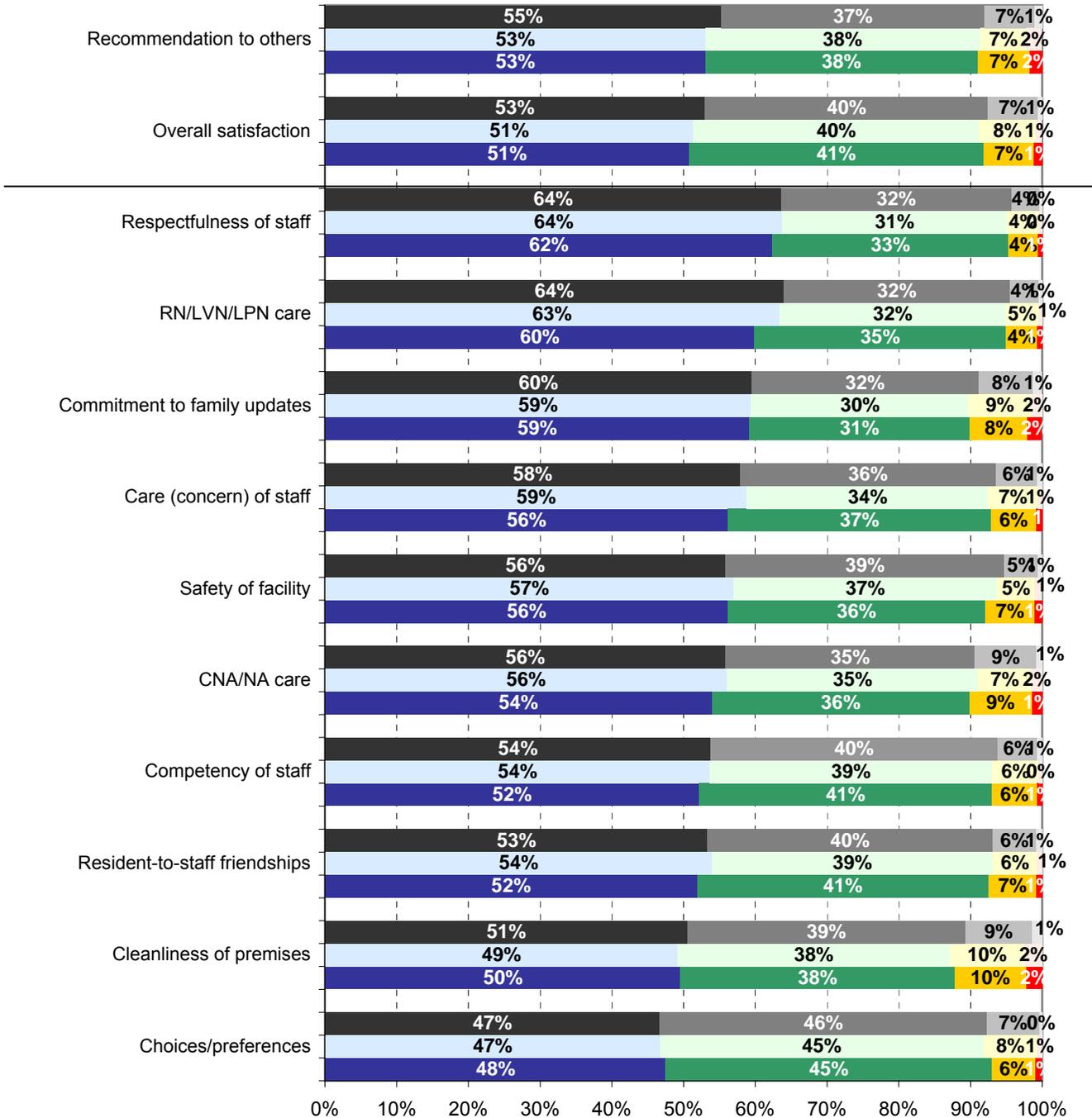
If Quadrant D has less than five items, the Priority Action Agenda will list only those items in the quadrant.

- 11 Adequate staff to meet needs**
- 16 Responsiveness of management**
- 12 Attention to resident grooming**

FAMILY SATISFACTION

ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2011, 2012 AND 2013

Year	EXCELLENT	GOOD	FAIR	POOR
2011	EXCELLENT	GOOD	FAIR	POOR
2012	EXCELLENT	GOOD	FAIR	POOR
2013	EXCELLENT	GOOD	FAIR	POOR



Items are ranked from highest to lowest on the percent of responses rated "Excellent" for the most recent year. (May not total 100% due to rounding.)

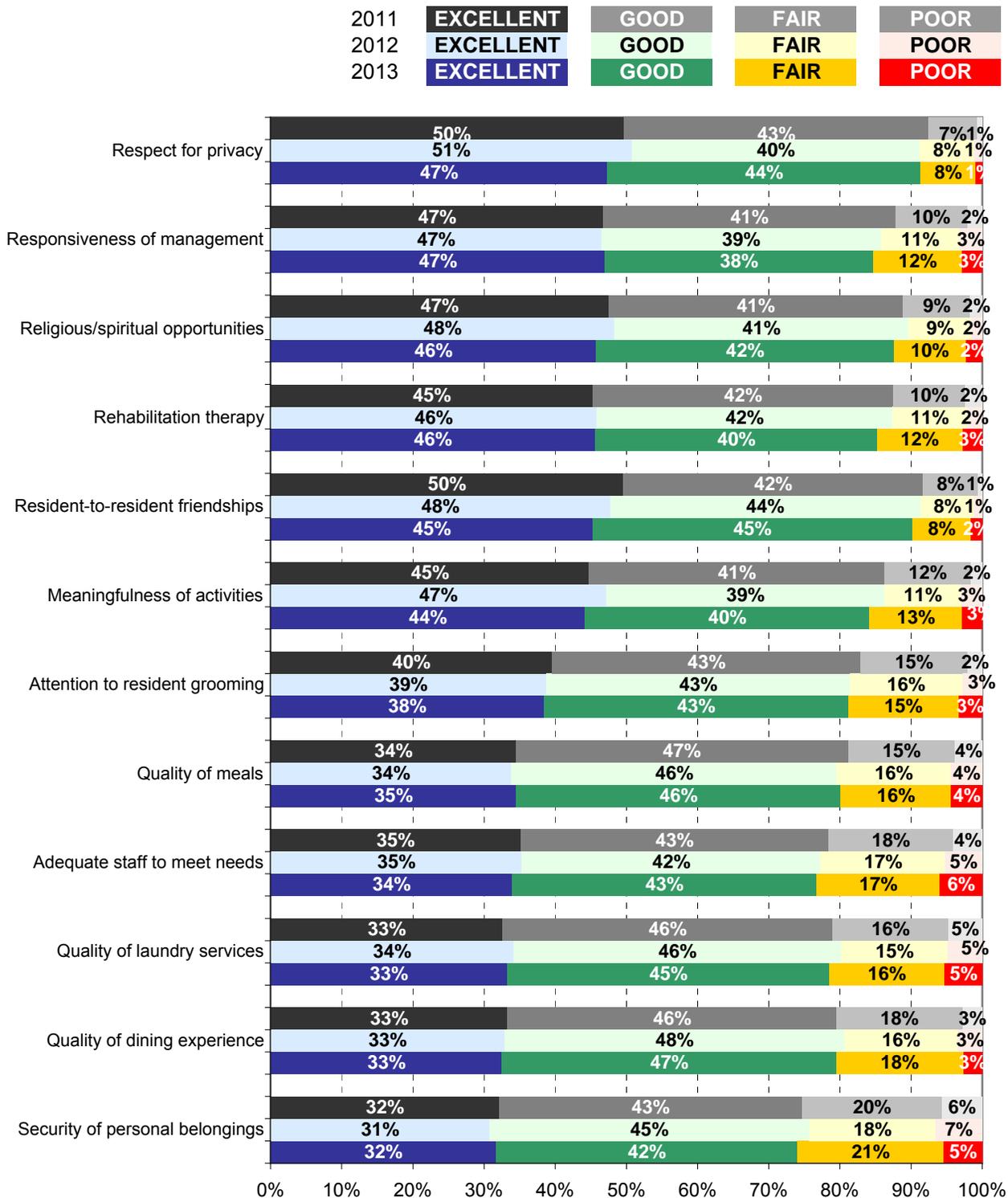
RHODE ISLAND

FAMILY SATISFACTION

ITEMS RANKED BY PERCENT "EXCELLENT" FOR 2011, 2012 AND 2013

4

CONTINUED



Items are ranked from highest to lowest on the percent of responses rated "Excellent" for the most recent year. (May not total 100% due to rounding.)

RHODE ISLAND

FAMILY SATISFACTION

ITEMS RANKED WITHIN DOMAIN BY AVERAGE SCORES FOR 2013

5

		2012	2011	2013 MIV
Recommendation to others		81	82	77
Overall satisfaction		80	82	76
QUALITY OF LIFE	Respectfulness of staff	86	86	81
	Safety of facility	82	83	79
	Resident-to-staff friendships	81	82	78
	Choices/preferences	80	79	75
	Respect for privacy	79	80	77
	Resident-to-resident friendships	78	79	77
	Religious/spiritual opportunities	77	78	75
	Meaningfulness of activities	75	77	73
	Quality of dining experience	70	70	66
	Security of personal belongings	67	67	65
QUALITY OF CARE	RN/LVN/LPN care	85	86	80
	Care (concern) of staff	83	84	78
	Commitment to family updates	82	83	79
	Competency of staff	81	82	77
	CNA/NA care	81	82	76
	Rehabilitation therapy	76	77	75
	Attention to resident grooming	72	72	67
	Adequate staff to meet needs	68	69	63
QUALITY OF SERVICE	Cleanliness of premises	78	79	74
	Responsiveness of management	76	77	72
	Quality of meals	70	71	67
	Quality of laundry services	69	69	67

RHODE ISLAND

FAMILY SATISFACTION

AVERAGE SCORES BY ITEM BY LOCATION TYPE FOR 2013

6

	Rhode Island	Rural	Suburban	Urban	
QUALITY OF LIFE	Recommendation to others	81	82	82	78
	Overall satisfaction	80	82	81	78
	Respectfulness of staff	86	87	86	84
	Safety of facility	82	83	83	81
	Resident-to-staff friendships	81	83	81	80
	Choices/preferences	80	82	80	78
	Respect for privacy	79	79	80	78
	Resident-to-resident friendships	78	78	79	77
	Religious/spiritual opportunities	77	79	78	74
	Meaningfulness of activities	75	76	77	72
	Quality of dining experience	70	70	71	68
	Security of personal belongings	67	67	68	65
	QUALITY OF CARE	RN/LVN/LPN care	85	86	85
Care (concern) of staff		83	85	83	80
Commitment to family updates		82	84	84	79
CNA/NA care		81	82	82	78
Competency of staff		81	83	82	79
Rehabilitation therapy		76	78	76	75
Attention to resident grooming		72	74	72	70
Adequate staff to meet needs		68	71	69	65
QUALITY OF SERVICE	Cleanliness of premises	78	81	79	75
	Responsiveness of management	76	78	77	74
	Quality of meals	70	72	71	68
	Quality of laundry services	69	70	70	67

All scores represent average scores across survey respondents. Each item was measured on a four-point scale:

Poor = 0 Fair = 33.3 Good = 66.7 Excellent = 100

Items are listed by domain as they appear in the survey. The shading in the Rural, Suburban and Urban columns reflects a comparison to the state average: Green = higher than the state average; yellow = same as the state average; red = lower than the state average.

RHODE ISLAND

FAMILY SATISFACTION

DEMOGRAPHICS AND BACKGROUND INFORMATION FOR 2013

7

RESIDENT

Gender of resident		Age of resident	
Female	76%	19 or under	0%
Male	24%	20 to 29	0%
		30 to 39	0%
		40 to 49	0%
		50 to 59	2%
		60 to 69	5%
		70 to 79	10%
		80 to 89	40%
		90 or older	43%

FACILITY CHOICE

Homes visited		Reason for choosing		Length of stay	
None	31%	Convenient location	26%	Less than 1 month	1%
Only this one	13%	Good reputation	40%	1 to 3 months	3%
Two	27%	Doctor or hospital	11%	3 to 6 months	5%
Three	16%	Relative or friend	10%	6 months to 1 year	16%
Four	8%	Insurance requirement	2%	1 to 3 years	38%
Five or more	6%	Other reason	11%	3 or more years	37%

SURVEY RESPONDENT

Relationship to resident	
Spouse	12%
Child	63%
Brother or sister	7%
Grandchild	1%
Friend	2%
Other relationship	14%

VISITOR

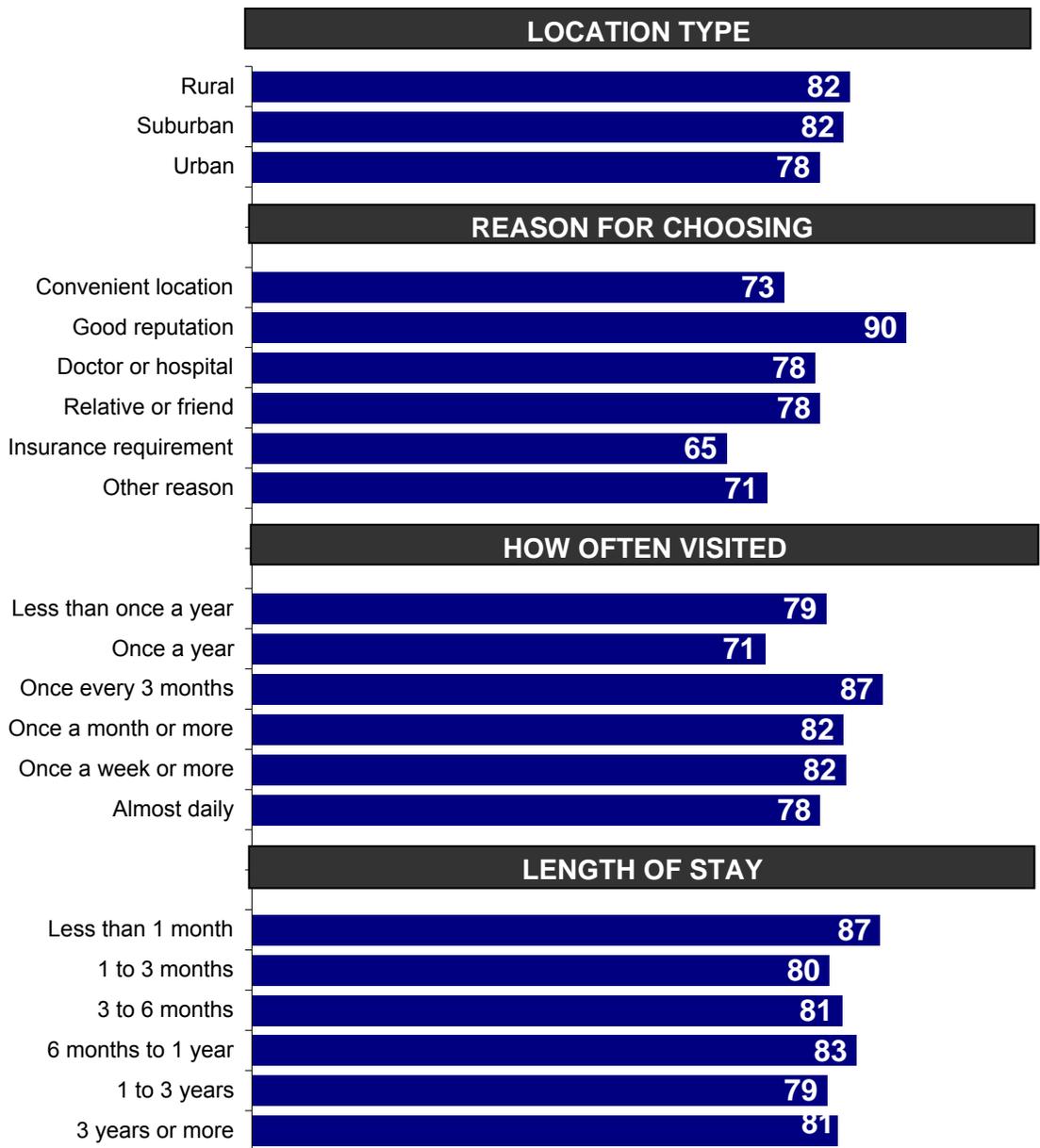
Person visiting most		How often visited	
Spouse	13%	Less than once a year	0%
Child	62%	Once a year	0%
Brother or sister	9%	Once every 3 months	3%
Grandchild	2%	Once a month or more	11%
Friend	3%	Once a week or more	50%
Another person	11%	Almost daily	35%

(May not total 100% due to rounding.)

RHODE ISLAND

FAMILY SATISFACTION

AVERAGE SCORES FOR "RECOMMENDATION TO OTHERS" BY DEMOGRAPHICS FOR 2013

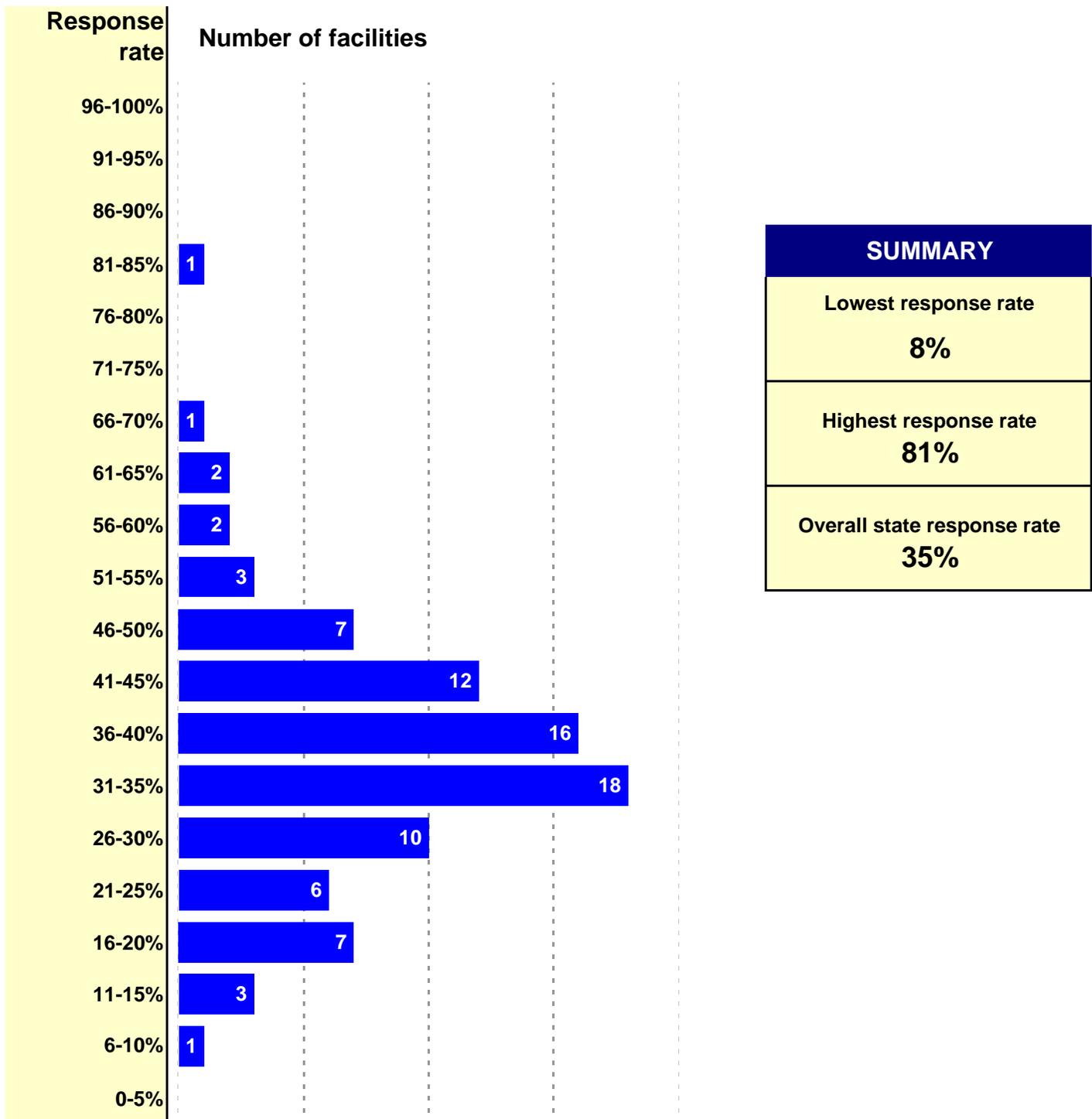


FAMILY SATISFACTION

DISTRIBUTION OF RESPONSE RATES FOR 2013

9

Results are for 89 participating facilities.



RHODE ISLAND

FAMILY SATISFACTION

SKILLED NURSING FAMILY SATISFACTION SURVEY REFERENCE

ITEM NUMBER/LABEL	ORIGINAL SURVEY STATEMENT
GLOBAL SATISFACTION DOMAIN	
23 Overall satisfaction	How would you rate your overall satisfaction with this facility?
24 Recommendation to others	What is your recommendation of this facility to others?
QUALITY OF LIFE DOMAIN	
	Rate this facility on ...
1 Choices/preferences	Meeting the resident's/patient's choices and preferences
2 Respectfulness of staff	The respect shown to the resident/patient by staff
3 Respect for privacy	Meeting the resident's/patient's need for privacy
4 Resident-to-resident friendships	Offering the resident/patient opportunities for friendships
5 Resident-to-staff friendships	Offering the resident/patient opportunities for friendships with staff
6 Meaningfulness of activities	Offering the resident/patient meaningful activities
7 Religious/spiritual opportunities	Meeting the resident's/patient's religious and spiritual needs
17 Safety of facility	How safe it is for the resident/patient
18 Security of personal belongings	The security of the resident's/patient's personal belongings
21 Quality of dining experience	How enjoyable the dining experience is for the resident/patient
QUALITY OF CARE DOMAIN	
	Rate this facility on ...
8 RN/LVN/LPN care	The quality of care provided by the nurses (RNs/LVNs/LPNs)
9 CNA/NA care	The quality of care provided by the nursing assistants (CNAs/NAs)
10 Rehabilitation therapy	The quality of rehabilitation therapy (occupational, physical, speech)
11 Adequate staff to meet needs	Providing an adequate number of nursing staff to meet care needs
12 Attention to resident grooming	Meeting the resident's/patient's need for grooming
13 Commitment to family updates	Keeping you and your family informed about the resident/patient
14 Competency of staff	The competency of staff
15 Care (concern) of staff	The staff's care and concern for the resident/patient
QUALITY OF SERVICE DOMAIN	
	Rate this facility on ...
16 Responsiveness of management	Management's responsiveness to your suggestions and concerns
19 Cleanliness of premises	The cleanliness of the room and surroundings
20 Quality of meals	The quality of the meals
22 Quality of laundry services	The quality of laundry services
DEMOGRAPHICS AND BACKGROUND INFORMATION	
25 Length of stay	How long has the resident/patient lived at this facility?
26 Person visiting most	Who visits the resident/patient most often?
27 How often visited	How often does this person visit the resident/patient?
28 Homes visited	How many nursing homes did you (or your family) visit before choosing this facility?
29 Reason for choosing	What is the most important reason you (or your family) chose this facility?
30 Gender of resident	What is the resident's/patient's gender?
31 Age of resident	What is the resident's/patient's age?
32 Relationship to resident	What is your relationship to the resident/patient?

© 2009. Reproduction or duplication requires written permission from National Research Corporation.

Healthcare Quality Reporting Program - Nursing Home Information

Nursing Homes:

The Rhode Island Department of Health's (HEALTH) Healthcare Quality Reporting Program is requesting that all RI Nursing Homes take 10-15 minutes to complete a brief questionnaire about your agency, services and service areas.

Nursing Home Administrators are asked to work with their teams to consider the [questions](#) and submit a single response by **COB on Friday - December 13th**.

The information you provide will serve two needs:

1. **To create a new Nursing Home Summary Report** designed to inform consumers' decision making by helping them understand how your facility compares to your peers. This short report will summarize some of the existing information now available from HEALTH and Medicare and will be published on [HEALTH's website](#). Case managers will be able to provide copies to patients.
2. **To create a Nursing Home Resource Guide for referring hospitals**. Healthcentric Advisors' [Safe Transitions team](#) will compile your responses into a resource guide. This detailed guide will be shared with referring ED and Case Management departments so they have a better understanding of the services that each facility is able to offer and contact information for key personnel.

All nursing homes are required by regulations to submit data and information to HEALTH, as requested. In the event that you do not respond by December 13th, your facility will have missing information in the consumer and hospital reports and you may be subject to a state citation.

Thank you in advance for your timely response. Please don't hesitate to contact us with questions.

Sincerely,

[Samara Viner-Brown, MS](#)

Chief, Center for Health Data and Analysis

[Gail Patry, RN](#)

Chair, Nursing Home Subcommittee

Healthcare Quality Reporting Program - Nursing Home Information

Please provide the following information about your organization.

Facility Name:	<input type="text"/>
Facility Address:	<input type="text"/>
City/Town:	<input type="text"/>
State:	<input type="text"/>
ZIP Code:	<input type="text"/>
RI County:	<input type="text"/>
Phone:	<input type="text"/>
Fax:	<input type="text"/>

Please provide your license info:

RI License Number:	<input type="text"/>
Medicare Provider ID (if certified):	<input type="text"/>

Please provide names and phone numbers for the following members of your management team.

Administrator Name:	<input type="text"/>
Administrator Phone:	<input type="text"/>
DON Name:	<input type="text"/>
DON Phone:	<input type="text"/>
Assistant DON Name:	<input type="text"/>
Assitant DON Phone:	<input type="text"/>

Please provide the following information about the Admissions Director at your facility.

Admissions Director Name:	<input type="text"/>
Phone:	<input type="text"/>
Other (e.g., pager or alternate contact)	<input type="text"/>
Admission Availability (hours):	<input type="text"/>
Admission Availability (days of week):	<input type="text"/>

Healthcare Quality Reporting Program - Nursing Home Information

Please provide names and phone numbers for the following medical staff.

Medical Director Name:

Medical Director Phone:

Assistant Medical Director Name:

Assistant Medical Director Phone:

Nurse Practitioner Name:

Nurse Practitioner Phone:

If you would like to list additional medical staff, please use this space to include their names, titles and phone numbers.

Healthcare Quality Reporting Program - Nursing Home Information

Please indicate which insurance plans your facility accepts. (Select all that apply.)

- | | | |
|--|---------------------------------------|--|
| <input type="checkbox"/> Aetna | <input type="checkbox"/> Medicare | <input type="checkbox"/> UnitedHealthcare |
| <input type="checkbox"/> BCBSRI | <input type="checkbox"/> Neighborhood | <input type="checkbox"/> Veteran's Affairs |
| <input type="checkbox"/> Cigna | <input type="checkbox"/> Private pay | <input type="checkbox"/> Workers' compensation |
| <input type="checkbox"/> Long-term care | <input type="checkbox"/> Rlte Care | |
| <input type="checkbox"/> Medicaid | <input type="checkbox"/> Tufts | |
| <input type="checkbox"/> Other (please specify): | | |

What is your bed capacity?

Total capacity:	<input type="text"/>
Short-stay beds (skilled only):	<input type="text"/>
Long-stay beds:	<input type="text"/>
Respite care:	<input type="text"/>
Assisted living:	<input type="text"/>
Independent living:	<input type="text"/>
Other (Please specify):	<input type="text"/>

Healthcare Quality Reporting Program - Nursing Home Information

Does your direct-care staff have consistent assignment? (i.e., do they care for the same residents daily?)

- No
- Yes, on some units
- Yes, on all units

Please indicate how often you have primary care clinician services (at least one physician, NP, or PA in the facility).

- <3 days per week
- 3-4 days per week
- 5+ days per week
- Other (please specify):

Is there a clinician available during off hours? (Please select all that apply)

- No
- Yes, there is a clinician on-call in the evenings
- Yes, there is a clinician on-call overnight

Please indicate which therapies your facility has available. (Select all that apply.)

- Occupational
- Outpatient Occupational
- Physical
- Outpatient Physical
- Respiratory
- Outpatient Speech
- Speech
- Other (please specify):

Please indicate how often you have physical therapy services.

- <3 days per week
- 3-4 days per week
- 5+ days per week
- Not applicable, we do not offer this service

Other (please specify)

Healthcare Quality Reporting Program - Nursing Home Information

Please indicate how often you have occupational therapy services available.

- <3 days per week
- 3-4 days per week
- 5+ days per week
- Not applicable, we do not offer this service

Other (please specify)

Healthcare Quality Reporting Program - Nursing Home Information

Please indicate which diagnostic testing your facility provides. (Select all that apply.)

- | | | |
|--|--|---|
| <input type="checkbox"/> Bladder Ultrasound | <input type="checkbox"/> INR | <input type="checkbox"/> Troponin |
| <input type="checkbox"/> Brain Natriuretic Peptide | <input type="checkbox"/> Stat lab tests (<8 hrs) | <input type="checkbox"/> Venous Doppler |
| <input type="checkbox"/> Cardiac Echo | <input type="checkbox"/> Stat x-rays (<8 hrs) | <input type="checkbox"/> Ultrasound |
| <input type="checkbox"/> EKG | <input type="checkbox"/> Swallow Studies | |
| <input type="checkbox"/> Other (please specify): | | |

Please indicate which consultants your facility has available. (Select all that apply.)

- | | | |
|--|--|--------------------------------------|
| <input type="checkbox"/> Cardiology | <input type="checkbox"/> Optometry | <input type="checkbox"/> Pulmonology |
| <input type="checkbox"/> Dentistry | <input type="checkbox"/> Palliative Care | <input type="checkbox"/> Urology |
| <input type="checkbox"/> Dietary /Nutritional | <input type="checkbox"/> Podiatry | <input type="checkbox"/> Wound Care |
| <input type="checkbox"/> Hospice | <input type="checkbox"/> Physiatry | |
| <input type="checkbox"/> Neurology | <input type="checkbox"/> Psychiatry | |
| <input type="checkbox"/> Other (please specify): | | |

Please indicate which social and psychological services your facility has available. (Select all that apply.)

- Licensed Social Worker
- Psychological Evaluation and Counseling by a Licensed Clinical Psychologist
- Other (please specify):

Does your facility have a dementia care unit?

- No, we do not have a dementia care unit
- Yes, we have a secure dementia care unit
- Yes, we have a non-secure dementia care unit

Please indicate which of the following end-of-life services your facility has. (Select all that apply.)

- Hospice care (in house)
- Hospice care (consulting)
- Palliative care (in house)
- Palliative care (consulting)
- Other (please specify):

Please indicate which nursing services your facility has available. (Select all that apply.)

- | | |
|---|--|
| <input type="checkbox"/> Glucose monitoring at least every shift | <input type="checkbox"/> Nebulizer treatments |
| <input type="checkbox"/> Daily weights | <input type="checkbox"/> Neurological checks |
| <input type="checkbox"/> Frequent vital signs (e.g., every 2 hrs) | <input type="checkbox"/> O2 saturation |
| <input type="checkbox"/> Incentive spirometry | <input type="checkbox"/> Strict intake and output (I & O) monitoring |
| <input type="checkbox"/> Other (please specify): | |

Does your facility have the capacity to take a patient who is currently on a ventilator?

- Yes
- No

Please indicate which interventions your facility has available. (Select all that apply.)

- | | | |
|---|---|--|
| <input type="checkbox"/> Advanced CPR (ACLS capability) | <input type="checkbox"/> IV meds - Other (e.g., furosemide) | <input type="checkbox"/> Respiratory: CPAP |
| <input type="checkbox"/> Analgesic pumps | <input type="checkbox"/> Nutrition: G-tube | <input type="checkbox"/> Respiratory: Nebulizers |
| <input type="checkbox"/> Automatic defibrillator | <input type="checkbox"/> Nutrition: J-tube | <input type="checkbox"/> Respiratory: Puerex |
| <input type="checkbox"/> Central Line | <input type="checkbox"/> Nutrition: NG-tube | <input type="checkbox"/> Specialize in dementia care |
| <input type="checkbox"/> Dialysis | <input type="checkbox"/> Nutrition: PD | <input type="checkbox"/> Surgical drain management |
| <input type="checkbox"/> Dialysis: Peritoneal | <input type="checkbox"/> Nutrition: TPN | <input type="checkbox"/> Tracheostomy management |
| <input type="checkbox"/> Isolation (for MRSA, VRE, etc.) | <input type="checkbox"/> Ostomy care | <input type="checkbox"/> Wounds: Complex dressings |
| <input type="checkbox"/> IV antibiotics | <input type="checkbox"/> PICC insertion | <input type="checkbox"/> Wounds: VACS-KCL |
| <input type="checkbox"/> IV Clysis | <input type="checkbox"/> PICC management | |
| <input type="checkbox"/> IV fluids (initiation and maintenance) | <input type="checkbox"/> Respiratory: Bi-pap | |
| <input type="checkbox"/> Other (please specify): | | |

Please indicate which pharmacy services your facility has available. (Select all that apply.)

- Emergency kit with common medications for acute conditions
- New medications filled within 8 hours
- Other (please specify):

Please share your social media outlet links: (optional)

Website:

Facebook:

Twitter:

LinkedIn:

Please share any additional thoughts regarding your facilities' capabilities or the use of this information by patients/families or referring hospitals (ED/Case Management).

Thank you for completing these questions. If you would like confirmation of your participation in this survey for your records, please print this screen. Unfortunately, this survey tool does not permit us to send you individual confirmation of survey completion.

With additional questions, please contact:

[Samara Viner-Brown, MS](#)

Chief, Center for Health Data and Analysis

[Gail Patry, RN](#)

Chair, Nursing Home Subcommittee



Healthcare Quality Reporting Program Nursing Home Summary Report

The Rhode Island Department of Health publishes information about nursing homes. If you know that you or a family member will need nursing home care, this information can help you compare nursing homes and choose among them. You may also want to visit nursing homes and to ask friends and family members for their thoughts and experiences.

This report summarizes information from the Department of Health (www.health.ri.gov/nursinghomes/about/quality) and Medicare (www.medicare.gov/nursinghomecompare). Reports with more information are available at those websites.

This report is updated every time there is new information for one of the columns below. You can learn more about what is in this report, including definitions and time periods for each column of information, by reading the Methods Report. Please contact nursing homes directly with questions, to inquire about private insurance, to check on bed availability or to schedule a tour.

Contact Information:				Capacity			Certification		Quality And Satisfaction:					
Facility,				Number of Beds	Number of Skilled Beds	Secure Dementia Unit	Medicare	Medicaid	Quality Of Care	Health Inspections	Resident Satisfaction	Family Satisfaction	Healthcare Workers Who Received	Influenza Vaccination
Alphabetical By County	City	Phone	Fax											
Bristol County														
Crestwood Nursing Home	Warren			76										
Grace Barker Nursing Home	Warren			86										
Saint Elizabeth Manor, East Bay	Bristol			133										
Silver Creek Manor	Bristol			128										
Warren Skilled Nursing & Rehabilitation	Warren			63										
Kent County														
Alpine Nursing Home	Coventry			60										
Avalon Nursing Home	Warwick			31										
Brentwood Nursing Home	Warwick			96										

Reports with more information about quality and satisfaction are available at www.health.ri.gov/nursinghomes/about/quality.

Failure to Become Immunized When Caring for Patients: An Ethical and Professional Obligation

LORI KEOUGH, PhD, MEd, FNP-BC

In late September 2012, changes to the Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for Health Care Workers (R23-17-HCW) were proposed to reflect the most current (2011) recommendations of the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP). One of the proposed changes drew many people to a public hearing: the requirement that all Health Care Workers (HCW) either receive seasonal influenza vaccine or wear a mask when providing face-to-face patient care during "period(s) in which flu is widespread." A brief review of the rationale for mandating seasonal influenza vaccination among HCWs follows, along with ethical implications. The risks and benefits of seasonal influenza vaccination are reviewed as well.

Who Must Be Vaccinated And Why?

HCWs make valuable contributions to our health care system and are essential in meeting patients' health care needs. HCWs, broadly defined, are those individuals who are employed or volunteer in a health care facility and have direct contact with patients, including, but not limited to, physicians, physician assistants, nurses, nursing assistants, pharmacists, clinicians and therapists from all disciplines (for a complete definition see RI Regulations: R23-17-HCW, 2012). When individuals become licensed HCWs, they accept the responsibility to uphold professional standards of care and practice, defined by a specific code of ethics. Regardless of professional discipline, all HCWs are obligated to adhere to the general ethical principles of *non-maleficence*, the duty "to do no harm," and *beneficence*, to behave in way that promotes patients' best interests. These principles imply an obligation not to expose patients to vaccine-preventable illnesses which HCWs may themselves contract and transmit to patients, in short, to make provisions (e.g., vaccination of HCWs) to avoid doing harm to patients and to enable HCWs to continue giving care to patients (by themselves avoiding illness).

The notion that HCWs may spread pathogens dates back to Ignaz Semmelweis' 19th-century data on the infection of patients whose providers had not washed their hands. Since that time, HCWs have been enjoined to minimize the risk of disease transmission to patients (and vice versa) by washing



hands before and after patient encounters, by allowing themselves to be screened for communicable diseases such as tuberculosis, and by allowing themselves to be vaccinated against vaccine-preventable communicable diseases such as rubella. (See, for example, relevant Rhode Island regulations: <http://www.health.ri.gov/immunization/for/healthcareworkers/index.php>).

Why Vaccinate?

Seasonal influenza is a significant public health issue. In the United States alone, it causes more than 200,000 hospitalizations and 36,000 deaths annually.¹

Fortunately, seasonal influenza vaccines have proven to be effective in preventing illness onset in a majority of exposed-but-vaccinated people, with the exception of those who are immune-compromised or immune-suppressed. Several random control trials have demonstrated significant reductions in influenza-related mortality – as high as 44% among nursing home residents and hospital inpatients – when HCWs are vaccinated.²⁻⁹ Similarly, mathematical models of seasonal influenza vaccination of HCWs in nursing homes suggest a 60% prevention of influenza virus infections among vulnerable patients.¹⁰

Reasons to vaccinate *both* patients *and* HCWs against influenza are well documented. HCW vaccination *indirectly* protects high-risk patient populations for which *direct* immunization does not suffice to reduce risk, e.g., infants, elders, and patients who are immune-compromised or immune-suppressed.⁶ As well, vaccination reduces the risk that HCWs will become infected, thus contributing to societal immunity ("herd immunity"), and reducing workforce attrition during influenza outbreaks.^{10,11}

In fact, many scientific and government organizations have recognized the importance of HCW seasonal influenza vaccination, and have supported efforts to increase the proportion of HCWs thus vaccinated. Since July 2007, for example, the Joint Commission has required some hospitals and long-term care centers to establish onsite influenza vaccination programs, including education and the evaluation of coverage. In this vein, the Centers for Medicaid and Medicare Services is likely to require hospitals (beginning in 2013) to report influenza vaccination coverage as part of inpatient quality reporting. Furthermore, many professional

societies have endorsed influenza vaccination requirements for HCWs: the Infectious Diseases Society of America, the National Foundation for Infectious Diseases, the Society for Healthcare Epidemiology of America, the Association for Professionals in Infection Control, and the American College of Physicians. (See: <http://www.immunize.org/honor-roll/>)

Table 1. Benefits and risks associated with administration of influenza vaccine

Costs	Benefits
Vaccine Side Effects: Soreness at the injection site, low-grade fever, aches, Guillian Barre Syndrome, allergic reaction	Patient Safety and Public Health: <ul style="list-style-type: none"> • Decreased morbidity and mortality • Increased safety and quality of care
Economics: Upfront costs for employers offering vaccines at no cost to employees	Economics: Savings in influenza related health care expenditures and time missed from work due to illness

The Historical and Scientific Aspects of Vaccine Controversy

The controversy surrounding mandatory vaccination, in general, dates back almost a century (Stern, 1927), and perhaps even further. The controversy incorporates issues of individual rights *as well as* ethical obligations to do no harm and to promote the best interests of patients, and the costs and benefits of seasonal influenza vaccination for various groups (Table 1).

Safety Issues

Safety concerns (vaccine side effects) likely represent the most commonly cited reason to not be vaccinated. Although seasonal influenza vaccine is both safe and effective *most* of the time, adverse reactions can and do occur. These events are closely monitored and researched by the CDC’s Vaccine Adverse Events Reporting System (VAERS). In 1990, VAERS was established as a national passive reporting system, accepting reports from the public on adverse events associated with vaccines licensed in the United States. According to VAERS (<http://www.cdc.gov/flu/professionals/acip/adverse-tiv.htm>), serious adverse events are rare, often 1 or 2 per million, and in clinical trials, serious adverse events associated with the use of seasonal influenza vaccine were reported to occur in less than 1% of all vaccinations.^{12,13} Similarly, although it is true that an individual can be vaccinated and still contract the flu, being vaccinated significantly decreases the chance of disease transmission.²⁻⁹

Why Mandate?

Significant precedents for mandatory vaccination are well established in the United States.¹⁴ In the early 20th century, for example, the country was ravaged by communicable diseases that have been virtually eliminated since that time because of mandatory vaccination (Table 2).¹⁴

Specific to seasonal influenza vaccines, the CDC has *recommended* that health care workers get yearly influenza vaccine

since 1981, with a national goal of 90% of HCWs vaccinated (CDC, 2012). As noted, some health care organizations *offer* no cost vaccines to their workforce and others *assure* high vaccination rates by *mandating* vaccination. Nonetheless, during the 2009-2010 influenza season, an estimated 61.9% of HCWs were vaccinated, and during the 2010-2011 influenza season – the season *after* the 2009 H1N1 pandemic – an estimated 63.5% of HCWs were vaccinated. In comparison, 98.1% of HCWs whose employers *assured* vaccination were vaccinated in the 2010-2011 influenza season.¹⁵⁻¹⁷

Given the history of vaccine uptake percentages in HCWs whose employers offer optional influenza vaccination, it is unlikely that voluntary programs will achieve vaccination rates sufficient to protect the health and safety of patients. Therefore, in line with licensed health professionals’ obligation “to do no harm” (non-maleficence), on the one hand, and to promote health (beneficence), on the other, mandating seasonal influenza vaccination is essential.

We should note that In the United States, HCWs are not the only group required to be vaccinated against communicable diseases. Children, for example, are required to be vaccinated prior to enrollment in school, camp or child care settings – a requirement that dates back to the 1850s in Massachusetts for smallpox vaccination.¹⁵⁻¹⁷

Why Regulate?

In the past, seasonal influenza vaccination has been left in the hands of individual health care organizations, under the aegis of quality and safety standards. Some *offered* vaccination; others *required* it. Some *offered vaccine at no cost* to HCWs, while others *passed on the cost* to HCWs. In a situation such as this, rules and regulations, under the aegis of strong laws, are a good way to achieve uniformity.

Newly promulgated (December 2012) regulations in Rhode Island do not require HCWs to obtain annual vaccinations for seasonal influenza, but rather, require HCWs to protect their patients against influenza transmission one way or another: *either* by being vaccinated, *or* by wearing a mask for direct patient contact during periods in which flu is widespread. This approach places responsibility on the individual HCW, who, not withstanding possible medical exemptions, is accountable for his/her choice to obtain, or not obtain, the influenza vaccine.

Ever since society began understanding the mechanisms of communicable disease transmission, HCWs have had an

Table 2. Early 20th Century Reports of Communicable Disease Cases and Deaths in the United States¹⁴

Year of Reporting	Communicable Disease	Number of Cases	Number of Deaths
1900	Smallpox	21,064	894
1920	Measles	469,924	7,575
1920	Diphtheria	147,991	13,170
1922	Pertussis	107,473	5,099

ethical obligation to protect themselves and their patients from exposure. Now, the obligation to protect patients from seasonal influenza has been enshrined in Rhode Island law and its accompanying rules and regulations. This development will work to protect patients, enhance the public's trust, and protect a much-needed healthcare workforce.

References

1. MMWR (Update: Influenza Activity – United States, 2010-11 Season, and Composition of the 2011-12 Influenza Vaccine. *MMWR Morb Mortal Wkly Rep.* 2011 June 3;60(21):705-712).
2. Pearson ML, Bridges CB, Harper SA. Influenza vaccination of health-care personnel: recommendations of the Health care Infection Control personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2006;55(9)(RR-2):1-16.
3. Potter J, Stott DJ, Rovers MA, et al. Influenza vaccination of health care workers in long-term care hospitals reduces the mortality of elderly patients. *Journal of Infectious Disease.* 1997; 175:1-6.
4. Carman, WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomized controlled trial. *Lancet.* 2000;355(9198):93-7.
5. Potter J, Stott DJ, Rovers MA, et al. Influenza vaccination of healthcare workers in long-term care hospitals reduces the mortality of elderly patients. *Journal of Infectious Disease.* 1997; 175(1):1-6.
6. Hayward AC, Harling R, Wetten S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents; cluster randomised controlled trial. *BMJ.* 2006;333(7581):1241.
7. Talbot, et al. Revised SHEA position paper: Influenza vaccination of healthcare personnel. *Infection control and hospital epidemiology.* 2010;31(10)987-995.
8. van den Dool C, Bonten MJ, Hak E, Heijne JCM, Wallinga J. The Effects of Influenza vaccination of health care workers in nursing homes: insights from a mathematical model. *PLoS medicine.* 2008;5(10):1453-60.
9. Chicaiza-Becerra LA, Garcia-Molina M, Ballesteros M, Gamboa, O, Diaz J, Vega R. Economic evaluation of influenza vaccine applied to health personnel attending hospitalized oncological patients. *Revista de Salud Publica.* 2008;10(5):756-766.
10. Carman WWF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of healthcare workers on mortality of elderly people in long-term care; a randomised controlled trial. *Lancet.* 2000;355(9198):93-97.
11. Davis RL, Kolczak M, Lewis E, Nordin J, Goodman M, Shay DK, Platt R, Black S, Shinefield H, Chen RT. Active surveillance of vaccine safety: a system to detect early signs of adverse events. *Epidemiology.* 2005;16(3):336-341.
12. Chen RT, DeStefano F, Davis RL, Jackson LA, Thompson RS, Mullooly JP, Black SB, Shinefield HR, Vadheim CM, Ward JL, Marcy SM. The Vaccine Safety Datalink: immunization research in health maintenance organizations in the USA. *Bulletin of the World Health Organization.* 2000;78(2):186-194.
13. Ottenberg AL, Wu JT, Poland GA, Jacobson RM, Koenig BA, Tilburt JC. Vaccinating health care workers against influenza: The ethical and legal rationale for a mandate. *American Journal of Pubic Health.* 2011;101(2).
14. CDC. Ten great public health achievements of the United States, 1900-1999. *MMWR* 1999; 48:241-3.
15. CDC COCA Conference Call. Update on Influenza Vaccination for Health Care Personnel: Recent Coverage, Recommendations, Reporting, and Resources. November 15, 2011.
16. CDC. Influenza Vaccination Coverage Among Health-Care Personnel—United States, 2010-11 Influenza Season. *MMWR.* 2011;60:1073-1077.
17. CDC. Influenza vaccination of health-care personnel: recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). *MMWR.* 2006;55(No. RR-2).

Author

Lori Keough, PhD, MEd, FNP-BC is State Director of Nurse Registration and Nursing Education, Rhode Island Department of Health, and is also affiliated with the University of Mass., Dartmouth.

Financial disclosures

The author has no financial disclosures to report.

Correspondence

State Director of Nurse Registration and Nursing Education
Rhode Island Department of Health
3 Capitol Hill
Providence, RI 02908
LLORIK@aol.com

Original Investigation

Association Between Influenza Vaccination and Cardiovascular Outcomes in High-Risk Patients

A Meta-analysis

Jacob A. Udell, MD, MPH, FRCPC; Rami Zawi, MD; Deepak L. Bhatt, MD, MPH; Maryam Keshtkar-Jahromi, MD, MPH; Fiona Gaughran, MD; Arintaya Phrommintikul, MD; Andrzej Ciszewski, MD; Hossein Vakili, MD; Elaine B. Hoffman, PhD; Michael E. Farkouh, MD, MSc, FRCPC; Christopher P. Cannon, MD

IMPORTANCE Among nontraditional cardiovascular risk factors, recent influenzalike infection is associated with fatal and nonfatal atherothrombotic events.

OBJECTIVES To determine if influenza vaccination is associated with prevention of cardiovascular events.

DATA SOURCES AND STUDY SELECTION A systematic review and meta-analysis of MEDLINE (1946-August 2013), EMBASE (1947-August 2013), and the Cochrane Library Central Register of Controlled Trials (inception-August 2013) for randomized clinical trials (RCTs) comparing influenza vaccine vs placebo or control in patients at high risk of cardiovascular disease, reporting cardiovascular outcomes either as efficacy or safety events.

DATA EXTRACTION AND SYNTHESIS Two investigators extracted data independently on trial design, baseline characteristics, outcomes, and safety events from published manuscripts and unpublished supplemental data. High-quality studies were considered those that described an appropriate method of randomization, allocation concealment, blinding, and completeness of follow-up.

MAIN OUTCOMES AND MEASURES Random-effects Mantel-Haenszel risk ratios (RRs) and 95% CIs were derived for composite cardiovascular events, cardiovascular mortality, all-cause mortality, and individual cardiovascular events. Analyses were stratified by subgroups of patients with and without a history of acute coronary syndrome (ACS) within 1 year of randomization.

RESULTS Five published and 1 unpublished randomized clinical trials of 6735 patients (mean age, 67 years; 51.3% women; 36.2% with a cardiac history; mean follow-up time, 7.9 months) were included. Influenza vaccine was associated with a lower risk of composite cardiovascular events (2.9% vs 4.7%; RR, 0.64 [95% CI, 0.48-0.86], $P = .003$) in published trials. A treatment interaction was detected between patients with (RR, 0.45 [95% CI, 0.32-0.63]) and without (RR, 0.94 [95% CI, 0.55-1.61]) recent ACS (P for interaction = .02). Results were similar with the addition of unpublished data.

CONCLUSIONS AND RELEVANCE In a meta-analysis of RCTs, the use of influenza vaccine was associated with a lower risk of major adverse cardiovascular events. The greatest treatment effect was seen among the highest-risk patients with more active coronary disease. A large, adequately powered, multicenter trial is warranted to address these findings and assess individual cardiovascular end points.

JAMA. 2013;310(16):1711-1720. doi:10.1001/jama.2013.279206

← Editorial page 1681

+ Author Video Interview at jama.com

+ Supplemental content at jama.com

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Jacob A. Udell, MD, MPH, FRCPC, Women's College Research Institute, Women's College Hospital, University of Toronto, 76 Grenville St, Toronto, ON M5S-1B1, Canada (jay.udell@utoronto.ca).

Among nontraditional cardiovascular risk factors, there remains interest in a potential association between respiratory tract infections, of which influenza and influenza-like illnesses are common causes,^{1,2} and subsequent cardiovascular events.³⁻⁹ Prior studies suggest that seasonal influenza-like illnesses may explain a major determinant of the timing of acute thrombotic vascular events in patients with previously stable coronary artery disease (CAD) and cerebrovascular disease.³ Further supporting this hypothesis, several epidemiological studies have suggested a strong inverse longitudinal relationship between influenza vaccination and the risk of fatal and nonfatal cardiovascular events.^{4,10-19} A few small randomized clinical trials (RCTs) have explicitly tested whether influenza vaccination may reduce the risk of cardiovascular events with large treatment effects.²⁰⁻²⁴ Based largely on observational findings, medical association guidelines recommend universal vaccination in patients with, or at risk of, cardiovascular disease for protection from general influenza complications.²⁵⁻²⁷ Cardiovascular associations specifically recommended influenza vaccination for the secondary prevention of ischemic heart disease in 2006 based on the earliest reported RCT.²⁸⁻³¹ Because of the potential for confounding in an observational study of this subject³²⁻³⁴ and because prior meta-analyses included observational studies but omitted a systematic review of all influenza vaccination randomized trials,^{7,35,36} we set out to perform a systematic review and meta-analysis of all randomized clinical trials of influenza vaccine that studied cardiovascular events as efficacy or safety outcomes.

Methods

Study Research

A systematic literature search of Ovid MEDLINE (1946-August 2013), EMBASE (1947-August 2013), and the Cochrane Library Central Register of Controlled Trials (inception through August 2013) was conducted to identify all published randomized clinical trials involving humans and comparing influenza vaccination with placebo or standard care. The search used key terms including *influenza*, *influenza vaccine*, and *cardiovascular* (eMethods in the Supplement). The search was not restricted to any language. We subsequently searched and evaluated all reference lists of eligible articles, online resources such as cardiovascular and infectious disease conference abstracts from 2000 to 2013, and clinicaltrials.gov to ensure identification of all published and unpublished studies.

Study Selection, Data Extraction, and End Points

Two investigators (J.A.U. and R.Z.) identified and scrutinized studies independently for potential inclusion. Disagreements were resolved by consensus. Baseline characteristics, outcomes, and safety events were extracted from the published articles and confirmed by contacting the corresponding investigator of each selected trial (eMethods in the Supplement). An estimate of influenza virulence during each study period was also identified and categorized into levels of activity³⁷ by searching the open-access online databases of the

World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), and the WHO FluNet registry (available at www.who.int/fluNet; eTable 1 in the Supplement).³⁸

The primary end point of this analysis was a composite of major adverse cardiovascular events (ie, cardiovascular death or hospitalization for myocardial infarction, unstable angina, stroke, heart failure, or urgent coronary revascularization). The justification to select this composite primary end point was because eligible trials included such events as either a composite primary or secondary end point (efficacy trial) or as part of severe adverse event monitoring (safety trial) in each study (eTable 2 in the Supplement). If a composite end point was indeterminate, fatal and nonfatal myocardial infarction and stroke events were used. The secondary end point was cardiovascular mortality and other individual cardiovascular events. All events occurring within 12 months of follow-up were included.

Selection Criteria

We applied the following screening criteria to determine qualitative eligibility: randomized clinical trials of adults comparing experimental or commercially approved influenza vaccinations with either placebo, control, or a strategy of more intense vs standard vaccination; short-term efficacy (duration of follow-up, 28 days to 1 year); and a sample size of at least 50 patients. A strategy of a more intense vaccination included comparisons between standard-dose intramuscular vaccines with either a higher dose or higher concentration of intramuscular vaccine, a booster of standard vaccine among poor seroresponders, experimental virosomal vaccine with higher antigenicity, or concomitant intranasal vaccine vs similar placebo (eMethods in the Supplement).

Quality Assessment

The methodological quality of each trial was evaluated for risk of bias using standard criteria: method of randomization; allocation concealment; patient, investigator, and outcome assessor blinding; selective outcome reporting; incomplete outcome ascertainment; and other potential sources of bias as recommended by the Cochrane Collaboration.³⁹ Studies were categorized (Table) as high quality if at least the first 3 criteria were clearly described and accounted for, as low quality if any aspect of the first 3 criteria was unaccounted for, or as otherwise of uncertain risk of material bias. An alternative quality score for evaluating RCTs⁴⁹ was also applied with a score of 3 or greater indicative of high quality (Table).

Statistical Analysis

Data from each trial were entered on an intention-to-treat basis according to the recommendations of the Cochrane Collaboration and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.⁵⁰ Baseline characteristics were summarized, and weighted means and rates according to individual trial sample size were reported. Trials were compared with risk ratios (RRs) as the measure of effect, because accurate time-to-event data were not available in all trials. Summary RRs and 95% CIs were calculated using a random-effects model for combining results across

Table. Characteristics of Studies Included in the Meta-analysis

Source	Patient Cohort	Age, Mean (SD), y ^a	Women (%)	No. With Cardiac Disease (%)	Follow-up, Mean (Range), Mo	Control Therapy	No. in Control Cohort	Vaccine Therapy	No. in Intervention Cohort	Influenza Activity ^b	Trial Quality (Score) ^c	Region
Efficacy Trials: Influenza Vaccine vs Placebo/Control												
FLUVACS, ^{20,21} 2004	Inpatients with recent ACS or outpatients with stable CAD and planned PCI	65 (NR)	62 (31)	301 (100)	12 (1.0-12.0)	No treatment	147	IM TIV	145	Sporadic	Low (2)	Argentina
FLUCAD, ^{22,23} 2008	Outpatients with recent ACS or stable CAD with planned PCI	60 (10)	181 (27.5)	658 (100)	9.8 (0.1-12.2)	IM placebo	333	IM TIV	325	Regional	High (5)	Poland
IVCAD, ⁴⁰ 2009 ^d	Inpatients and outpatients with recent ACS or stable CAD	55 (NR)	90 (33.8)	266 (100)	12 (NR)	IM placebo	131	IM TIV	135	Unknown	Low (1)	Iran
Phrom-mintikul et al, ²⁴ 2011	Inpatients with recent ACS	66 (9)	193 (43.7)	439 (100)	11.8 (0.1-12.0)	No treatment	218	IM TIV	221	Sporadic and Widespread	Low (3)	Thailand
Safety Trials: Influenza Vaccine vs Placebo/Control												
Govaert et al, ⁴¹ 1994	Outpatients	67 (NR)	969 (52.7)	249 (13.5)	5.0 (2.5-5.0)	IM placebo	911	IM QIV	927	Regional	Uncertain (4)	the Netherlands
De Villiers et al, ⁴² 2009	Outpatients	70 (7)	1961 (60.5)	525 (16.2)	8.0 (0.1-8.0)	INL placebo	1622	INL LAIV	1620	Sporadic	High (5)	South Africa
Total		67 (7)	3456 (51.3)	2438 (36.2)	7.9		3362		3373			
Safety Trials: Experimental vs Standard Influenza Vaccine												
Jackson et al, ⁴³ 1999	Outpatients	70 (3)	65 (32.5)	129 (64.5)	1.0 (1.0)	IM TIV plus INL placebo	100	IM TIV and INL LAIV	100	Sporadic	High (4)	United States
De Bruijn et al, ⁴⁴ 2005	Outpatients	52 (NR)	205 (53.7)	203 (53.1)	6.0 (NR)	Standard IM TIV	126	Virosomal IM TIV	256	Sporadic	Low (2)	the Netherlands
FEVER, ⁴⁵ 2007	Outpatients	83 (9)	184 (66.9)	46 (16.7)	8.0 (4.0-9.0)	Standard IM TIV	142	Booster IM TIV	133	Regional	Low (3)	UK
Falsey et al, ⁴⁶ 2009	Outpatients	73 (6)	2008 (52.3)	523 (13.6) ^e	6.0 (NR)	Standard IM TIV	1260	High-Dose IM TIV	2573	Regional	High (5)	United States
Forrest, et al, ⁴⁷ 2011	Outpatients	69 (7)	1871 (62.2)	1908 (63.4)	8.0 (0.1-8.0)	Standard IM TIV	1501	INL LAIV	1508	Sporadic	Low (3)	South Africa
Diaz-Granados, ⁴⁸ et al 2013	Outpatients	73 (6)	4915 (53.7)	2200 (24.0)	6.0 (NR)	Standard IM TIV	3050	High-Dose IM TIV	6108	Widespread	High (5)	United States
Total		72 (7)	9248 (55.8)	5009 (30.2)	6.9		6179		10 678			

Abbreviations: ACS, acute coronary syndrome; CAD, coronary artery disease; INL, intranasal; IM, intramuscular; LAIV, live attenuated influenza vaccine; NR, not reported; PCI, percutaneous coronary intervention; TIV, trivalent, inactivated influenza vaccine; QIV, quadrivalent, inactivated influenza vaccine.

^a Some cells are without SD due to the mean data derived from distribution of participants within age categories or group means being reported without SD.

^b Levels of influenza activity according to the Centers for Disease Control and Prevention and World Health Organization reports were categorized as (1) no activity; (2) sporadic: isolated laboratory-confirmed influenza cases or a laboratory-confirmed outbreak in 1 institution, with no increase in activity; (3) local: increased incidence of influenzalike illness (ILI), or less than 1 institutional outbreak of ILI or laboratory-confirmed influenza in 1 region with recent laboratory evidence of influenza in that region; virus activity no greater than sporadic in other regions; (4) regional: outbreaks of ILI or laboratory-confirmed influenza in more than 1 region with a combined

population of less than 50% of the state's total population; and (5) widespread: outbreaks of ILI or laboratory-confirmed influenza in more than 50% of the regions in the state.

^c Trial quality was determined as high quality by the Cochrane criteria if at least the first 3 criteria were accounted for, low quality if any aspect of the first 3 criteria was unaccounted for, or otherwise of uncertain risk of material bias. Trial scores were graded as high quality by the Jadad score criteria if the quality of reporting of the aforementioned criteria provided a score of 3 or greater. If the score was less than 3, the trial was considered low quality. Risk of bias was evaluated by the method of randomization; allocation concealment; double-blinding; outcome reporting and ascertainment; and other sources.

^d Unpublished.

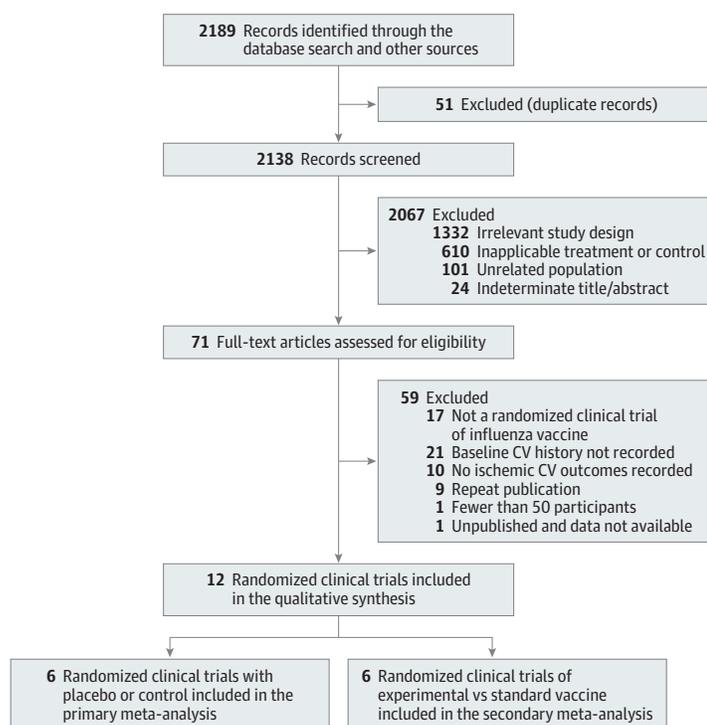
^e Represents past history of coronary artery disease only.

studies, which incorporates between- and within-study variance. A random-effects model was selected because heterogeneity among patient characteristics and vaccination efficacy would unlikely result in a similar treatment effect across trials.⁵¹ If an outcome of interest achieved pooled statistical

significance, then the number needed to treat (NNT) and its 95% CI to avoid 1 event was derived from the inverse of the pooled estimated absolute-risk difference and SE.

Primary analyses focused on published trials comparing influenza vaccination with either placebo or control. When data

Figure 1. Study Flow Diagram



CV indicates cardiovascular.

were available, analyses were further stratified by patients with and without recent acute coronary syndrome (ACS) within 1 year of randomization. We focused on such patients because of the seemingly greater effect size seen in the randomized trials and the pathobiology in which a greater effect might be anticipated in these patients with more active coronary disease. Secondary analyses included published and unpublished trials. We further analyzed trials of more intense vs standard influenza vaccination to explore the consistency of association of more immune activation against influenza with cardiovascular risk.

When no events were observed within a treatment group, a 0.5 correction factor was added to all values of that end point for calculation of the RR and its variance.^{52,53} To determine whether there was heterogeneity between individual trials, we assessed the *Q* statistic (a weighted index of effect estimate differences across studies assuming a χ^2 distribution) and *I*² statistic ($[Q - df]/Q \times 100$). Because the *I*² value quantifies heterogeneity on a scale of 0% to 100% and represents the extent of inconsistency among trial results rather than a sampling error independent of the number of studies, an *I*² of 75% or greater was considered representative of high heterogeneity.⁵⁴ To assess for publication bias risk, funnel plots (precision [inverse of SE] vs logarithmic RR) were evaluated. Further statistical tests for funnel plot asymmetry were not conducted given the limited specificity and power of these tests when fewer than 10 studies are included in a primary meta-analysis.⁵⁵

Sensitivity Analysis

To test for heterogeneity among published and unpublished trials, sensitivity analyses examining the robustness of the re-

sults were explored by comparing random-effects results with both fixed-effects and Yusuf-Peto models. This was achieved by adding unpublished trial results to the pooled effect estimate, and then sequentially removing each study result from the pooled effect estimate. Heterogeneity among preplanned subgroups was further explored in patients with and without recent ACS, by trial quality, trial duration, sample size, use of placebo, circulating influenza activity, and intention to study cardiovascular efficacy or safety. Interaction terms representing these categories were tested for differences in treatment effect between subgroups.⁵⁶

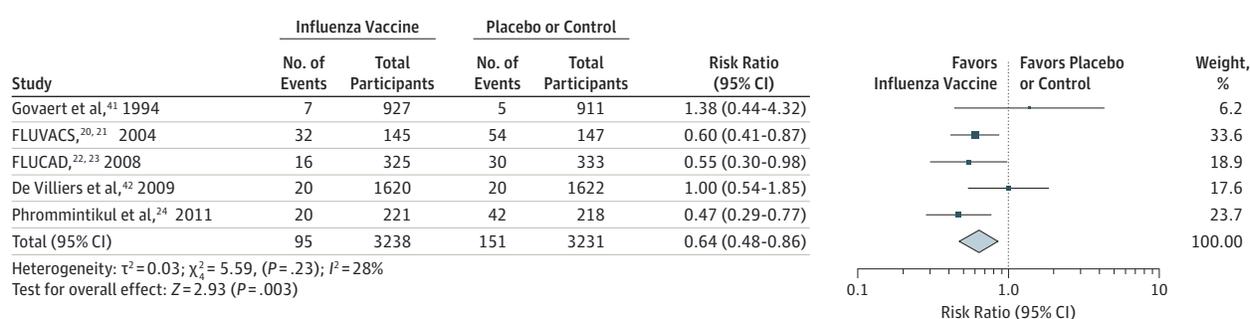
Two-sided *P* values were calculated with a *P* value less than .05 considered significant for all tests. Statistical analyses were performed with Review Manager (RevMan; Cochrane Collaboration), version 5.2.3.

Results

Baseline Characteristics

We screened 2189 articles for eligibility and identified 71 potentially relevant studies for further review. After excluding 59 studies, a total of 12 RCTs met our inclusion criteria for final meta-analysis (Figure 1).^{21,23,24,40-48} Among the 6 placebo or control RCTs, 1753 patients were randomly assigned to receive 1 intramuscular injection of standard influenza vaccination, 1620 to receive a live, intranasal attenuated vaccine, 1375 to receive intramuscular placebo, 1622 to receive intranasal placebo, and 365 to receive no treatment. Five trials were previously published,^{21,23,24,41,42} and 1 trial is unpublished.⁴⁰ These trials were included in the final meta-analysis of influenza vac-

Figure 2. Major Adverse Cardiovascular Events Comparing Influenza Vaccine vs Control



FLUCAD indicates FLU Vaccination Coronary Artery Disease; FLUVACS, FLU Vaccination Acute Coronary Syndromes. Square data markers represent risk ratios (RRs); horizontal lines, the 95% CIs with marker size reflecting the

statistical weight of the study using random-effects meta-analysis. A diamond data marker represents the overall RR and 95% CI for the outcome of interest. Evaluated using the random-effects Mantel-Haenszel test.

cine vs placebo or control and their characteristics are summarized in the Table. Overall, 6735 participants (mean age, 67 years; 51.3% women; 36.2% with a cardiac history) were followed up for a mean duration of 7.9 months. An additional 6 trials comprising 16 857 patients (mean age, 72 years; 55.8% women; 30.2% with cardiac history) randomized to various strategies of experimental ($n = 6179$) vs standard ($n = 10 678$) influenza vaccination for a mean duration of 6.9 months are described in the Table.

Among the 12 trials, 5 were conducted with rigorous randomization, allocation concealment, and double-blinding that met the Cochrane criteria for high quality (low risk of bias; Table and eFigure 1 in the Supplement). Allowing inclusion of single-blinded designs resulted in 4 more trials graded as high quality (eTable 3 in the Supplement). The remaining studies were considered low or uncertain quality. Definitions of cardiovascular outcomes were reported or provided by each efficacy trial, followed standardized cardiovascular guideline diagnostic criteria, and were generally comparable across trials. Outcome assessment varied by frequency, type of follow-up (including telephone, hospital or clinic, and home visit contact), and adjudication across trials.

Major Adverse Cardiovascular Events

For the 5 published RCTs comparing influenza vaccine with placebo or control, individual and pooled RRs for composite cardiovascular events are provided in Figure 2. Among the 3238 patients treated with influenza vaccine, 95 patients (2.9%) developed a major adverse cardiovascular event compared with 151 of the 3231 patients (4.7%) treated with placebo or control within 1 year of follow-up (RR, 0.64 [95% CI, 0.48-0.86]; $P = .003$; $I^2 = 28\%$; Figure 2). This association represented an absolute risk difference of 1.74% (95% CI, 0.81%-2.67%; $P = .003$) or an NNT of 58 (95% CI, 38-124) to prevent 1 major adverse cardiovascular event. The addition of the unpublished data did not materially change the results (2.9% influenza vaccine vs 4.6% placebo or control; RR, 0.64 [95% CI, 0.49-0.84]; $P = .001$; eFigure 2 in the Supplement).

In a subgroup analysis of 3 RCTs of patients with CAD, there was a significant interaction between the association of influenza vaccine and cardiovascular risk among patient cohorts

with and without recent ACS (P for interaction = .02; Figure 3). Influenza vaccine was particularly associated with a lower risk of major adverse cardiovascular events among patients with a history of recent ACS (10.25% influenza vaccine vs 23.1% placebo or control; RR, 0.45 [95% CI, 0.32-0.63]; $P < .001$; $I^2 = 0\%$) than patients with stable CAD (6.9% influenza vaccine vs 7.4% placebo or control; RR, 0.94 [95% CI, 0.55-1.61]; $P = .81$; $I^2 = 0\%$). Among the 789 patients with a history of recent ACS, the absolute-risk difference of influenza vaccine vs placebo or control was 12.9% (95% CI, 7.75%-18.0%; $P < .001$) or an NNT of 8 (95% CI, 6-13) to prevent 1 cardiovascular event. Results were similar with the addition of unpublished data (P for interaction = .03; eFigure 3 in the Supplement).

Cardiovascular Mortality and All-Cause Mortality

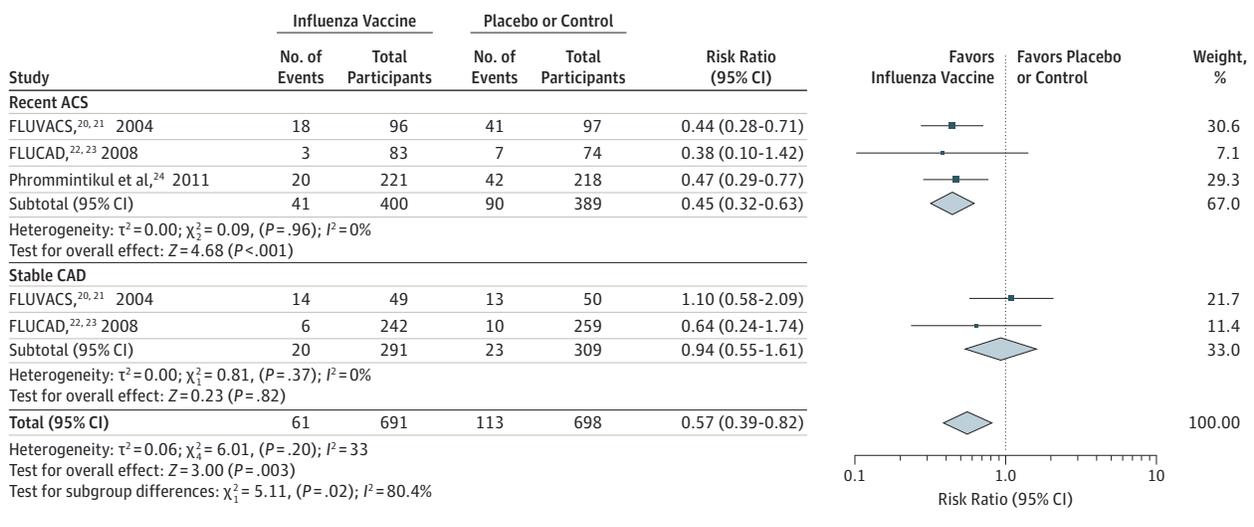
In the 5 published RCTs comparing influenza vaccine with placebo or control that recorded fatal cardiovascular events, 42 of 3238 patients (1.3%) died of cardiovascular causes within 1 year of being treated with influenza vaccine compared with 55 of 3231 patients (1.7%) treated with placebo or control (RR, 0.81 [95% CI, 0.36-1.83]; $P = .61$; $I^2 = 68\%$; Figure 4). Subgroup analysis in trials in which data were available demonstrated no significant interaction with a recent history of ACS (2.5% influenza vaccine vs 8.4% placebo or control; RR, 0.34 [95% CI, 0.13-0.85]) compared with patients with stable CAD (2.1% influenza vaccine vs 2.3% placebo or control; RR, 0.90 [95% CI, 0.31-2.59]; P for interaction = .17; eFigure 4 in the Supplement). Results were similar with the addition of unpublished data for cardiovascular mortality overall (eFigure 5 in the Supplement) and by history of ACS (eFigure 6 in the Supplement).

The majority of deaths observed across all 6 trials (including published and unpublished data) were considered due to a cardiovascular cause. Consequently, results were similar when influenza vaccine was compared with placebo or control for all-cause mortality (1.9% influenza vaccine vs 2.1% placebo or control; RR, 0.85 [95% CI, 0.45-1.61]; $P = .62$; $I^2 = 61\%$; eFigure 7 in the Supplement).

Other Cardiovascular Events and Active Control Trials

Individual nonfatal cardiovascular events, including myocardial infarction, stroke, heart failure, hospitalization for un-

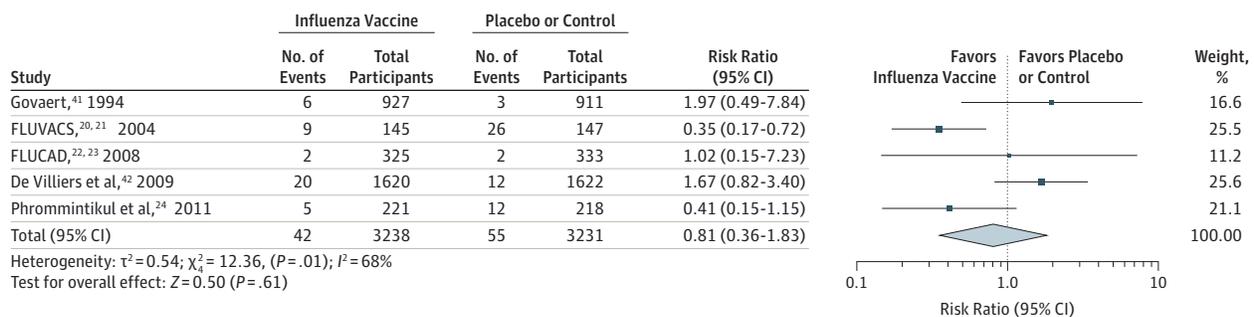
Figure 3. Major Adverse Cardiovascular Events Comparing Influenza Vaccine vs Control Stratified by Timing of Acute Coronary Syndrome



ACS indicates acute coronary syndrome; FLUCAD, FLU Vaccination Coronary Artery Disease; FLUVACS, FLU Vaccination Acute Coronary Syndromes. Square data markers represent risk ratios (RRs); horizontal lines, the 95% CIs with marker size reflecting the statistical weight of the study using random-effects

meta-analysis. Diamond data markers represent each subgroup and overall RR and 95% CI for the outcome of interest. Evaluated using the random-effects Mantel-Haenszel test.

Figure 4. Cardiovascular Mortality Comparing Influenza Vaccine vs Control



FLUCAD indicates FLU Vaccination Coronary Artery Disease; FLUVACS, FLU Vaccination Acute Coronary Syndromes; IVCAD, Influenza Vaccine for Coronary Artery Disease. Square data markers represent risk ratios (RRs); horizontal lines, the 95% CIs with marker size reflecting the statistical weight of the study using

random-effects meta-analysis. A diamond data marker represents the overall RR and 95% CI for the outcome of interest. Evaluated using the random-effects Mantel-Haenszel test.

stable angina or cardiac ischemia, and urgent coronary revascularization occurred infrequently and were not universally recorded across all 6 trials. None of these individual nonfatal cardiovascular events were statistically significant (eFigures 8-12 in the Supplement). In the 6 active control trials, 42 of 10 678 patients (0.39%) developed a major adverse cardiovascular event with more potent vaccine compared with 37 of 6179 patients (0.60%) treated with standard vaccine (RR, 0.72 [95% CI, 0.42-1.13]; $P = .16$; $I^2 = 0\%$; eFigure 13 in the Supplement).

Sensitivity Analyses

No significant heterogeneity was detected for either the primary or any secondary end points. Visual inspection of funnel plots suggested no evidence of publication bias (eFigures 14-16 in the Supplement). Results for the primary end point were similar when analyses were compared with fixed-

effects or Yusuf-Peto models and remained significant after removal of any trial from the pooled result (eTable 4 in the Supplement). In addition, there was no significant difference in the cardiovascular risk associated with influenza vaccine among other subgroups, level of influenza activity, or duration of follow-up (all P for interaction values $\geq .14$), except for the comparison of trials recording efficacy or safety events (P for interaction = .03; eTable 5 in the Supplement).

Discussion

In our meta-analysis of 6735 patients with varying degrees of cardiovascular risk, influenza vaccination was associated with a significantly lower risk of major adverse cardiovascular events. The risk associated with influenza vaccination was ro-

bust, with a greater association seen among patients with recent ACS compared with patients with stable CAD.

Influenza and Cardiovascular Risk

Although acute influenza infection is an independent risk factor for fatal and nonfatal cardiovascular events, the mechanism underlying that risk is less clear, but may relate to triggering the rupture of a vulnerable atherosclerotic plaque, fluid overload heart failure, myocarditis, arrhythmia, or the susceptibility of a frail and vulnerable patient.^{4,7,9,57,58} Several observational studies support a potential association between the proximity of an acute respiratory infection and an increased risk of acute cardiac and cerebrovascular events.^{3,4,8,15} Whether influenza vaccination can prevent these events remains controversial.⁵⁹ As we reviewed the literature, there appeared to be a considerable amount of evidence supporting an association between influenza vaccination and a lower risk of major clinical outcomes, such as cardiovascular mortality or nonfatal cardiovascular events, based on case-control, case-series, cohort studies, and limited prior reviews of RCTs with inherent potential for confounding and bias.^{4,7,10-19,32-36} This may explain in part why less than a third of the general population in North America and less than half of high-risk patients annually consent to influenza vaccination.⁶⁰⁻⁶⁴ Nevertheless, influenza is one of the most common, contagious, and morbid respiratory infections with a seasonal pattern of affliction during winter climate.^{19,65} Several seasonal influenza vaccines are manufactured annually and universally provided with the dual goal of decreasing viral transmission and preventing influenza-related morbidity and mortality.^{27,64} If severe influenza-associated morbidity and mortality is in part due to acutely triggered ischemic cardiovascular events, and a vaccine preventing influenza could decrease the risk of cardiovascular events, then this therapy could address a sizable component of residual cardiovascular risk not addressed by current therapy and provide yearlong coverage through 1 simple inoculation.

Randomized Studies of Influenza Vaccine and Cardiovascular Risk

There has been no large, adequately powered multicenter RCT testing influenza vaccination for the prevention of cardiovascular events. Several small RCTs have been conducted that either explicitly tested whether influenza vaccine compared with placebo or control may reduce cardiovascular events or carefully reported adverse events within trials of influenza vaccine for other purposes that can inform clinical practice.^{20-24,40-48} Four of the 6 trials explicitly tested the cardiovascular benefit hypothesis. The FLU Vaccination Acute Coronary Syndromes (FLU-VACS) trial was the first to report on 301 patients with stable CAD and myocardial infarction randomized in a single-blind manner in Argentina to either influenza vaccine or no therapy.^{20,21} Vaccination reduced the RR of the primary end point of cardiovascular death and the secondary composite outcome of cardiovascular death, myocardial infarction, or unstable angina requiring coronary revascularization, which was modestly attenuated over time but remained robust at 1 year.²¹ Two subsequent single-center trials studied patients with stable CAD.

The Influenza Vaccination in Secondary Prevention From Coronary Ischemic Events in Coronary Artery Disease (FLUCAD) study, which randomized 658 patients in a double-blind fashion after angiography to influenza vaccine or placebo from 2004 through 2005 in Poland,^{22,23} demonstrated no effect on the primary end point of cardiovascular death but a nonstatistically significant reduction in the secondary composite outcome of cardiovascular death, myocardial infarction, coronary revascularization, or cardiac ischemia driven primarily in patients with recent ACS. The Efficacy of Influenza Vaccine in Reducing Cardiovascular Events in Patients With Coronary Artery Diseases (IVCAD) study is an unpublished single-center, single-blind, 1-year outcomes trial that demonstrated no reduction in cardiovascular death or myocardial infarction in 266 randomized patients during the 2007-2008 influenza season in Iran.⁴⁰ A fourth trial of 439 patients with recent ACS without a history of prior influenza vaccination was conducted in Thailand from 2007 to 2009.²⁴ Patients were openly randomized before hospital discharge to receive influenza vaccination or routine care with a 1-year blinded end point ascertainment. The composite primary end point of cardiovascular death, myocardial infarction, unstable angina, heart failure, or stroke was significantly reduced in vaccinated patients.²⁴ Although levels of traditional influenza activity were low during this period, there was a well-publicized outbreak of a pandemic influenza A(H1N1) pdm09 virus in the latter half of the trial that had an uncertain influence on participants.⁶⁶ The inability to demonstrate a reduction in fatal events within the 2 trials that studied patients with relatively stable CAD, FLUCAD and IVCAD, may have been a result of studying a patient population with low absolute rates of subsequent fatal cardiovascular events.^{22,23}

Several other RCTs of influenza vaccination recorded cardiovascular events as part of a safety evaluation throughout the past 20 years. However, in these trials it is likely that both the relative lower proportion of participants studied with acute coronary disease and the potential for selective outcome ascertainment of cardiovascular events contributed to why these studies added relatively few cardiovascular events to our analysis.⁴¹⁻⁴⁸ Still, despite differences in trial designs, risk of bias, sample size, cardiovascular risk of participants, circulating influenza activity, vaccination strategy, duration of follow-up, and number of observed events, our meta-analysis demonstrated a consistent association between influenza vaccination and a lower risk of cardiovascular events.

When results across trials were stratified by whether treated patients had a recent ACS, influenza vaccination was associated with the lowest risk of cardiovascular events in patients with the highest risk.⁵⁹ Our findings provide some support for current guideline recommendations for influenza vaccination of patients with ACS.²⁹⁻³¹

Quality of Evidence and Limitations

Overall, our findings are based on a relatively small number of cardiovascular events (246 major adverse cardiovascular events and 97 cardiovascular deaths) among trials that varied in study design, intended primary outcomes, and patient populations. Subsequently, individual outcome analyses were of limited power. Moreover, several studies have design concerns re-

garding bias from inadequate randomization, concealment, and end point adjudication, which may limit our interpretation of the association of influenza vaccination with a lower risk of cardiovascular events.³⁵ For instance, a significant difference in the cardiovascular risk associated with influenza vaccine compared with placebo was detected among the subgroup of trials recording events as primary (efficacy) compared with secondary (safety) end points. This finding could suggest heterogeneity in outcome ascertainment between trials; however, it should be considered in context of multiple testing and chance of type I error. In addition, events such as unstable angina, cardiac ischemia, and coronary revascularization events included in a composite primary end point with myocardial infarction or cardiovascular death may not represent equal weighting of cardiovascular morbidity. Finally, our meta-analysis comprised a mix of both primary and secondary prevention populations, challenging our ability to distinguish the association of influenza vaccine with lower cardiovascular risk in each group.

The strengths of the current study include efforts to identify and systematically review all influenza vaccine RCTs since the inception of major biomedical literature databases, thereby limiting the likelihood of publication bias and risk of confounding from nonrandomized studies. In addition, we performed a number of sensitivity analyses that revealed no suggestion of inconsistency among trial results or missing data confirming the robustness of our primary results. In fact, funnel plots suggest potential small trials of cardiovascular benefit may remain unpublished.

Clinical and Policy Implications

The widespread influenza activity of 2012-2013 was a strong reminder of the potential cardiovascular complications that may occur in association with a severe respiratory tract infection.⁶⁷ Greater attention to prevention of cardiovascular events is therefore imperative to address the specific pathophysiology underlying this complication, particularly in elderly patients. Influenza vaccination may prevent cardiovascular events via avoidance of atherosclerotic plaque rupture or other forms of cardiac injury in a vulnerable patient and represents a simple once-annual protective therapy to reduce cardiovascular events. This finding has considerable clinical and health policy importance, given the profound underuse of vaccination among the general public and the potential impact this preventive strategy may have on high-risk patients.^{60,61}

Conclusion

Within this global meta-analysis of RCTs that studied patients with high cardiovascular risk, influenza vaccination was associated with a lower risk of major adverse cardiovascular events within 1 year. Influenza vaccination was particularly associated with cardiovascular prevention in patients with recent ACS. Future research with an adequately powered multicenter trial to confirm the efficacy of this low-cost, annual, safe, easily administered, and well-tolerated therapy to reduce cardiovascular risk beyond current therapies is warranted.

ARTICLE INFORMATION

Author Affiliations: Women's College Research Institute and Cardiovascular Division, Department of Medicine, Women's College Hospital, University of Toronto, Toronto, Ontario, Canada (Udell); Medical University of the Americas, Nevis, West Indies (Zawi); VA Boston Healthcare System, Harvard Medical School, Boston, Massachusetts (Bhatt); Cardiovascular Division, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts (Bhatt, Hoffman, Cannon); Clinical Research and Development Center, Shahid Modarres Medical Center, Infectious Diseases and Tropical Medicine Research Center, Shahid Beheshti University (MC), Tehran, Iran (Keshtkar-Jahromi); Division of Infectious Disease, Department of Medicine, Pennsylvania State University School of Medicine, Hershey (Keshtkar-Jahromi); Institute of Psychiatry, King's College London, London, United Kingdom (Gaughran); South London and Maudsley National Health Service Foundation Trust, London, United Kingdom (Gaughran); Department of Internal Medicine, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand (Phrommintikul); Institute of Cardiology, Warsaw, Poland (Ciszewski); Cardiovascular Research Center, Shahid Modarres Medical Center, Shahid Beheshti University (MC), Tehran, Iran (Vakili); Peter Munk Cardiac Centre, University Health Network, Heart and Stroke Richard Lewar Centre of Excellence in Cardiovascular Research, University of Toronto, Toronto, Ontario, Canada (Farkouh).

Author Contributions: Dr Udell had full access to all of the data in the study and takes responsibility

for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Udell, Bhatt, Farkouh, Cannon.

Acquisition of data: Udell, Zawi, Keshtkar-Jahromi, Gaughran, Phrommintikul, Ciszewski, Vakili.

Analysis and interpretation of data: Udell, Bhatt, Keshtkar-Jahromi, Ciszewski, Vakili, Hoffman, Farkouh, Cannon.

Drafting of the manuscript: Udell.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Udell, Keshtkar-Jahromi, Ciszewski, Vakili, Hoffman.

Administrative, technical, or material support: Udell, Zawi, Gaughran, Cannon.

Study supervision: Bhatt, Cannon.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Bhatt reports serving on the advisory board for Elsevier Practice Update Cardiology, Medscape Cardiology, and Regado Biosciences; serving on the board of directors for Boston VA Research Institute and the Society of Cardiovascular Patient Care; serving as chair for the American Heart Association Get With The Guidelines steering committee; receiving honoraria from the American College of Cardiology, Belvoir Publications, Duke Clinical Research Institute, Population Health Research Institute, Slack Publications, and WebMD; serving as a senior associate editor for the *Journal of Invasive Cardiology*; serving on data monitoring committees for Duke Clinical Research Institute,

Harvard Clinical Research Institute, Mayo Clinic, and the Population Health Research Institute; receiving grant funding from Amarin, AstraZeneca, Bristol-Myers Squibb, Eisai, Ethicon, Medtronic, sanofi-aventis, and The Medicines Company; and conducting research for FlowCo, PLx Pharma, and Takeda. Dr Gaughran reports receiving grant funding from Guys and St Thomas' Charitable Trustees and Abbott; receiving honoraria from various pharmaceutical companies for advisory, consultation or lecturing work in the field of mental health, including Bristol-Myers Squibb, Lundbeck, Roche, and Sunovion; and having a family member with professional affiliations to Eli Lilly and GlaxoSmithKline. Dr Vakili reports receiving grant funding from Shahid Beheshti University. Dr Farkouh reports consulting for AstraZeneca, Eli Lilly, Pfizer, sanofi-aventis; and receiving grant funding from Merck. Dr Cannon reports serving on a data safety and monitoring board for a trial sponsored by Merck; consulting for Alnylam, Bristol-Myers Squibb, CSL Behring, Lipimedix, and Pfizer; serving as clinical advisor and equity shareholder for Automedics Medical Systems; receiving grant funding from Accumetrics, AstraZeneca, Essentialis, GlaxoSmithKline, Merck, Regeneron, sanofi-aventis, and Takeda; and receiving reimbursement for travel accommodations from AstraZeneca, GlaxoSmithKline, Merck, Regeneron, sanofi-aventis, and Takeda. No other disclosures were reported.

Funding/Sponsor: Dr Udell is supported by a Canadian Institutes for Health Research and

Canadian Foundation for Women's Health postdoctoral research fellowship award.

Role of the Sponsor: The Canadian Institutes for Health Research and the Canadian Foundation for Women's Health had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: We thank Mona Frantzke, MLSc (Health Sciences Library, Women's College Hospital), for providing assistance in the literature search; Jos Nauta, MSc (Abbott), for providing unpublished data from the trial by de Bruijn et al; Carlos A. DiazGranados, MD, MSc (Sanofi Pasteur), for providing unpublished data from the trials by Falsey et al and DiazGranados et al; Rob Lambkin-Williams, PhD (Retroscreen Virology), for providing unpublished data from the FEVER trial; and Herve Caspard, MD, ScD (MedImmune), and Bruce D. Forrest, MD, MBA (B D Forrest & Company), for providing unpublished data from the trials by De Villiers et al and Forrest et al. No compensation was received by any individual for assistance with this study.

REFERENCES

- Lim WS, Macfarlane JT, Boswell TC, et al. Study of community acquired pneumonia aetiology (SCAPA) in adults admitted to hospital: implications for management guidelines. *Thorax*. 2001;56(4):296-301.
- Rubin MA, Ford LC, Gonzales R. Pharyngitis, sinusitis, otitis, and other upper respiratory tract infections. In: Longo DL, Fauci AS, Kasper DL, Hauser SL, Jameson JL, Loscalzo J, eds. *Harrison's Principles of Internal Medicine*. 18th ed. New York, NY: McGraw-Hill; 2012.
- Smeeth L, Thomas SL, Hall AJ, Hubbard R, Farrington P, Vallance P. Risk of myocardial infarction and stroke after acute infection or vaccination. *N Engl J Med*. 2004;351(25):2611-2618.
- Nichol KL, Margolis KL, Wuorenma J, Von Sternberg T. The efficacy and cost effectiveness of vaccination against influenza among elderly persons living in the community. *N Engl J Med*. 1994;331(12):778-784.
- Bainton D, Jones GR, Hole D. Influenza and ischaemic heart disease—a possible trigger for acute myocardial infarction? *Int J Epidemiol*. 1978;7(3):231-239.
- Madjid M, Aboshady I, Awan I, Litovsky S, Casscells SW. Influenza and cardiovascular disease: is there a causal relationship? *Tex Heart Inst J*. 2004;31(1):4-13.
- Warren-Gash C, Smeeth L, Hayward AC. Influenza as a trigger for acute myocardial infarction or death from cardiovascular disease: a systematic review. *Lancet Infect Dis*. 2009;9(10):601-610.
- Warren-Gash C, Bhaskaran K, Hayward A, et al. Circulating influenza virus, climatic factors, and acute myocardial infarction: a time series study in England and Wales and Hong Kong. *J Infect Dis*. 2011;203(12):1710-1718.
- Corrales-Medina VF, Musher DM, Shachkina S, Chirinos JA. Acute pneumonia and the cardiovascular system. *Lancet*. 2013;381(9865):496-505.
- Naghavi M, Barlas Z, Siadaty S, Naguib S, Madjid M, Casscells W. Association of influenza vaccination and reduced risk of recurrent myocardial infarction. *Circulation*. 2000;102(25):3039-3045.
- Siscovick DS, Raghunathan TE, Lin D, et al. Influenza vaccination and the risk of primary cardiac arrest. *Am J Epidemiol*. 2000;152(7):674-677.
- Lavallée P, Perchaud V, Gautier-Bertrand M, Grabli D, Amarenco P. Association between influenza vaccination and reduced risk of brain infarction. *Stroke*. 2002;33(2):513-518.
- Nichol KL, Nordin J, Mullooly J, Lask R, Fillbrandt K, Iwane M. Influenza vaccination and reduction in hospitalizations for cardiac disease and stroke among the elderly. *N Engl J Med*. 2003;348(14):1322-1332.
- Grau AJ, Fischer B, Barth C, Ling P, Lichy C, Bugge F. Influenza vaccination is associated with a reduced risk of stroke. *Stroke*. 2005;36(7):1501-1506.
- Madjid M, Miller CC, Zarubaev VV, et al. Influenza epidemics and acute respiratory disease activity are associated with a surge in autopsy-confirmed coronary heart disease death: results from 8 years of autopsies in 34 892 subjects. *Eur Heart J*. 2007;28(10):1205-1210.
- Nichol KL, Nordin JD, Nelson DB, Mullooly JP, Hak E. Effectiveness of influenza vaccine in the community-dwelling elderly. *N Engl J Med*. 2007;357(14):1373-1381.
- Hung IF, Leung AY, Chu DW, et al. Prevention of acute myocardial infarction and stroke among elderly persons by dual pneumococcal and influenza vaccination: a prospective cohort study. *Clin Infect Dis*. 2010;51(9):1007-1016.
- Siriwardena AN, Gwini SM, Coupland CA. Influenza vaccination, pneumococcal vaccination, and risk of acute myocardial infarction: matched case-control study. *CMAJ*. 2010;182(15):1617-1623.
- Macintyre CR, Heywood AE, Kovoor P, et al. Ischaemic heart disease, influenza, and influenza vaccination: a prospective case control study. *Heart*. 2013.
- Gurfinkel EP, de la Fuente RL, Mendiz O, Mautner B. Influenza vaccine pilot study in acute coronary syndromes and planned percutaneous coronary interventions: the FLU Vaccination Acute Coronary Syndromes (FLUVACS) Study. *Circulation*. 2002;105(18):2143-2147.
- Gurfinkel EP, Leon de la Fuente R, Mendiz O, Mautner B. Flu vaccination in acute coronary syndromes and planned percutaneous coronary interventions (FLUVACS) study. *Eur Heart J*. 2004;25(1):25-31.
- Ciszewski A, Bilinska ZT, Brydak LB, et al. Influenza vaccination in secondary prevention from coronary ischaemic events in coronary artery disease: FLUCAD study. *Eur Heart J*. 2008;29(11):1350-1358.
- Ciszewski A, Bilińska ZT, Kepka C, Kruk M, Księżycka-Majczyńska E, Rużyłło W. The protective effect of influenza vaccination on the clinical course of coronary disease in patients with acute coronary syndromes treated by primary PCI—a report from FLUCAD study. *Postępy w Kardiologii Interwencyjnej*. 2010;6(1):6-11. doi:10.5114/pwki.2010.13820.
- Phrommintikul A, Kuanprasert S, Wongcharoen W, Kanjanavanit R, Chaiwarith R, Sukonthasarn A. Influenza vaccination reduces cardiovascular events in patients with acute coronary syndrome. *Eur Heart J*. 2011;32(14):1730-1735.
- Harper SA, Fukuda K, Uyeki TM, Cox NJ, Bridges CB. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2005;54(RR-8):1-40.
- Goldstein LB, Bushnell CD, Adams RJ, et al. Guidelines for the primary prevention of stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2011;42(2):517-584.
- Advisory Committee on Immunization Practices. Recommended adult immunization schedule: United States, 2013. *Ann Intern Med*. 2013;158(3):191-199.
- Smith SC, Allen J, Blair SN, et al; AHA/ACC; National Heart, Lung, and Blood Institute. AHA/ACC Guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update. *Circulation*. 2006;113(19):2363-2372.
- Davis MM, Taubert K, Benin AL, et al; American Heart Association; American College of Cardiology. Influenza vaccination as secondary prevention for cardiovascular disease: a science advisory from the American Heart Association/American College of Cardiology. *Circulation*. 2006;114(14):1549-1553.
- Smith SC Jr, Benjamin EJ, Bonow RO, et al; World Heart Federation; Preventive Cardiovascular Nurses Association. AHA/ACC Secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: a guideline from the American Heart Association and American College of Cardiology Foundation. *Circulation*. 2011;124(22):2458-2473.
- Hamm CW, Bassand JP, Agewall S, et al; ESC Committee for Practice Guidelines. ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: the task force for the management of acute coronary syndromes (ACS) in patients presenting without persistent ST-segment elevation of the European Society of Cardiology (ESC). *Eur Heart J*. 2011;32(23):2999-3054.
- Hashim AB, McKeever T, Kelly SJ, Nguyen-Van-Tam JS. Evaluation of inter-pandemic influenza vaccine effectiveness during 8 consecutive winter seasons in England and Wales in patients with cardiovascular risk factors. *J Infect Public Health*. 2010;3(4):159-165.
- Eurich DT, Marrie TJ, Johnstone J, Majumdar SR. Mortality reduction with influenza vaccine in patients with pneumonia outside "flu" season: pleiotropic benefits or residual confounding? *Am J Respir Crit Care Med*. 2008;178(5):527-533.
- Johnstone J, Loeb M, Teo KK, et al; Ongoing Telmisartan Alone and in Combination With Ramipril Global End Point Trial (ONTARGET); Telmisartan Randomized Assessment Study in ACE Intolerant Subjects With Cardiovascular Disease (TRANSCEND) Investigators. Influenza vaccination and major adverse vascular events in high-risk patients. *Circulation*. 2012;126(3):278-286.
- Keller T, Weeda VB, van Dongen CJ, Levi M. Influenza vaccines for preventing coronary heart

- disease. *Cochrane Database Syst Rev*. 2008;(3):CD005050.
36. Loomba RS, Aggarwal S, Shah PH, Arora RR. Influenza vaccination and cardiovascular morbidity and mortality: analysis of 292 383 patients. *J Cardiovasc Pharmacol Ther*. 2012;17(3):277-283.
 37. Centers for Disease Control and Prevention. *Manual for the surveillance of vaccine-preventable diseases*. Atlanta, GA: Centers for Disease Control and Prevention; 2008.
 38. World Health Organization. Global atlas of infectious diseases. <http://gamapserver.who.int/globalatlas/home.asp>. Accessed September 19, 2013.
 39. Higgins JP, Altman DG, Gøtzsche PC, et al; Cochrane Bias Methods Group; Cochrane Statistical Methods Group. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ*. 2011;343:5928.
 40. Keshtkar-Jahromi M, Vakili H, Rahnavardi M, et al. The efficacy of influenza vaccination in reducing cardiovascular events in patients with coronary artery diseases: IVCAD study. *Clin Microbiol Infect*. 2009;15:395.
 41. Govaert TM, Thijs CT, Masurel N, Sprenger MJ, Dinant GJ, Knottnerus JA. The efficacy of influenza vaccination in elderly individuals: a randomized double-blind placebo-controlled trial. *JAMA*. 1994;272(21):1661-1665.
 42. De Villiers PJ, Steele AD, Hiemstra LA, et al; LAIV Elderly Study Trial Network. Efficacy and safety of a live attenuated influenza vaccine in adults 60 years of age and older. *Vaccine*. 2009;28(1):228-234.
 43. Jackson LA, Holmes SJ, Mendelman PM, Huggins L, Cho I, Rhorer J. Safety of a trivalent live attenuated intranasal influenza vaccine, FluMist, administered in addition to parenteral trivalent inactivated influenza vaccine to seniors with chronic medical conditions. *Vaccine*. 1999;17(15-16):1905-1909.
 44. de Bruijn IA, Nauta J, Cramer WC, Gerez L, Palache AM. Clinical experience with inactivated, virosomal influenza vaccine. *Vaccine*. 2005;23(suppl 1):39-49.
 45. Gaughran F, Walwyn R, Lambkin-Williams R, et al; Flu-Effect of Vaccine in Elderly Residents Trial team. Flu: effect of vaccine in elderly care home residents: a randomized trial. *J Am Geriatr Soc*. 2007;55(12):1912-1920.
 46. Falsey AR, Treanor JJ, Tornieporth N, Capellan J, Gorse GJ. Randomized, double-blind controlled phase 3 trial comparing the immunogenicity of high-dose and standard-dose influenza vaccine in adults 65 years of age and older. *J Infect Dis*. 2009;200(2):172-180.
 47. Forrest BD, Steele AD, Hiemstra L, Rappaport R, Ambrose CS, Gruber WC. A prospective, randomized, open-label trial comparing the safety and efficacy of trivalent live attenuated and inactivated influenza vaccines in adults 60 years of age and older. *Vaccine*. 2011;29(20):3633-3639.
 48. DiazGranados CA, Dunning AJ, Jordanov E, Landolfi V, Denis M, Talbot HK. High-dose trivalent influenza vaccine compared to standard dose vaccine in elderly adults: safety, immunogenicity and relative efficacy during the 2009-2010 season. *Vaccine*. 2013;31(6):861-866.
 49. Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials*. 1996;17(1):1-12.
 50. Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *BMJ*. 2009;339:2535.
 51. DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials*. 1986;7(3):177-188.
 52. Cox DR. The continuity correction. *Biometrika*. 1970;57(1):et al-219. doi: 10.1093/biomet/57.1.217.
 53. Friedrich JO, Adhikari NK, Beyene J. Inclusion of zero total event trials in meta-analyses maintains analytic consistency and incorporates all available data. *BMC Med Res Methodol*. 2007;7:5.
 54. Higgins JP, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Stat Med*. 2002;21(11):1539-1558.
 55. Sterne JA, Sutton AJ, Ioannidis JP, et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. *BMJ*. 2011;343:4002.
 56. Altman DG, Bland JM. Interaction revisited: the difference between 2 estimates. *BMJ*. 2003;326(7382):219.
 57. Bratincsák A, El-Said HG, Bradley JS, Shayan K, Grossfeld PD, Cannavino CR. Fulminant myocarditis associated with pandemic H1N1 influenza A virus in children. *J Am Coll Cardiol*. 2010;55(9):928-929.
 58. Muhammad S, Haasbach E, Kotchourko M, et al. Influenza virus infection aggravates stroke outcome. *Stroke*. 2011;42(3):783-791.
 59. Natarajan P, Cannon CP. Myocardial infarction vaccine? evidence supporting the influenza vaccine for secondary prevention. *Eur Heart J*. 2011;32(14):1701-1703.
 60. Ajani UA, Ford ES, Mokdad AH. Examining the coverage of influenza vaccination among people with cardiovascular disease in the United States. *Am Heart J*. 2005;149(2):254-259.
 61. Kwong JC, Rosella LC, Johansen H. Trends in influenza vaccination in Canada, 1996/1997 to 2005. *Health Rep*. 2007;18(4):9-19.
 62. Madjid M, Alfred A, Sahai A, Conyers JL, Casscells SW. Factors contributing to suboptimal vaccination against influenza: results of a nationwide telephone survey of persons with cardiovascular disease. *Tex Heart Inst J*. 2009;36(6):546-552.
 63. Williams WW, Lu PJ, Lindley MC, Kennedy ED, Singleton JA; Centers for Disease Control and Prevention. Influenza vaccination coverage among adults—National Health Interview Survey, United States, 2008-09 influenza season. *MMWR Morb Mortal Wkly Rep*. 2012;61(suppl):65-72.
 64. Talbot TR, Talbot HK. Influenza prevention update: examining common arguments against influenza vaccination. *JAMA*. 2013;309(9):881-882.
 65. Dolin R. Influenza. In: Longo DL, Fauci AS, Kasper DL, Hauser SL, Jameson JL, Loscalzo J, eds. *Harrison's Principles of Internal Medicine*. 18th ed. New York, NY: McGraw-Hill; 2012.
 66. Ungchusak K, Sawanpanyalert P, Hanchoworakul W, et al. Lessons learned from influenza A(H1N1)pdm09 pandemic response in Thailand. *Emerg Infect Dis*. 2012;18(7):1058-1064.
 67. Centers for Disease Control and Prevention. 2012-2013 Influenza Season Week 38 ending September 21, 2013. <http://www.cdc.gov/flu/weekly/>. Accessed September 28, 2013.