Key Question 2

What is the comparative effectiveness of 3DRT, IMRT, SBRT, and PBRT regarding tumor control and patient survival?

Key Question 3

Are there differences in comparative effectiveness of 3DRT, IMRT, SBRT, and PBRT for specific patient and tumor characteristics?

Key Question 4

Is there variation in comparative effectiveness of 3DRT, IMRT, SBRT, and PBRT because of differences in user experience, treatment planning, treatment delivery, and target volume delineation?

PICOTS (Population, Intervention, Comparator(s), Outcomes, Timing, Setting)

Identify for each key question:

Population(s)

KQs 1–4: Populations of interest include patients with head and neck cancer. To define what constitutes head and neck cancer, we consulted clinical resources such as the National Cancer Institute's Physician Data Query (PDQ) Cancer Information Summary and the National Comprehensive Cancer Network. The consensus definition of head and neck cancer includes tumors of:

1. larynx
2. pharynx (hypopharynx, oropharyx and nasopharynx)
3. lip and oral cavity
4. paranasal sinus and nasal cavity
5. salivary gland
6. occult primary of the head and neck

The following tumors are excluded:

1. brain tumors
2. skull base tumors
3. uveal/choroidal melanoma, other ocular and eyelid tumors
4. otologic tumors
5. cutaneous tumors of the head and neck (including melanoma)
6. thyroid cancer
7. parathyroid cancer
8. esophageal cancer
9. trachea tumors

All therapeutic strategies will be included. Radiotherapy (RT) can be delivered as primary (curative) intent therapy or as an adjunct to surgery. Chemotherapy can also be given as an adjunct to radiation therapy, particularly in patients with more advanced cancer (i.e., stages III or IV). We will seek direct evidence for one intervention compared to another, with or without chemotherapy or surgery.

Interventions

The primary interventions of interest in all therapeutic settings are:

1. 3 dimensional conformal radiotherapy (3DRT): Defined as any treatment plan where CT-based forward treatment planning is used to delineate radiation beams and target volumes in three dimensions
2. intensity modulated radiotherapy (IMRT): Defined as any treatment plan where intensity-modulated radiation beams and computerized inverse treatment planning is used
3. stereotactic body radiation therapy (SBRT): Defined as conformal RT (forward or reverse-planned) delivered in 3 to 5 relatively larger doses of ionizing radiation than typically delivered in a standard conformal schedule of 25–35 doses
4. proton beam radiotherapy (PBRT): Defined as any treatment plan where proton beam radiation is used

Interventions may occur as part of a multimodal treatment strategy if the comparisons only differ with respect to the radiation therapy given.

Comparators

All therapies will be compared to each other as part of a continuum of treatment for patients with head and neck cancer. Thus, we will include studies in which a RT method was compared to a different method, for example with or without chemotherapy or surgery. We will include all studies from which we can be reasonably certain additional treatments are contemporary and similar, leaving the major comparison that between RT modalities; those that we cannot ascertain from the publication will be excluded. To ensure chemotherapy or other treatments are similar and contemporary, we will consult accepted guidelines such as those from the National Comprehensive Cancer Network (NCCN) or National Cancer Institute (NCI). We will not extract details on chemotherapy dosages or schedules, but rather will ascertain their degree of general similarity and the proportions of patients who receive and complete such regimens. We will categorize and synthesize evidence according to overall treatment, for example concurrent chemoradiotherapy, or adjuvant radiotherapy, not mixing these in the strength of evidence synthesis.

Outcomes

KQ 1, 3 & 4:

1. Final outcomes: quality of life (QoL) and adverse events including; radiation induced toxicities, xerostomia, mucositis, taste changes, dental problems, and dysphagia.

2. Intermediate outcomes: Salivary flow, probability of completing treatment according to protocol.

We will search for evidence related to user experience, treatment planning, and target volume delineation within the context of KQ4. In the absence of an evidence-base on these measures, these issues will be addressed as appropriate in both the future research needs and discussion sections of the report.

Based on input received from the TEP, any outcomes not adequately addressed in the literature will be stated as evidence gaps for primary research in the future research needs section of the report.

KQ 2, 3 & 4:

1. Final outcomes: Overall survival and cancer specific survival.

2. Intermediate outcomes: Local control, and time to recurrence.

Timing

All durations of follow-up will be considered.

Settings

Inpatient and outpatient.

Dated: March 6, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–05389 Filed 3–11–14; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day 14–0787]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Personal Flotation Devices (PFDs) and Commercial Fishermen: Preconceptions and Evaluation in Actual Use—Reinstatement with Change (0920–0787,

expiration date 8/31/2010)—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH has the responsibility under Public Law 91–596 section 20 (Occupational Safety and Health Act of 1970) to conduct research relating to innovative methods, techniques, and approaches for dealing with occupational safety and health problems.

Commercial fishing is one of the most dangerous occupations in the United States, with a fatality rate 30 times higher than the national average. Most fishermen who die on the job drown subsequent to a vessel sinking (52%) or fall overboard (31%). Because drowning is the leading cause of death for commercial fishermen, its prevention is one of the highest priorities for those who work to make the industry safer.

The risk of drowning for commercial fisherman is high, yet most fishermen do not wear Personal Flotation Devices (PFDs) while on deck. Of the 182 fishermen who died from falls overboard between 2000 and 2011 none of them were wearing a personal flotation device (PFD). Many were within minutes of being rescued when they lost their strength and disappeared under the surface of the water.

NIOSH recently conducted a study to establish a baseline understanding of Alaska fishermen's perceptions of risk, safety attitudes, and beliefs about PFDs; and to evaluate a variety of modern PFDs with commercial fishermen to discover the features and qualities that they like and dislike. Based upon these results, NIOSH developed an intensive risk communication strategy to raise awareness to newer (potentially more satisfactory) PFD models, to address barriers, and to encourage increased PFD use among fishermen working in Alaska.

The purpose of this study is to first, determine if fishermen's perception of risk, safety attitudes, and beliefs about PFDs has shifted or remained the same since the implementation of the initial survey (2008–2009); and second, to evaluate the effectiveness of the NIOSH intensive risk communication intervention.

NIOSH is requesting OMB approval to administer a survey to fishermen operating in Alaska fisheries. This questionnaire will contain questions that measure fishermen's risk perceptions, safety attitudes, and beliefs about PFDs, as well as recognition and influence of NIOSH risk communication activities. The questionnaire will take approximately 20 minutes to complete. Consistent with the previous OMB-approved data collection protocol, the sample size was determined to be 400 total respondents to achieve a 95% confidence level. Two hundred independent respondents will be sampled just prior to the 2014 season and an additional two hundred will be sampled just prior to the 2015 season.

This study has the potential to greatly benefit the fishing industry. As a result of previous research, NIOSH has gained a baseline understanding of fishermen's reasons for not wearing PFDs. With this empirical data at hand, an intensive risk communication intervention has been developed to address fishermen's concerns and remove the barriers that are currently in place.

There are no costs to respondents other than their time. The total estimated annual burden hours are 134.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
Fishermen	2014 Fishing Season: Fishing for Facts: A survey of fishermen's opinions about the risk of falls overboard and PFDs.	200	1	20/60	67
Fishermen	2015 Fishing Season: Fishing for Facts: A survey of fishermen's opinions about the risk of falls overboard and PFDs.	200	1	20/60	67

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–05273 Filed 3–11–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Cooperative Research Agreements to the World Trade Center Health Program (U01) PAR 12–126, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Times and Dates:

8:00 a.m.–5:00 p.m., April 1, 2014 (Closed);

8:00 a.m.–12:00 p.m., April 2, 2014 (Closed).

Place: Atlanta Marriott Century Center, 2000 Century Boulevard NE., Atlanta, Georgia 30345, Telephone (404) 325–0000.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Cooperative Research Agreements Related to the World Trade Center Health Program (U01) PAR 12–126.''

Contact Person for More Information: Nina Turner, Ph.D., Scientific Review Officer, CDC/NIOSH, 1095 Willowdale Road, Mailstop G905, Morgantown, West Virginia 26505, Telephone: (304) 285–5975.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of