Multifaceted role of the registered nurse on an oral immunotherapy clinical team

Anne F. Russell, M.S., R.N.,[1,2] Abigail J. Tarr Cooke, M.S.N.-Ed.(c), R.N.,[3,4] Olga Kagan, Ph.D., R.N.,[5,6] and Elisabeth S. Stieb, B.S.N., R.N.[7]

ABSTRACT

Oral immunotherapy (OIT) emerged into clinical practice, and its delivery highlights the multifaceted expertise of registered nurses (RN) as central to allergy/immunology interprofessional collaborative teams. The allergist–RN model of clinical evidenced–based OIT provision is presented. RN competencies, role components, and intervention examples are included to assist RNs and allergists in maximizing RN capabilities. RNs' patient-centered focus, and the ability to evaluate and incorporate physical, psychological, and sociological patient aspects are assets to OIT teams. RNs can establish best practices, initiate scholarly inquiry, and disseminate new knowledge to interdisciplinary colleagues. RNs also implement allergist-prescribed standing protocols within their legal practice scope by using their clinical judgment during evaluation of a patient receiving OIT. The same RN may serve as a nurse clinician, patient and family educator, case manager, research collaborator, and OIT program manager. Allergy/immunology practices use diverse staffing models, which thus require adaptation of presented descriptions per clinical team needs and resources.

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Oral immunotherapy (OIT) is an elective noncurative therapy aimed at mitigating allergic reaction risk from trace exposures in patients with persistent diagnosed immunoglobulin E (IgE) mediated food allergy (FA) by increasing clinical tolerance through desensitization to the allergen dose threshold.[1–4] The standard treatment for immunoglobulin E–mediated FA is strict allergen avoidance and epinephrine administration to treat anaphylaxis.[5] However, the diagnosis is associated with lower quality of life (QoL) because hypervigilance to avoid ubiquitous food allergens and the threat of anaphylaxis negatively impacts patients and families socially, financially, emotionally, and physically.[6,7] OIT is an option for those patients selecting it after medical evaluation, OIT protocol education, therapy goal clarification, risk/benefit discussion, cost explanations, and other shared decision-making topics in consultation with allergists and allergy/immunology (A/I) team members to determine candidate suitability.[1,8]

OIT requires adequate staffing, space, equipment, medications, supplies, and prompt emergency medical services access.[4,9,10] Although diverse A/I staffing models exist, the example presented is allergist and A/I RN collaboration for allergist-supervised OIT. It is beyond this article's limits to describe multiple staffing models that involve varied scopes of practice that may also differ among states and countries based on laws, nurse practice acts, and regulations. Therefore, for this article, RN refers to nurses with a bachelor degree of science in nursing (RN/BSN) and/or an associate degree in nursing (RN/ADN) versus other nursing degrees. The presented model describes OIT RN roles, suggested competencies, and clinical activity examples. The same RN may serve as a nurse clinician, educator, patient advocate, case manager, research collaborator, and OIT program manager. RN roles and activity examples are described in the text, Fig. 1, and Tables 1 to 3, although these are not exhaustive listings. Descriptions require adaptation to individual practice setting needs.

There is scant literature that describes the RN's role in OIT and oral food challenges (OFC). Results of surveys indicate allergists not offering OIT would strongly consider doing so with sufficient staff.[11] Greiwe *et al.*[12]

From the [1]School of Nursing and Health Sciences, Spring Arbor University, Spring Arbor, Michigan; [2]Food Allergy and Anaphylaxis Michigan Association, Ann Arbor, Michigan; [3]Allergy and Asthma Associates, Durango, Colorado; [4]School of Nursing, Colorado State University-Pueblo, Pueblo, Colorado; [5]The Barbara H. Hagan School of Nursing and Health Sciences, Molloy College, Rockville Center, New York; [6]The City University of New York School of Professional Studies, New York, New York; and [7]Food Allergy Center, Massachusetts General Hospital for Children, Boston, Massachusetts

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Address correspondence to Anne F. Russell, M.S., R.N., School of Nursing and Health Sciences, Spring Arbor University, 106 E. Main St., Spring Arbor, Michigan 49283-9799

E-mail address: anne.russell@arbor.edu

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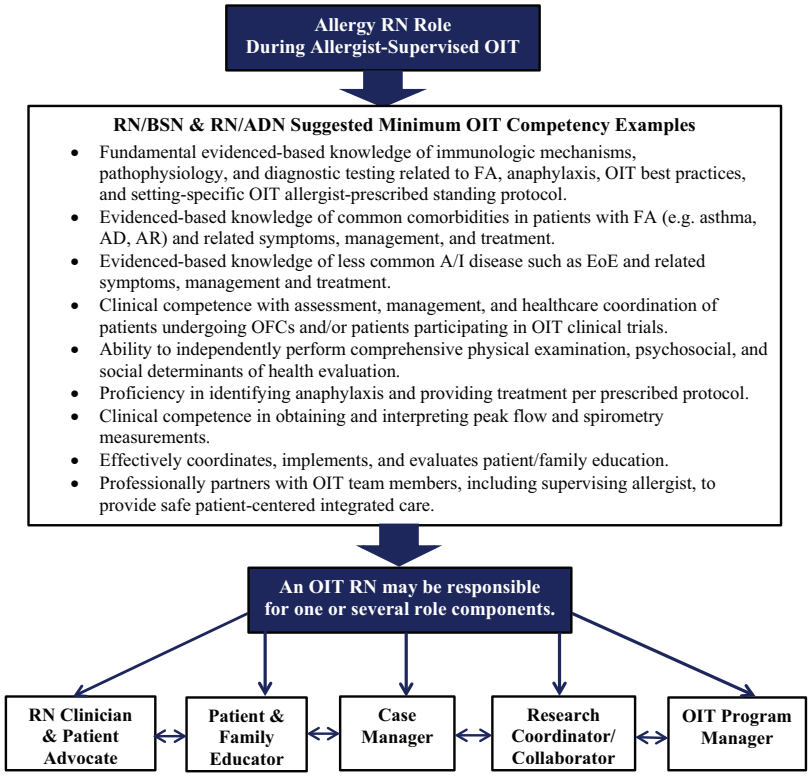

Figure 1. *Overview of OIT RN/BSN and RN/ADN suggested competencies and role examples. OIT = Oral immunotherapy; RN = registered nurse; BSN = bachelor of science in nursing; ADN = associate degree in nursing; A/I = allergy/immunology; AD = atopic dermatitis; AR = allergic rhinitis; EoE = eosinophilic esophagitis; FA = food allergy; OFC =oral food challenge. *Includes nine RN/BSN and RN/ADN minimum competencies for involvement in OIT provision and identifies several roles that nurses may execute; this is not an exhaustive list but rather examples to consider; the legal scope of practice for RNs may vary between states and countries.*

identified a higher prevalence of nurses involved in OFC preexamination, food administration, and progress monitoring compared with medical assistants, physician assistants, or nurse practitioners. This suggests that many A/I RNs are experienced in conducting allergist-supervised OFCs, which are valuable clinical skills for OIT.

OIT is a rigorous process that requires months of lengthy office visits and involves frequent RN assessment and interventions to promote patient safety. RNs may implement allergist-prescribed OIT standing protocols by using their clinical judgment during patient evaluation. The allergist may concurrently provide health care for other patients while overseeing OIT. This is analogous to health-care delivery in hospital settings (*e.g.,* acute care units) whereby RNs implement physician-prescribed protocols by using their clinical judgment during patient evaluations, thereby providing protocol-defined interventions when medically appropriate.[13–15]

RN PRACTICE SCOPE

RN practice scope must adhere to laws, state nurse practice acts, academic credentials, and nursing ethics code.[16–19] RN practice includes independent (*e.g.,* evaluates treatment response), dependent (*e.g.,* administers physician-prescribed medication), and interdependent (*e.g.,* appropriately implements physician-prescribed standardized procedures after patient evaluation) functions.[20] RNs are liaisons between patients and their families and physicians by optimizing communication, obtaining informed consent, ensuring treatment adherence, and providing evidence-based health-care delivery.[18,19] RNs perform patient examinations, take medical histories, provide health promotion counseling, administer medications, and coordinate health care delivery,[18,19] which correlate with published OIT preparation, staffing, and workflow descriptions.[9,10]

RN PROVIDES NURSE CLINICIAN SERVICES

During OIT, nurse clinician services include administering OIT dosing if medically appropriate; treating reactions; and monitoring physical, psychological, and emotional patient responses. RNs use acute observation, clinical judgment, and OIT protocol implementation for dosing and/or treating reactions. A nurse, depending on patient volume and staffing, may be responsible for one or several patients undergoing OIT at the same time. RNs can provide progress updates to allergists and alerts with regard to reactions or other concerns. See Tables 1 and 2 for additional RN clinical activity examples.

Psychosocial Considerations and Patient Advocacy

FA related anxiety is a motivating factor for OIT participation in some children.[21] Patients in OIT and/or families accept new burdens of daily management, reaction risk, and potential food aversions in exchange for severe reaction mitigation.[22] During OIT, children often experience anxiety, which RNs are capable of addressing by using age-appropriate explanations,

Table 1 **Allergy/immunology RN/BSN and RN/ADN clinical intervention examples before and during OIT office visits***

Activity Examples
Intervention examples before an OIT office visit
• Provides individualized or group OIT education to patients and/or families considering participation during SDM
• Reinforces realistic OIT therapy aims are in alignment with patient and/or family goals
• Ensures that informed consent is complete, documented, periodically reviewed, and updated as needed
• Instructs about items to bring to office visit (*e.g.,* diversional activities, safe snacks, food for mixing with OIT dose, two unexpired prescribed SIEs)
• Prepares room before the office visit (*e.g.,* accessible emergency medications and equipment)
• Ensures that the OIT product and masking agents are available, stored properly, and acceptable per office protocol
• Assesses patient and/or family knowledge of food allergy and OIT process; provides needs-based education and evaluates understanding
• Prepares OIT dosing per protocol (*e.g.,* double-checks dose calculation with another clinical team member)
Intervention examples during an OIT office visit
• Obtains interval history (*e.g.,* home dosing issues, symptoms) and reviews related precautions as needed
• Reviews current medications, adherence, refill needs, and patient and/or family understanding of use
• Evaluates coexisting asthma before OIT dosing; holds OIT dosing and alerts the physician if asthma is inadequately controlled; assesses adherence to an individualized asthma action plan with review and/or reinforcement education as needed
• Ensures that other atopic comorbidities are well controlled; provides education as needed; holds OIT doses and alerts the physician if comorbidities are not well controlled or eosinophilic esophagitis symptoms are suspected
• Screens for nutritional concerns or deficits and ensures registered dietician referral as needed
• Assesses patient and/or family understanding of food allergy, anaphylaxis, and OIT; provides educational review, reinforcement as needed, and evaluates retention
• Ensures that the patient and/or family has two unexpired prescribed SIEs available; reviews SIE use, indications, and administration technique; evaluates willingness to administer SIE and competency in the injection technique
• Performs baseline examination before the start of OIT dosing
• Prepares and administers OIT dosing by using masking agents for any texture and/or taste aversions per OIT protocol
• Monitors patient progress with regular physical, emotional, and mental health assessments
• Alerts the allergist of adverse reactions and treats as needed per prescribed OIT protocol
• Assists the patient and/or family with any fear and/or anxiety; ensures referral to mental health professional as needed
• Ensures that the patient and/or family has a current anaphylaxis emergency plan and reviews the steps
• Continues monitoring the patient after the last OIT dose per protocol time frame; alerts the physician if a reaction occurs and treats as prescribed
• Provides post–office-visit instructions (*e.g.,* OIT product preparation and/or dosing) and contact information (*e.g.,* on-call telephone and/or pager number) to reach the physician and/or RN with concerns

RN = Registered nurse; BSN = bachelor of science in nursing; ADN = associate degree in nursing; OIT = oral immunotherapy; SDM = shared decision-making; SIE = self-injectable epinephrine.

**This table provides examples of RN/BSN and RN/ADN clinical activities during OIT and is not an exhaustive listing of interventions that OIT RNs provide. Listed examples may vary based on state nurse practice acts, regulations per country, and/or practice-specific staffing models and resources. A clinical staff RN, office manager RN or OIT RN program manager could be cross-trained to perform listed interventions. The same RN may perform multiple clinical responsibilities and interventions due to overlapping roles as nurse clinician, patient educator, case manager, research collaborator-coordinator, and/or OIT program manager.*

Table 2 **Allergy/immunology RN/BSN and RN/ADN clinical intervention examples after OIT office visits and ongoing***

Activity Examples
Intervention examples after the OIT office visit
• Provides follow up (*e.g.*, *via* telephone, telehealth) with the patient and/or family after each OIT office visit, reinforces post–OIT office visit instructions, and screens for referrals (*e.g.*, registered dietician, social worker, community resources)
• Plans and educates about OIT maintenance and follow-up protocols (*e.g.*, dosing consistency, diagnostic tests)
Ongoing intervention examples
• Performs administrative responsibilities when required (*e.g.*, staff training, quality assurance and/or quality improvement**)**
• Develops, implements, and evaluates education materials for patients in OIT
• Coordinates group classes for patients in OIT and families for ongoing education and peer support opportunity
• Coordinates patient and/or family care conferences as needed (*e.g.*, to include clinical team members)
• Serves as the liaison with school and/or camp nurses as they adapt to students undergoing OIT regimens
• Provides community outreach for public health education on food allergy, anaphylaxis, and OIT subtopics
• Identifies gaps in evidence, which results in research questions that initiate studies
• Prepares or collaborates on research budgets and study materials with primary investigators
• Coordinates recruitment, screening, consent, and scheduling of research participants
• Educates staff, potential subjects, and families on OIT protocols, treatment, and possible adverse reactions
• Facilitates research protocol, the data base, and study activity records, and reports to regulatory agencies (*e.g.*, institutional review board)
• Writes publications, study posters, and presentations of study findings in collaboration with the research team
• Participates in professional development and continued education, and maintains current certifications

RN = Registered nurse; BSN = bachelor of science in nursing; ADN = associate degree in nursing; OIT = oral immunotherapy.

**This table provides examples of RN/BSN and RN/ADN clinical activities during OIT and is not an exhaustive listing of interventions that OIT RNs provide. Listed examples may vary based on state nurse practice acts, regulations per country, and/or practice-specific staffing models and resources. A clinical staff RN, office manager RN or OIT RN program manager could be cross-trained to perform listed interventions. The same RN may perform multiple clinical responsibilities and interventions due to overlapping roles as nurse clinician, patient educator, case manager, research collaborator-coordinator, and/or OIT program manager.*

anticipatory guidance, and shared decision-making involvement (*e.g.*, child selects the food vehicle).[23] Children commonly develop smell, taste, and/or texture aversions of OIT foods. Some children may feel performance pressure to please caregivers and therefore OIT dosing may become stressful for them.[24] RNs can institute reward systems for dose ingestion to elicit cooperation. Older patients may be motivated by an increasing sense of control, independence, and accidental trace exposure protection.[25]

During OIT, RNs evaluate patient's psychosocial readiness and identify OIT regimen barriers. Potential barriers include time, cost, distance, transportation, lifestyle modifications, patient's maturity level, mental health conditions, comorbidities, maladaptive coping skills, fear and/or anxiety, and food aversions. Shared decision-making consultations should address such factors before initiating OIT, during dose escalations, and throughout maintenance. OIT requires considerable commitment to complete all phases. On RN evaluation and allergist consultation, patients with identified barriers may need referrals (*e.g.*, psychologist, diagnostic testing, dietician) before and during OIT protocol. As advocates, RNs involve patients in age-appropriate decision-making and assist in health-care system navigation. QoL improvements during maintenance are well documented.[26–29] However, reactions can occur with dose escalations and during maintenance with triggers (*e.g.*, exercise, infections, uncontrolled asthma, anxiety).[30–32] RNs reevaluate patients at each OIT office visit and during long-term follow-up assessments for physical, psychosocial, or emotional changes.

RN PROVIDES EDUCATION

RNs can provide patient and family education, which gives allergists more time to focus on the diagnostic process because comprehensive education is time intensive. Shared decision-making consultations may include RNs

Table 3 **RN OIT program manager administrative activity examples***

Activity Examples
• Partners with an allergist to develop, implement, and evaluate an OIT program and protocol
• Collaborates with an allergist on FDA-required certification for the Palforzia (Aimmune Therapeutics, Brisbane, California, USA) REMS program
• Manages the integration of OIT into clinical practice (*e.g.,* space, supplies, equipment)
• Oversees the overall OIT program operation in the clinical setting with the supervising allergist
• Manages the OIT program budget and staff scheduling
• Recruits, hires, trains, and supervises licensed OIT clinical personnel as needed
• Provides clinical nursing services during OIT per staffing needs
• Conducts RN-to-RN performance reviews, remediation, and files incidence reports as needed
• Creates, evaluates, and updates patient and staff OIT education materials
• Orders, replaces, and dispenses OIT-related medications, supplies, and products
• Seeks external grant funding to sustain OIT program as needed
• Serves as a grant writer in collaboration with other OIT clinical team members
• Captures longitudinal outcomes and benchmark data (*e.g.,* patient satisfaction, quality of life surveys) for program development and future research
• Conceptualizes and/or collaborates on OIT-related research projects
• Coordinates the development of OIT professional continuing education opportunities

RN = Registered nurse; OIT = oral immunotherapy; FDA = U.S. Food and Drug Administration; REMS = risk, evaluation and mitigation strategy; BSN = bachelor of science in nursing; ADN = associate degree in nursing.

**This table provides several examples of RN/BSN and RN/ADN OIT program manager responsibilities and is not an exhaustive listing of the activities that an OIT RN program manager provides; listed examples may vary based on state nurse practice acts, regulations per country, and/or practice-specific staffing models and resources; a clinical staff RN or office manager RN could be cross-trained to assist and/or be fully responsible for listed OIT program manager responsibilities.*

providing individualized or group OIT education. Clinical teams should provide consistent evidenced-based OIT education to avoid patient and/or family confusion. An educational protocol that clarifies message uniformity may help. Delivery modes and teaching aides that support varied learning styles may include individualized or group education, handouts, posters, action plans, simulation, role playing, PowerPoint presentations, counseling videos,[33] interactive apps, and online modules. OIT education should be evidenced based, culturally appropriate, empathetic, empowering, suitable to health literacy levels, and include language translators as needed. Clarifying information received from social media, the Internet, support groups, family, friends, and other individuals and/or organizations may be needed.

Social cognitive theory provides one theoretical framework that supports the educational process aimed at behavioral changes needed for successful disease self-management. Social cognitive theory constructs include modeling, outcome expectations, self-efficacy, and behavioral capability, thereby addressing self-regulatory skills and environmental health determinants that support disease self-management.[34,35] Time-intensive OIT office visits provide rich opportunities to deliver in-depth OIT education and discussion on goal progression, self-management competency evaluation, and also education on atopic comorbidities. Contact frequency allows pacing of content presentation, which minimizes risk of overwhelming patients and families.

Cost-Effective RN-Led Patient Education

There is evidence that RN-led atopic disease management education after the physician's diagnosis is cost-effective and promotes positive health outcomes by improving disease understanding, medication adherence, disease control, self-efficacy, and QoL.[36–39] For example, uncontrolled asthma is often associated with medication mismanagement, which may reflect deficient patient education.[37] OIT is contraindicated for patients with uncontrolled asthma because it increases the risk of a reaction.[2–4,9,10] Patients and/or families interested in OIT should demonstrate asthma self-management competency and the ability to access care. In patients with uncontrolled asthma, RN-led asthma education and case management may improve their self-management skills and thereby subsequently increase the potential they may be viable candidates for OIT.

The chronic disease self-management process includes the following:

- Goal selection (*e.g.,* the patient and/or family accepts realistic OIT goals)
- Information collection (*e.g.,* the patient and/or family monitors and records home health data as directed)

- Information interpretation (*e.g.*, the patient and/or family identifies mild adverse reaction after home dosing)
- Decision-making (*e.g.*, the patient and/or family decides to treat)
- Action (*e.g.*, the patient and/or family treats a reaction as directed)
- Self-efficacy (*e.g.*, the patient and/or family is confident in executing health-promoting action)[35]

The patient and family educational process includes the following:

- Educational needs assessment (*e.g.*, relevant competencies, knowledge gaps)
- Readiness to learn assessment (*e.g.*, asks questions, nondistracted)
- Educational content provision and measurable goals discussion
- Comprehension evaluation

Competency examples to evaluate in OIT patients with co-existing asthma include the following:

- Identifies asthma signs and/or symptoms
- Understands the purpose of β-agonists and inhaled corticosteroids
- Appropriately uses an asthma medication inhaler and spacer devices
- Correctly utilizes an asthma symptom screening tool
- Measures peak flow at home if indicated
- Monitors for and reports asthma symptoms at the time of occurrence for dose adjustment
- Understands that OIT dose adjustments may occur[40]

Competency examples to evaluate in OIT patients with co-existing atopic dermatitis include the following:

- Notes areas of active eczema and follows eczema care plan
- Monitors for and reports increasing severity of eczematous areas with dosing, knowing that OIT dose adjustments may occur[40]

Competency examples to evaluate in OIT patients with co-existing allergic rhinitis include the following:

- Identifies aeroallergen triggers and institutes environmental controls that mitigate exposure
- Administers prescribed oral antihistamines, nasal steroids, and/or nasal antihistamines
- Monitors for and reports increased nasal symptoms, sneezing, and itching associated with an OIT dose, knowing that OIT dose adjustments may occur[40]

Competency examples to evaluate for all OIT patients and families include the following:

- Follows an anaphylaxis plan for OIT or non-OIT food
- Reports reactions, dose adjustments, or dosing interval changes with anaphylaxis[40]
- Monitors for and reports nausea, emesis, or abdominal discomfort while understanding that gastrointestinal symptoms are common during OIT[10,41]
- Recognizes eosinophilic esophagitis or OIT eosinophilic esophagitis–related syndrome potential; monitors for and reports symptoms (dysphagia, globus, choking, emesis, impaction, pain), knowing that OIT discontinuation may occur[10,40]
- Treats concurrent food protein–induced enterocolitis syndrome per plan and reports

General education topic examples for OIT patients and families include the following:

- Do not administer the dose if the child is sick, has asthma exacerbation, or other uncontrolled atopic comorbidities; contact allergist for dose hold or adjustment[40]
- Do not take a dose on an empty stomach[40]
- Take a dose at the same time each day[40]
- Take a dose when a 1-hour observation period after taking the dose is possible[40]
- Contact the allergist if there is a missed dose > 48 hours[40]
- Do not exercise 30–60 minutes before a dose or 2 hours after a dose[10]
- Do not take a warm bath or shower or use a hot tub 30 minutes before a dose or 2 hours after a dose[40]
- Menses, sleep deprivation, and nonsteroidal anti-inflammatory drugs can exacerbate a reaction[40]
- Report surgeries or dental procedures[40]
- Do not consume alcohol within 2 hours before or after a dose[40]
- Report an inability to keep appointments to plan a dose hold and review OIT supply[40]

General education topic examples regarding home dosing for OIT patients and families include the following:

- Precise dose measurement is crucial and, therefore, is reviewed during office visits[40]
- Vehicle food should be food that is safely ingested and that has ingredient and nutrition labeling
- Vehicle food should allow for homogenous OIT dose distribution[40]
- Appealing vehicles: fruit purees, baby foods, puddings, yogurts (dietary restrictions permitting)
- Strongly flavored masking agents (chocolate, peppermint) cover taste more effectively

RN PROVIDES CASE MANAGEMENT

RNs can provide case management (CM) for patients in OIT and their families. Each OIT RN may have a caseload of patients whom he or she

consistently follows up. Such continuity may maximize accurate communication and anticipation of patient and/or family needs while minimizing any patient and/or family anxiety associated with not having a consistent RN providing their OIT. CM includes RNs serving as liaison with entities with which patients are involved. For example, RNs are liaisons to schools attended by patients undergoing OIT. Only 52% of U.S. public schools have a full-time school nurse, which emphasizes the need for OIT teams to promote patient safety at school.[42] School staff may require additional education or review with regard to OIT, anaphylaxis management, and the need for continued avoidance.[43] A/I RNs who partner with school nurses may aid in initiating or amending individualized school health-care plans and ensure that school medication forms and asthma and anaphylaxis action plans are current.

Certain patients may require assistance to facilitate OIT regimen compliance (*e.g.*, student athletes, frequent travelers). The goal remains to minimize adverse effects and to ensure timely treatment with successful OIT buildup and maintenance. RNs providing CM ensure that patients and/or families have the necessary forms, letters, and referrals. For example, self-injectable epinephrine access barriers include cost and/or poor insurance coverage.[44] RN CM includes providing referrals to drug manufacturer's patient assistance programs, generic options, and/or online drug coupon sites. See Table 2 for more activity examples.

RN AS RESEARCH COORDINATOR

RNs serve as research coordinators, collaborating with interdisciplinary teams and generating new knowledge, expanding evidence-based decisions, and facilitating quality patient outcomes. They work with patients and/or families from informed consent procurement to data analysis. See Table 2 for additional activity examples.

RN AS OIT PROGRAM MANAGER

RN OIT program manager and allergist partner to create, implement, and evaluate the program and protocol. The RN may serve full-time as a program manager or may divide time between administrative duties and clinical RN responsibilities. Role activity examples are listed in Table 3.

STATE OF A/I NURSING

The United States lacks A/I-specific RN practice standards and A/I-specific RN board certification. There is a need for formalized training and competencies of RNs who specialize in A/I. Currently, on employment into an A/I practice, RNs without A/I specialty clinical experience optimally receive comprehensive nursing orientation from senior A/I RNs. The OIT RN program manager may also provide training. This article provides guidance on OIT RN competencies and role delineation (Fig. 1) for RNs and allergists to consider.

CONCLUSION

Patient access to board-certified allergist's direct evaluation and disease management is imperative to determine OIT eligibility. OIT accessibility for interested viable candidates requires a coordinated interprofessional effort to achieve. Best practice consensus guidelines for safe OIT administration and educational tools are needed. OIT provision highlights the valuable multifaceted expertise of RNs as central to A/I clinical teams. This article clarified the role components of the RN/BSN and the RN/ADN in allergist-RN OIT delivery. RNs can implement allergist-prescribed OIT standing protocols. The same RN may serve as a nurse clinician, educator, patient advocate, case manager, and/or research collaborator. Each OIT RN may have a patient caseload to consistently provide nurse clinician services, CM, education, and coordinated care continuity. The RN as an OIT program manager may involve the same RN fulfilling administrative and clinical responsibilities. RN expertise is vital to the goal of providing safe, high-quality, comprehensive, evidenced-based healthcare to patients who elect to participate in OIT.

CLINICAL PEARLS

- Utilizing RN/BSNs and RN/ADNs to implement an allergist-prescribed OIT protocol can be time-efficient, cost-effective, and maximize the allergist's ability to concurrently provide health care for other patients while overseeing OIT.
- Frequent time-intensive OIT office visits promote strong professional relationships with patients and/or families, thereby fostering effective RN clinician services, education, CM, and advocacy.
- The increase in the numbers of patients on OIT requires flexible staffing model adaptation.

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