Sanofi US Medical

Request for Proposal

Date: 12 October 2021		
Disease State: Diabetes		
Therapeutic Area: Type 2 Diabetes		
Area of Interest: T2DM Therapeutic Options for Older Adults/LTC Settings		
Geographic Scope: US - National		
Internal Requestor Information:		
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Due Date: 5pm on 7 December 2021		
Submission Portal: https://sgrants.envisionpharma.com/vt_sgrants/		
RFP Title (to include in request): 2021 DM IME Older Adults/LTC RFP		

The Health Care Gap:

The Centers for Disease Control and Prevention (CDC) estimates that in 2018, over 34 million Americans had diabetes, the majority with type 2 diabetes (T2DM).[1] Approximately 27% of adults diagnosed with T2DM are over age 65, and that number is expected to grow.[1-2]

Approximately half of all long-term care admissions are related to diabetes, with $18.6 billion in costs attributable to diabetes care.[3] Older adults with diabetes are at greater risk for common geriatric syndromes, such as cognitive impairment, polypharmacy, depression, injurious falls, persistent pain and urinary incontinence, in addition to microvascular and macrovascular complications.[4-5] Chronic kidney disease, decreased liver function and frailty may also be present, contributing to increased risk of hypoglycemia in older adults.[4-6] Cognitive impairment and hypoglycemia unawareness that prevents communication of symptoms further complicates diabetes management.[4-5] While targets may be relaxed for this population, symptomatic hyperglycemia may cause risk of dehydration, electrolyte abnormalities, urinary incontinence, poor wound healing, dizziness, falls, and hyperglycemic hyperosmolar syndrome (HHS) and must be avoided.[4,5,7,9] Further, staffing ratios, varied knowledge of diabetes management/lack of education, complex therapeutic regimens, and poor interdisciplinary communication may also affect diabetes management in the long-term care setting.[6,8]

Recommendations for older adults with diabetes include evaluation of frailty, geriatric syndromes and comorbidities to aid in individualized selection of diabetes therapeutics that would reduce risk of hypoglycemia.[4,5,7] Glycemic targets should be a balance between hypoglycemia and complications of hyperglycemia and should consider age, life expectancy, and disease duration, as well as renal status, impaired cognition, polypharmacy and nutrition status in order to individualize diabetes management. [4-5,7,9] Use of sliding scale insulin protocols and regimens that are resource intensive are discouraged [4-6,9] Agents with glucose-dependent mechanisms of action are preferred where possible, and guidelines offer alternative approaches.[4-5,7,9] Convenient diabetes therapeutic regimens that reduce risk of hypoglycemia are particularly important in people with diabetes over age 65.[6-7,9] Further recommendations regarding diabetes management for older adults in LTC include educating staff on managing diabetes in this population and performance improvement projects to optimize management strategies. [4,6]

For older adults that are not meeting glycemic targets and are already on basal insulin, addition of meal-time insulin or premixed insulins are on option, but may increase risk of hypoglycemia, particularly when patients have irregular eating habits, and may be additionally burdensome to patients and staff related to timing of insulin administration and blood glucose monitoring.[4,7,9-10] In an effort to assess the effect on glycemic control while simplifying treatment options and addresing hypoglycemia among older adults, one study deintensified insulin regimens by switching to a basal insulin and replacing meal-time insulins with non-insulin therapies, as recommended for older adults.[5,7,9,20] The non-insulin therapies used in the study along with basal insulin

included metformin, sulfonylurea, DPP4 inhibitors and GLP-1 receptor agonists (GLP-1 RA). [20] While more information is needed, the study suggests that it may be possible to maintain glycemic control when simplifying diabetes regimens in older adults to reduce hypoglycemia and diabetes distress. [20] A recently published UK expert consensus statement for managing the older type 2 diabetes patient provides guidance regarding de-escalation of complex insulin regimens by either dose reduction or switching to more manageable regimens such as basal insulin + GLP-1RA. [21] Other literature shows that once-daily fixed-ratio combinations of basal insulin and GLP-1 RA are comparable to the addition of meal-time insulin or premixed insulin, but with lower rates of hypoglycemia, less weight gain/neutrality due to less requirements for insulin and reduced requirements for blood glucose monitoring.[10-11] Fixed-ratio combinations of GLP-1 RA and basal insulin (FRC) are recommended for patients who are still not achieving A1c goals with values >1.5% above target while on metformin alone, or when fasting plasma glucose (FPG) goals have been met on basal insulin but A1c remains high.[7] FRCs address multiple defects contributing to diabetes and may help patients meet glycemic goals faster with less daily injections and less side effects (i.e. weight gain, hypoglycemia, gastrointestinal effects).[12] Further, these once-daily FRCs are generally well-tolerated and result in weight neutrality to slight weight loss while targeting both fasting and postprandial hyperglycemia, with documented patient preference.[10,13-15]

Sanofi US seeks innovative initiatives to address the above gaps for older patients with T2DM with activities designed to enhance multi-disciplinary practitioner knowledge, including those working in long-term care facilities regarding use of once daily fixed-ratio combinations of GLP-1 RA plus basal insulin versus more complex regimens (e.g. adding meal-time insulin to basal insulin/pre-mix insulins) to help meet individualized glycemic targets while reducing hypoglycemia risk, reducing the frequency of monitoring and resource burden overall, including long-term care settings.

Preference will be given to innovative methodologies designed to improve knowledge/competence/performance in health care providers caring for older adults overall and in long-term care settings, such as geriatricians, consultant pharmacists, and integrated delivery networks (e.g. performance improvement, point of care tools, simulations, etc.), as well as to partnerships with related societies (e.g. AGS, ASCP, AMDA, etc.).

Preference will also be given to programs designed to measure behavior change.

Proposal should include the following information:

- **Needs Assessment/Gaps/Barriers**: Include a comprehensive needs assessment that is well referenced and demonstrates an understanding of the specific gaps and barriers of the target audiences (in alignment with ACCME criteria). **The needs assessment must be independently developed and validated by the accredited provider, as applicable.**

- **Target Audience and Audience Generation:** Proposal should indicate the target audience(s) and provide a rationale for how and why this target audience is appropriate for closing the identified healthcare gap. In addition, please describe methods for reaching the target audience including description of any rationale for recruitment and placement strategies to maximize participation according to need. Any unique recruitment efforts specific to the target audience should be highlighted.

- **Learning Objectives and Content Accuracy:** Provide clearly defined and measurable learning objectives framed as expected practice improvements in relation to the identified gaps and barriers. Include an overview of program content and explanation of criteria that will guide content selection, considering level of evidence and other variables. Sanofi US is committed to the highest standards in ensuring patient safety; the applicant should describe methods to ensure complete, accurate, evidence-based review of key safety data for any therapeutic entities discussed in the activity. Explain how content will be updated if necessary throughout the program period, and how accuracy will be ensured.

- **Educational Methods:** Sanofi US supports the ACCME guidance for educational methods to be clearly designed to address the knowledge, competence and/or performance gaps that may underlie an identified healthcare gap. Your proposal should demonstrate an understanding of instructional design as it relates to the gaps in the knowledge, competence, or performance of the targeted audience. Educational methods and design should be based on current literature in CME best practice and consistent with ACCME accreditation criteria, as applicable. For example, systematic reviews have suggested that the most effective continuing education is clearly linked to clinical practice, uses methods including interaction, reflection, strategies that ensure reinforcement through use of multiple educational interventions, and more.[16-18] Preference will be given to applications that utilize methods that have been shown to result in practice improvements, and/or with data on the effectiveness of other programs of the same type. ACCME criteria recognize that barriers may be related to systems, lack of resources, or tools etc. and these may be included if relevant in your discussion of the gap and the educational methods you propose. In addition, the educational preferences of the target audience(s) may be considered to maximize attendance/participation and lead to practice improvements.

- **Faculty Recruitment and Development:** Provide Information on the expected qualifications of contributors and description of methods to ensure recruitment of course directors and faculty who meet the qualifications. Explain any methods that will be used to ensure that faculty are fully trained in the program expectations and any skills that may be needed to ensure effective delivery of intended education.

- **Program Evaluation and Outcomes:** Provide a description of the approach to evaluate the reach and quality of program delivery; methods for monitoring individual activities and for ensuring ongoing quality improvements. For ACCME accredited programs, refer to accreditation elements and criteria, as applicable. Describe methods that will be used to determine the extent to which the activity will close the identified healthcare gap, and the qualifications of those involved in the design and analysis of the outcomes. Preference will be given to programs with Objectives and Outcomes Plans with objective measures of changes in knowledge, and/or additional measures of improvements in competence, performance, patient health, population health, and/or system improvements, as aligned with the design of the intervention.[19]

- **Budget:** Include a detailed budget with rationale and breakdown of costs, per unit, and description of each budget line item. In addition, please include any registrations fees paid by the learner, and how the fees will be applied.

- **Accreditation**: If proposal involves an accredited program, the accreditation must be provided by an appropriate accrediting body and fully compliant with the accrediting body's criteria and applicable government guidelines and regulations.

- **Fair Balance:** The proposal should briefly describe methods for ensuring fair and balanced content, identification and resolution of conflict of interest, in alignment with applicable ACCME criteria.

- **Communication and Publication Plan**: Provide a description of how the provider will keep Sanofi US informed of progress. If applicable, include description of how the results of this educational intervention will be presented, published or disseminated.

References

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