

sanofi-aventis U.S.
Medical Affairs
Request for Proposal

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Date: August 8, 2011
Disease State: Diabetes
Therapeutic Area: Metabolism
Area of Interest: Early Treatment Intensification to Prevent Sequelae in T2DM
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Health Care Gap

Type 2 diabetes is epidemic¹. Despite the existence of several well-established guidelines for the management of type 2 diabetes and physicians' recognition that achieving specific glycemic goals can substantially reduce morbidity the goal of achieving near normoglycemia (A1c<7.0%) has not been met for the majority of patients^{2,3}. A study from the National Institutes of Health showed that only 37% of patients with diabetes achieve blood glucose control of A1C < 7%².

Prevention of complications (ie. cardiovascular disease, neuropathy, retinopathy, etc.) rests on the timely initiation of drug therapy by the health care provider and patients compliance with recommended treatment(s)^{4,5,6,7,8}. However, there is significant data showing that clinicians do not escalate treatments in patients as needed to achieve therapeutic goals, referred to as clinical inertia^{9,10}. The average patient accumulates nearly 5 years of glycemic burden (A1C >8.0%) before insulin therapy is started¹¹.

Barriers to evidence-based diabetes care have been identified for primary care physicians and include inadequate knowledge on how to manage insulin therapy and cardiovascular risk, a lack of awareness of one's own performance referred to as 'blind spots', and health care providers' attitudes and motivation^{12,13}. Providers, when interviewed, showed skepticism about evidence-based treatment and collaborative care although coordinated care with nurses, clinical pharmacists and others, as part of a team approach, has been shown to be efficacious in meeting patients' medical and psychosocial needs^{12,14}.

Sanofi is seeking proposals to close this independently identified gap of delayed insulin initiation in type 2 diabetes patients failing to reach glycemic targets through education that has the potential to result in improved glycemic control by addressing the barriers that have been identified in the literature as described above.

Preference will be given to proposals that measure the impact of the educational initiative on patient health.

Please note that proposals are expected to include an analysis of the barriers and root causes for this gap and appropriately designed educational interventions.

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 (ie, ACCME accreditation element 2). **The needs assessment must be independently developed and validated by the accredited provider**
- **Target Audience and Audience Generation:** Proposal should describe the target audience(s) and provide a rationale for how and why this target audience is important to closing the identified healthcare gap. In addition, please describe methods for reaching the target audience(s) including description of and 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-aventis 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:** The ACCME calls for educational methods that are clearly designed to address the knowledge, competence and/or performance gaps that may underlie an identified healthcare gap. Your proposal should demonstrate an understanding instructional design issues as they relate to the gaps in the knowledge, competence, or performance of the targeted audience. Education methods and design should be based on current literature in CME best practice and consistent with ACCME accreditation elements 3,4,5,6. 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.^{15,16,17} 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 (Accreditation elements 12, 13, 14, 15). Describe methods that will be used to determine the extent to which the activity has served to close the identified healthcare gap. (Accreditation Elements 10, 11, 12), 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 of Moore level 4-6.¹⁸

- **Budget:** Include a detailed budget with rationale including breakdown of costs, clear explanation of the units, and calculations of:
 - Content cost per activity
 - Out-of-pocket cost per activity
 - Management cost per activity

- **Accreditation:** Programs must be accredited by the appropriate accrediting bodies and fully compliant with all ACCME criteria and Standards for Commercial Support™. ***If you are a non-accredited provider, the accredited provider must be involved from the concept origin, fully knowledgeable of the grant submission and documentation should be provided on the website grant application section entitled, “Other Information”.***

- **Resolution of Conflict:** The proposal should briefly describe methods for ensuring fair and balanced content, identification and resolution of conflict of interest, with particular emphasis on ACCME criteria 7, 8, 9.

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

References:

1. Nathan DM et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care* 2009;32(1):193-203.
2. Saydah SH, Fradkin J, Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA* 2004;291(3):335-342.
3. American Diabetes Association. Executive summary: standards of medical care in diabetes – 2010. *Diabetes Care* 2011;33(S1):S4-S10.
4. Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus: The Diabetes Control and Complications. *N Engl J Med* 1993;329:978-986.
5. UK Prospective Diabetes Study Group (UKPDS): Intensive blood-glucose control with sulfonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998;352:837-853.
6. Nathan DM et al. Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. *N Engl J Med* 2005;353:2643-2653.
7. Stratton IM et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ* 2000; 321:405-412.
8. Grundy SM et al. Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines. *J Am Coll Cardiol* 2004;44:720-732.
9. Phillips LS et al. Clinical Inertia. *Ann Intern Med* 2001;135:825-834.
10. Ziemer D, Miller C, Rhee M. Clinical inertia contributes to poor diabetes control in primary care setting. *Diabetes Educ* 2005;31:564-571.
11. Brown JB, Nichols GA, Perry A. The burden of treatment failure in type 2 diabetes. *Diabetes Care* 2004;27(7):1535-1540.
12. Goderis G et al. Barriers and facilitators to evidence based care of type 2 diabetes patients: experiences of general practitioners participating to a quality improvement program. *Implementation Science* 2009;4:41.
13. Cabana MD et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. *JAMA* 1999;282(15):1458-65.
14. Willens D et al. Interdisciplinary Team Care for Diabetic Patients by Primary Care Physicians, Advanced Practice Nurses, and Clinical Pharmacists. *Clinical Diabetes* 2011; 29(2):60-68.

15. Davis, D, Barnes, BE, Fox, R. (2003). The continuing professional development of physicians – From research to practice; Chicago, IL: AMA.
16. Davis DA, Thomson MA, Oman, D, et. al. (1999). Impact of formal continuing medical education – Do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes? *JAMA*. 282: 867-874.
17. AHRQ. (2007). Effectiveness in continuing medical education. Evidence Report No. 149.
18. Moore, D.E., Green, J.S., and Gallus, H.A. (2009) Achieving Desired Results and Improved Outcomes: Integrating Planning and Assessment Throughout Learning Activities. *JCEHP*, 29(1):1-15.