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## Addressing Concerns Regarding the Use of Gadolinium in a Standardized MRI Protocol for the Diagnosis and Follow-Up of Multiple Sclerosis

The “Consortium of MS Centers Task Force for a Standardized MRI Protocol and Clinical Guidelines for the Diagnosis and Follow-Up of Multiple Sclerosis”<sup>1</sup> recommended the use of brain MR imaging with gadolinium for the diagnosis and routine follow-up of patients with multiple sclerosis. Soon after the publication of these recommendations, we became aware of the concerns regarding gadolinium deposition in the brain.<sup>2</sup> Because the adverse health effects of gadolinium deposits in the brains of patients are unknown, we believe gadolinium-based contrast agents (GBCA) should be used judiciously as part of a standardized MR imaging protocol. This is an important change compared with our recommendations published earlier this year.<sup>1</sup>

The US Food and Drug Administration announcement noted that accumulation of GBCA may occur after  $\geq 4$  MR imaging scans, even long after administration.<sup>2</sup> Low-stability agents are the GBCA most often associated with gadolinium deposits in the brain.<sup>3</sup> To date, although there have been no reports of signs or symptoms of central nervous system toxicity related to GBCA, to reduce the potential for gadolinium accumulation, the FDA has recommended that “health care professionals should consider limiting GBCA use to clinical circumstances in which the additional information provided by the contrast is necessary. Health care professionals are also urged to reassess the necessity of repetitive GBCA MRIs in established treatment protocols.”<sup>2</sup>

Using a standardized protocol to follow patients with MS is of the utmost importance. Annual MRIs that detect new clinically silent disease activity enable health care providers to treat patients earlier in the course of the disease and modify and change therapy. Thus, routine monitoring of individuals with MS is recommended. The use of GBCA is helpful but not essential for detecting subclinical disease activity because new T2 MS lesions can be identified on well-performed standardized MR imaging.

GBCA continue to play an invaluable role in specific circumstances related to the diagnosis and assessment of individuals with MS.<sup>1</sup> It is important to use GBCA in patients presenting with their first clinical attack (or so called “clinically isolated syndrome”) in the initial diagnosis of MS; the use of GBCA allows an earlier diagnosis by demonstrating lesion dissemination in space and

time, the hallmarks for a diagnosis of MS, with the first MR imaging scan. Early diagnosis is a special circumstance in which gadolinium is indispensable because an early diagnosis leads to early treatment, which helps in preventing disease progression and may improve the patient’s long-term prognosis.

There are a number of other clinical circumstances in which use of GBCA is essential, including following a patient with highly active disease, when a patient’s condition is rapidly declining and unexplained, and when there is a high concern regarding an alternate diagnosis other than MS. However, pending a revision of the recommendations published earlier this year, gadolinium could be considered optional for the routine monitoring of an otherwise stable patient with MS.

Use of a standardized protocol for patients with active disease is especially important. The new phenotypes as defined by Lublin et al<sup>4</sup> include the objective criteria of disease activity provided by imaging findings in addition to disease progression. Use of MR imaging is important in providing accurate clinical course descriptions,<sup>4</sup> but again, this may be accomplished without the use of GBCA for every scan by the detection of new T2 lesions on standardized T2/FLAIR sequences, which can be compared across studies.

Physicians and health care professionals caring for patients with MS are strongly encouraged to adopt the “Recommendations of the Consortium of MS Centers Task Force for a Standardized MRI Protocol and Clinical Guidelines for the Diagnosis and Follow-Up of Multiple Sclerosis.”<sup>1</sup> As indicated, we would recommend judicious use of GBCA in certain circumstances, including early diagnosis of MS. We anticipate revisions to the guidelines based on evolving knowledge surrounding gadolinium safety and the new McDonald criteria.

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