Psoriasis and Psoriatic Arthritis Video Project 2010: A Report from the GRAPPA Annual Meeting

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ABSTRACT. Investigators use several physical examination measures to assess clinical features and severity of psoriasis and psoriatic arthritis (PsA), primarily when conducting clinical trials but also in clinical registries and clinical practice. No training modules for these measures are widely acknowledged or available. At the GRAPPA (Group for Research and Assessment of Psoriasis and Psoriatic Arthritis) meeting adjacent to the 2009 International Federation of Psoriasis Associations in Stockholm, members were updated on the development status of online training videos of psoriasis and PsA examination measures. Dermatology assessment modules include the Psoriasis Area and Severity Index, the Static Physician Global Assessment, body surface area, the original and modified Nail Psoriasis Severity Index, the Palmar-Plantar Pustular Psoriasis Area and Severity Index, and the Psoriasis Scalp Severity Index. Rheumatology modules include assessment of tender and swollen joint counts used in the American College of Rheumatology criteria, Disease Activity Score, and other composite arthritis scores; enthesitis assessment used in various enthesitis scoring systems; dactylitis; and spine disease. Each module will include background information for each measure, diagrams and photographs to emphasize teaching points, demonstration video of examination where applicable, and an optional examination at the end. Future plans include evaluating the modules for their influence on interrater and intrarater reliability and development of additional modules.

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Investigators use several physical examination measures to assess clinical features and severity of psoriasis and psoriatic arthritis (PsA), primarily when conducting clinical trials but also in clinical registries and clinical practice. No training modules for these measures are widely acknowledged or available. At the GRAPPA (Group for Research and Assessment of Psoriasis and Psoriatic Arthritis) meeting adjacent to the 2009 International Federation of Psoriasis Associations, GRAPPA members were updated by Kristina Callis Duffin and Philip Mease on the development of online training videos of psoriasis and PsA measures.

The primary objective of this project is to provide an enduring set of training modules for use by investigators in clinical studies. Secondary objectives include provision of: (1) online training for clinicians who enter patients into long-term clinical registries and who must provide physical examination information for the database; (2) online standardized training for dermatology residents and rheumatology fellows; and (3) online education for clinicians interested in improving their physical examination skills when evaluating patients in clinical practice. For the most part, investigators must obtain training in psoriasis and PsA assessments during clinical fellowships, from other researchers, or at investigator meetings. Regulatory agencies expect sponsors of clinical trials to provide training to their investigators on efficacy measures. Indeed, most studies require formal certification of this training in order to achieve regulatory compliance. For most psoriasis and PsA studies, lead investigators typically provide slide-based or occasionally live-patient demonstrations of how to perform study-specific endpoint measures. Sponsors of rheumatology studies regularly employ live-patient demonstrations to ensure that swollen and tender joint counts are performed accurately. Outside of clinical trial settings, options for training are limited. Further, most training modules have never been assessed to verify that they actually result in accurate assessment and are effective at improving investigators’ interrater or intrarater reliability.

GRAPPA has contracted with Accela Communications (Southborough, MA, USA) to produce high quality training presentations, and utilize an internet-based media platform to provide password-protected access to interested users. Each module will include a presentation of the background for each measure, and actual demonstration video of the presenters performing each examination on patients where applicable, as well as diagrams and photographs to emphasize teaching points. At the end of each module, an optional
examination will be provided, which is intended to reinforce teaching points of the training module, but also can be utilized to collect data to measure the success of the program. Industry partners or sponsors who choose to subscribe to this training program could potentially utilize these modules for study-site training for new study personnel, reinforcement of training done at investigator meetings, or to confirm completion of training. It is intended that by completing these training modules and demonstrating comprehension and quality of examination, investigators can be formally certified as proficient to perform these measures.

Proposed dermatology assessment modules include: the Psoriasis Area and Severity Index\(^1\); Static Physician Global Assessment (currently a 6-point scale, where scores 0–5 correspond to clear–severe)\(^2\); body surface area, using a handprint method (one handprint = 1%)\(^3\); the original and modified Nail Psoriasis Severity Index\(^4,5\); the Palmar-Plantar Pustular Psoriasis Area and Severity Index\(^6\); and the Psoriasis Scalp Severity Index\(^7\). Proposed rheumatology modules include assessment of tender and swollen joint counts used in the American College of Rheumatology criteria, Disease Activity Score, and other composite arthritis scores\(^8\), and evaluations of enthesitis, dactylitis and axial disease\(^9,10,11\).

Following their completion and trial period of use, the training modules will be evaluated to verify their effectiveness at improving comprehension and competence of performing the skin and joint assessments. Ideally, the training modules will improve interrater and intrarater reliability in the study setting. Post-module surveys have been incorporated to obtain feedback from users.

GRAPPA members involved in this project acknowledge that although video training is not an ideal substitute for many measures, this project has the potential to be valuable in consistently training physicians in the assessment of psoriasis and PsA measures. If successful, GRAPPA will likely develop additional modules, including various assessment tools such as surveys or composite measures and continuing medical education topics.

REFERENCES
3. Thomas CL, Finlay AY. The ‘handprint’ approximates to 1% of the total body surface area whereas the ‘palm minus the fingers’ does not. Br J Dermatol 2007;157:1080-1.