PRECISION IMAGE ANALYSIS

Precision Image Analysis Quality Statement

Improving accuracy through evidence-based protocol development, training, certification, and quality control programs

Protocols

The foundation of PIA's success lies in the thoroughness of its post-processing protocol development. The initial protocol development is a collaboration between the client, the analyst team, and the medical director. Custom protocols are generated for each client, which are either modified from existing analyses or developed based on literature review of the most up-to-date peer-reviewed publications and close oversight by the medical director.

Although each protocol is catered to the client's needs, PIA adheres to industry gold-standard practices whenever applicable. For clinical cardiac magnetic resonance cases (CMR), PIA strictly follows the Society for Cardiovascular Magnetic Resonance's guidelines[1].

Table 1 shows a sample of services that PIA provides and examples of publications that contributed to the development of the protocols.

Our analysis protocols are written by a single analyst originator and assessed by several internal reviewers. Before implementation, all protocols must be vetted and approved by the medical director. The protocols are integrated in our analyst certification programs, and various properties of the protocols, such as official changes and contributing writers and reviewers are documented and tracked. Adherence to protocols is enforced through PIA's certification programs and quality control program, as discussed below.

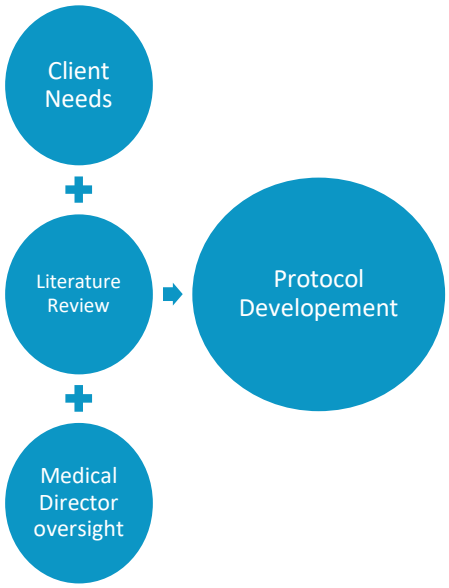

Figure 1. *Protocol Development Strategy*

Table 1. *A sample of resources used for Left Ventricular Scarring and T2* protocol development*

Analysis	Resources
Left Ventricular Scarring	– SCMR Post processing Standards section on post processing of late gadolinium enhancement studies[1] – Late gadolinium enhancement and phase-sensitive inversion recovery[2] – Myocardial Late Enhancement in Contrast-Enhanced Cardiac MRI[3] – ACCF/ACR/AHA/NASCI/SCMR 2010 Expert Consensus Document on CMR, Section 3.4 on Myocardial Infarction/Scar[4] – Prognostic significance of microvascular obstructions [5]
T2*	– SCMR Post processing Standards section on post processing of T2* imaging[1] – Most up-to-date T2* calibration for derivation of liver iron concentration from T2* relaxation time (updated Pennell equation)[6] – Overview of cardiac T2* and its relation to LIC[7] – ACCF/ACR/AHA/NASCI/SCMR 2010 Expert Consensus Document on CMR, Sections 2.7 on Tissue Characterization and 3.5.8 on Hemochromatosis[4]

Certification Programs

PIA has developed certification programs to ensure the consistency and competency of analysts. For every type of analysis, there is a certification program which must be passed before analyses can be performed. Although each program varies in length and complexity, the end goal of all certification programs is to ensure that analysts have the proper technical and theoretical knowledge to perform the analysis and that the analyst meets specific qualitative and quantitative standards.

Figure 2 shows the general timeline of a typical certification program at PIA. The certification process begins with a new analyst reviewing the protocol and relevant publications. The analyst will then watch either a senior analyst demonstrate the software and analysis or watch an instructional video. After practice studies, the analyst will analyze "certification cases", cases that have been analyzed by our medical director and used as gold standards for comparison of various metrics. Based on adequate completion of certification cases, the analyst will then enter a probationary period. During the probationary period, the new analyst's work will be thoroughly checked by a senior analyst. If the analyst shows competency of the analysis at the end of the probationary period, then the analyst will be certified and able to perform the analysis independently. After certification, analysts are encouraged to discuss questions and concerns with their superiors, and complicated cases are always assessed with the Medical Director.

Figure 2. Certification Program

Quality control

Quality control programs are in place to ensure that all cases are analyzed accurately and consistently. These include tracking inter- and intra-observer variability, retrospective review of reports, and continuing education for analysts.

PIA has tracked inter- and intra-observer variability for cardiac functional analysis, shown in Tables 2 and 3. These reproducibility calculations were modeled after those done by Luijnenburg et al[8], and our results are comparable. Moving forward, we are implementing a quality system that randomizes 10% of all cases for intra- and inter-observer calculation. With this system in place, we will be able to track the progress and consistency of analysts as well as report variability in analyses that have not previously been published in the medical literature.

PIA's manager of clinical operations performs retrospective review of all cases. Weekly status reports are generated that track metrics such as turnaround time and analyst productivity. Outgoing reports are double checked for accuracy of essential content and overall completion by a second analyst. Particularly unusual cases or findings are typically reviewed by the entire senior analyst team and medical director.

Continuing education is encouraged for all analysts. PIA's medical director suggests new publications and web conferences for the analyst to read and attend. Analyst also regularly attend scientific conferences, meet with clients, and collaborate in clinical research studies.

Table 2. Intra-Observer Variability

PIA intra-observer variability n = 30	LV EDV	LV ESV	RV EDV	RV ESV
Mean difference ± SD (ml)	0.4 ± 5.0	0.3 ± 3.7	-1.0 ± 7.1	0.8 ± 5.0
Limits of Agreement (ml)	-9.4 to 10.1	-6.9 to 7.4	-15.0 to 13.0	-9.0 to 10.7
Mean value ± SD (ml)	206.8 ± 71.1	107.9 ± 57.2	218.5 ± 60.1	126.8 ± 49.4
Coefficient of Variability (%)	2.4	3.4	3.3	4.0

Table 3. Inter-observer variability

PIA inter-observer variability n = 25	LV EDV	LV ESV	RV EDV	RV ESV
Mean difference ± SD (ml)	1.8 ± 8.1	1.6 ± 4.1	-0.6 ± 8.8	-1.9 ± 7.7
Limits of Agreement (ml)	-14.1 to 17.6	-6.4 to 9.6	-17.8 to 16.6	-16.9 to 13.2
Mean value ± SD (ml)	211.7 ± 74.7	109.6 ± 62.5	221.6 ± 53.7	126.0 ± 43.9
Coefficient of Variability (%)	3.8	3.7	4.0	6.1

References

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