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The ISCE ECG Genome Pilot Challenge: A 2004 Progress Report

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Abstract: The International Society for Computerized Electrocardiography (ISCE) "genome project" began in 2000 as an open-ended discussion of ECG database needs and opportunities. Cooperation within ISCE led to a "pilot challenge" of the database concept, which called for establishment of methodology for transmission, storage, and integrated re-analysis of digitized waveforms of three different ECG manufacturers. The present report documents the early implementation of that goal. **Key words:** Database, digitized ECGs, XML.

The International Society for Computerized Electrocardiography (ISCE) "genome project" began in 2000 as an open-ended discussion of ECG database needs and opportunities. It was realized that the good will fostered by ISCE among industry, academia, and ECG users might facilitate the development of a "cross-platform" database of ECG records that would be of value to our constituents. In this context, "cross-platform" was used to indicate the possibility and feasibility of storing and re-analyzing ECG data that was originally derived from equipment of different manufacturers. Database "value" was defined by useful properties, including growth by continuous addition of new material, representative and validated demographics, ascertained correlative information, re-analyzability by new algorithms, and accessibility to the ISCE constituency.

The database project was stimulated by both engineering and management support from key manufacturers and, coincidentally, by evolving FDA interest in uniform access to annotated ECGs used in clinical trials. As reported last year (1), cooperation within ISCE led to proposal of a "pilot challenge" of the database concept, intended as a demonstration of technical feasibility of the cross-platform initiative. This "pilot challenge" recognized that without cooperation from industry in enabling cross-platform pooled data, detailed consideration of the many other technical and administrative problems confronting the use of an ECG database would be moot. Therefore, the pilot project called for establishment of methodology for transmission, storage, and integrated re-analysis of digitized waveforms of 3 different ECG manufacturers as a starting point. The purpose of the present report is to document the early implementation of that goal.

An overview of the nature of the "pilot challenge" is shown in Figure 1. It was planned that ECG data from manufacturers A, B, and C would be

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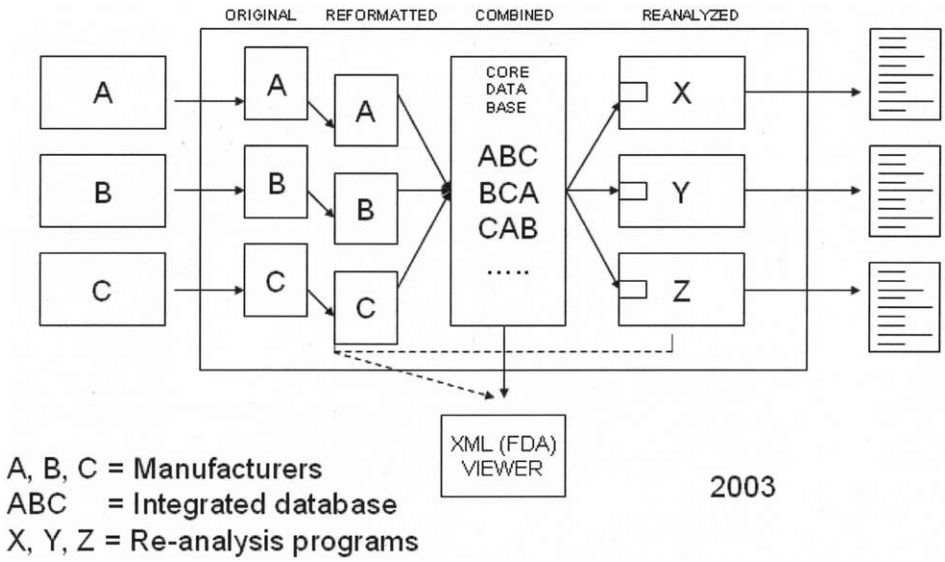

Fig. 1. Original outline of the ISCE "genome pilot challenge," proposing proof of concept trial for pooled analysis (X,Y,Z) of digitized ECGs from three manufacturers (A,B,C).

transmitted to the pilot core laboratory (contained within a PC maintained by Paul Kligfield at Cornell, who has served as the project "facilitator"). It was originally anticipated that transmitted data would be in proprietary format from each manufacturer and converted to XML format within the core laboratory, using software provided by each manufacturer, before being pooled into the common database. It was further planned to make the common database available to re-analysis by multiple reporting programs, illustrated by X, Y, and Z in the figure, as well as viewable by a program in development for FDA use.

Philips Medical Systems, Mortara Instrument, and General Electric Healthcare Technologies were selected to provide ECGs and engineering support for the pilot project. Each manufacturer committed to providing approximately 100 ECGs and capability for transforming the tracings to common XML format within 12 months. During the project year, the challenge was considerably simplified by the development by each manufacturer of an FDA compliant XML export capability for ECG transmission. This eliminated the need to convert proprietary files to standard XML data files for the participating manufacturers for the immediate purpose of the pilot study. Accordingly, the ISCE genome project was greatly facilitated by technology promoted by the FDA initiative. AMPS-LLC (Analyzing Medical Parameters for Solutions) was selected to provide technical support for viewing and re-analysis of the database ECGs. AMPS provides on-line shareware for viewing XML ECGs (2) and committed to providing liason with each manufacturer where needed and customized software for visually based computer measurements of ECGs within the pooled XML database.

All ECG tracings from the three manufacturers were readable with the XMLFDA viewer. One example of a 12-lead ECG from the database is shown in Figure 2. For individual measurements within the pooled database, 20 ECGs from each manufacturer were selected of patients who were in sinus rhythm and had unpaced QRS complexes. Using a customized version of the AMPS software package for on-screen measurements (CalECG), each of the 60 tracings were examined by a single observer (PK), using visually guided calipers to derive computer-based measurement of global PR interval, global QRS interval, global QT interval, R wave amplitude in aVL, and S wave amplitude in V3. An example of the caliper placement for global measurements made from superimposed representative complexes of an ECG from the database is shown in Figure 3. In addition, CalECG stored the analyzed ECGs in FDA XML output files, which allow review of the annotations used for measurement by the XMLFDA viewer.

Measurements from the 60 selected tracings were exported to an Excel spreadsheet and entered into SPSS for examination and analysis. Within SPSS, RaVL was added to SV3 to derive Cornell voltage criteria for left ventricular hypertrophy (3). Analysis of the database allowed frequency distributions, histograms, mean values, and boxplots of the pooled ECG data from the three manufacturers to

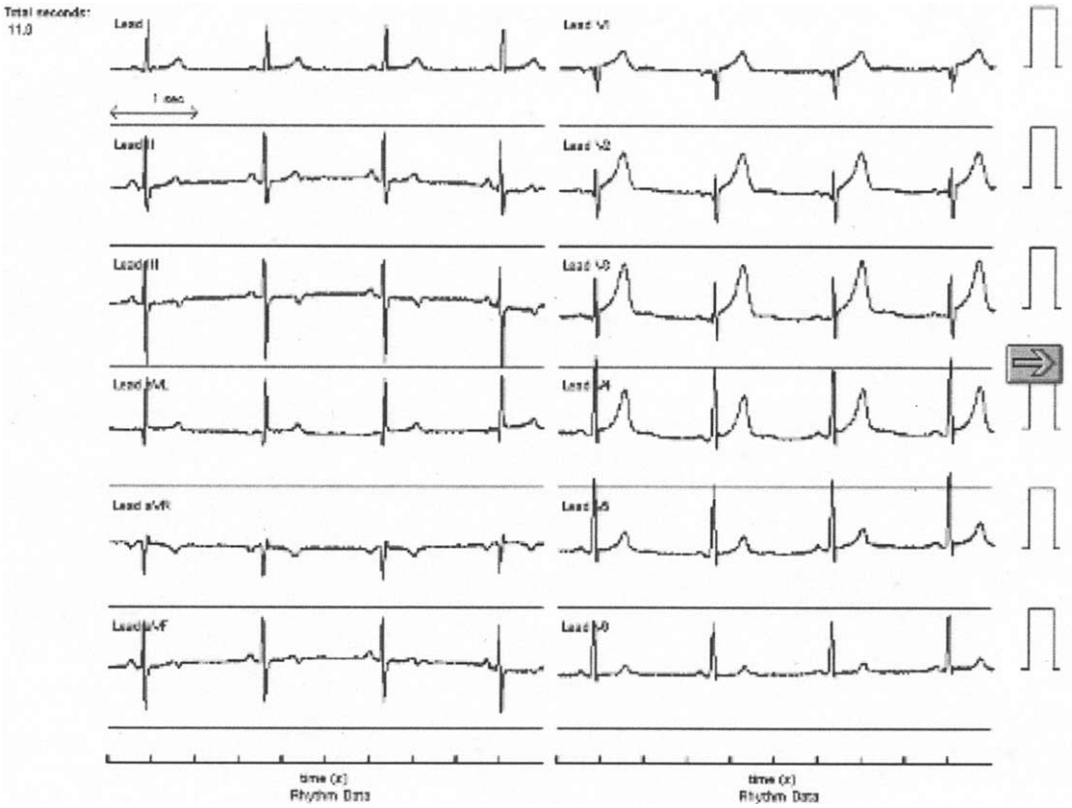

Fig. 2. Twelve lead tracing of XML sample in pooled database, as represented by XMLFDA viewer.

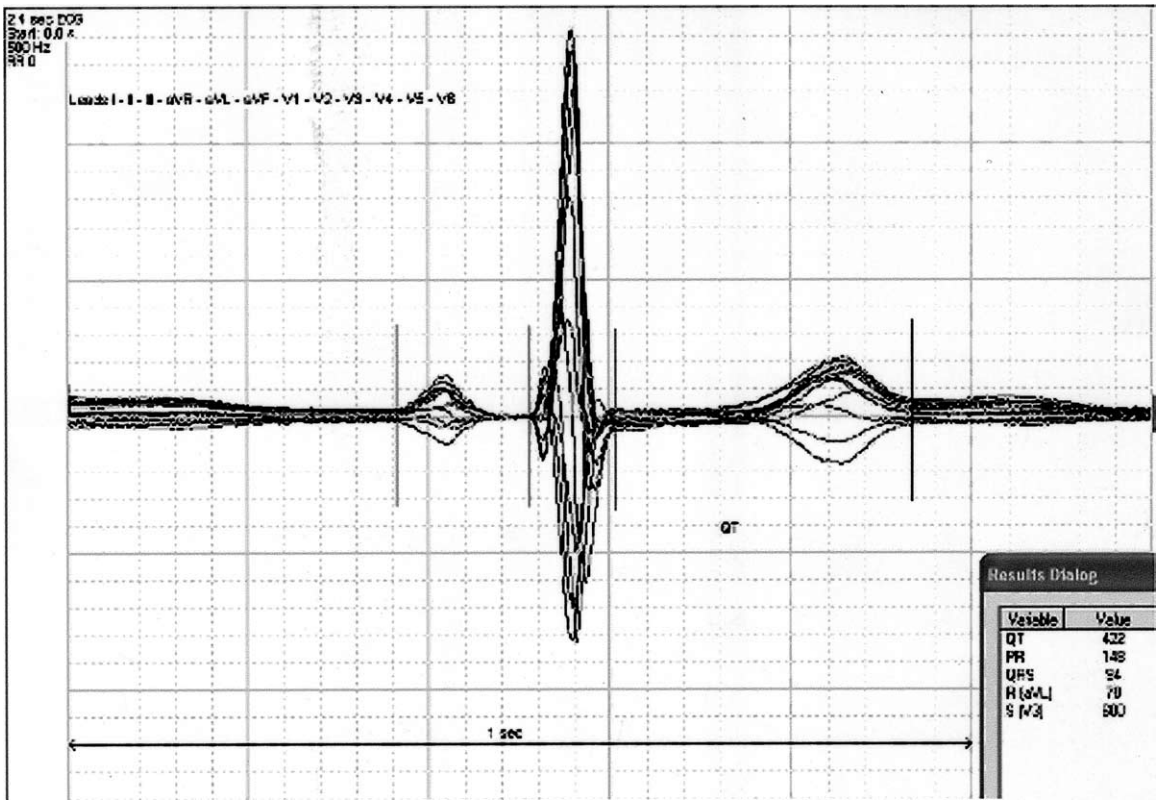

Fig. 3. Manually placed landmarks for computer based global measurements of PR, QRS, and QT intervals from XML sample in pooled database.

PR Interval

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	116	1	1.7	1.7	1.7
	124	2	3.3	3.3	5.0
	126	2	3.3	3.3	8.3
	130	1	1.7	1.7	10.0
	136	2	3.3	3.3	13.3
	140	1	1.7	1.7	15.0
	144	2	3.3	3.3	18.3
	146	3	5.0	5.0	23.3
	148	2	3.3	3.3	26.7
	150	1	1.7	1.7	28.3
	152	3	5.0	5.0	33.3
	154	4	6.7	6.7	40.0
	156	3	5.0	5.0	45.0
	158	1	1.7	1.7	46.7
	160	4	6.7	6.7	53.3
	164	1	1.7	1.7	55.0
	166	1	1.7	1.7	56.7
	168	4	6.7	6.7	63.3
	172	5	8.3	8.3	71.7
	176	1	1.7	1.7	73.3
	184	2	3.3	3.3	76.7
	186	3	5.0	5.0	81.7
	191	1	1.7	1.7	83.3
	192	1	1.7	1.7	85.0
	194	3	5.0	5.0	90.0
	198	2	3.3	3.3	93.3
	200	1	1.7	1.7	95.0
	226	1	1.7	1.7	96.7
	248	1	1.7	1.7	98.3
	260	1	1.7	1.7	100.0
	Total	60	100.0	100.0	

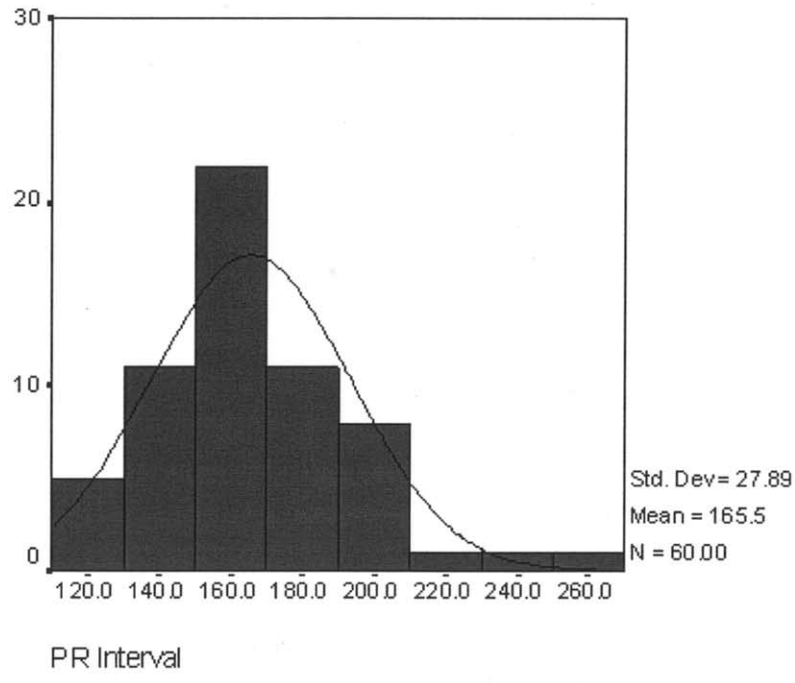

Fig. 4. Tabulated frequencies and distribution of global PR intervals from 60 XML ECGs in pooled database from 3 manufacturers.

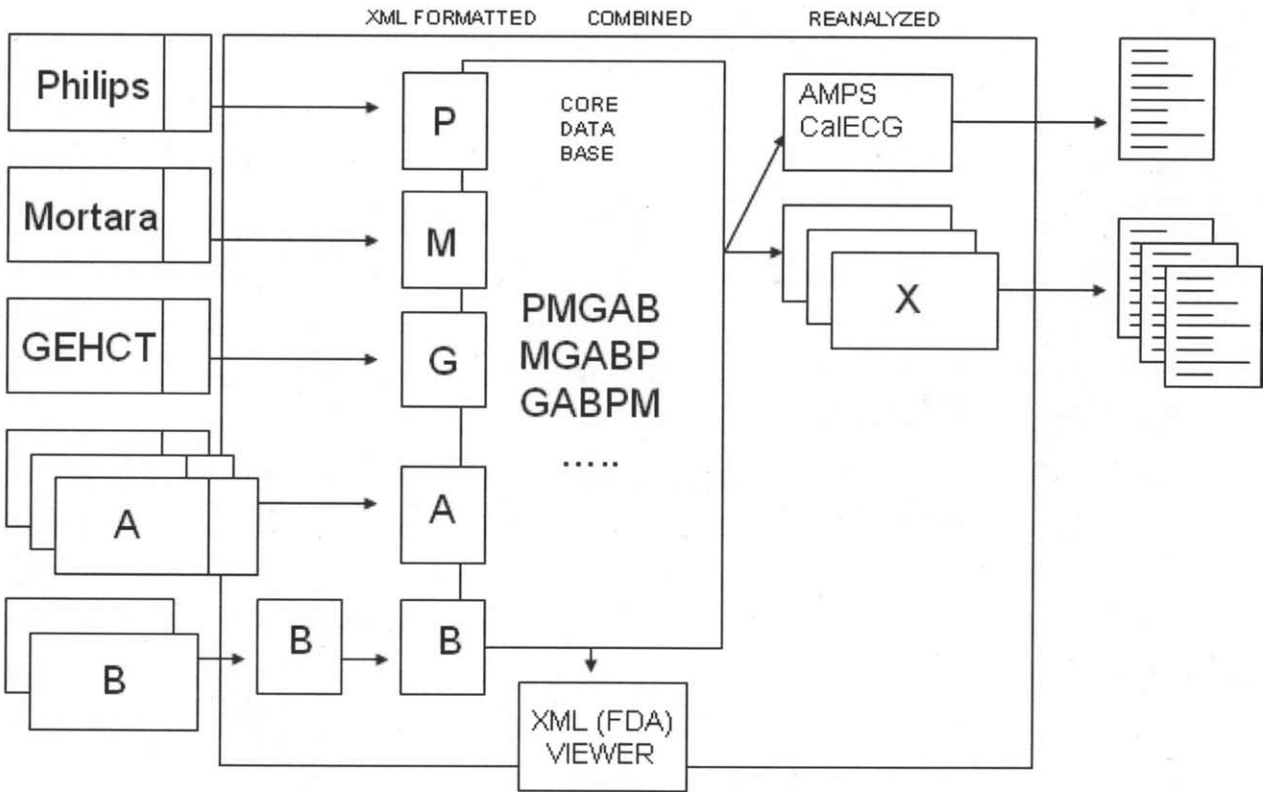

Fig. 5. (A, B) Future directions of ISCE database, incorporating data from additional manufacturers and examining additional viewers and measurement algorithms (X).

be derived and examined as one group. An example of pooled data of PR intervals derived from the SPSS statistical package is shown in Figure 4 to illustrate this feasibility.

Multiple problems and opportunities confront the use and management of pooled databases, and these extend beyond the scope of the present "pilot challenge" to include issues of data management, support, access, ownership, and use. The present findings represent nothing more than a technical proof of concept trial. Future structural and organizational directions of the database project are shown in Figure 5. Although this pilot project report includes only three ECG manufacturers and one viewer program, the ISCE "genome project" is open to contributions from all members who are interested in participating in further development. Additional ECG manufacturers are welcomed to provide sample tracings and technical support for inclusion in either of 2 ways. For consistency of measurements, time-coherent representative complexes should be available. Tracings converted to FDA compatible XML format may be transmitted for direct review and incorporation into the sample database. Alternatively, with appropriate engineering support, proprietary ECG formats may be transmitted for review and conversion to XML format within the project. Similarly, additional groups are welcome to submit proprietary or public domain software to view tracings or to derive re-analysis measurements from the pooled database.

In the spirit of the "genome" description of this project, we should add that it has not escaped our notice that large, carefully designed databases gathered in this manner can stimulate and facilitate important electrocardiographic research in the future.

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