BD

CLIAC Meeting
Feb. 14, 2012
Automated Cytology Workload

Good afternoon. My name is Peggy Parker and I have been a cytotechnologist for over 30 years. I work for BD Diagnostics – Women's Health and Cancer, in the Training and Education Department. As you know, we are the manufacturer of the SurePath liquid-based Pap test and the BD FocalPoint GS Imaging System.

On behalf of BD I would like to ***acknowledge the workload and quality concerns*** expressed by all participants at this meeting today and the cytopathology community. BD's is committed to supporting patient safety, product quality, and the working environment of our customers and colleagues, the cytotechnologists. We appreciate this opportunity to share some comments today.

1. First, ***BD recognizes the efforts put forth by the ASC Task Force***. Thank you for your hard work with the goal of improving patient safety and the working environment of cytotechnologists.

2. I'd like to make a few comments regarding the clinical trial and highlight a few points from the Product Insert It states "*The work environment was the same in both study arms*". There were 4 CT's at each site with experience ranging from 2 to 36 years. They participated in the study in their laboratories and the conditions very closely mimicked what a "real world" situation would be.

The workload limit of 100 slides established by the FDA took into consideration the following:

The BD FPGS Imaging System limit of 100 slides in an 8-hour workday includes all actions to interpret and report slide results as follows:

- Review clinical history and Slide Profiler information.
- Location Confirmation of the first FOV.
- Screen up to 10 FOVs at the Review Station microscope.
- Full slide review as needed at the Review Station microscope.
- Record Results and triage appropriately.

3. Before lowing the daily limit from 100 to 70 slides we would recommend further robust scientific studies be conducted. The literature review of the reference articles supporting this lower number are derived from different study designs, different screening methods used and environments that do not consistently reflect clinical practice.

All of these issues indicate the data may not be robust or standardized and should not be pooled or extrapolated across products or current practice. ***Further studies are indicated.***

4. The 2 imaging technologies do share some similarities but there are significant differences. Our product design has always primarily focused on product effectiveness, providing tools to help the CT more efficiently locate and correctly classify the cells of interest. The FocalPoint GS does more than simply reducing the area of the slide needing review, i.e. increased productivity. The FP scans and analyzes every slide, assigns a score, and ranks that slide relative to all the other slides in that batch. It then directs the QC review to be done on the highest scoring 15% of the cohort. It also assigns a score to each FOV and presents up to 10 in a ranked order. Decreasing false negatives is the primary goal of the system.

We recommend that any future workload studies take these system differences into consideration and evaluate the systems separately.

Thank you.