Message from the Editor

Dear Fellow CCS Members,

Welcome to the first edition of the Clinical Cytometry Society e-Newsletter.

Of course, the “e” stands for electronic. Don’t expect a printed copy! Every quarter you will receive e-mail notification with a link to a document residing in the members section of the CCS website. Through this electronic resource you will be able to connect, and share information and views, with the worldwide cytometry community.

The “e” is also a reminder that this newsletter is a product of the newly formed CCS “Education” Committee with members Sindhu Cherian, David Grier, Paul Wallace, and myself as Chair. When this Committee was formed, I outlined what I saw as the Society’s educational objectives and believe that these can be applied equally well to the e-Newsletter: to provide educational resources to increase knowledge, promote quality, encourage discussion, and facilitate standardization in the practice of flow cytometry.

With these goals in mind, the e-Newsletter will have several regular features including a web Case Study Interpretation (e-CSI) challenge, submitted articles, and a Forum for discussion. In this inaugural issue, Sindhu Cherian presents an e-CSI challenge, Bruce Greig gives a status report on the quest for flow cytometry certification, and Teri Oldaker and I discuss reimbursement for flow cytometry in the US. Future issues of the Newsletter will also include a “How I Practice Cytometry” section provided by an invited expert. In addition to the e-Newsletter, the education committee is busy working on other web-based educational resources. Building on the success of the CSI session at the annual meeting, we will be posting further e-CSI challenges covering a broader range of topics: unusual cases, findings characteristic of a disease entity, a technical issue, or an approach to performing flow cytometry for a particular medical indication. These e-CSI challenges will include some fcs files that can be downloaded and analyzed in your own laboratory, files representing the analysis performed in the submitters laboratory, and a discussion of the case.

The “e” also stands for “everyone”, and this means you! Do you have an interesting case that would make a great e-CSI challenge? Would you like to contribute an article? Any announcements or suggestions? Just visit the CCS Website for submission instructions and information about the review process.

From your e-editor, Fiona Craig

Understanding Reimbursement

Understanding Reimbursement for Flow Cytometry in the U.S.

Recently Brent Wood notified ICCS members of changes in reimbursement practice proposed by a US Medicare A/B contractor (http://www.cytometry.org). How well do you understand the current Medicare reimbursement scheme and the proposed changes?

Test your knowledge with the following quiz.

1. Medicare spending currently accounts for greater than 50% of the US national health expenditure. True or False?

2. Recently changes in reimbursement were proposed by a Medicare administrative contractor and would affect a LCP. What is an LCP?
   a. Lymphocyte CD phenotype
   b. Local coverage policy
   c. Legislative claim postponement
   d. Legal contractor proposal

3. In the current Medicare scheme, reimbursement is capped at 16 markers. True / False?

4. Which code is used to document medical necessity, ICD-9 or CPT?

5. In the draft document LCD DL30692, the Medicare contractor Palmetto GBA proposed a limit on the number of antibodies reimbursed for some diagnoses? True / False?

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Submit Online at: http://mc.manuscriptcentral.com/cc
Flow Cytometry Certification

Recent History and Future Plans

During the 2006 Bethesda International Consensus Conference on Immunophenotyping of Hematolymphoid Neoplasia, there were numerous references made regarding the lack of standardization around training and education. A subcommittee was formed to make recommendations on this topic. This subcommittee consisted of Bruce Greig, Teri Oldaker, Mike Warzynski and Brent Wood. Along with the other subcommittees publishing recommendations, this committee published a recommendation for Training and Education to perform clinical flow cytometry. Part of this document included the proposal to create a Specialty certification in flow Cytometry similar to the ASCP Specialty in Blood Bank. Based on this recommendation by members of the CCS Certification committee the ASCP was contacted to discuss changing the current designation, QCYM (Qualification in Cytometry), to a Specialty certification. The ASCP agreed to perform a feasibility survey to measure interest before committing to making any changes in the flow qualification designation. In the Fall of 2008, an on-line survey was sent out to the CCS membership as well as ISAC and the European Flow Society, ESCCA. Results of that survey did indeed identify a desire by those polled to see some type of certification be created. However, the numbers needed to make such a specialty financially feasible for the ASCP were not enough to guarantee both an initial cohort of at least 250 people to take the first exam and at least 50 more in each year thereafter to be worthwhile.

ISAC has been independently discussing the need for a certification in flow cytometry. During this time meetings between the leadership of CCS and ISAC were advancing the idea of looking beyond the ASCP for a credentialing program; one that would be more universal in scope and include more international participation. There are several other professional certification agencies that conduct exams and create credentials for highly specialized professions who employ personnel requiring unique and definable skill sets. One example is the NCA (National Credentialing Agency) certification of cytogeneticists. This very specialized discipline shares many of the same issues and understandings that cytometrists use in their jobs. As this idea was advancing additional work needed to be done to better understand who would want such a credential and what should the credential signify. After a series of conference calls between CCS and ISAC leadership next steps to pursue certification were planned.

It was decided that another survey needed to be taken to more clearly define the interest in creating a flow cytometry certification that would encompass more of cytometry than just clinical applications as well as be recognized internationally. The Wallace Coulter Foundation agreed that this was an important project and offered to provide financial assistance. In 2009, ISAC and CCS contracted with the Professional Examination Service (PES) to conduct a market analysis feasibility survey for a certification in the cytometry field. Responses to the survey were overwhelmingly positive and showed support for certification from all work settings and career levels. Moreover, there was confirmation that there existed a core of knowledge that all cytometrists need to know, no matter where they work or what they work on. This core body of knowledge could be used to form the basis of a certification program.

Next Steps

The next stage in the process of creating such a program is to conduct a role delineation study. The purpose of the study is to determine the core body of knowledge needed to perform flow cytometry and create a blueprint for a certification examination. In February 2010 ISAC and CCS will contract with a leading company in the testing industry to carry out the role delineation study in collaboration with the certification advisory committee composed of members of ICCS and ISAC. The advisory committee members include the current and past presidents of both ICCS and ISAC. Brent Wood, Mike Borowitz, Robert Murphy, Paul Smith, as well as members of both ICCS and ISAC. Bruce Greig, Teri Oldaker, Tim Bushnell, Derek Davies, Lori Anderson, and the ISAC administrator Todd Philbrick.

The advisory committee will be asking for volunteers to serve as “Subject Matter Experts (SME).” These SME’s will have a face-to-face meeting to develop an extensive survey of the necessary knowledge, skills and abilities for cytometrists. The membership of ISAC & CCS, as well as volunteers from affiliated societies and regional cytometry groups, will then be asked to complete the survey. A final report will be generated from the survey responses, which will form the basis for creating an initial certification exam.

The timeline for completion has not been completely decided however as this effort progresses updates will be given to the memberships via the Societies web sites, mailings, and / or meeting announcements. Remaining work to be done before the certification is in place includes designing and administering the exam, deciding how it will be maintained as well as keeping it current as the technology evolves and formulating the rules for renewal. The success of this project will depend heavily on both input and participation by members of both Societies as well as all practitioners of flow cytometry.

(Special thanks to Teri Oldaker for her contributions to this story)

Bruce Greig, MT (ASCP)QCYM
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Answers:

1. Medicare spending currently accounts for greater than 50% of national health expenditure in the US. Answer: False.

Medicare is a government funded program that is currently only available for people over 65, under 65 with certain disabilities, and people of all ages with end-stage renal disease. In 2008, Medicare spending represented 20%, and private spending 53%, of total national health expenditure in the US. However, if Medicare reimbursement practices change, private policies would undoubtedly follow suit.

2. Recently changes in reimbursement were proposed by a Medicare administrative contractor and would affect a LCP. What is an LCP? Answer: b. Local coverage policy.

Medicare is run through the Centers for Medicare and Medicaid Services (CMS), a component of the Department of Health and Human Services (HHS). However, CMS has contracted with private companies (Medicare administrative contractors), such as Palmetto GBA to operate as intermediaries between the government and medical providers.

Some “local” Medicare contractors cover several States e.g. Palmetto GBA covers Jurisdiction 1 (California, Nevada, Hawaii and Guam) and Jurisdiction 11 (Virginia, North and South Carolina and West Virginia). A local coverage policy describes the coverage provided by a Medicare contractor in regard to medical necessity. An LCP typically includes accepted indications and limitations of coverage, reasons for non-coverage and the documentation that is required before a claim is accepted.

3. Which code is used to document medical necessity, ICD-9 or CPT? Answer: ICD-9.

ICD-9 codes are diagnosis codes that are required for every claim for outpatient testing (Medicare Part B). Coding must be performed to the highest degree of certainty and should not include anything that is tentative e.g. rule-out, probable, suspected. In addition to codes for diagnoses, there are ICD-9 codes for some symptoms and signs.

CPT codes identify which specific test or service has been provided. Flow cytometric testing is covered by a few CPT codes. For example, the technical component for qualitative flow cytometric testing for cell surface, cytoplasmic, or nuclear markers would be billed using the following CPT codes: CPT 88184 for the first marker and 88185 for each additional marker.

4. In the current US Medicare scheme, all reimbursement for flow cytometric testing is capped at 16 markers. Answer: False.

The US Medicare system bases reimbursement for the technical component on the number of markers performed, as indicated by CPT code 88184 to bill for the first marker and multiples of CPT code 88185 for each additional marker. The professional component is reimbursed by Medicare using a three tier system capped at 16 markers: flow cytometry interpretation for 2 to 8 markers (CPT code 88187), for 9 – 15 markers (CPT code 88188), and for 16 or more markers.

5. In the draft document LCD DL30692, the Medicare contractor Palmetto GBA proposed a limit on the number of antibodies reimbursed for some diagnoses? Answer: True.

The draft document LCD DL30692 (link), from the Medicare contractor Palmetto GBA proposed changes in practice that would adversely impact flow cytometry reimbursement for leukemia and lymphoma testing. These are some of the proposed changes that have caused concern:

- Reimbursement based on final diagnosis rather than medical indication.
- Restriction of reimbursement to only 10 markers for diagnoses other than acute leukemia or non-Hodgkin lymphoma.
- A cap in reimbursement for acute leukemia or non-Hodgkin lymphoma at 21 markers.
- Requirement of submission of the flow report and justification from the medical record before consideration of any claim that exceeds these limits.

This draft proposal raised concern in the flow cytometry community because it does not reflect current practice as outlined in guidelines developed by an international group of experts at the 2006 Bethesda consensus conference (Davis, et al., Cytometry B Clin Cyt 2007; 72 Suppl 1:S5-13 and Wood, et al., Cytometry B Clin Cytom 2007; Suppl 1:S14-22). Flow cytometric testing is usually driven by medical indications / signs and symptoms, rather than a diagnosis, and laboratories are often required to perform extensive testing based on these indications to exclude, rather than establish, a diagnosis of neoplasia. The difference between the approach outlined at the consensus conference and that proposed by the LCP can be illustrated by considering the example of flow cytometric testing for mast cell disease (MCD). The draft LCP would limit reimbursement to 10 markers, if justified by a diagnosis, and recommend that laboratories “limit marker selection as appropriate for the identification of mast cells.” However, given that MCD can be identified by the presence of aberrant antigen expression and is often associated with clonal hematological, non-mast cell lineage disease, many laboratories would adopt the following approach: if there is clinical concern for MCD perform flow cytometric testing to identify mast cells, assess mast cells for aberrant expression of antigens, screen for other major categories of hematopoietic neoplasia and perform additional testing for further characterization if another abnormal population is identified. Although justifiable, the latter approach would certainly take more markers.

It is apparent from the proposed LCP that there is still confusion about the standard clinical practice of flow cytometry for the evaluation for hematolymphoid neoplasia. The ICCS has taken a lead in submitting a response to this proposal (http://www.cytometry.org). In addition, ICCS has volunteered to work with relevant organizations to revise the current reimbursement system. Revision would undoubtedly require a change in billing codes and therefore, is not something that can be done by local carriers, but it is important that ICCS and its members get involved in moving the field in that direction.

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Director of Lab Operations, NeoGenomics

Fiona Craig, MD
Associate Professor, University of Pittsburgh and Medical
Director Clinical Flow Cytometry Laboratory, UPMC Health System
Case Study Interpretation (CSI)

We would like to introduce the Quarterly CSI Challenge Case, a new feature offered on our website. Each quarter, a CSI Challenge Case history will be presented in our newsletter. The list mode files corresponding to each case will be available for review on the Quarterly CSI Challenge Case website along with a presentation describing the analysis and findings in the case. The cases presented will focus on common dilemmas (both technical and diagnostic) encountered in the clinical flow cytometry laboratory. The goal of this feature is to share knowledge with our peers through case presentation. Below is the case history for the first Quarterly CSI Challenge Case. We invite you to submit your cases (see below for case submission guidelines).

Spring 2010 Quarterly CSI Challenge Case

A 62 year old man presents to his primary care physician with lymphadenopathy. A CBC demonstrates the following: WBC 20.73 thousand cell/microliter (12% neutrophils, 83% lymphocytes, 4% monocytes 1% eosinophils, 0% basophils). Flow cytometry was conducted on the peripheral blood. Visit http://cases.cytometry.org to view the additional information and to download FCS files for analysis.

Tube 1: CD20V450 // Kappa FITC / Lambda PE / CD5 PE-Cy5 / CD19 PE-Cy7 // CD38 Alexa 594 // CD10 APC/ CD45 APC-H7
Tube 2: FMC7 FITC/ CD23 PE/ CD19 ECD/ CD5 PE-Cy5
Tube 3: ZAP 70 FITC/ CD38 PE/ CD19 ECD/ CD5 PE-Cy5

Want to Contribute a CSI Case?

1. Submit a brief clinical history including age of the patient, specimen type, and indication for flow cytometry.
2. Submit de-identified List Mode files labeled with a key detailing antibodies and fluorochromes used to be posted on the CSI Challenge Case website for ICCS members to analyze. For each file please note the software platform in which the file was generated and the format in which files were collected (FCS2.0 or FCS3.0, etc).
3. Submit a de-identified PDF showing an example of what a correct and complete analysis should look like. This may be used for analysis by participants who are not able to assess the listmode data due to software incompatibility.
4. Submit a brief power point presentation including clinical history, results of flow cytometric analysis with relevant histograms displayed, accompanying morphology and ancillary data (molecular studies, cytogenetics, etc.), a discussion of your findings, and relevant references.
5. All submissions will be reviewed by two members of the ICCS Education Committee and, where necessary, an additional ICCS member selected for their expertise in the topic area. Submissions will be judged on merit, including educational value and clarity of the presentation.

Sindhu Cherian, MD
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University of Washington

Discussion Forum

Is there anything you would like to see in the Newsletter?

Is there a flow topic you would like to discuss with the community?

Would you like to introduce us to your local flow group?

Just send your comments, announcements, and suggestions to: info@cytometry.org

Future ICCS Meeting Dates

SAVE THE DATE!

25th Annual International Clinical Cytometry Meeting and Course
October 1 - 5, 2010
Houston, Texas

26th Annual International Clinical Cytometry Meeting and Course
October 14 - 18, 2011
Portland, Oregon

27th Annual International Clinical Cytometry Meeting and Course
October 5 - 9, 2012
New Orleans, Louisiana

28th Annual International Clinical Cytometry Meeting and Course
October 11 - 15, 2013
Fort Lauderdale, Florida