

The NCDR® ICD Registry™ Version 2.0

Pre-requested Questions/Results

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GuidePoint

Simplifying Reimbursement

Cardiac Rhythm Management
and Electrophysiology

Updated March 2010

#	Question	Result
1	Do you think this expanded registry will eventually become mandatory for hospitals? Either federally or through Medicare?	<i>NCDR does not have information regarding the probability of future mandates. We do encourage all facilities to participate to the fullest extent of the ICD Registry. In the event that future mandates should occur, your facility will already be submitting appropriately.</i>
2	When will the v2.0 form and data definitions be available on ACC-NCDR?	<i>Based on participant feedback, we will be posting the ICD Registry V2.0 Data Collection Forms and the Data Dictionary before the annual meeting. The actual posting date has not been determined, but the information will be accessible via the ICD Registry website.</i>
3	How often will you be updating the lead selection list in the database? It seems that this will be a huge task!	<i>The Master Leads File will be updated on a monthly basis occurring at the same time (the end of each month) as the Master Device File update.</i>
4	I would assume that the 1.08 access being "terminated forever" means that ENTRY is terminated, not access to lookup?	<i>When Version 1.08 is officially "sunset" at midnight June 30th 2010, participants will no longer have the ability to enter data or submit to the DQR via V1.08. We will leave limited access to V1.08 for the purposes of viewing data via "data extract" functionality.</i>
5	Are you certifying outside vendors to submit this data as you do now?	<i>All ICD Registry vendors were issued the vendor specifications last Fall 2009. All ICD Registry third party vendors will have to go through a certification process for version 2.0.</i>
6	What if patient had a generator change and one new lead placed or replaced? The form had only 3 choices	<i>When you enter data into the Online tool, we have provided a "Lead Counter" which will allow you to create a page for every lead involved in your procedure. The lead counter will number your leads and will keep the information separate. The paper form is limited in space, so if you have more than three leads, you will have to make a copy of the form to add additional pages if necessary.</i>

7	What is the status of vendor releases for version 2.0 of the ICD data collection tool?	<p>All ICD Registry Vendors were issued the Version 2.0 specifications in the Fall of 2009. The vendors are hopeful to have their products ready by the April 1st 2010 launch, but in the event some are not ready you will have the following options:</p> <p>*Wait for your vendor product. This means you will not be able to enter any data into the version 2.0 software until you have your product. Version 2.0 will begin with discharge dates of April 1st - June 30th 2010 (Q2). The deadline for this data submission is September 30th 2010. If your vendor is not ready by this date, you will risk missing the CMS deadline as well as missing inclusion in the ICD Registry V2.0 Outcomes report.</p> <p>*Enter and submit your data into the ACC online tool. All participants will have access to the ACC online tool until your vendor product is ready for use. If you enter and submit your data via the ACC online tool, you will simply need to migrate your data into your third party vendor software as soon as it is available to you. This will ensure that you do not miss the September 30th data deadline.</p>
8	Will the pediatric data be mandatory for the "Limited" centers doing only primary prevention? Will Medicaid be requesting this for Medicaid patients only?	<p>At this time, there is not a CMS mandate for Medicaid patients. The current mandate is for Medicare patients receiving ICD or CRT-D implants for the purposes of primary prevention.</p>
9	Will slides and Q&A responses from this presentation be available to us?	<p>Boston Scientific will have a link to the webcast, the slides, and FAQ's posted on their website @ http://www.cardiacrhythmresources.com/cardiac-rhythm-resources/reimbursement/Reimbursement-GuidePoint-Webcasts.html</p>
10	How about biv icd lv lead information? Does it need to be entered?	<p>All ICD or CRT-D leads including; newly implanted leads, existing leads extracted, abandoned, or reused must be reported.</p>
11	How many more data elements in v2 than in v1?	<p>Including all parent/child relationships, roughly 100.</p>
12	Many Free Standing Same Day Surgery Centers are performing ICD implants. Do these Free Standing Same Day Surgery Centers need to partake in the ICD Registry?	<p>The CMS Mandate is a device based mandate requiring the reporting of ICD and CRT-D device implants. If CRT-D or ICD devices are implanted for the purposes of primary prevention at your facility, and billed to Medicare as primary or secondary source of insurance, participation in the ICD Registry is mandated. Participation is mandatory regardless of the status of the facility implanting the devices. Each implanting facility must have a unique participant ID and membership with the ICD Registry.</p>
13	Do we collect epicardial leads implanted in surgery?	<p>All ICD or CRT-D leads including; newly implanted leads, existing leads extracted, abandoned, or reused must be reported. This includes epicardial leads implanted in surgery.</p>

14	Is the absence of syncope for structural heart disease an indication for ICD primary prevention?	<i>A patient could have sustained uniform VT without syncope and be a secondary prevention. So syncope with SHD makes a secondary prevention but the absence of syncope doesn't make for primary prevention.</i>
15	Can you describe the financial implications of not participating in the registry for Medicare patients? Do you anticipate payer requirements for the peds population?	<i>The CMS mandate is a Federal Mandate. Purposeful non-compliance of this mandate could potentially result in CMS request of refund for previous reimbursements from your facility and/or loss of Medicare reimbursement going forward for your facility. At this point in time, NCDR does not have information regarding future mandates.</i>
16	Is ACC considering modifying the submission requirements so that HIPPA sensitive elements can be excluded from non Medicare cases? This is what prevents us from being able to submit all payer types.	<p><i>Thank you for your questions concerning the collection of Protected Health Information in the ICD Registry. The ICD Registry is mandated by a coverage decision of the Centers for Medicare and Medicaid Services. This coverage decision requires that you submit ICD Registry data to the ACCF for primary prevention patients. In order to meet the coverage decision requirements your sight consented to allow the ACCF to forward your data to CMS including Protected Health Information in order for CMS to confirm your compliance with the coverage decision. When you enrolled in the ICD Registry your site signed a Business Associate Agreement permitting such disclosures as well as Data Release Consent Form authorizing the ACCF to transfer data to CMS on your behalf.</i></p> <p><i>Please note that the ACCF only discloses PHI to sub- contractors who are under an agreement with the ACCF that is more stringent then the Business Associate Agreement and only on a need to know basis in order to fulfill duties assigned by the contract with the ACCF. There are no plans to develop a Limited Data Set.</i></p>
17	will lead fracture or lead recall be noted 2.0	<i>Yes</i>
18	Why do you require an EKG on ICD replacements and upgrades? Why do you require 100% data submission for QRS and PR interval in order to be included in the national comparison?	<i>The goal of the ICD Registry is to assess and improve the care of patients receiving ICD's. The data set includes elements such as QRS and PR interval to help determine the clinical characteristics as well as relative long term outcomes of this patient population. The data set was also developed from the most current guidelines such as the ACC/AHA/HRS Guidelines for Device-Based Therapy. The Registry seeks to answer questions such as: How do the characteristics of patients compare between those involved in randomized trials and those receiving and placing the device following approval? What are the characteristics of the patient? What are the indications for the ICD? What are the in-hospital procedure related complications? As well as what are the reasons for subsequent hospitalization for procedure or device-related complication and care?</i>

19	How come in the old sheets and now this new sheet there is no area for us to track weather the device was actually used to defibrillate. How can we tell who we are helping if we do not track who is getting defibrillated?	<i>Version 2.0 does supply data elements which will address ATP or Shock therapy.</i>
20	What if it takes 3 attempts with 3 different leads to finally get one to stay in the CS, would you report all 3 or just the final one that was implanted?	<i>For the purposes of the ICD Registry, please code the leads which were extracted from or implanted into the patient during the lab visit. If a new lead was not successfully placed for three attempts with three different leads, report the final lead only.</i>
21	How would you classify patients who are "non-healers" secondary to uncontrolled diabetes? They are not technically infected.	<i>For the purposes of V2.0, if the patient experienced an infection related to the procedure which required antibiotics, this would be coded as an infection.</i>
22	How essential are dates for CABG if a patient cannot remember date and H&P does not state a date. Does an estimated date suffice?	<i>The previous CABG dates are important, however, if you are unable to provide the information due to lack of documentation, please code as we have done in Version 1.08. That is, if you do not know the month or day of the CABG, please code 01/01/YYYY. If you do not know the year, please code to the best of your ability from the previous hospitalization information you do have.</i>
23	IF there is just a pocket revision completed nothing to the lead/generator system - do we need to report with a new form?	<i>If the procedure does not involve a new ICD or CRT-D generator, or if the leads are not extracted/implanted, you will not have to take action in terms of reporting. If the patient is admitted for and undergoes a pocket revision only, reporting should not take place.</i>
24	We had trouble hearing the section about the centers who collect only CMS primary prevention ICD implants. Can you explain again if these centers will need to fill in the lead form in V2?	<i>"CMS Only" submitting facilities will not have to provide leads data at this point in time. If you are a "CMS Only" submitting facility, please do not complete section "G" of the Data Collection Form.</i>

<p>25</p>	<p>Day 1: Patient has new device implant</p> <p>Day 2: Patient returns for lead revision but same generator is used.</p> <p>Do you complete the new generator and lead form only or does a lead only form need to be completed as well?</p> <p>a) What if same lead just revised? b) What if day old lead removed and different lead implanted but all during same admission</p> <p>Also, question about the antibiotic within one hour: What if antibiotic is given but for some reason misses that one hour window. Patient still did get antibiotic but current form doesn't seem to capture that.</p>	<p><i>Answer : Generator and leads procedure is coded</i></p> <p><i>Answer: Leads only procedure is coded</i></p> <p><i>Answer: Leads only procedure is coded</i></p> <p><i>Answer: Leads only procedure is coded</i></p> <p><i>Answer: The patient either received antibiotics within 1 hour or he did not. The purpose is to capture the timeframe as opposed to giving antibiotics at any time.</i></p>
<p>26</p>	<p>I am a little confused about syncope. What if the syncope is not cardiac related? Is that still considered secondary?</p>	<p><i>For the purposes of the ICD Registry, Syncope must be cardiac related in order to exclude the indication of a primary prevention implant. If syncope is documented as relating to another source other than cardiac, it should not be a determining factor or criteria for secondary prevention.</i></p>
<p>27</p>	<p>This may be beyond the scope of this presentation but in regards to 90 day outcomes - how will data be validated to confirm that, for example, a tamponade or a hematoma is related to the ICD implant and not another procedure</p>	<p><i>For the purposes of the ICD Registry, all ICD related adverse events must be coded prior to the patient discharge from the facility. Adverse events are reported for this timeframe only, and will not be followed post discharge. NCDR is currently working on possibilities of a Longitudinal ICD Registry which would allow data post discharge.</i></p>
<p>28</p>	<p>We enter only primary prevention patients as required by CMS. Resource allocation keeps us from participating in "All Patient" reporting. Will we have to report leads in version 2.0 if we are just doing CMS only cases?</p>	<p><i>If you are currently submitting CMS only cases to the ICD Registry for the purpose of meeting the Federal mandate, you will not have to do anything additional at the time of the release of version 2.0. Leads data will not be a requirement for CMS only submissions. You will however, still need to learn the new Data Collection tool, review the new data elements and definitions, as well as the new DQR process associated with version 2.0. Please look for training opportunities posted on the ICD Registry home page.</i></p>

<p>29</p>	<p>Section F ICD procedure, Reasons for re-implantation. If a generator is changed due to ERI or near ERI status and lead replaced due to malfunction (noise, etc) during same surgery does that constitute "Device Malfunction"? In other words, device isn't malfunctioning (assuming ERI is expected and not premature) but the lead is malfunctioning. Should that box "Device Malfunction" be checked as well? Some of our data acquisition team feels "Device" refers only to the generator; others feel "Device" refers to "gen/lead system" as a whole. Please clarify.</p>	<p><i>In section "F" of the new Data Form, "device malfunction" is in reference to the device itself and should not be selected based on a faulty lead. The Leads Data page will capture the lead malfunction in section "G</i></p>
<p>30</p>	<p>On one slide of today's ICD presentation it addressed when/how to use the new generator and leads form. Scenarios:</p> <p>1.) Collecting Medicare PP (limited): all sections except G on form.</p> <p>2.) Collecting Primary and Secondary gen, leads, peds (Premier): entire form.</p> <p>Our facility collects, DQR's, and submits all patients to the registry. This would put us in group 2.) Above: collecting Primary and Secondary and therefore completing the entire form.</p> <p>Please confirm</p> <p>Also, in the case where only a lead is involved, and we are not a Premier facility, clarify as to whether the facility has to complete the lead only form.</p>	<p><i>You can only submit one of two populations per quarter;</i></p> <p><i>CMS Only - If you are submitting primary prevention patients only (billed to Medicare) to meet the CMS mandate, you will not have to complete section "G" of the data collection tool. If this is the population you have chosen, you will not have to report "leads only" procedures in the event a patient returns to the lab for a new lead.</i></p> <p><i>All Patient Population - If you are submitting "All Patients" for the purpose of ICD Registry Outcomes reporting and Premier inclusion, you must submit all patients and all leads associated with the ICD or CRT-D. If the patient comes back to the lab for a lead procedure, you must fill out the "Leads Only" form.</i></p>

31	<p>I have some questions from yesterday's webcast. Someone made a comment about the 1st Q of 2010, about when it is due? I thought they said April 1st, but how can that be. What date do we start using the new 2.0 form?</p>	<p><i>Version 1.08 will be available until June 30th 2010. After this time, you will no longer be able to enter and submit data to NCDR via Version 1.08. Now is the time for participants to enter and submit anything which may have been overlooked, dating all the way back to the beginning of the ICD Registry. After this date of June 30th 2010, if you find a record which should have been reported but was not, you will not be able to provide that information to CMS. It is extremely important that you ensure that all of your Version 1.08 cases are entered and submitted by June 30th 2010.</i></p> <p><i>Regarding Q4 2009 data: The current deadline for submission for this data is April 15th 2010. The only way you will be able to enter and submit this data is via Version 1.08. Please follow the same protocol you have been using for the past years. Version 1.08 will still be up and running.</i></p> <p><i>Regarding Q1 2010 data: The current deadline for submission for this data is June 30th 2010. The only way you will be able to enter and submit this data is via Version 1.08. Please follow the same protocol you have been using for the past years. Version 1.08 will still be up and running. Q1 2010 contains data from January 1st 2010 to March 31st 2010. March 31st 2010 is the last "date stamp" on a patient data form which version 1.08 will allow data entry. If you try to enter a case date stamped 04/01/2010 into version 1.08, the V1.08 system will not allow it.</i></p> <p><i>Regarding Q2 2010 data: The current deadline for Q2 2010 data submission is September 30th 2010. This deadline is set for data coded for patients with discharge dates of April 1st 2010, and greater. The only way you will be able to enter and submit this data will be via Version 2.0. Version 2.0 will be up and running. If you attempt to code a patient into Version 2.0 with a discharge date stamp of 03/31/2010 or before, the Version 2.0 system will not allow it.</i></p>
32	<p>Do we track leads that were part of pacemaker systems that are removed or reutilized at the time of ICD upgrades</p>	<p><i>The Registry will track leads that are or were a part of an ICD system. Therefore a lead that was a part of a pacemaker system that is reused in an ICD system would be tracked. A lead that was removed or abandoned and was never part of an ICD system would not be tracked.</i></p>
33	<p>Are ICDs that are implanted in patients with genetic syndromes (egg LQT, CPVT, HCM) and syncope classified as primary or secondary prevention?</p>	<p><i>"secondary"</i></p>
34	<p>An LV lead placement is attempted but fails and no LV lead is implanted. The lead was never part of an ICD system. Is the lead to be tracked</p>	<p><i>Yes even though it was not part of an ICD system the intent was to implant it.</i></p>
35	<p>A defibrillation lead has a sensing problem leading to noise and an inappropriate shock. Is this a pacing function problem or a defibrillation function problem or both?</p>	<p><i>This is a pacing problem as the problem relates to sensing and <u>inappropriate defibrillation not ineffective defibrillation</u>. The type of lead does not define the type of problem.</i></p>

36	A patient undergoes an attempted lead procedure to improve lead performance but it is found that the lead cannot be manipulated and the lead is simply left as it was. Is this procedure to be tracked and if so, how is it to be categorized?	<i>Yes the procedure is to be tracked. It would be categorized as a lead repositioning even though that was not accomplished.</i>
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Source

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