

**MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)  
CARDIAC CATHETERIZATION  
STANDARD ADVISORY COMMITTEE (CCSAC) MEETING**

Monday, August 14, 2017

South Grand Building  
333 S. Grand Ave,  
1<sup>st</sup> Floor, Grand Conference Room  
Lansing, MI 48933

**APPROVED MINUTES**

**I. Call to Order**

Chairperson David called the meeting to order at 9:45 A.M. and asked for introductions of members and staff.

**A. Members Present:**

Ernest Balcueva – American Heart Association  
Lynne F. Carter, MD – Blue Cross Blue Shield of Michigan  
Shukri David, MD, Chairperson – Ascension | Michigan  
Michele L. Davis – Electrical Workers’ Joint Board of Trustees  
Simon Dixon, MD – Beaumont Hospital  
Hitinder S. Gurm, MD – University of Michigan  
Ryan D. Madder, MD – Spectrum Health  
Kristopher J. Selke, DO – Mercy Health and St. Joseph Mercy Health System  
Sunita Vadakath, MD – MidMichigan Health

**B. Members Absent:**

Henry E. Kim, MD – Henry Ford Health System  
Theodore L. Schreiber, MD – Detroit Medical Center  
Ibrahim Shah, MD – McLaren Greater Lansing

**C. Michigan Department of Health and Human Services Staff present:**

Tulika Bhattacharya  
Amber Myers  
Tania Rodriguez  
Brenda Rogers

**II. Declaration of Conflicts of Interests**

No conflicts were declared.

**III. Review of Agenda**

No changes were made to the agenda. Agenda was approved.

**IV. Review and Approval of July 13, 2017 Minutes**

Motion by Dr. Dixon, seconded by Ms. Davis to approve the minutes as presented. Motion Carried.

**V. Discussion of Charge #5: Review section 11 to determine if it is appropriate to incorporate additional interventional procedures that are performed in a cardiac catheterization laboratory but are not currently identified or weighted in section 11**

Dr. Dixon provided an overview. (See Attachment A)

Discussion followed.

Recommendations will be provided at the next meeting.

**VI. Discussion of Charge #1: Determine if modifications are necessary to section 10(5)(f), specifically whether or not this section should apply only to facilities that do not have on-site open heart surgery (OHS)**

Dr. Selke provided an overview.

Discussion followed.

Motion by Dr. Dixon, seconded by Dr. Gurm to make Section 10(5)(f) applicable to only those without on-site OHS. Motion carried in a vote of 9- Yes, 0- No, and 0- Abstained.

The SAC asked Ms. Bhattacharya to review section 10(5)(i) for a future meeting.

**VII. Discussion of Charge #2: Determine if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ambulatory surgical centers (ASCs) or only in licensed hospitals**

Dr. David provided an update.

Discussion followed.

**VIII. Discussion of Charge #4: Review section 10(5)(c) to determine if it is appropriate to exclude patients with cardiogenic shock**

Dr. Gurm on behalf of Dr. Schreiber provided an overview. (See Attachment B)

Discussion followed.

Motion by Dr. Gurm, seconded by Dr. Selke to exclude patients with cardiogenic shock under Section 10(5)(c). Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

**IX. Next Steps**

Ms. Bhattacharya will report back on Section 10(5)(i).

Dr. David will report back on Charge #2 *“Determine if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ambulatory surgical centers (ASCs) or only in licensed hospitals.”*

Dr. Dixon will provide recommendations on Charge #5 *“Review section 11 to determine if it is appropriate to incorporate additional interventional procedures that are performed in a cardiac catheterization laboratory but are not currently identified or weighted in section 11.”*

Dr. Selke will review Charge #6 *“Consider revisions to clarify section 4(13)(a) and (b).”*

**X. Future Meeting Dates**

September 14, 2017; October 19, 2017; November 9, 2017; & December 20, 2017.

**XI. Public Comment**

None

**XII. Adjournment**

Meeting adjourned at 11:10 A.M.

*Cardiac Catheterization Services Standard Advisory Committee*

# **Review of Charge #5: Additional Interventional Procedures**

**Simon R. Dixon, MBChB, FACC  
Beaumont Hospital - Royal Oak  
August 14, 2017**

## Charge #5

- Review section 11 to determine if it is appropriate to incorporate additional interventional procedures that are performed in a cardiac catheterization laboratory but are not currently identified or weighted in section 11.

# Section 11

## Current methodology for determining procedure equivalents

Procedure Type	Procedure equivalent	
	Adult	Pediatric
Diagnostic cardiac catheterization/peripheral sessions	1.5	2.7
Therapeutic cardiac catheterization/peripheral sessions	2.7	4.0
Complex percutaneous valvular sessions*	4.0	7.0
* Complex percutaneous valvular sessions includes, but is not limited to, procedures performed percutaneously or with surgical assistance to repair or replace aortic, mitral and pulmonary valves such as transcatheter aortic valvular implantation (Tavi) procedures. These sessions can only be performed at hospitals approved with OHS services.		

The current methodology was introduced in 2011

# Prior Methodology

Procedure Type	Procedure Equivalent	
	Adult	Pediatric
Diagnostic Cardiac Cath	1.0	3.0
Therapeutic Cardiac Cath	1.5	3.0
Therapeutic Other (PFO/ASD/Vplasty/LVAD)	2.5	3.5
Diagnostic Peripheral	1.0	2.0
Therapeutic Peripheral (Carotid/Subclavian/Renal/Iliac/Mesenteric)	1.5	2.5
Therapeutic Peripheral: SFA	2.5	2.5
Infrapopliteal	3.0	3.0
Aorta	4.0	4.0
Diagnostic EP	2.0	3.5
Therapeutic EP: PPM/ICD	2.5	5.0
Ablation (Non-AF)	3.0	5.0
Ablation (AF/VT)	4.0	6.0
Cardioversion	1.0	1.0
•Other (IVC Filter/TTVP/IABP, other rad procedure)	1.0	2.0

Introduced 2008

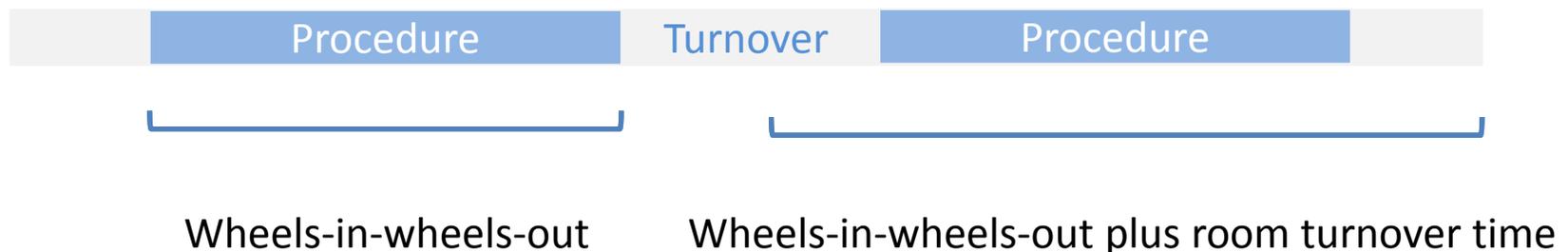
# Definition Therapeutic Procedures

- Section 2 (1) (q)
  - PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantation, left sided arrhythmia procedures

# What is a Procedure Equivalent?

- “... means a unit of measure that reflects the relative average **length of time** one patient spends in one session in a laboratory based on the type of procedures being performed”.

Note: Length of time is not well defined, for example:



# Importance of Procedure Equivalents

- A minimum number of procedure equivalents are required to:
  - Initiate cardiac catheterization service
  - Replace cardiac cath lab
  - Expand (add) cardiac cath lab

# Definition Therapeutic Procedures

- Section 2 (1) (q)
  - PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantation, left sided arrhythmia procedures

*Additional procedures: Watchman, CTO, Impella, paravalular leak closure, alcohol septal ablation*

# Procedure Time Data

Median time in minutes

Procedure	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
PCI						
PCI for CTO	157					
Impella	154					
TAVR	188					
MitraClip	240					
Alcohol septal ablation	165					
Paravalvular leak	277					
Watchman	135					

*New procedures highlighted red. Other procedures provided as reference*

# Summary

1. Current procedure equivalent methodology does not encompass several newer therapeutic procedures as noted earlier
2. These newer procedures are more complex and require longer procedure time compared to conventional therapeutic procedures such as (non-CTO) PCI

# Summary

3. Current procedure equivalent weighting is imperfect as “therapeutic” category includes a very broad spectrum of procedures with markedly different procedure times (eg: pacemaker to AF ablation)

# Discussion Points

- What additional procedures should be included?
- What is the appropriate weighting for new procedures?
- Should the current procedure equivalent categories be modified?

# Recommendations

1. Based on available procedure time data from hospitals in Michigan, and within the current category framework, newer therapeutic procedures should be weighted as shown below:

Procedure	Weighting
PCI for CTO	
Impella	
Alcohol septal ablation	4.0
Paravalvular leak closure	4.0
Watchman	

# Requirement to Initiate Service

Service	Site	Total procedure equivalent volume
Adult diagnostic	Rural	Project 500 (300 diagnostic)
Adult diagnostic	Metropolitan	Project 750*
Adult diagnostic	2 or more labs	Project 1000*
Adult therapeutic		Performed 300 diagnostic
Adult therapeutic	No OHS	Performed 500 (400 diagnostic)
Pediatric		Project 600

\*Must include 300 procedure equivalents in diagnostic cath category  
 Procedure equivalent volume based on data from the most recent 12-month period preceding the date the application

## Rodriguez, Tania (DHHS)

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**To:** Schreiber, Theodore  
**Subject:** RE: Data for CON meeting

**From:** Schreiber, Theodore [<mailto:TSchreib@dmc.org>]  
**Sent:** Friday, August 11, 2017 10:32 AM  
**To:** Rodriguez, Tania (DHHS) <[RodriguezT1@michigan.gov](mailto:RodriguezT1@michigan.gov)>  
**Cc:** Schreiber, Theodore <[TSchreib@dmc.org](mailto:TSchreib@dmc.org)>  
**Subject:** FW: Data for CON meeting  
**Importance:** High

This message was sent securely using ZixCorp.

Tania, please attach this email from Dr.Gurm to me on Monday's agenda. I may be unable to attend due to a last moment clinical emergency.  
I recommend that we do exclude all cardiogenic shock cases from door-to-balloon time requirements and other regulations from Section 10-5-c.  
Can you please confirm receipt and forward this to Dr.S.David , Chairperson.  
Thanks  
Ted

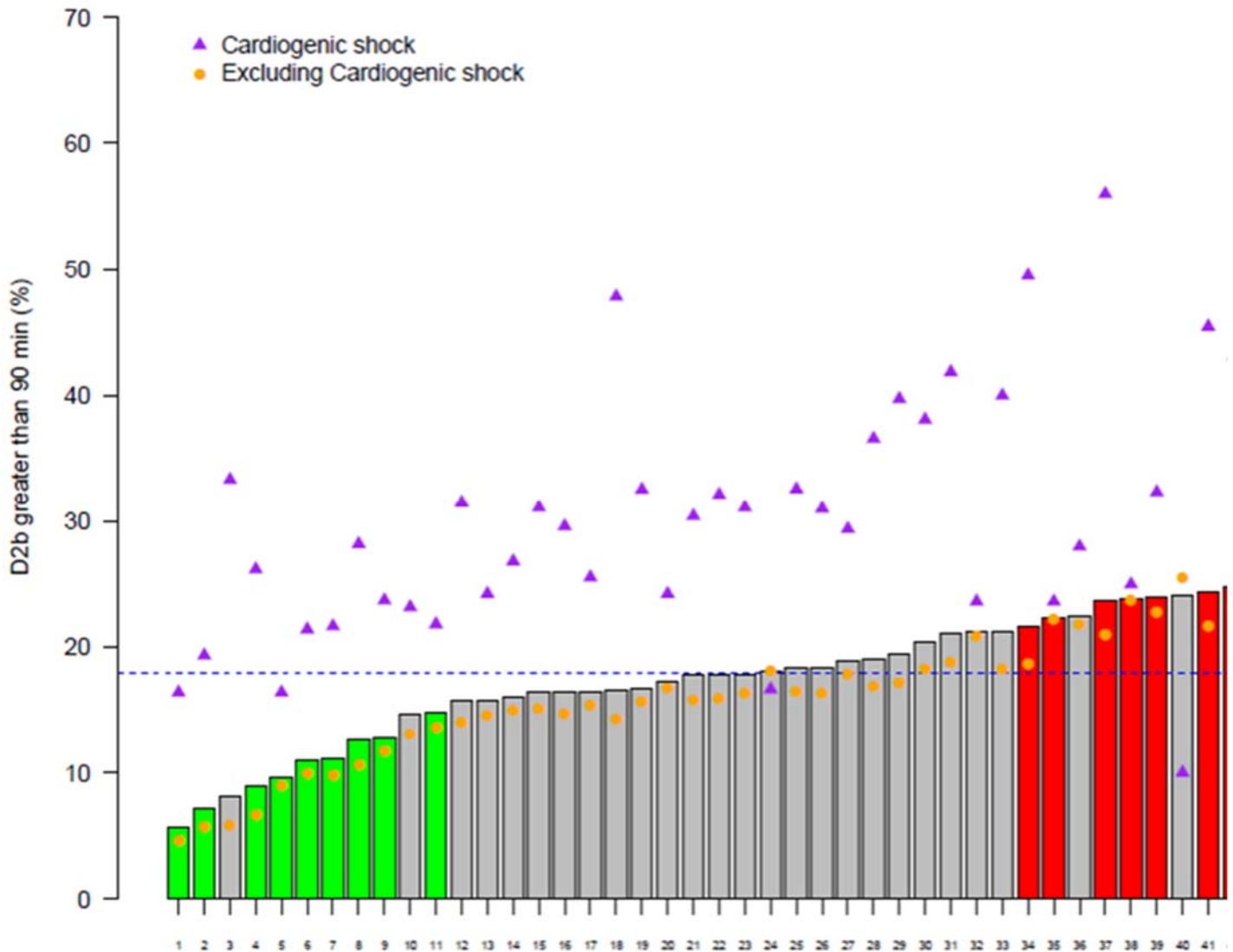
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**From:** Gurm, Hitinder [<mailto:hgurm@med.umich.edu>]  
**Sent:** Thursday, July 20, 2017 4:41 PM  
**To:** Schreiber, Theodore  
**Subject:** FW: Data for CON meeting

Hi Ted,  
Please see attached. It seems that 18% of our patients exceed D2B of 90 minutes and the shock patients have much longer D2 B times. However, the exclusion of these patients does not really impact the proportion of patients exceeding 90 minutes in a meaningful fashion since shock patients make up a small minority of the total. However, for a legal status, I am inclined to agree that it is probably best to exclude these patients . I will get you the specific D2B times for those with shock versus no shock

HG

Door to Balloon time greater than 90 min (% of cases)  
 Blue dashed line is overall rate of 18.0%  
 Sites with rates significantly different from overall rate  
 are colored green and red depending on whether they lie below or above the o



**From:** Seth, Milan  
**Sent:** Thursday, July 20, 2017 1:38 PM  
**To:** Gurm, Hitinder  
**Cc:** Frazier, Kathleen  
**Subject:** Re: Data for CON meeting

Shock patients did have much longer d2b times, and much higher proportion greater than 90 minutes, but excluding them does not greatly impact the site median d2b or the proportion >90 min due to the relatively small number of cases (10.5% were shock).

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