

# *Testimony* *Medicare Coverage Advisory*

*LVAI Therapy*

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# *ISHLT testimony overview*



- REMATCH provided *proof of principle*
- translation into practice is *challenging*
- a strategy focusing on *safety and efficacy* is needed
- *different options* to identify chronic MCSD-centers exist
- ISHLT recommends *criteria-based* center identification
- *mandatory MCSD Database* is an answer to the challenge

# *ISHLT MCSD database rationale*



- REMATCH is small database > *more data needed*
- RCT are *time consuming & restricted*
- current registries are *insufficient*
  
- characterize worldwide *overall practice*
- assess *MCSD safety* with uniform definitions
- evaluate *MCSD efficacy* with HF stratification

# *MCSD voluntary vs mandatory*



## *voluntary registry*

- **reduces resources +**
- **no penalties +**

## *mandatory database*

- **captures more centers +**
- **complete data +**
- **more credibility +**
- **more inferences +**
- **more funding +**

# *recommended role of database*



**REQUESTOR** *registry should be maintained*

**ISHLT** *mandatory reporting to centralized database*

**ACC** *mandatory reporting*

**STS/AATS** *mandatory participation in centralized database*

**ASTS**

**AHA** *registry should be established*

# *IOM 2001 vision & chronic MCSD*



- **system inability to *translate knowledge into practice &***
- **to apply new technology *safely and appropriately***
- **rec # 7 *performance and outcomes measurements***
- **rec # 8 *ongoing analysis & synthesis of evidence***
- **rec # 10 *payment incentivizing quality enhancement***
  
- **> *unique opportunity to create a model for this agenda by***
- **mandating *participation in MCSD database for reimbursement***