INCORPORATING PROSPECTIVE DATA COLLECTION INTO CLINICAL PRACTICE - THE HOLD EXPERIENCE

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- I do not intend to discuss an unapproved / investigative use of a commercial product/device in my presentation

- Information contained in this presentation is from previously presented/or published peer reviewed material

OUTLINE

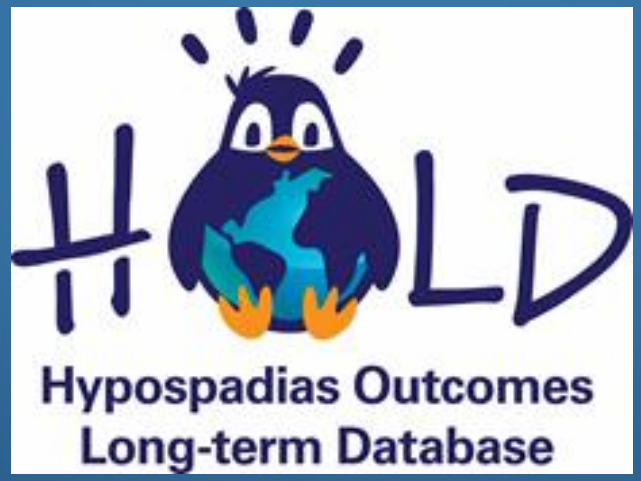
- Background
- Rationale for the HOLD Project
- CIHR International Task Force
- Prospective Database (REDCap)
- Getting engaged

REVIEW OF THE LITERATURE

HOLD
Hypospadias Outcomes Long-term Database

- Complication rates vary widely
- More than 300 surgical techniques reported
- Short to mid-term follow-up
- What matters for patients is still lacking

WHY A MULTICENTRE PROSPECTIVE HYPOSPADIAS DATABASE?



RATIONALE FOR HOLD

Hypospadias Outcomes Long-term Database

- Different surgeons use different surgical techniques
- Few studies address long-term outcomes
- No standardized way of reporting pre- and post-operative results
- Even the largest centers do not have enough numbers to answer the necessary questions.

RATIONALE FOR HOLD

Hypospadias Outcomes Long-term Database

- 3 **P's** for improving practice and clinical outcomes
  - **Prospective** data collection – better quality of research
  - **Periodic** outcomes review – understand own and others' results
  - **Practice** change – personal improvement – better outcomes – better patient care

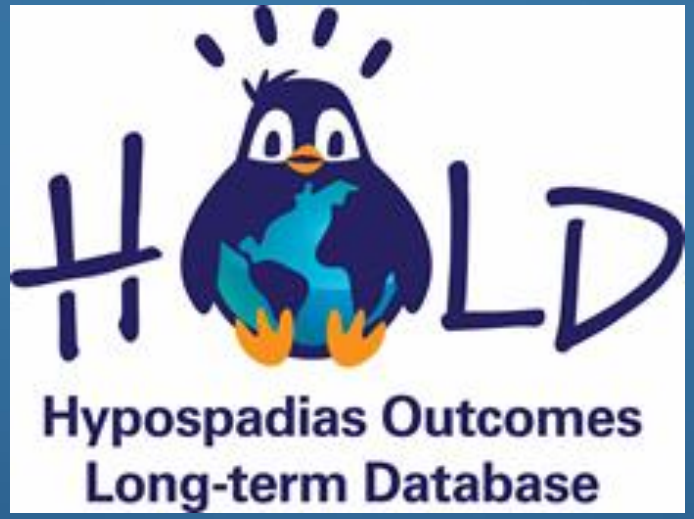
(Snodgrass W, AUA Univeristy, www.auanet.org)

OBJECTIVES OF THE HOLD PROJECT

Hypospadias Outcomes Long-term Database

- What are the most common techniques?
- What is the true complication rate at an institutional, provincial and national level and what factors affect it?
  - Preoperative hormone stimulation / Regional blocks
  - Glans size
  - Glans groove / Urethral plate
  - Severity of VC
  - Number of cases – (distal vs. proximal)
- How satisfied are adolescents with their hypospadias repair outcomes?

HOW IT ALL STARTED



International Pediatric Urology Task Force on Hypospadias

Standardizing Surgical Outcomes in Clinical Research

Date: **September 18th to 19th, 2013**
Location: **Aria Hotel, Las Vegas, Nevada**

HOLD
Hypospadias Outcomes Long-term Database

Hosted by Dr. Luis Braga of McMaster University, in collaboration with the Hospital for Sick Children and Pediatric Urology researchers from across Canada, the USA, Brazil, France, Italy, and the United Kingdom.

Held immediately prior to the Pediatric Urology Fall Congress

MEETING OBJECTIVES

Hypospadias Outcomes Long-term Database

- Improve quality of reporting in hypospadias literature - a 20-item instrument adapted from STROBE.
- Create a Summary of Findings (SoF) table highlighting key points of studies.
- Set minimum standards for data collection through expert consensus.
- Create networks for future global/international cooperation in hypospadias research.

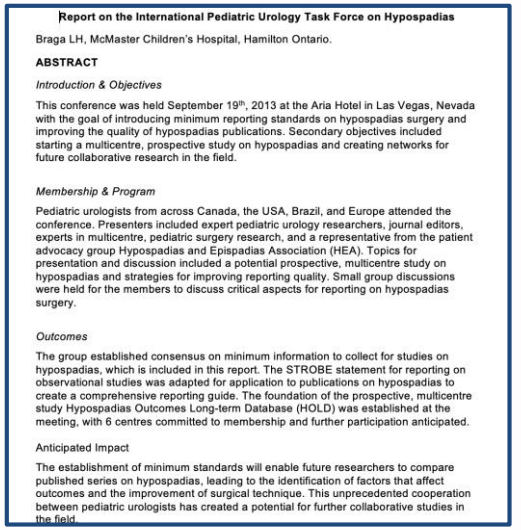
HOLD TASK FORCE

HOLD
Hypospadias Outcomes Long-term Database

MEETING OUTCOMES

Hypospadias Outcomes Long-term Database

- Meeting Minutes circulated and posted as a white paper ✓
- Consensus statement on data collection and reporting on hypospadias **(in progress)**
- Application of the STROBE statement to the hypospadias literature ✓



Report on the International Pediatric Urology Task Force on Hypospadias

Braga LH, McMaster Children's Hospital, Hamilton Ontario.

ABSTRACT

Introduction & Objectives

This conference was held September 19th, 2013 at the Aria Hotel in Las Vegas, Nevada with the goal of introducing minimum reporting standards on hypospadias surgery and improving the quality of hypospadias publications. Secondary objectives included starting a multicentre, prospective study on hypospadias and creating networks for future collaborative research in the field.

Membership & Program

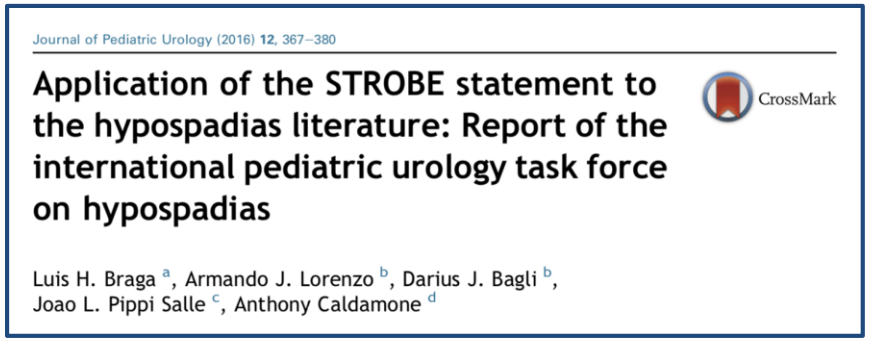
Pediatric urologists from across Canada, the USA, Brazil, and Europe attended the conference. Presenters included expert pediatric urology researchers, journal editors, experts in multicentre, pediatric surgery research, and a representative from the patient advocacy group Hypospadias and Epispadias Association (HEA). Topics for presentation and discussion included a potential prospective, multicentre study on hypospadias and strategies for improving reporting quality. Small group discussions were held for the members to discuss critical aspects for reporting on hypospadias surgery.

Outcomes

The group established consensus on minimum information to collect for studies on hypospadias, which is included in this report. The STROBE statement for reporting on observational studies was adapted for application to publications on hypospadias to create a comprehensive reporting guide. The foundation of the prospective, multicentre study Hypospadias Outcomes Long-term Database (HOLD) was established at the meeting, with 6 centres committed to membership and further participation anticipated.

Anticipated Impact

The establishment of minimum standards will enable future researchers to compare published series on hypospadias, leading to the identification of factors that affect outcomes and the improvement of surgical technique. This unprecedented cooperation between pediatric urologists has created a potential for further collaborative studies in the field.



Journal of Pediatric Urology (2016) 12, 367–380

Application of the STROBE statement to the hypospadias literature: Report of the international pediatric urology task force on hypospadias

CrossMark

Luis H. Braga [a], Armando J. Lorenzo [b], Darius J. Bagli [b], Joao L. Pippi Salle [c], Anthony Caldamone [d]

MINIMAL REPORTING ITEMS

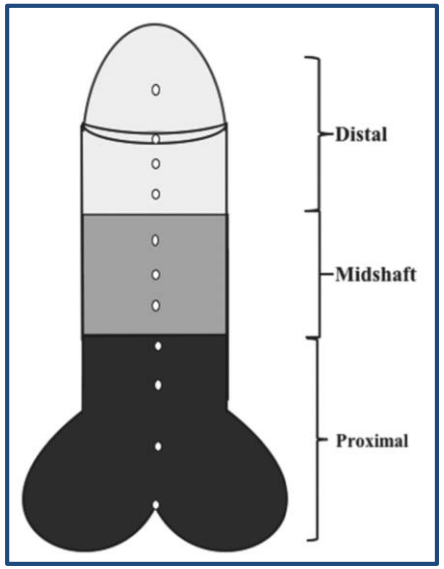
Hypospadias Outcomes Long-term Database

Preoperative Assessment

- Meatal location and/or level of division of corpus spongiosum, as defined by Figure 1
- Presence of associated genital anomalies
- Measured degree of penile torque
- Measured degree of ventral curvature
- Prior circumcision
- Use and details of preoperative hormone stimulation
- Details of any previous surgery for hypospadias

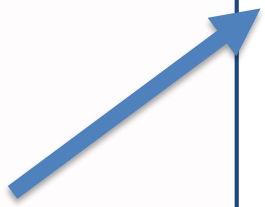
Intraoperative Assessment

- Fully-stretched dorsal penile length and diameter of the glans
- Depth of the groove separating the glans wings
- Length and width of the urethral plate (UP), extending from the ectopic ventral meatus to the tip of the glans
- Presence of hypoplastic urethra below the meatus, characterized by an absence of surrounding corpus spongiosum tissue
- Deficiency of the ventral skin
- Ventral curvature of the penis
- Elasticity or rigidity of the UP tissue



MINIMAL REPORTING ITEMS

Hypospadias Outcomes Long-term Database



Surgical Technique

Anaesthesia and methods to achieve hemostasis

Severity and ventral curvature re-assessment after de-gloving

Degree of ventral curvature and steps taken for correction

Type of surgical procedure performed, including any modifications

Grafting use, including the donor site and its management

Use of UP incision, including post-incision width

Details of urethroplasty, including number of layers, suture size, suture type, and closure

Glansplasty, if used, including suture size, type, and closure

Barrier layers, if used, including number of layers and tissue used

Additional procedures performed

Skin closure, including suture size, type, and suture closure

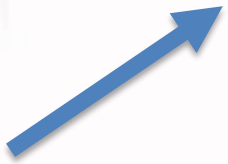
Urinary diversion and dressing

Meatal position at the end of the procedure

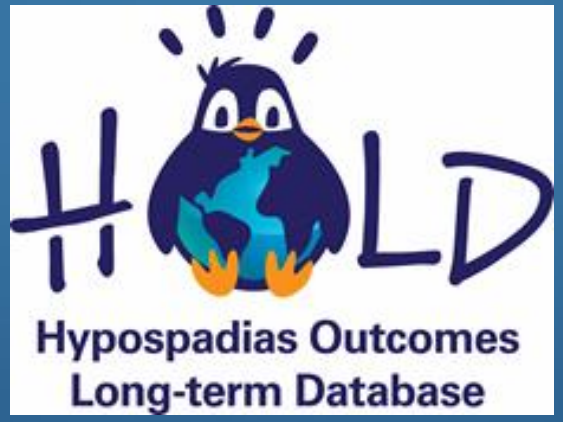
Foreskin management (preputioplasty or circumcision)

MINIMAL REPORTING ITEMS

Follow-up and Outcome Assessment
Age at follow-up
Duration of follow-up
Developmental milestones reached
Presence of complications and their severity
Assessment of voiding
Cosmetic assessment



HYPOSPADIAS LONG - TERM OUTCOMES DATABASE (HOLD)



McMaster Children's Hospital

McMaster University

McMaster Pediatric Surgery Research Collaborative

Advancing Evidence-Based Surgical Care for Children

HOLD

Hypospadias Outcomes Long-term Database

- Prospective data collection on all hypospadias surgeries from 2010 – present
  - Importance - consecutive cases
- Online database using REDCap to collect and store information
  - Infrastructure and Security to support multiple centres

HOLD FORMS

Hypospadias Outcomes Long-term Database

Surgery Form 2.1

Patient ID: ☐☐☐
Physician Code: ☐☐
Centre Code: ☐☐

Clearly print all details. Please INITIAL and DATE all corrections. Indicate ☒ where applicable.

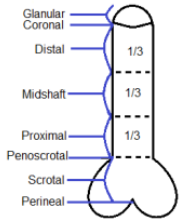
Please complete Surgery Forms 2.1-2.7 for the infant currently referred for this database.

1. Date* ☐☐☐☐☐☐ (YY MM DD)
2. Age in months* ☐☐ (months)
3. Weight at surgery ☐☐ (kg)

1. Did the position of the meatus change after testosterone administration?* ☐ No ☐ Yes

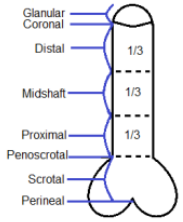
2. Please indicate the intraoperative position of the meatus*

☐ Glanular
☐ Coronal
☐ Subcoronal
☐ Distal shaft
☐ Mid shaft
☐ Proximal shaft
☐ Penoscrotal
☐ Scrotal
☐ Perineal



3. Please indicate the intraoperative position of the division of the corpus spongiosum*

☐ Glanular
☐ Coronal
☐ Subcoronal
☐ Distal shaft
☐ Mid shaft
☐ Proximal shaft
☐ Penoscrotal
☐ Scrotal
☐ Perineal



Version 5.0 December 12, 2014 **denotes a required field*

Surgery Form 2.3

Patient ID: ☐☐☐
Physician Code: ☐☐
Centre Code: ☐☐

Clearly print all details. Please INITIAL and DATE all corrections. Indicate ☒ where applicable.

Please complete Surgery Forms 2.1-2.7 for the infant currently referred for this database.

3. Degree of VC* ☐ <30° (mild) ☐ 30-70° (moderate) ☐ >70° (severe)
4. VC Measurement ☐ Visual estimate ☐ Measured in degrees[1]
   [1]Please specify the degrees of VC before degloving _____°
5. Degree of VC After Degloving ☐ None ☐ <30° ☐ 30-70° ☐ >70°
6. VC Measurement after degloving ☐ Visual estimate ☐ Measured in degrees[2]
   [2]Please specify the degrees of VC after degloving* _____°
7. VC Type*
   ☐ Lateral bands (fibrosis) ☐ Penoscrotal curvature ☐ Other (please specify): _____
   ☐ Glans tilt ☐ Corporal disproportion
   ☐ Short urethral plate ☐ VC with no hypospadias
8. VC Correction Procedure*
   ☐ Degloving ☐ Proximal dissection of urethra beyond peno-scrotal junction
   ☐ Release of lateral bands ☐ Fairy cuts (Ventral transverse releasing incisions)
   ☐ Urethral plate lifting
   ☐ Dorsal plication[3] [3]If checked, please answer **Questions 10-11.**
   ☐ Ventral penile lengthening (grafting the corpora)[4] [4]If checked, please answer **Question 12.**
   ☐ Transection of urethral plate[5] [5]If checked, please answer **Question 13-14.**
9. Dorsal Penile Length (after VC correction)* _____ mm
10. Dorsal Plication Type* ☐ Midline (Baskin) ☐ Lateral (Nesbitt)
11. Number of stitches used for Dorsal Plication _____
12. Corporal Grafting Type
    ☐ Skin (inner prepuce) ☐ Tunica vaginalis ☐ Dura
    ☐ 1-layer SIS ☐ 4-layer SIS ☐ Other (please specify): _____
13. Degree of VC After Transection of Urethral Plate* ☐ None ☐ <30° ☐ 30-70° ☐ >70°
14. Method of VC assessment after UP transection ☐ Visual ☐ Measured[6]
    [6]Degrees of VC after UP transection _____°

Version 5.0 December 12, 2014 **denotes a required field*

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WHY USE REDCap?

Hypospadias Outcomes Long-term Database

Research Electronic Data Capture (REDCap)

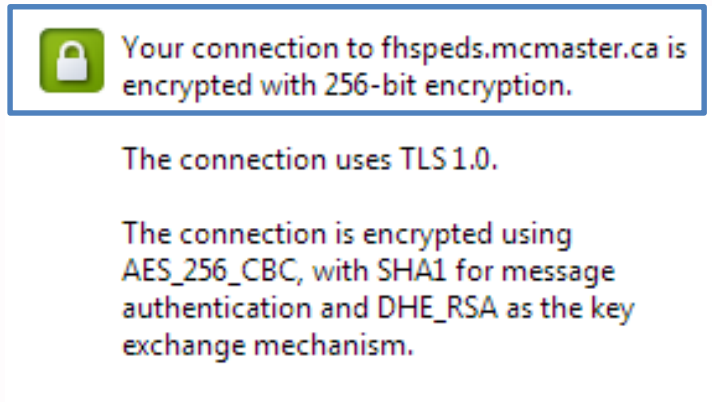
- Online tool to collect and manage data
- Accessible online (smartphones, tablets, etc)
- Intuitive, user friendly interface
- Customizable
- Free to add users and create projects
- Secure: designed to support HIPAA compliance

867 institutions in 71 countries

SECURITY

Hypospadias Outcomes Long-term Database

- Data stored on McMaster Server, encrypted and backed-up nightly.
- 256-bit encryption system designed to provide communication security over the internet.
- Audit trails track data manipulation and export by all users.



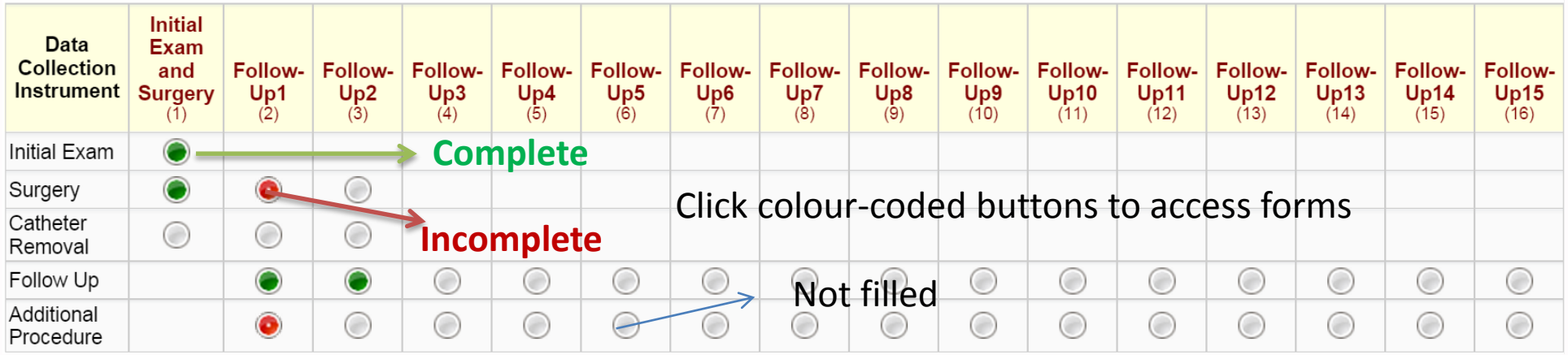
Time / Date	Username	Action	List of Data Changes OR Fields Exported
12:46pm 11/20/2013	david	Manage/Design	Edit project field
12:36pm 11/20/2013	david	Manage/Design	Create project field

User activity shown in detail

CUSTOMIZATION

Longitudinal Data Entry

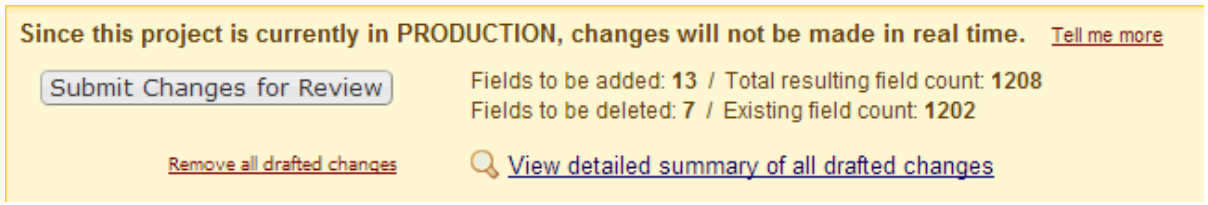
- Forms can be used once or multiple times per record
- Keeps study info organized by visit
- Complete forms - green, incomplete - red, and unverified - yellow

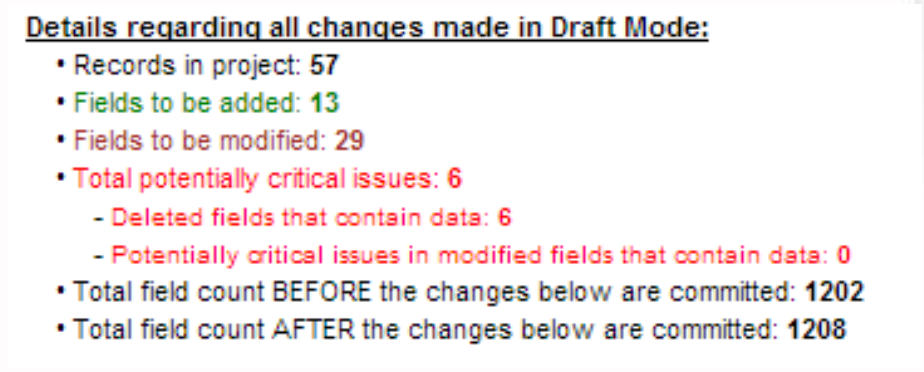


CUSTOMIZATION

Hypospadias Outcomes Long-term Database

- REDCap has safeguards in place to prevent data loss while making changes to the database.
- During development, changes can be made in real time.
- After data collection begins, projects can still be safely updated.
- All updates during production are reviewed by an administrator





HOLD

Hypospadias Outcomes Long-term Database

- Policy for Data Access and Authorship **(Data sharing agreement)**
  - Same model as other registries
    - Hydronephrosis – (Tony Herndon)

- Research output - Presentations / Publications
  - CUA: 2013-19
  - ESPU: 2015, 2016, 2019
  - AUA: 2016, 2017, 2018, 2019

HOLD – PUBLICATIONS

Hypospadias Outcomes Long-term Database

Hypospadias

0022-5347/17/1973-0845/0
THE JOURNAL OF UROLOGY®

Cause and Effect versus Confounding—Is There a True Association between Caudal Blocks and Tubularized Incised Plate Repair Complications?

Luis H. Braga,* Kizanee Jegatheeswaran, Melissa McGrath, Bethany Easterbrook, Mandy Rickard, Jorge DeMaria and Armando J. Lorenzo

CURRENT DATABASE - DESCRIPTIVES

Hypospadias Outcomes Long-term Database

- 848 patients included in the database
- Location
  - Distal: 616 (72%)
  - Midshaft: 100 (13%)
  - Penoscrotal/perineal: 132 (15%)
- Median age at surgery: 16.9 mos.

CURRENT DATABASE DESCRIPTIVE

Hypospadias Outcomes Long-term Database

Complications

- Overall complication rate = 14.7%
- Fistula - 9%
- Glans dehiscence - 6%

CURRENT CENTRES

HOLD
Hypospadias Outcomes Long-term Database

- McMaster University – Started 2010
- Children's Hospital of Eastern Ontario – February 2016
- Rhode Island Hospital – March 2015
- Hospital Geral Roberto Santos – Bahia Brazil - June 2015

PARTICIPATING CENTRES

HOLD
Hypospadias Outcomes Long-term Database

Centres in Ethics Approval Process

- Dalhousie Univeristy, Nova Scotia, Canada
- Hamad Medical Corporation, Qatar
- All India Institute of Medical Services, India

BARRIERS

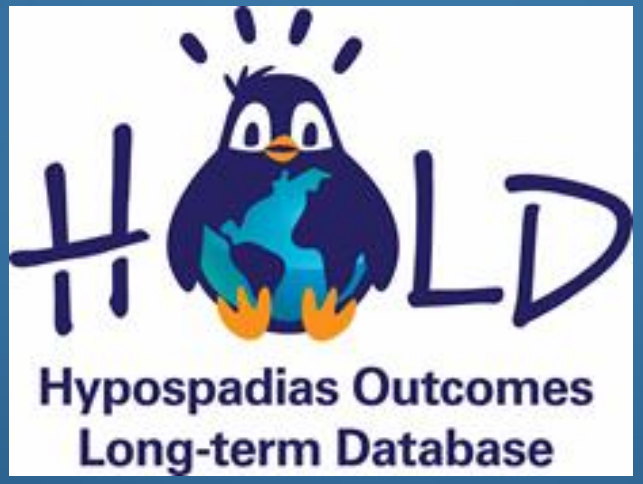
- There needs to be a research **CULTURE** shift
- Research happens all the time
  - Clinics, OR, meetings, rounds, etc
- It is part of what we do, how we grow !!!
- Research support – **VERY IMPORTANT**
  - if you don't have it - volunteers

MINDSET

"START WHERE
YOU ARE.
USE WHAT
YOU HAVE.
DO WHAT
YOU CAN."

- ARTHUR ASHE

GETTING INVOLVED



WHY SHOULD ONE GET INVOLVED ?

Hypospadias Outcomes Long-term Database

- **Clinical Benefits**
  - Evidence-based improvement tool for your own practice
  - Establish minimal standards of care
  - Generalizability of published results

- **Research Benefits**
  - Publication of centre specific data
  - Collaboration in multi-centre projects
  - Professional recognition (Merit)
  - Evidence-based research - higher quality (in the absence of RCTs)

GETTING STARTED

IN THE END

Our legacy

- We own to the new generation of pediatric urologists and to our patients to try to do better

THANK YOU!

Hypospadias Outcomes Long-term Database

If you are interested in getting started with your own databases, please contact Melissa McGrath (mcgram2@mcmaster.ca)