

Survey for patients on Cyanotic Congenital Heart Disease (CCHD)

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LA NOSTRA
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BACKGROUND

This survey was developed within the Work Package 3 (WP3) of the OrphaDev4Kids European project.

The main goal of this project is to create a better environment for developing medical devices (MDs) to benefit children with rare diseases.

BACKGROUND

WP3 is working on designing a special wearable biosensor for **two key purposes:**



To **help prevent lactic acidosis** in children with congenital heart defects that haven't been repaired.



To **monitor** how children with repaired congenital heart defects **respond to pulmonary valve replacement.**

GOAL OF THE SURVEY



The purpose of this survey is to **collect important feedback** to help doctors and researchers **design the wearable biosensor** for children with Cyanotic Congenital Heart Disease (CCHD).

THE SURVEY

3 sections:

1

General Info about
the survey

2

Definitions

3

**Questions of the
survey**



Answers to the survey will be
anonymous

THE SURVEY: General Info



This survey is part of Work Package 3 (WP3) of the OrphaDev4Kids European project. The main goal of this project is to create a better environment for developing medical devices (MDs) to benefit children with rare diseases.

WP3 is working on designing a special wearable biosensor for two key purposes:

- 1.To help prevent lactic acidosis in children with congenital heart defects that haven't been repaired.
- 2.To monitor how children with repaired congenital heart defects respond to pulmonary valve replacement.

PROJECT GOAL

The OrphaDev4Kids project is coordinated by the Clinical Validation from Biopharmaceutical Findings (CVBF) and works with several important partners:

- Teddy European Network of Excellence for Paediatric Research (TEDDY)
- European Paediatric Translational Research Infrastructure (EPTRI)
- Gianni Benzi Foundation for Pharmacological Research (FGB)
- University of Bari "Aldo Moro"
- IRCCS Eugenio Medea
- JEM TECH
- Children's Memorial Health Institute (IPCZD)
- Medical University Graz (MUG)

PROJECT PARTNERS

The purpose of this survey is to collect important feedback to help doctors and researchers on improving the wearable biosensor being developed for children with Cyanotic Congenital Heart Disease (CCHD).

SURVEY GOAL

•**Anonymity:** Your answers are anonymous. No personal data and identifiers will be processed, therefore the GDPR (Reg. UE 2016/679) is not applicable

•**Time:** It will take about 10 minutes to complete the survey.

SURVEY CHARACTERISTICS

If you have any questions or need more information, you can contact Roberta Nossa at roberta.nossa@lanostrafamiglia.it.
Thank you very much for helping us by answering this survey!

FINAL REMARKS

THE SURVEY: General Info



PROJECT GOAL

PROJECT PARTNERS

SURVEY GOAL

SURVEY CHARACTERISTICS

FINAL REMARKS

THE SURVEY: General Info



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SURVEY CHARACTERISTICS

FINAL REMARKS

THE SURVEY: Definitions



Medical device: in this survey, for medical device we mean any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations.

Analyte: a substance whose chemical constituents are being identified and measured.

Biosensor: is a device that can report the presence or activity of analytes using a biomolecular component providing specificity to the sensor by binding or interacting with the analyte and is able to cause a detectable change in mass, fluorescence, electric charge, or refractive index, and a transducer element, able to transform this interaction into a suitable electronic signal.

Single-use device: means a device that is intended to be used on one individual during a single procedure.

THE SURVEY: Questions



1.How old are you?

2.What are the most significant challenges you face in managing your condition? (Select all that apply)

- I often feel tired or weak
- It's hard to keep up with other kids in physical activities
- I don't like having to take medicine regularly
- [...]

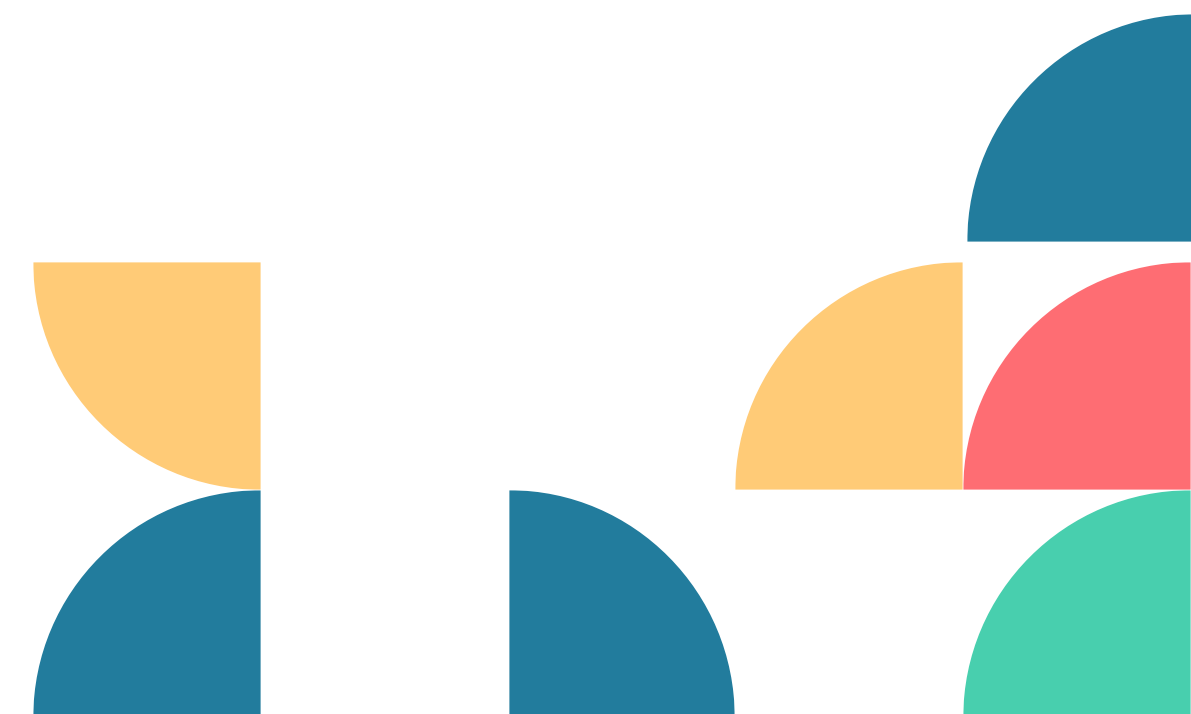
3.Which is/are the monitoring method(s) you currently use? (Select all that apply)

- Blood oxygen levels
- Heart rate and rhythm
- Blood pressure
- [.....]

[.....]

18.Please, add any suggestions or comments:

**Multiple
choice**



INSTRUCTIONS



- At this stage, you are **not required** to complete the questionnaire but only to review it.
- You will have from **12:30 to 14:00** to review the survey.
- The questionnaire will be distributed in **paper format** for review.
- You will receive a link to a **Google Form** to submit your feedback on the survey.
- The form consists of **four sections**:
 1. **Review of the general information** about the survey.
 2. **Review of the definitions** provided in the survey.
 3. **Review of the survey questions.**
 4. **General considerations about the survey.**
- Once the review is completed, we will collect your feedback and the survey will be revised based on your feedback.
- Next days, patients with CCHD will receive the updated version to answer the final version of the survey.

REVISIONS FROM THE PEC

General Info

These questions regard the **General Info** section at the beginning of the survey

Are the informations included in this section clear and understandable?

1 2 3 4 5
Completely unclear ☐ ☐ ☐ ☐ ☐ Totally understandable

Do you think something could be improved? If you think so, tell us how

☐ No
☐ Altro: _____

Is the 10 minutes completion time realistic in your opinion? If no, please specify

☐ Yes
☐ Altro: _____

Definitions

The next few questions are about the **Definitions** section

Are the definitions complete and easy to understand? If not please give us suggestions

☐ Yes
☐ Altro: _____

Are there other definitions you think we should include in this section? If so, please tell us

☐ No
☐ Altro: _____

2

1

REVISIONS FROM THE PEC



Survey for patients

The following section will collect feedback from the core of the survey.

Do you think question 1 *"How old are you?"* is a relevant question?

- ☐ Yes
- ☐ No
- ☐ Maybe

Is question 2 *"What are the most significant challenges you face in managing your condition?"* **clear?**

Totally unclear 1 2 3 4 5 Really clear and understandable

☐ ☐ ☐ ☐ ☐

Would you pose question 2 differently? How?

La tua risposta _____

Is question 3 *"Which is/are the monitoring method(s) you currently use?"* **clear?**

1 2 3 4 5

Totally unclear ☐ ☐ ☐ ☐ ☐ Really clear and understandable

Would you pose question 3 differently? How?

La tua risposta _____

Is question 4 *"Do you think the current monitoring method(s) of your condition works well for you?"* **clear?**

1 2 3 4 5

Totally unclear ☐ ☐ ☐ ☐ ☐ Really clear and understandable

Would you pose question 4 differently? How?

La tua risposta _____

REVISIONS FROM THE PEC

General aspects of the survey

Are there questions that need to be modified and improved?

La tua risposta

Do you think the survey collects all necessary data to analyze and cater for each patient's needs?

La tua risposta

Do you find the content engaging and easy to read?

Totally NOT engaging 1 2 3 4 5 Really engaging

Do you think adding images or practical examples would help with understanding?

La tua risposta

Do you have any suggestions on how to improve the document or make the content more suitable for young people?

La tua risposta

Is there anything you particularly liked or something you would prefer to exclude from the survey?

La tua risposta

What do you think is the aim of the document?

La tua risposta



THANK YOU

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