



101005177 — COVID-RED

COVID-RED

WP4 – Health Economics
Analysis

D4.1: Report on the interventions costs/price of the Ava monitoring device

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Document History

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Introduction

In this deliverable, we report the cost related to the intervention implemented in relation to the COVID-RED trial (Brakenhoff et al., 2021). The COVID-RED trial is a prospective, randomized, single-blinded, crossover trial to investigate the effect of a wearable device and machine-learning algorithm in addition to a daily symptom diary for remote detection of SARS-CoV-2. The purpose of this deliverable is to report on the costs related to the intervention. Possible changes in use of health care services including changes in number of SARS-CoV-2 tests related to the intervention will be reported later in a separate deliverable.

The intervention in the COVID-RED trial consists of an Ava bracelet¹, a machine learning algorithm and a smartphone app. The Ava bracelet is worn by night where it tracks breathing rate, skin temperature, perfusion, heart rate and heart rate variability. The data is then synced and processed by the machine learning algorithm via the smartphone app. The subjects can - besides the bracelet data - keep track of symptoms using an in-app symptom diary. Based on the bracelet and symptoms diary the smartphone app gives the subjects an indication (green, yellow, or red light) on whether they might have a SARS-COV-2 infection.²

The control group are only using the symptoms diary in the smartphone app but also get a signal (green, yellow or red) based on the recommendations from RIVM (The National Institute for Public Health and the Environment in The Netherlands). The symptoms leading to a red signal are: cold symptoms (such as a nasal cold, runny nose, sneezing, sore throat), coughing, shortness of breath, elevated temperature or a fever or sudden loss of taste and smell (without nasal congestion) (RIVM, 2021). To make sure the study is blinded for the subjects, the control group are provided with a bracelet, but the data collected from the bracelet are not used when signalling to the subjects.

Methods and Data

To report on the intervention costs, we use the approach proposed by Drummond et. al. (Drummond, Sculpher, Claxton, Stoddart, & Torrance, 2015). Using this approach, we first identify the relevant cost components, then we measure the resource use in natural units and finally we find the monetary value of the resources consumed by use of an appropriate price.

We limit the analysis to a health care provider perspective. This means we do not estimate the opportunity cost of the time spent by the subjects and we do not estimate the cost of having a smartphone available.

¹ AVA is a private company specialised in helping women track their menstrual cycle with the help of the AVA bracelet and an underlying machine-learning algorithm trained to predict ovulation.

² Green light: No deviations in physical health (symptoms or biophysical parameters) detected. No recommendation is given to the subjects. Yellow light: Subjects are experiencing some symptoms but not those strictly defined as related to COVID-19 or biophysical parameters deviate slightly from baseline but do not meet the threshold value for a Red light indicator. The Yellow light indicator asks participants to consider self-isolating and keeping an eye on the Ava COVID-RED app the following day. Red light: Significant changes in biophysical parameters have been detected or symptoms that meet the RIVM criteria have been reported. The Red light indicator suggests subjects consider getting tested for COVID-19 and/or to consult a medical professional.

We identified the cost components in collaboration with the partners in the trial (Ava and Julius Clinical). The resource use was collected during the trial.

Results

In the results section, we first list the identified costs and secondly report on the quantities and valuation.

Identified cost components

The identified cost components of the intervention provided by Ava are:

- Cost of producing the Ava bracelet;
- Development cost of the machine learning algorithm; and,
- Customer support at Ava.

The costs of the Ava bracelet, algorithm development and customer support are valued using a collective price provided by Ava. This is done to ensure external validity of the intervention costs, as this price is relevant for future implementation. The development costs associated with the algorithm development accrued during the study are investment costs funded within the study. These costs should however not be neglected, and they are together with future improvements of the algorithm part of the proposed price (Burnett, 2009).

Other identified cost components are

- Welcoming package: Handling, packaging, and sending of a welcoming package including an introduction booklet, welcome letter and the Ava bracelet to participants.

These costs are valued using a per item cost. All costs are distributed across participants as the within subject design ensures that all participants end up in the intervention arm at some point in the trial. The cost of the welcome package is handled as a marginal attributable cost of the intervention.

Other costs that are inherent to the trial design and thus not relevant for a future implementation are:

- Finger prick tests used for serology tests;
- A helpdesk set up within the trial, separate from the technical Customer Support provided by Ava; and,
- Safety physicians employed within the trial.

As these costs are inherent to the trial and not the intervention itself; they are not expected in an implementation and are thus excluded from the cost analysis following the best practice recommendations (Ramsey et al., 2015; Fox-Rushby & Cairns, 2005).

Measuring and valuing costs

Each subject received one welcoming package including one Ava bracelet. The estimated costs for each subject was:

- Bracelet, algorithm development and customer support: € 155

- Welcoming packages: € 13,19
 - o Handing and sending the bracelets, including assembling the starter packages cost €4,86 per unit;
 - o Instruction Booklet: € 0,28;
 - o Welcome Letter € 0,08; and,
 - o Shipment costs per Starter Package: € 7,97.

The total cost per individual participant was thus € 168,19.

Discussion and Conclusion

This report provides an estimate of the intervention cost in the COVID-RED trial. The cost per subject was estimated at € 168,19.

We have identified the cost components in collaboration with the providers and valued the identified costs using the available prices. In the following deliverables we will calculate the costs associated with health care utilization and compare the total attributable costs of the intervention to the possible effects.

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