CASE STUDY

ICHOM International Consortium for Health Outcomes Measurement

IMPLEMENTING ICHOM'S STANDARD SETS OF OUTCOMES: CLEFT LIP AND PALATE AT ERASMUS UNIVERSITY MEDICAL CENTRE IN THE NETHERLANDS

DECEMBER 2016

Implementing ICHOM's Standard Sets of Outcomes: Cleft Lip and Palate at Erasmus University Medical Centre in the Netherlands

Authors: Dr. Jason Arora[1] & Dr. Mona Haj[2]
Designer: Matthew Salt[1]
Acknowledgements: Maarten Koudstaal[2], Jet De Gier[2], Mariska Van Veen[2], Leon Van Adrichem[2], Irene Mathijssen[2], Sarah Versnel[2], Elske Strabbing[2], Eppo Wolvius[2], Francien Meertens[2], Jolanda Okkerse[2],Titia Cohen[2], Henriette Poldermans[2], Lindsay Heijkoop[2], Jan Hazelzet[2], Esther Snoek[2], Thea Van 'T Zon[2], Roel Faber[2]
[1]International Consortium For Health Outcomes Measurement (ICHOM), London, UK
[2]Erasmus Mc, Rotterdam, Nl

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Corresponding author: Jason Arora, MD, MPH; j.arora@ichom.org

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ICHOM STANDARD SET IMPLEMENTER PROFILE

Location: Rotterdam, Netherlands

Provider type: Academic Medical Centre

Standard Set: Cleft Lip & Palate

Standard Set complexity: Very High

The Netherlands provides universal healthcare through mandatory health insurance for all Dutch residents. Public healthcare is funded through taxation of income, and insurers are required to accept all applicants.

Erasmus MC, affiliated with Erasmus University, is one of the largest academic medical centres in Europe and a top-ranking medical institution internationally. It has over 1300 beds and 13000 employees and is located over three sites – the main Erasmus MC location, the Sophia Children's Hospital, and the Daniel den Hoed oncology centre.

BACKGROUND

Dr. Jan Hazelzet was appointed Professor of Health Care Quality and Outcomes at Erasmus MC in 2015. Previously a paediatric intensivist and Chief Medical Information Officer, Dr. Hazelzet had become increasingly interested in VBHC as a vehicle for transforming Erasmus MC into a health care provider of the future. This involved working closely with Erasmus MC's CEO at the time, Professor Hans Büller. Professor Büller had returned from a course at Harvard Business School on Value-Based Health Care in 2012 with an ambitious plan for transforming Erasmus MC into a true value innovator. This 5-year strategy would place better outcomes, lower cost, and patient-centred care as the organisation's three primary goals. Erasmus MC's senior management – led by current CEO Professor Ernst Kuipers - subsequently spent the entirety of 2013 winning 'hearts and minds' amongst staff, outlining the benefits of VBHC to every segment of their workforce – clinicians, administrators, technologists and researchers. By early 2014, Erasmus MC were ready to operationalise their new VBHC strategy.

As is widely understood, the starting point for achieving VBHC is to define and measure the metrics that represent true success in health care: the outcomes that matter most to the patient. Erasmus MC therefore began pilot projects to develop outcome sets in six disease areas based on a combination of factors – departmental ambition, clinical interest, the potential for patient pathway modification, and the organisation's desire to cover adult, paediatric, acute and chronic medical conditions to maximize overall learning.

FIGURE 1 | ERASMUS MC'S ADOPTION OF PROFESSOR PORTER'S STRATEGY FOR VALUE TRANSFORMATION

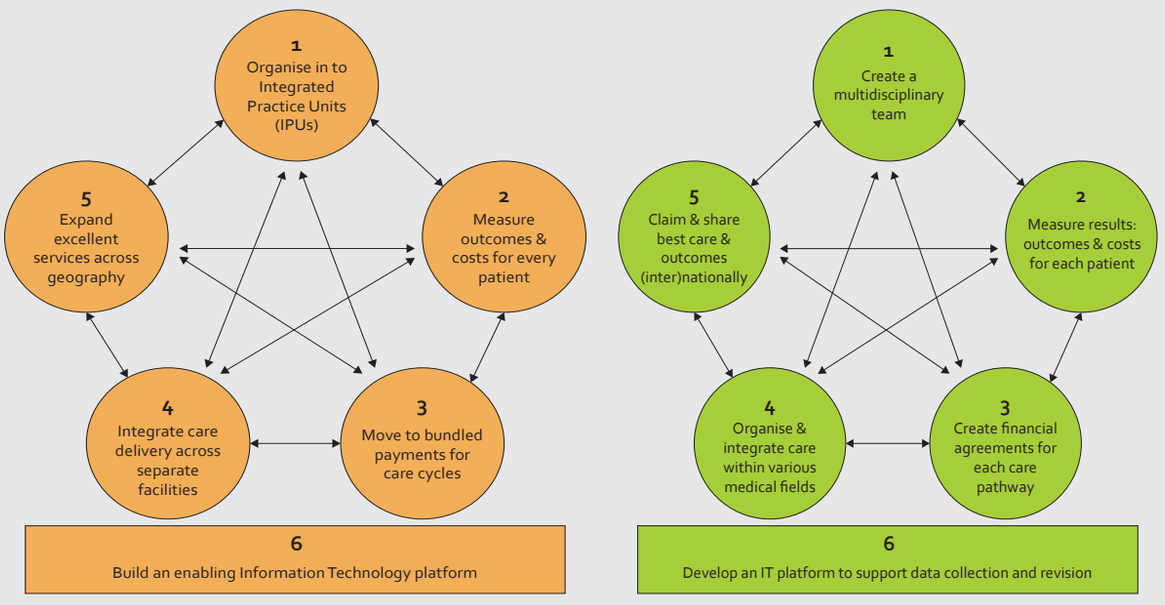


Figure 1A (left): Professor Porter's Strategy for Value Transformation[2]

Figure 1B (right): Erasmus MC's adoption of Porter's model

Through one of Erasmus MC's oncology clinical leads, Dr. Chris Bangma, Dr. Hazelzet discovered ICHOM. Dr. Bangma was an ICHOM Working Group member for the Localised Prostate Cancer Standard Set in 2013 – one of ICHOM's first four Standard Sets. Keen to amplify Erasmus MC's involvement in ICHOM's efforts to develop global – rather than local - outcome sets, Dr. Hazelzet encouraged more clinicians at Erasmus MC to join ICHOM Working Groups in other disease areas. He was keen for Erasmus MC to maximize the scale on which they could benchmark, and thought it would be self-limiting to develop local outcome sets at Erasmus MC alone. Internally, Erasmus MC established a dedicated team – supported by a regularly allocated budget – to support the implementation of a selection of ICHOM Standard Sets that were of strategic importance to Erasmus MC.

Nearly three years on, one of the most successful ICHOM Standard Set implementation programs - for Cleft Lip and Palate (CLP) – has resulted in routine collection of the full ICHOM CLP Standard Set.

THE ICHOM STANDARD SET FOR CLEFT LIP AND PALATE

Between 2014 and 2015, ICHOM facilitated the development of a comprehensive, globally standardised Standard Set of outcomes for CLP[3,4]. The aim was for this dataset to be collected throughout childhood. A summary of the ICHOM CLP Standard Set is shown in **Figure 2**.

FIGURE 2 | ICHOM STANDARD SET FOR CLEFT LIP AND PALATE, INCLUDING TIME POINTS FOR DATA COLLECTION

Details

1 Includes number of interventions requiring anesthesia

2 Includes bleeding requiring return to OR, bleeding requiring transfusion, infection requiring return to OR, infection or exposure of graft material requiring return to OR for removal or replacement, wound: complete dehiscence, wound: palatal dehiscence requiring return to OR, palatal flap necrosis, wound: oronasal fistula, respiratory distress: requires mechanical ventilation (major), LRI, death, and the number of hospitalized days following a procedure

3 Includes percentile on growth chart and change in percentile between birth and 3 months

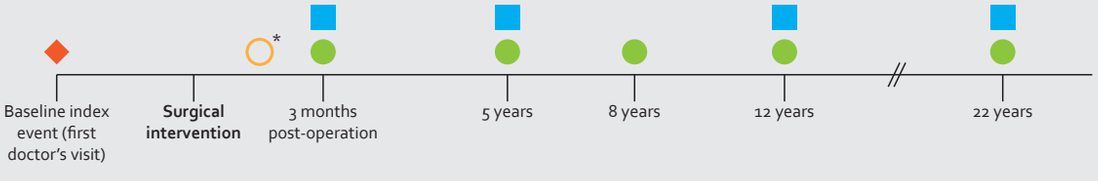
4 Recommended to track via Cleft Q Face, Jaw, and Dental Appearance Scales along with facial photographs

5 Recommended to track via Cleft Q Eating and Drinking Scales

6 Recommended to track via the DMFT, the COHIP Oral Symptoms Scale, the 5 Year Index, the GOSLON, and lateral cephalogram

7 Includes articulation, intelligibility, and velopharyngeal competence. Recommended to track via the modified PCC, the Velopharyngeal Competence Scale, the Intelligibility in Context Scale, and the Cleft Q Speaking and Speech Scales

8 Recommended to track via the Cleft Q Social Life and School Life Scales and the Cleft Q How Do You Feel Scale and Shaped You As A Person Scale



Development of the CLP Standard Set was championed at Erasmus MC by Dr. Maarten Koudstaal, a Maxillofacial Surgeon based at Erasmus MC's cleft department in the Sophia Children's Hospital.

Cleft Lip and Palate

During fetal development, the structures that form the upper lip and/or palate may fail to properly fuse together, resulting in a 'cleft' (split, gap or division). This manifests as a cleft lip, cleft palate, or a combination of the two. The cleft palate can involve the hard palate (bony front of the roof of the mouth), soft palate (soft rear portion of the roof of the mouth) and gum tissue (alveolus).

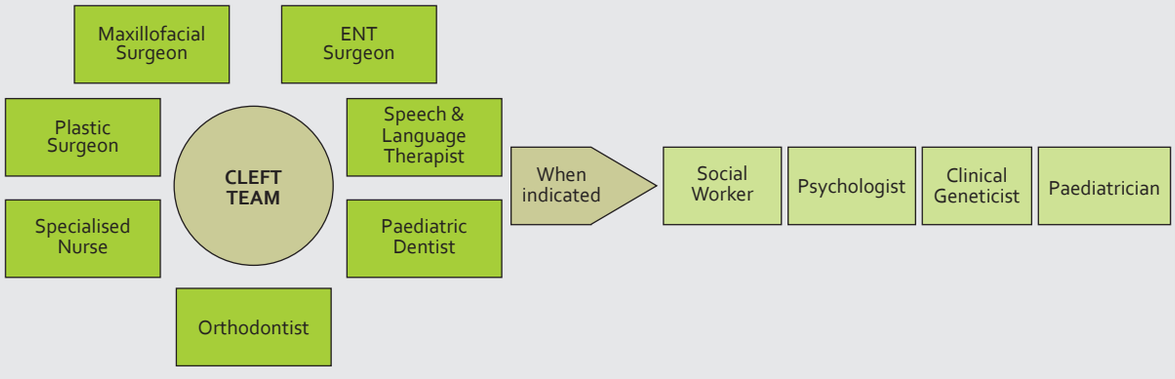
CLP affects approximately 1 in 700 newborns annually and can result in problems with appearance, function (eating, hearing, speech, and oral health) and psychological and social development. Consequently, the outcomes for patients with CLP can be poor and/or extremely variable, affecting multiple aspects of the child's life into adulthood. This can be compounded due to the numerous lines of interaction required between different medical specialties. Patients with CLP are also expensive to manage due to the multiple interventions, re-interventions, and maintenance treatment required over a prolonged period of time, resulting in a high 'value burden' to the patient and health system overall – that is, on both outcomes and cost. Therefore, CLP presents a particularly high-yield opportunity for the implementation of VBHC.

ERASMUS MC'S CLEFT DEPARTMENT AT SOPHIA CHILDREN'S HOSPITAL

The cleft department is located at the Sophia Children's Hospital, a single site within the Erasmus MC health system. This is one of the largest cleft departments in the Netherlands.

CLP patients are seen by a multi-disciplinary team, comprising experts from between seven and eleven specialist areas as show in **Figure 3**. Patients are seen by at least seven experts in each clinic appointment, which is scheduled to last 15 minutes.

FIGURE 3 | ERASMUS MC'S MULTI-DISCIPLINARY CLEFT TEAM



Erasmus MC's multidisciplinary cleft team comprises a broad range of specialties. When indicated, additional specialists are also brought in to provide input.

IMPLEMENTING THE ICHOM CLP STANDARD SET

The cleft department at Sophia Children's Hospital began implementing the ICHOM CLP Standard Set in May 2015.

In order to make the implementation process a success, the cleft department decided to focus on three key areas: project management, patient pathways, and informatics.

1. Project Management

The cleft team, in conjunction with Erasmus MC's senior management, put together a core project team comprising representatives from the cleft clinical team, IT team, and recently appointed VBHC project management team. When required, the meetings also involved staff from Erasmus MC's information management team (the "Business Intelligence Centre"), and an epidemiologist.

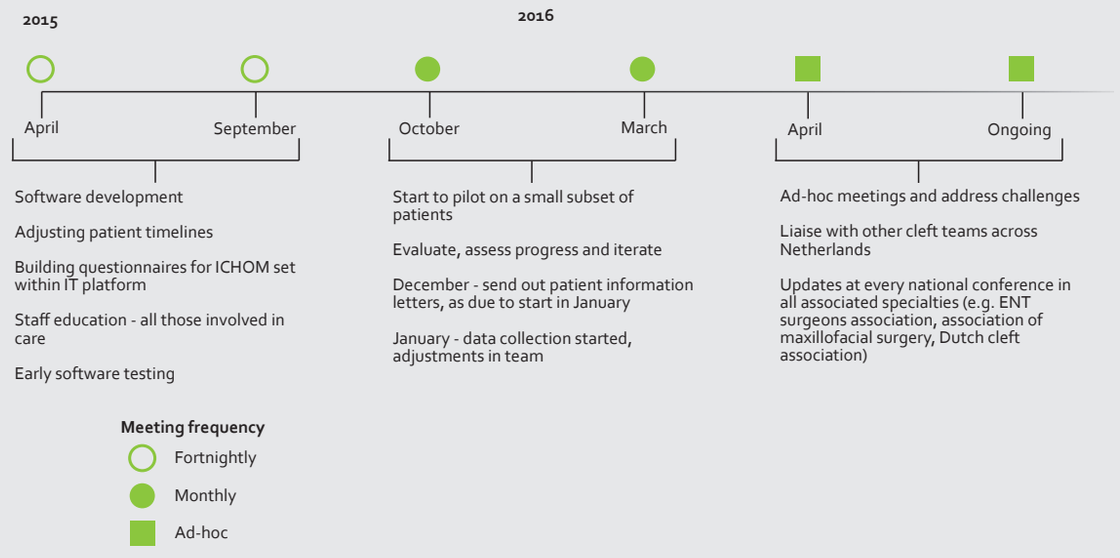
It was essential that all relevant disciplines were involved in owning and driving the project from the beginning. An overview of the Project Team can be found in **Table 1** below.

TABLE 1 | ERASMUS MC CORE PROJECT TEAM

	Discipline	Specialists	Purpose	Representative
Essential	Clinical	Consultant Cleft Surgeon	Clinical leads in charge of CLP patient care	Maarten Koudstaal
		Consultant ENT Surgeon		Henrietta de Gier
		Academic Cleft Research Clinician	Coordination between teams	Mona Haj
	IT	Computer Scientist	Software development	Roel Faber
	VBHC Project Management	Project Managers	Project management	Esther Snoek, Thea de Zon
Ad-Hoc	Business Intelligence	General Administrators	Check cleft database mailing list for diseased patients, updating administrative patient information	Linda van der Slujis, Tim Gravelink
	Epidemiology	Epidemiologist	Dashboard development, data extraction/reporting	Nikki van Leeuwen

The cleft team, led by Dr. Maarten Koudstaal, set a target for Erasmus MC to run a successful data collection pilot on a small cohort of patients and refine their implementation efforts by the end of 2015. This would be followed by streamlined data collection for a selection of cleft patients by January 2016, and permanent modifications to patient pathways in line with the ICHOM CLP Standard Set across all Erasmus MC cleft patients from January 2017. An overview of the project timeline with milestones can be found in **Figure 4**, below.

FIGURE 4 | PROJECT TIMELINE FOR IMPLEMENTATION OF THE CLP STANDARD SET



Project meetings would last 1-2 hours and take place in the evenings after clinic had finished. If team members did not attend, decisions were made with whomever was present and the project continued to move forward to maintain momentum. Dedicated project management and oversight were key to coordinating the multiple teams involved and ensuring that milestones were met and deliverables achieved.

2. Recalibrating Patient Pathways

In 2013, prior to the widespread adoption of VBHC within the organisation, the cleft team had already decided to streamline their patients' care pathways in a bid to deliver more efficient care. Fortuitously in line with organisation-wide efforts to implement VBHC, the cleft team were able to reinforce their efforts to evolve patient pathways around outcomes and value, and received further resources to do so. This involved a review of each patient's cleft care pathway and a process-mapping exercise of clinic operations in order to identify suitable opportunities for data collection. The cleft team appointed a research doctor, Dr. Mona Haj, to manage this process.

Figure 5 shows how data collection time points were integrated into pre-existing patient pathways. It was vital to attempt to align as much as possible with existing patient pathways, utilising data collection time windows. For example, 'Age 5' data was initially collected at ages 4 and 6. As an interim measure before changing clinical schedules to match data collection time points, this was deemed to be sufficient.

FIGURE 5A | PREVIOUS PATIENT PATHWAY WITHOUT ICHOM METRICS

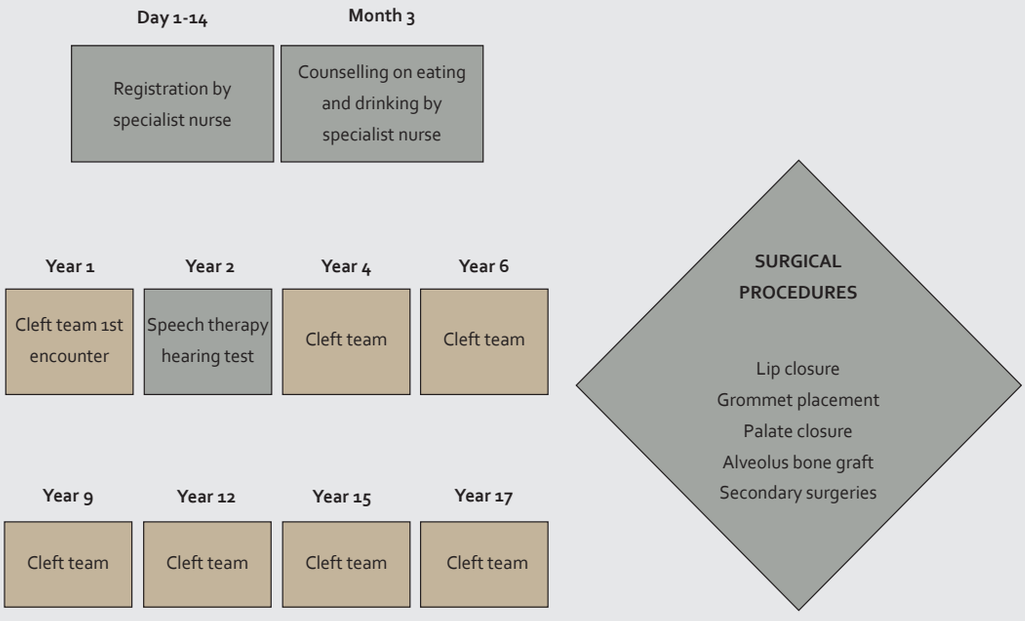


FIGURE 5B | NEW PATHWAY WITH ICHOM METRICS

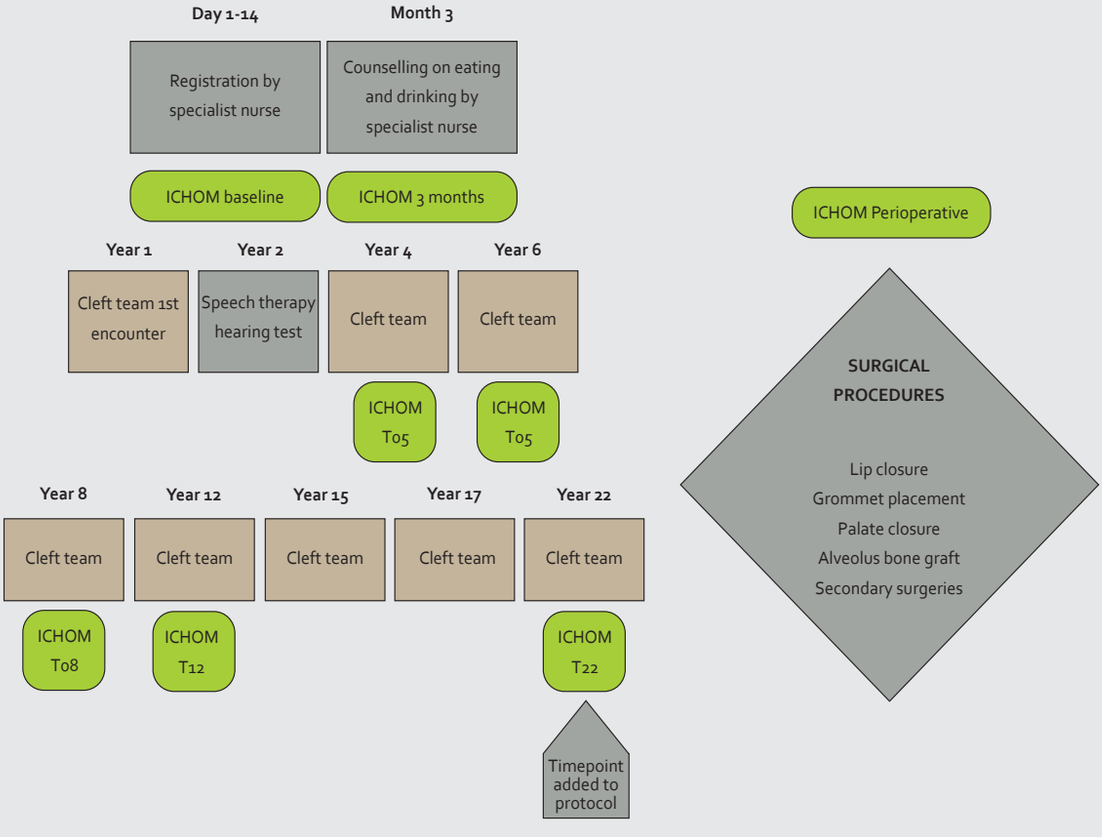
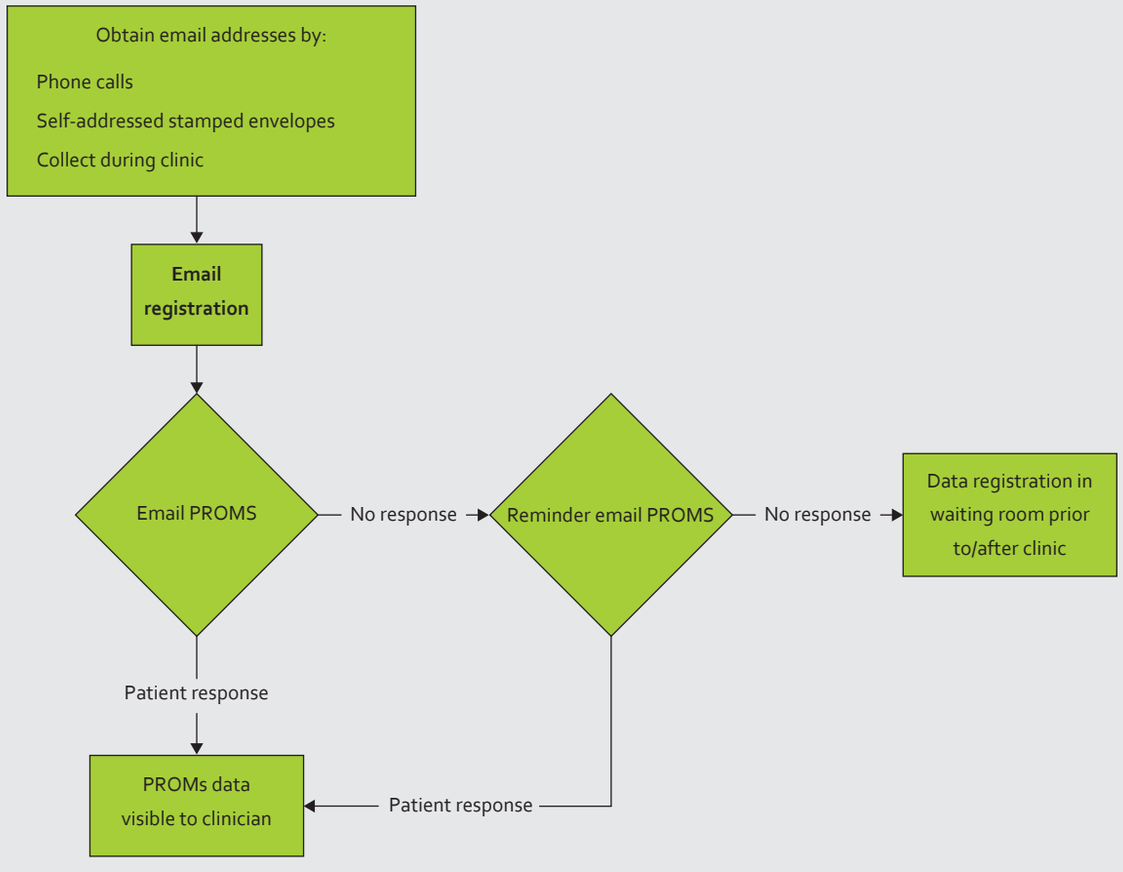


Figure 5A shows the previous patient pathway, which involves multidisciplinary specialty interaction at different time points. Figure 5B shows, in green, how this was adapted to match the ICHOM Standard Set, with approximations of time points used where necessary (e.g. T05 data point collected at ages 4 and 6). For Age 22, an additional appointment was added to the pilot protocol (T22).

It was important for the cleft team to engage patients in a dialogue before any changes took place. To address this, the cleft department began to run meetings with local patient groups and send out letters, emails and brochures to explain the goal of the changes that would take place - the introduction of patient-reported outcome measures (PROMs), the use of a web-based patient data collection portal, changes to patient flow in clinic, and modifications to patient appointment schedules to fit data collection in order to improve care.

The project team developed an algorithm for ensuring that PROMs data was captured efficiently. This is shown in **Figure 6**. The first-pass approach is to capture PROMs data via email, with an email reminder and then data collection in the clinic waiting room as secondary and tertiary approaches, respectively. Emails contain a link to the web-based tool, where patients can complete the PROMs questions. It takes patients 15-20 minutes to complete their PROM questions for a given data point.

FIGURE 6 | THE PROJECT TEAM'S ALGORITHM FOR CAPTURING PROMS DATA

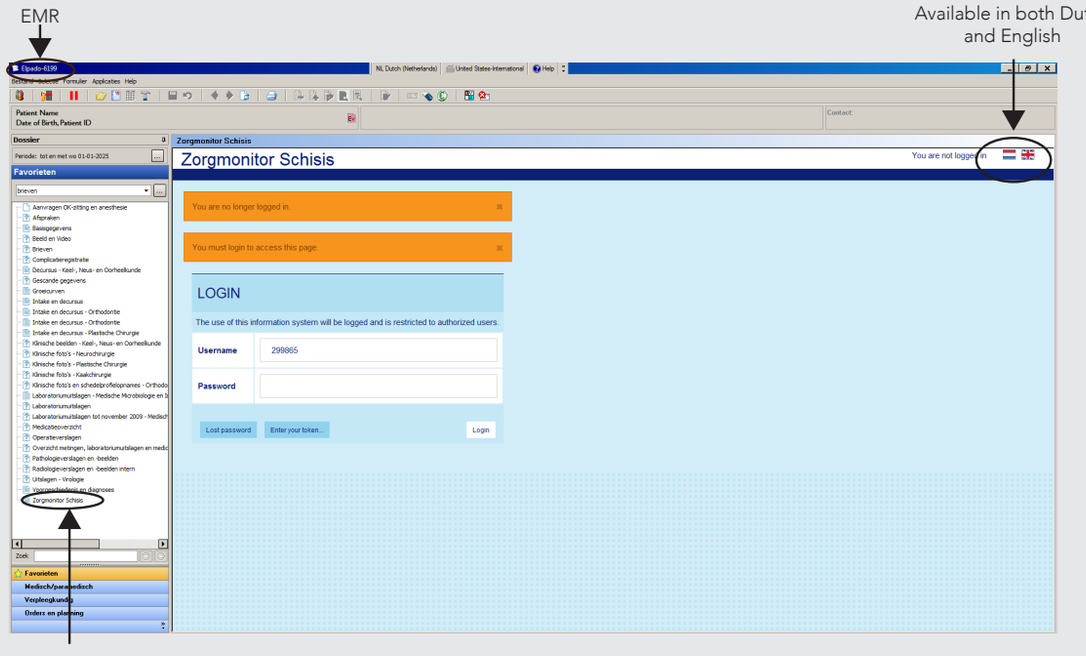


3. Informatics

The IT team decided to build an in-house informatics platform for data capture. They developed a secure platform using two interfacing software: GemsTracker and LimeSurvey, which together have come to be known as Zorgmonitor Schisis ("Care Monitor Cleft"). The clinical team worked closely with the IT team to ensure the platform was both user-friendly and fit for use in the clinic. This involved several iterations to the software and beta testing before deployment.

LimeSurvey (www.limesurvey.org) is a free, open-source web-based tool in which an unlimited number of questionnaires in various formats can be built. Within Zorgmonitor, GemsTracker is an application developed by Erasmus MC to facilitate the distribution of questionnaires and associated data collection. The team would build the questionnaires in LimeSurvey and then use GemsTracker to distribute them. Zorgmonitor has been designed to plug into Erasmus MC's Electronic Medical Record (EMR), Elpado (see **Figure 7**). Data such as name, date of birth and email addresses can therefore be directly extracted from the EMR, avoiding double-entry of data. Together, this provides an end-to-end data collection solution that causes minimal disruption to both care processes and clinic staff.

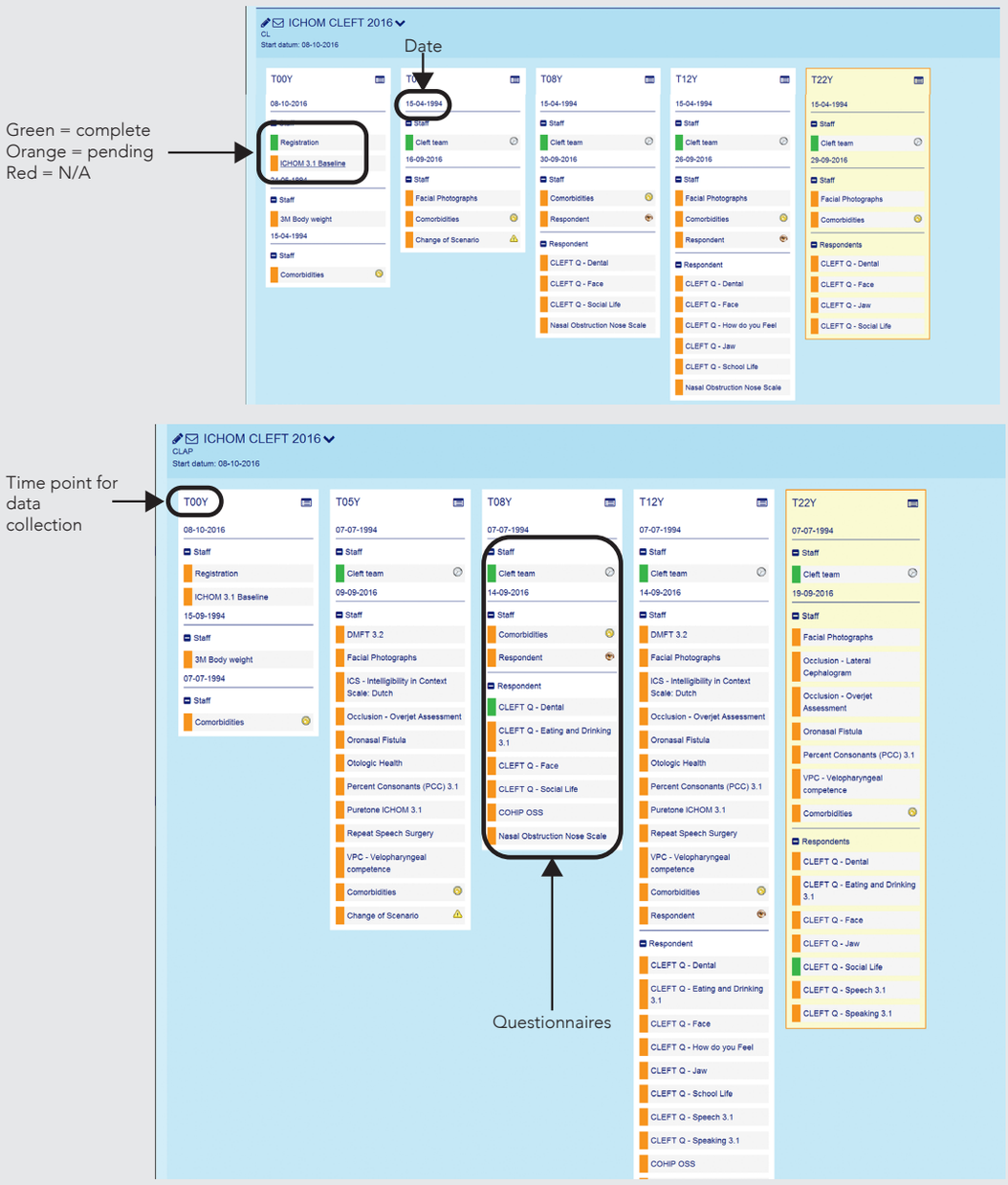
FIGURE 7 | ZORGMONITOR ACCESSED WITHIN ERASMUS MC'S EMR, ELPADO



Zorgmonitor was also built in both Dutch and English to facilitate international use of this application and also benchmarking – the user language can be adjusted with just a single click. The interface allows synchronous access by multiple users, making it suitable for data visualisation and submission by both clinicians and patients across multiple physical sites in tandem.

Different data collection pathways can be built into the platform to match different patient data collection profiles – in this case, for the four patient phenotypes within the ICHOM CLP Standard Set: Cleft Lip (CL), Cleft Lip with Alveolus (CLA), Cleft Lip and Palate with Alveolus (CLAP) and Cleft Palate (CP). See **Figure 8** for CL and CLAP profiles within Zorgmonitor.

FIGURE 8 | CL AND CLAP DATA COLLECTION IN ZORGMONITOR



Screenshots from Zorgmonitor for Cleft Lip (CL) and Cleft Lip and Palate (CLAP). These comprise a selection of questionnaires at each time point (e.g. ToY, t5Y, etc). The specific clinic appointment dates are also displayed in line with each time point. A traffic-light style system signals whether or not a questionnaire has been completed - green indicating completion, orange indicating a questionnaire is pending completion, and red indicating a questionnaire is not applicable to that particular patient.

These data collection pathways include time points, data collection tools, and data sources (patient, clinician, or administrative). The system can be configured to 'push' questionnaires to patients via email at pre-determined time points. Patients can access and complete the PROMs questionnaires at home and the cleft team can view their responses at any time thereafter. If patient responses are not received by pre-determined time points, the system is set up to send reminders.

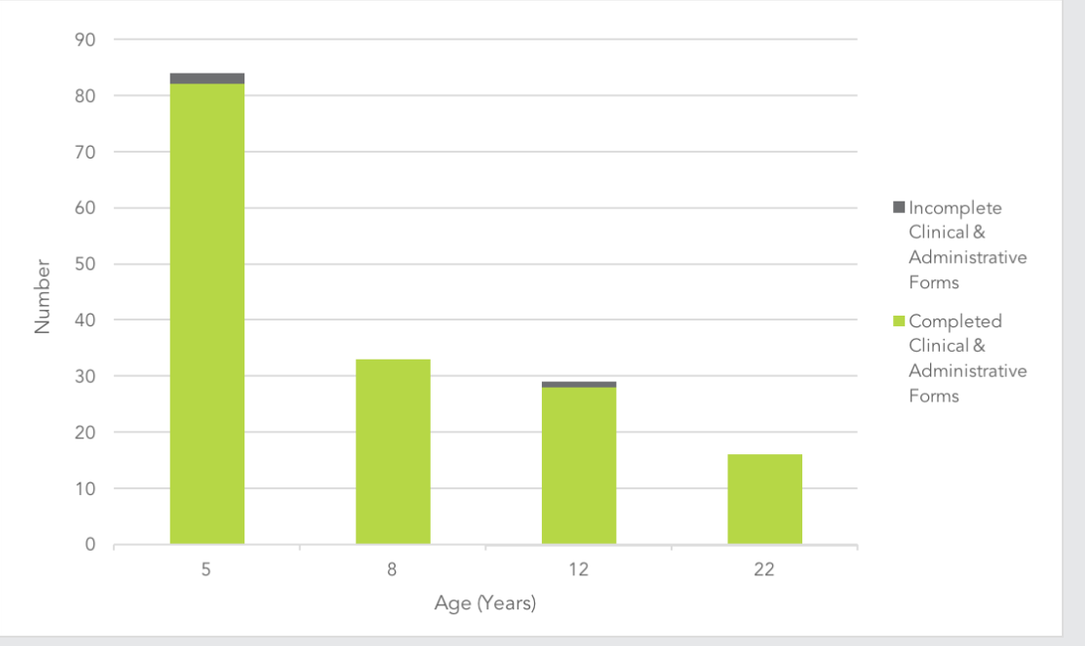
Prior to the patient's next clinic appointment, the multi-disciplinary team members review the results as part of their pre-clinic meeting preparation. This discussion is led by the specialist nurse. The team then discuss the results in the pre-clinic team meeting with action items identified as appropriate.

EARLY RESULTS AND IMPACT

Since January 2016, the cleft team has piloted the ICHOM CLP Standard Set in a single outpatient clinic every two weeks. The team sees approximately 20 patients in this clinic, which equates to 40 data points per month, or 480 data points per year.

Between January - August 2016, there has been 90% first-pass compliance for PROMs and 100% for clinical and administrative metrics within the ICHOM CLP Standard Set. The 10% of PROMS data points not collected or collected incorrectly has been due to the supply of incorrect email addresses, the lack of an email address/ account, or a loss to follow-up at the final time point, T22. At the end of the clinic, the clinic team check that all ICHOM metrics for all patients have been collected.

FIGURE 9 | DATA COLLECTION COMPLIANCE: CLINICAL AND ADMINISTRATIVE QUESTIONS



Patients have provided very positive feedback about the initiative thus far, "This really helps us prepare for the clinic ourselves by encouraging us to think about our upcoming appointment in a structured way. We're so used to just turning up, but this gives us more of a role that makes the appointment more tailored to what is important to us." reported one patient. The patient-reported outcomes element has provided this opportunity for patients to engage in their consultation in advance, tailoring it to their needs.

Clinicians have also seen many benefits. "When we know what is bothering the patient most, it helps us better structure our consultations. Everything becomes far more focussed when both patients and clinicians are better prepared", explained Dr. Maarten Koudstaal. But the impact has not just been limited to the consultation itself. "It is helping us think more broadly about the care we are providing. How important is the psychosocial element of the condition to this patient? Which part? What are we doing about that? This is such a multi-faceted condition that affects multiple aspects of a patient's life, and this new approach is really helping us question how many of these facets we are really tackling. Importantly, it tells us what is bothering the patient rather than what is important to the clinician. These two can often be very different, and through this initiative, we are really starting to see this and do something about it."

KEY LESSONS

1. DEDICATED RESOURCES ARE VITAL

Erasmus MC have established dedicated human and financial resources to make outcomes measurement core business.

2. CHANGE CULTURE AS WELL AS PRACTICE

Winning 'hearts and minds' is a key part of the process and must precede attempted changes in practice. Staff must see the value in implementing outcomes measurement before they will invest themselves in it. If the culture isn't already there, providers need to make active efforts to secure on-the-ground support for VBHC.

3. KEEP THINGS MOVING

Despite skepticism within the organisation, the VBHC champions at Erasmus MC persisted with their efforts and moved forward with the project regardless. They were aware that they'd never persuade every single member of the organisation to support the approach in the first instance. They did, however, see their initially hesitant colleagues step forward to contribute once they had begun to see the project's momentum and impact.

4. THE IT PLATFORM CAN BE A KEY ENABLER, OR DISABLER

The development of Erasmus MC's high-quality IT platform was a significant milestone in the implementation process. Progress slowed when the IT platform was having problems, and surged forwards when it was functioning well. It is essential to dedicate significant attention to the electronic data capture solution.

5. CONTINUOUSLY COMMUNICATE WHAT IS HAPPENING

There were active efforts to continuously update both staff and patients on the changes. Multiple channels were used to achieve this. Erasmus MC also invited opportunities for both staff and patients to get directly involved. Educating both patients and staff is essential for high compliance rates with clinician- and patient-reported questionnaires.

6. RUN PILOTS ON FERTILE GROUND, THEN SCALE

The cleft department was a natural place to run the first pilot at Erasmus MC – the clinicians were big believers of VBHC and had already demonstrated their proactive nature and willingness to make positive changes by streamlining patient pathways in the year prior.

7. SMALL, INCREMENTAL CHANGES RATHER THAN MASS OVERHAUL

Changes were made one-by-one on a small scale to avoid destabilising existing operations. This is key to ensuring continuous adaptation and course correction during the implementation process.

NEXT STEPS AND WIDER IMPACT BEYOND ERASMUS MC

Erasmus MC's Cleft department will continue their pilot program on the present cohort of patients until December 2016. During this phase, they will continue to fine-tune various aspects of the data collection process, from the breadth of time windows for data collection in the patient pathway to the clinician-facing user interface of the IT platform. The IT team are also developing a dashboard in which metrics can be presented to both clinicians and patients visually, using charts and graphs. In January 2017, Erasmus MC will shift care pathways to match the ICHOM Standard Set for all cleft patients.

Beyond Erasmus MC, the cleft team is working with the Dutch Association for Cleft and Craniofacial Anomalies (NVSCA) to build a national initiative under the ICHOM global effort. This will involve aligning all cleft teams across the Netherlands around the ICHOM CLP Set – that is, for these teams all to be collecting the ICHOM CLP Set - the same patient data, in the same format, at the same time points. This will facilitate a collective data pool and community for outcomes data-driven learning and improvement both within the Netherlands and also as part of a global initiative to which the Netherlands will contribute. A key component of this effort is Erasmus MC's willingness to share the electronic data collection platform they have developed – Zorgmonitor – which lowers the electronic data collection barrier for other centres. Erasmus MC's Cleft department is making Zorgmonitor freely available to all sites – both in the Netherlands and globally – who would like to implement the ICHOM CLP Standard Set. The software can also be translated into other languages beyond Dutch and English, which would further facilitate global implementation and benchmarking across borders.

Finally, Erasmus MC are leading efforts, with ICHOM, to build a global benchmarking program with key cleft sites around the world working together to implement the ICHOM CLP Set and pool their data, seeding the potential for learning and improvement initiatives on a much broader scale.

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www.ichom.org
ichomteam@ichom.org