

BP UNDER 3 PROJECT SUMMARY

In partnership with the Magical Mila Foundation

Dates: March 2020 to February 2021

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A child's brave battle, and her family's ongoing fight

We typically think of high blood pressure (BP) as a condition affecting adults. But it can appear at any age. For children younger than 3 years of age, high BP is a sign of a more serious underlying medical condition.

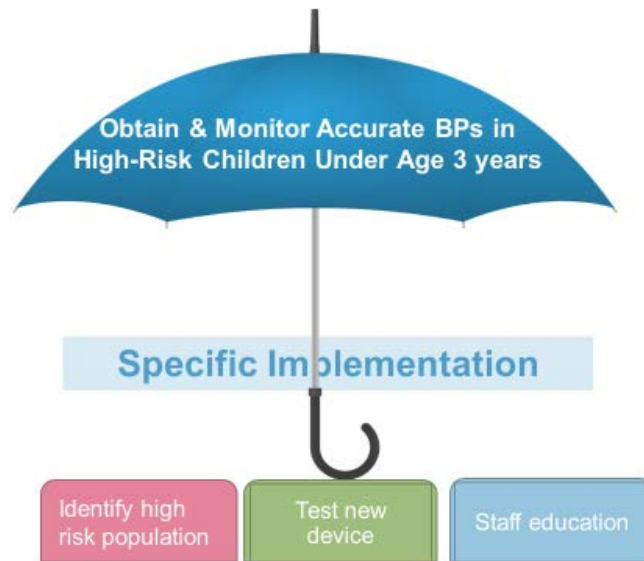
Mila Roomberg was about 2 months old when she was diagnosed with Neurofibromatosis (NF1), a genetic disorder that amongst other things causes tumors to form on nerve tissue. This condition is also associated with a vasculopathy (blood vessel disease) that may result in hypertension. Mila's vascular issues included severe mid-aortic syndrome (narrowing of her aorta near her diaphragm) and narrowing of both renal arteries. In her, both issues resulted in very high difficult to treat BP.

Historically, BP readings have been challenging for physicians to obtain in younger children due to technology limitations and clinical difficulties of measurement in infants. Mila's hypertension went undetected and was not discovered until she was 14 months of age. During a follow-up appointment, doctors took Mila's BP under sedation. A top number (systolic pressure) of over 140 mmHg indicates extremely high BP in this age that can damage blood vessels – Mila's was an alarming 240/110 mmHg. She would require vascular surgery to help correct this critical condition as BP medication was not sufficient. Shortly after undergoing the operation, Mila went into cardiac arrest and sadly succumbed to complications of the procedure.

After her parents lost their beloved daughter, they channeled their overwhelming grief into founding The Magical Mila Foundation. One of the foundation's crucial goals is to raise awareness for NF1 and its manifestations, especially high BP. Through a generous gift from The Magical Mila Foundation, Children's Hospital of Philadelphia (CHOP) has embarked on a program called, "BP Under 3." Our purpose is to test and pilot a new standard of care for measuring BP in children at increased risk of having hypertension under three years of age.

CHOP honors the memory of Mila Roomberg as we work to advance the way we measure BP in young patients with complex conditions such as NF1.

OVERALL PROGRAM GOAL



BP identification in high-risk populations

Children under the age of three, with conditions that have a high risk of associated hypertension, are also at greater risk of suffering long-term effects of disease and even death. Accurate blood pressure measurement is essential for diagnosing hypertension, and for the appropriate evaluation and early initiation of disease management. It is also essential to accurately identify children within these risk categories as being normotensive (normal blood pressure).

There are many categories of children under the age of three who are at risk of having elevated blood pressure. Per the 2017 American Academy of Pediatrics (AAP) guidelines, these include children with congenital heart disease, renal disease, solid-organ transplant, bone-marrow transplant, various categories of neonatal issues (for example, less than 32 week's gestation and use of umbilical artery lines) and many genetic conditions (such as NF1, Alagille syndrome, Turner syndrome and Williams syndrome). Improved identification of hypertension in these children has the potential to reduce the likelihood of target organ damage to the brain, heart, and kidneys. Accurate BP measurement will also help correctly identify children under 3 years in these risk categories who have normal BP.

Welch-Allyn® device evaluation & approval: March 2020 to September 2021

The Dynamap® is an automated BP measurement device that is industry-approved for use in children of all ages. However, it is fraught with issues. The device takes the BP after the cuff is inflated, which results in discomfort. If there is any movement from the child, Dynamap® will not record the BP. It will then pump the cuff to an even higher pressure which leads to greater discomfort. The machine also requires power cycling between each new child's BP measurement.

Due to the limitations of the Dynamap®, we are evaluating the use of the Welch-Allyn® machine, another industry-approved automated BP measurement device approved for use in children above the

age of three years. To evaluate the Welch-Allyn® machine, our team first ran a study within CHOP’s Main and Buerger Sedation Units. We compared the Welch-Allyn® device with the automated GE machine, which is used to monitor BP of children who are sedated. We took BP one minute apart using both machines after the child was sedated and recorded their values. This was done to minimize BP variation and measurement error. We created a detailed validation process flow for use in the sedation unit. We then recorded BP measurements with a REDCap data capture tool.

From March 2020 through November 2020, collected BPs from approximately 58 sedated patients under the age of three:

The Welch-Allyn® Validation Data - Full Cohort (n=58)			
	Automated BP Machine		
	Mean	Std. Dev	Range
Systolic	93.98	10.64	73-118
Diastolic	52.68	7.04	41-77
	Welch Allyn		
Systolic	89.72	9.02	68-115
Diastolic	55.84	7.84	38-79
	Difference (Automated-Welch)		
Systolic	4.258	9.45	-20 to 27
Diastolic	-3.19	6.79	-19 to 13
	Absolute Difference (Automated -Welch)		
Systolic	8.08	6.42	0-27
Diastolic	6.16	4.24	0-19

We presented the data to the CHOP Device Committee for their review on the use of the Welch-Allyn® BP device in children under three. In December 2020, the committee approved the Welch-Allyn® device to begin real-time data collection for children of this age category in nephrology, neurofibromatosis, and

neonatal follow-up outpatient clinics. The committee further requested data for sedated children under age one as the smallest group of children on whom there was data.

The process of collecting real-time data is now underway. Concurrently, we are working to standardize this process. We provided physicians, nurses, and MAs (medical assistants) educational training on the proper use of the Welch-Allyn® machine for children under three. For example, Nephrology and Neurofibromatosis clinics use distraction toys to calm and minimize patient movement during BP measurement.

In September 2021, medical device committee approved implementation of the Welch-Allyn® machine for use in Subspecialty care and Outpatient clinics for use in the under 3-year-old age group. All CHOP Outpatient Primary Care clinics are equipped with Welch-Allyn® machines and appropriate size of machine cuffs for children under the age of three.

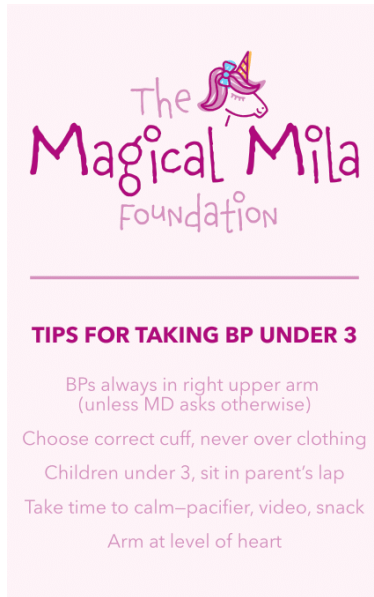
Our long-term vision is to extend the utilization of the Welch-Allyn® device to all outpatient Subspecialty and Specialty care areas at CHOP.

Staff education: September 2020 to December 2021

The goal of our education component is to provide MAs and nurses within all Specialty Care clinics the skills they need to ensure they can accurately measure BP in children less than 3 years of age. To help us achieve this, we created educational training videos, slides, posters and ID badge cards for MAs and other clinical staff, made possible through the generosity of The Magical Mila Foundation.



Photos of the posters. The Welch-Allyn® automated device is shown in the lower part of the left panel.



SCREENING BP VALUES REQUIRING FURTHER EVALUATION		
AGE (YEARS)	BLOOD PRESSURE (mmHg)	
1	98	54
2	100	56
3	101	60
4	102	62
5	103	64
6	105	66
7	106	68
8	107	69
9	107	70
10	108	72
11	110	74
12	113	75
≥13	120	80

Front and back photo of the ID badge

In our training video, we explain the purpose behind the BP Under 3 and demonstrate the proper technique to accurately utilize the Welch-Allyn® device in children under three. Child Life Specialists created voice-over slides highlighting a variety of distraction techniques appropriate for children of this age. In addition, we distributed a special ID badge throughout centers at CHOP Main, Buerger and Wood that illustrates six key points to remember when obtaining BP in children under, three per AAP guidelines.

While we aimed to complete education for all Specialty Care clinics and extend training to Primary Care, we experienced unforeseen delays due to COVID-19. Despite these unprecedented challenges, we held two successful educational fairs and training for about 30 MAs at the CHOP Main, Buerger, Wood and Seashore locations.

In December 2021, Re-education through fairs were conducted. About three skill fairs were held and open to all Medical assistants. One of the skill stations included education on vitals, which included a presentation of the Mila video, Dr. Meyer’s BP tutorial video, and the review of use of comfort holds and distraction techniques. Also, MAs and nurses received online education at Primary care sites, totaling 366 staff members. A webinar was provided for physicians, totaling 49 physicians. The MMF provided 2000 educational badge guides to taking BP, as well as providing wall posters. We worked with nursing to edit standard operating procedure for obtaining BPs under the age of three. All education materials and webinars are now posted on the CHOP community page and are accessible to all CHOP staff.

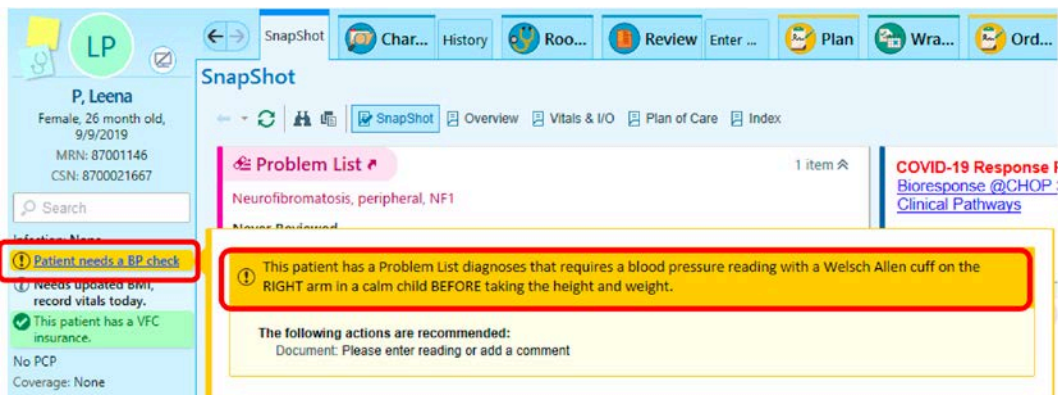
Our long-term vision is to monitor compliance and to provide ongoing education for all medical staff so that BP under 3 is sustainable in years going forward (in perpetuity).

BP record keeping: February 2021 to January 2022

One of our goals is to improve BP record keeping by creating EPIC (electronic medical record keeping system) interventions to minimize errors, help identify high risk populations, and generate an EPIC alert signal to remind clinicians to obtain BP in children under three.

In February 2021, the Primary care stakeholders agreed to implement an alert system in EPIC. By June 2021, received approval from EPIC committee to move forward and create an alert system specifically in Outpatient Primary care clinics. The purpose of this EPIC alert is to identify children under three at their well childcare (WCC) visit who are at increased (high) risk of hypertension. When these children come-in for a WCC visit, an alert is populated for medical assistants to obtain a BP. The medical assistant then takes the BP and records it within this alert along with appropriate comment. If the BP is high, then there is second alert populated for the primary care physician to retake the BP and recommend the appropriate follow-up.

This EPIC intervention will allow the clinical team to consistently monitor and document BPs in high-risk children seen in general pediatric clinics so there can be direct additional testing and/or referrals to Specialist Care.



EPIC Alert

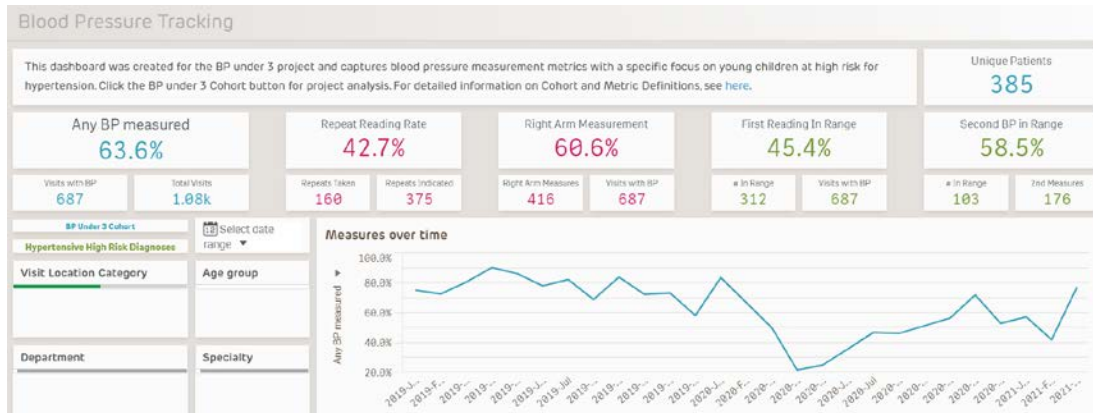
In addition to the CHOP specific EPIC alert, the EPIC Nationwide Nephrology Committee approved the threshold ranges for blood pressure in children under the age of 1 year. Previously infants under the age of one year did not have a BP threshold set-up in EPIC. This threshold will now enable physicians make informed decisions if the BP is above this threshold in children under 1 year of age.

Our plan is to incorporate this data into our BP under 3 dashboard so we can continue to monitor if accurate BPs are being obtained and acted upon, if high.

Dashboard creation:

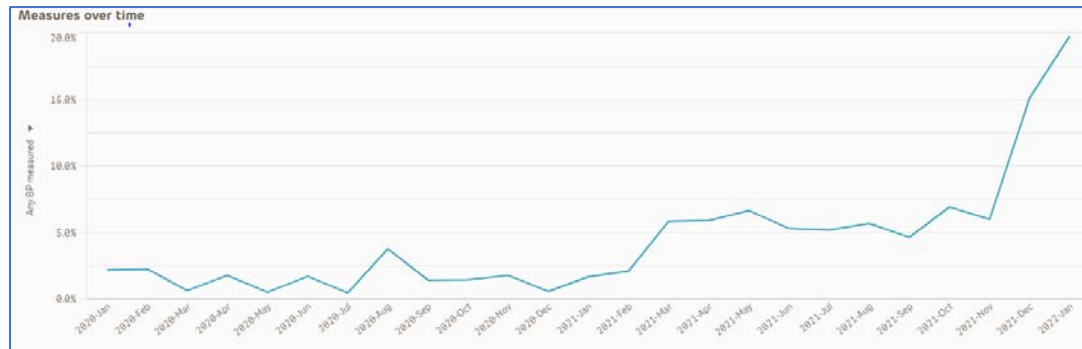
This tool is now live and is linked to the electronic medical record (EPIC). We will use it to monitor and track in real-time when BP is taken in a child under 3 years of age, when BP is repeated at the right time

and when BP is taken in the correct way. The data can be viewed collated or viewed per individual site and can show graphically the change of measurement practices over time.



Dashboard with metrics

Feb. 2021, BP measurements started to go-up due to Primary care stakeholder’s engagement in BP Under 3 initiative. Dec. 2022, there is an increase in numbers of BP measurements due to EPIC alert go-live.



Photocopy of graph from BP under 3 dashboards

Our next steps

For the next 15 months, we envision the following advancements to current projects:

Use of the Welch-Allyn® device in Specialty Care: We will continue to assess the impact of the Welch-Allyn® device in clinical practice to improve accurate BP measurements in children under the age of three years. We also want to extend utilization of Welch-Allyn® device in all Specialty Care sites.

Staff education: We will continue to train staff in all the Specialty Care clinics to advance skills, improve competency and increase adherence to AAP 2017 guidelines for measurement of BP in children under 3 years of age.

We will consistently document BPs in high-risk patients seen in general pediatric clinics so we can direct additional testing and/or referrals to Specialist Care.

Advocacy through national organizations

From a grateful Children's Hospital

When diagnosed with serious disease that can cause critical symptoms, such as NF1, patients and their families often face an uphill battle on the long road to recovery. By determining an accurate and efficient way to measure BP much earlier in a child's life, we can provide a better path to a healthier future. Thanks to the close partnership and generous support of The Magical Mila Foundation, we are making great strides in that direction.