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TITLE:

Reducing Blindness from Retinopathy of Prematurity (ROP) in Argentina: A Mixed Methods Analysis on International Collaboration, Policy Implementation and National Advocacy

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Abbreviated Running Title

An epidemic of blindness due to Retinopathy of Prematurity (ROP) in Argentina: a mixed methods study on policy, advocacy and legislation.

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Key Messages

- 1) Persistence and advocacy by a group of national professionals, legislation instigated by a mother of a blind child, and catalytic action by the Pan American Health Organization (PAHO) set the agenda for policy change for the control of visual loss from Retinopathy of Prematurity (ROP) in Argentina.
- 2) The following agencies collaborated to implement the national program for ROP: the Ministry of Health, UNICEF Argentina, professional societies and an international non-government organization
- 3) Further case studies with cross country synthesis and analysis could usefully be used to explore agenda setting and the role and impact of legislation in other countries in the region

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Authorship

All authors contributed to the conception of the study, study design, gathering of evidence and drafting of the manuscript. L.H produced the first draft, and all authors contributed to revisions. All authors confirm that the paper has not been published elsewhere nor submitted to another journal. All authors have approved the final version of the manuscript. None of the authors declare any potential conflict of interest, such as having received funds or fees from or holding a financial interest in, and organization that may profit or lose through publication of the paper.

Ethical Approval

We cleared the study protocol through the Institutional Review Boards of the University of Pennsylvania and the Ministry of Health in Buenos Aires, Argentina, which granted the study exempt status as it focused on public policy and deemed to pose minimal risk to informants.

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Retinopathy of prematurity (ROP) is a largely avoidable cause of blindness in children worldwide, requiring high quality neonatal care, early detection, and treatment. In middle-income countries throughout Latin America, Eastern Europe and South Asia, there has been a rise in ROP blindness due to a combination of increased survival of preterm infants, resource-scarce medical environments and lack of policies, training and human resources. However, Argentina is an example of country where rates of ROP blindness have declined and ROP programs have been successfully and effectively embedded within the health and legal system. The purpose of this study is to describe the activities and stakeholders, including Ministry of Health (MoH) and UNICEF, involved in the process, from recognition of an epidemic of ROP blindness to the development of national guidelines, policies and legislation for control. Using a retrospective mixed methods case study design, data on rates of severe ROP was collected from 13 neonatal intensive care units from 1999-2012, and on the proportion of children blind from ROP in nine blind schools in seven provinces. Legislative document review, focus group discussions and key informant interviews were conducted with neonatologists, ophthalmologists, neonatal nurses, parents, MoH officials, clinical societies, legislators and UNICEF officials in seven provinces. Results are presented using the stages heuristic policy framework including: agenda setting, policy formulation, implementation and evaluation. By 2012, ROP had declined as a cause of blindness in children in schools for the blind as had rates of severe ROP needing treatment in the NICUs visited. Multiple factors played a role in reducing blindness from ROP in Argentina and successfully coordinating its control including national advocacy, leadership, legislation and international collaboration. Lessons learned in Argentina can potentially be scaled to other LMICs in Latin America and beyond with further context specific research.

INTRODUCTION

Globally, up to 40% of blindness in children is potentially avoidable. The prevalence and causes of childhood blindness vary widely worldwide reflecting socioeconomic development, coverage of specific control measures, and access to high quality eye care (Rahi and Gilbert, 2016).

Visual loss from retinopathy or prematurity (ROP), a condition characterized by abnormal development of blood vessels, can largely be prevented through timely interventions. Risk factors include increasing prematurity, inadequately controlled supplemental oxygen, poor weight gain and sepsis. Rates of sight-threatening ROP (ST-ROP) which requires urgent treatment, reflect the overall level of care infants receive (Manja et al 2015; Darlow et al 2013; Zin et al 2010; Fielder et al 2005). Vision loss from ROP can largely be avoided by interventions that reduce preterm birth, by high quality neonatal care, and by early detection of ST-ROP with prompt, laser treatment. Several epidemics of blindness from ROP have been described, the first in high-income countries in the 1940s. The second occurred in the 1970-1980s due to increased survival of extremely preterm infants. In the late 1990s the “third epidemic” started in middle-income countries as neonatal care services expanded (Gilbert et al 1997).

In the early 21st century approximately 50-60,000 children aged 0-15 were blind from ROP worldwide (Gilbert 2008) with high numbers in Latin America (Gilbert et al 2005). The increase in the number of infants becoming blind from ROP was due to higher survival of preterm infants as neonatal intensive care expanded in many low and middle-income countries (LMICs), inadequate control of known risk factors and suboptimal coverage of screening and treatment (Gilbert 2008).

Over the last two decades many LMICs have developed programs for ROP control, although many have incomplete coverage and poor coordination. In a recent review of ROP services in 11 countries in Latin America and the Caribbean the following were associated with higher program coverage: national

guidelines; policies for prevention, detection and treatment of ROP; legislation that mandates eye examination of all preterm infants, and national data collection instruments (Arnesen et al; 2016). However, studies examining the role and impact of these factors have been limited.

We addressed these gaps by taking a theory-driven health policy analysis approach in order to understand the main factors influencing ROP control in Argentina, using established frameworks for broader relevance in practice and theory. Health policy analysis and “health systems thinking” are complex, dynamic and ill-defined fields, with limited research from LMICs (Gilson, 2014). In addition, studies undertaken in LMICs often do not use policy frameworks or health systems approaches that can *“complement classic approaches by offering a more holistic perspective to complex problems in a complex system”* (Walt 2008; Adam and de Savigny, 2012). Walt et al advocate the use of frameworks and theories at all stages of policy research which, in addition to “telling the story”, allows critical analysis of the influencing and diverse factors involved (Walt, 2008). We chose the stages heuristic framework, which includes agenda setting, policy formulation, implementation and evaluation (Walt, 2008; Laswell 1956; Brewer and deLeon 1983). Stages heuristic is a foundational framework that we augmented by considering interactions between the four stages, as processes in Argentina were not linear. As agenda setting is a critical first step, we also discuss the relative importance of the influencing factors described by Shiffman (Shiffman, 2007).

The purpose of this study was to explore the processes of formulating and implementing health policies, programs and strategies to control visual loss from ROP in Argentina over the last 15-20 years.

METHODS

The study was a retrospective health policy analysis from agenda setting to assessment of the impact of policy implementation. As some of the authors were key actors in the processes, this study can also be

characterized as self-evaluation. Data to explore each component of the stages heuristic framework were obtained using a sequential exploratory design (Guetterman, 2015). A Study Advisory Group (SAG) in Argentina guided all stages of the study with input from international and local experts. The lead author, (LH) was independent from this group and the policy process.

The study took place in Buenos Aires, the capital of Argentina and in seven of the other 24 provinces. The SAG purposively selected provinces where high rates of ROP blindness had been reported among children in schools for the blind. Provinces selected met the following additional criteria: 1) include public sector neonatal care units (NICUs) and have at least one school for the blind, 2) demonstrate a range of geographic regions and economic levels with Chaco and Corrientes being the poorest and Mendoza and Cordoba the better resourced (**Table I, Figure 1**). Data were collected over 6 weeks in 2013.

A mixed methods case study design was used to collect a more diverse, in-depth array of evidence than could be demonstrated by a single method alone (Creswell et al 2014).

Quantitative data

Quantitative methods were used to provide evidence of change in the proportion of infants developing ST-ROP and change in ROP blindness since 2002. Data on ROP between 2008 and 2011 were obtained from 13 NICUs, by collecting the following data for each year: number of premature babies examined, number developing any ROP, and number treated for ST-ROP. In each province, data were collected from head teachers on the proportion of blindness attributed to ROP among children attending schools for the blind. Relevant documents and publications were also reviewed.

Qualitative data

Qualitative methods were used to provide insights from the experience of key actors and stakeholders to understand public policy processes in relation to ROP in Argentina.

Interviews and focus group discussions

Participants, who were purposively selected, included the following: ophthalmologists (n=17), neonatologists (n=26), neonatal nurses (n=20), Ministry of Health (MoH) officials (n=16), legislators (n=1), legislative staff (n=2), hospital administrators (n=3), UNICEF health directors (n=2) and parents of infants treated for ROP (n=2). Snowballing was used to identify further key informants. Participants often overlapped in events, defined as a gathering between the lead interviewer and participants, as participants entered and left the room at different times. A total of 54 transcribed interviews were obtained, which often included crosstalk or overlap among participants (**Table II**). International ROP experts and leaders from the Pan American Health Organization (PAHO) were also interviewed for background data.

For each participant group, a series of prompt questions was developed by individuals with expertise and experience of neonatal care and ROP programs in Argentina and globally. For each participant group, SAG members defined questions tailored to ROP blindness prevention, and to explore their understanding of change in awareness of ROP, the quality of neonatal care and ROP blindness prevention programs, factors that brought about change, and obstacles to implementation of initiatives. The questions addressed a wide variety of topics including national leadership and advocacy, international cooperation and collaboration, national policies, legislation, neonatal care services, and the economic situation from the 1980s onwards. The SAG approved all questions.

Interviews and focus group discussions were conducted in Spanish by the lead investigator (LH), in a private location after obtaining written informed consent, including permission to record the event. Interviews were transcribed, de-identified and translated into English. Participants were assigned numbers to assure confidentiality. NVivo 10.0 was used to assist coding and analysis. We used an integrated approach to data analysis combining a grounded theory analytic approach with a content

analysis in which the data were examined to identify the presence or absence of key theoretical constructs based on our research question, with guidance from the SAG (Curry et al, 2013). The investigators derived two types of codes; an a priori set based on the key constructs of the research questions, and a set of key ideas, grounded in data that emerged from a line-by-line reading of the text (Curry et al, 2009). Coding definitions were developed and decision rules for use of each code were added to the codebook to standardize coding (available on request). Interviews were then coded by two coders from the Mixed Methods Research Lab (MMRL) at the University of Pennsylvania. Using the inter-rater reliability function in NVivo, there was 85% inter-rater reliability across coders. Discrepancies in coding were discussed with the lead investigator (LH) and resolved by consensus. After the dataset was coded, each code was summarized, examined for patterns and used to develop key themes. Four main themes and 17 sub-themes emerged (**Table III**). With expertise from the co-authors and literature reviews, the lead investigator (LH) mapped the 17 sub-themes to the Stages heuristic framework (**Table IV**). This framework has been widely used to understand and simplify the policymaking process and “*remains a useful heuristic to explore a complex world.*” (Laswell 1956; Fischer, 2007). Main theories about the qualitative data emerged from key code summaries.

RESULTS

The results are described using the stages heuristic framework with key definitions and findings outlined in **Table IV**. An overview timeline of key milestones is illustrated in **Figure 2**.

I. Agenda setting (1999-2002):

The national actors who initially identified the rapid increase in the number of infants requiring treatment for ROP, and an increase in the number of children with vision loss from ROP were a small group of national professionals comprising neonatologists, ophthalmologists and neonatal nurses. This group included a neonatal nurse who had an official role in the MoH, and an ophthalmologist who ran a

low vision clinic in Buenos Aires. A neonatologist stated: *“The first who detected the high number of blind babies were ophthalmologists. They notified us that there was a problem.....an epidemic of ROP. It was a multi-factorial cause of the epidemic from the lack of knowledge, financial crisis, careless use of resources and lack of leadership.”*

Many nurses did not know that oxygen could be damaging as they thought it was a “medication” and *“more oxygen was good.”* Examples of some of the statements from nurses and nursing supervisors about oxygen include: *“Later we learned during the workshops about how to use oxygen...how to use it without hurting the eyes.”* (Nurse). *“In 1990, for us oxygen was a medication, a thing that was good for pulmonary hypertension.....”* (Nursing supervisor)

During the late 1990’s, a national political priority to improve neonatal care in Argentina led to an overall increase and improvement in the quality and complexity of neonatal care. This led to greater survival of increasingly preterm infants, which increased the number at risk for ROP. Neonatal services, especially those in the public sector, had significant deficiencies in the number and expertise of neonatologists, and nurses and inadequate equipment for oxygen control. The ophthalmologists who visited NICUs to screen for ROP also had limited training and equipment. Finally, very few public NICUs had access to lasers, which often led to newborns being transported great distances for treatment (Lomuto, 2009).

Argentinean studies indicated that at the turn of the millennium, 50-90% of visually impaired children had ROP, declaring it the leading cause of blindness in children (Lomuto, 2009). National data also indicated that 10% of the 700,000 annual births were preterm and at risk of ROP. Using data on the proportion of preterm infants who developed ROP it was estimated that 4/1,000 live births would develop ROP (Lomuto, 2008), with ST-ROP affecting 1.1/1000 live births, 15% of whom would had a poor prognosis with a high possibility of severe visual loss (Lomuto, 2008). These statistics were quite

high compared to other Latin American countries at the time such as Chile, and developed countries such as the United States or Canada (Gilbert, 2005).

A 2007 study by Bouzas et al showed that in the late 1990's there was an alarming increase in the number of infants admitted to the neonatal unit in Hospital Garrahan, Buenos Aires for laser treatment of ST-ROP (**Figure 3**) (Bouzas et al 2007). Up to 800 infants were admitted annually, with 7% being referred too late for treatment (Vincintin, 1998, Benitez et al 2006, Bouzas et al 2004). Data from schools for the blind in seven provinces in Argentina in 1998 and 2002 showed that a high proportion of the children enrolled were ROP blind (**Table V**). In 1998 in Corrientes and Cordoba, approximately two-thirds of children enrolled were ROP blind. These children were aged five years and above, suggesting that the onset of the epidemic preceded the increase in referrals to Hospital Garrahan.

Interviews with key stakeholders and participants provided insights into a range of interrelated factors which could explain this increase, with the economic crisis in 1998-2002 resulting in an *“acute lack of equipment, and human resources, especially neonatal nurses”* (Neonatologist). The situation was compounded in the early 2000's by *“Very few ophthalmologists were trained to perform screening and treatment for ROP in the public sector across the country, making it necessary to refer almost 50% of children great distances for treatment”* (Neonatologist).

Hospital administrators and neonatologists felt that poor management of supplemental oxygen was a direct result of nurses not having enough time to monitor babies properly. Several thought the shortage was more acute in rural settings, and others described policies that allowed female nurses at least six months maternity leave, which compounded NICU staffing problems. The nursing shortage was likely multi-factorial, being influenced by low salaries, burn out, high rates of absenteeism due to illness and high staff turnover. One Hospital administrator stated, *“At times we only had one nurse for 10-15*

babies.” All stakeholders commented on the lack of eye examination equipment and equipment for delivering less than 100% oxygen and monitoring all infants receiving supplemental oxygen.

In response to these findings, the small group of leaders advocated for improvement in neonatal care, including ROP screening and treatment, and for the MoH to sponsor a national workshop on ROP. As a direct result of their leadership, advocacy and persistence, the Argentinean MoH officially declared an epidemic of blindness in children from ROP in 2002. According to a key neonatologist, it was also when “*WHO/PAHO directly phoned the Ministry*” that “*action was taken*”. The epidemic was attributed to unregulated expansion of neonatal care units, increased survival of premature infants, and a national economic crisis that led to a decrease in funding, equipment, and human resources for neonatal care and ROP prevention.

Another agenda-setting element that occurred in parallel with but in isolation from the elements described above, was initiated by the mother of a ROP-blind child who was staff to an Argentinean legislator. Realizing that this child and others need not have been blind they advocated for urgent legislation to mandate screening for ROP.

II. Formulation 2003-2007

As a result of advocacy by the informal group and PAHO, an official MoH ROP workshop was held in 2002, which was attended by representatives from the government, and facilitated by international ROP experts. Delegates included neonatologists, neonatal nurses and ophthalmologists from across the country. Data presented included that 34% of children in special education were blind from ROP and that 68% of blind children presenting to the eye department in Hospital Garrahan in 2002 were blind from ROP (Bouzas, 2007; Vincintin, 1998). They highlighted that ROP blindness was increasing, and

estimated that 50 children were becoming blind each year/million population (Benitez A, e al, 2006; Lomuto C et al, 2010; Lomuto C et al, 2008). The conclusion of the workshop was that there was an urgent need to develop a national program to control blindness from ROP.

The informal group approached the MoH again, and advocated for an official multidisciplinary working group to address ROP. As one of the leaders already had an official role in the MoH, the group argued that establishing such a group would be feasible and practical.

A. Formation of the MoH Multidisciplinary Collaborative ROP Working Group (2003):

In 2003 the MoH officially established the Multidisciplinary Collaborative ROP Working Group (hereafter called the Collaborative ROP Group or CRG)(Secretariat Resolution No. 26/03). The CRG comprised the MoH Department of Maternal and Child Health and representatives from the Argentina Society of Pediatrics (Neonatal Studies Committee), the Argentina Council of Ophthalmology, and the Argentina Society of Pediatric Ophthalmology. Their mission was to organize workshops and lectures on ROP, to create and publish National ROP Guidelines, and to collect and publish data on ROP. An official post was created in the MoH and the group met regularly.

B. Activities of the Collaborative ROP Group (CRG):

The CRG planned the following three key activities with financial support from the MoH as well as technical input from CBM and PAHO:

1) Situation analysis (2003):

A situation analysis of 100 NICUs across the country identified serious deficiencies in neonatal care and in ROP screening and treatment, and high rates of ROP were reported in NICUs. Rural provinces were particularly under-resourced with limited knowledge on ROP prevention (Benitez. et al, 2004).

2) Developing National ROP Guidelines (2003):

In 2003, with support from PAHO, national prevention, screening and treatment guidelines, were officially adopted. However, the CRG recognized there were barriers to implementing the guidelines due to limited communication and coordination between national and provincial departments of health and NICUs. Limited resources compounded the problem particularly in rural provinces. As one hospital administrator from a rural NICU in Chaco stated, *“There was little communication with Buenos Aires especially where we lived. We often felt disconnected from their efforts.”* (Hospital Administrator)

3) Proposal for MoH/UNICEF Initiative (2003):

In response to these limitations, the CRG developed a proposal for UNICEF. One of the strategies proposed was to develop “ROP referent teams” to educate staff and parents and to implement control efforts. UNICEF agreed to support training the ROP referent teams, comprising a neonatologist, an ophthalmologist and a neonatal nurse, in NICUs across the country together with initiation of the “Week of the Premature Infant”. Funding covered educational materials and stipends for the ROP referent teams.

One Hospital administrator responded favorably to the formation of the CRG: *“When the group formed in the Ministry it opened the doors for people from different sectors and provinces to provide the resources needed. It was not just that the people came and talked about the issue and found solutions, but rather, they had to get the resources... the oximeters, saturation monitors, and we started to see blenders in delivery rooms.”* (Hospital Administrator)

C. Formation of Legislation: Ley 26.279: Ley de Pesquisa en el Recien Nacido” (2007):

Legislation mandating screening for ROP was passed in 2007. However, the legislation included ROP among other conditions for newborn screening and did not specify that only preterm infants should be

screened for ROP. On the other hand, a benefit of legislation was that it had to be supported by a national program and resources from the MoH for implementation.

D. Development of national program for ROP:

The CRG realized that their priorities and goals would not have national scope and be sustainable over time unless a national program for the control of ROP was developed within the framework of the MoH. Development of the national plan accelerated after the CRG members learned about the legislation.

III. Implementation 2004-2010

A. Implementation of the MoH/UNICEF Initiative (2004-2008):

Between 2004 and 2008 the CRG and UNICEF Argentina trained ROP referent teams in 70 government NICUs in 20 Provinces across the country. **(Figure 3)**. They received a stipend to educate staff and report ROP cases. Educational materials were developed with support from UNICEF and equipment for screening and treatment was provided by the MoH. UNICEF also supported an initiative called the “Week of the Premature Infant”, based on their “Week of Lactation”, which was rolled out in all public and private NICUs across the country, with ROP being highlighted as one of the ten rights of the premature infant. The purpose was to engage and educate parents, families and hospital staff about ROP and to raise public awareness through promotional campaigns using celebrities as ambassadors.

Most of those interviewed said that the “ROP referent teams” and frequent educational workshops were key to scaling up effective ROP programs, and improved neonatal care and awareness of ROP.

Participants were unanimous in saying that these activities played a critical catalytic role in raising awareness of ROP, bringing resources, parents, hospital administrators and staff together, and uniting private and public providers to a common cause.

“I went to one of the workshops during the “UNICEF Week of the Premature Infant” and there were parents, doctors from the district areas, and also people from different sectors, for example the public sector. And there were legislators. So this was very interesting, there was also UNICEF”.

(Parent)

“UNICEF supported the initiative and so they participated in different places. Many of the hospitals that participated were private, others were public. That’s so good... they have their hands in everything. Each hospital organizes their activities. It basically has to do with reflecting on prematurity and coming together, sharing experiences, inviting members of the community that are in some way involved with the care of the premature infants.” (Neonatologist)

In addition to their coordinating and educational roles, the “ROP referent teams” also served as contacts whom the CRG and UNICEF could work with to solve problems.

After UNICEF support ended the coordination efforts stopped in several NICUs, as staff were unable to continue on a voluntary basis. However, since the infrastructure was in place, many NICUs continued to benefit. The CRG realized the gains would require continued investment to mobilize, train and retain NICU staff as well as ophthalmologists skilled in the detection and treatment of ROP.

B. Implementation of the ROP Legislation (2007):

Articles 1, 3, 4 and 8 of the legislation stipulated that the law applied to private and public providers and that equipment should be provided as well as a budget in each Province to facilitate screening. Articles 4 and 5 mandated that the MoH develop national programs for each disease, to implement community education campaigns, promote early diagnosis and treatment, coordinate with provinces, monitor follow-up and treatment, and train human resources. Upon reading the legislation, the CRG drafted and submitted a proposal to the MOH to form an official program for ROP with financial support. The

proposal included a framework for the program with central and provincial coordinating bodies.

(Figure 4).

A main limitation of the law was that the expertise of CRG members was not sought while it was being formulated and the law did not include screening protocols and controlling risk factors for ROP.

C. Implementation of the National ROP Blindness Prevention Program (2010 Resolution):

The MoH passed Resolution 1613 in 2010 to form the ROP Blindness Prevention Program. The resolution enabled the CRG to implement ROP screening and treatment to uphold the ROP legislation. The resolution also mandated monitoring, supervision and program evaluation, with resources and financial support from the Ministry. Roll out included purchasing ophthalmic equipment for screening and treatment, and pulse oximeters and blenders for NICUs in all provinces, particularly in Chaco and Corrientes. Provincial coordinators and leaders were appointed to oversee local implementation, and hospital administrators were supported to hire more staff. CRG members supported educational workshops and distributed educational materials in NICUs for staff and families. A data monitoring system was also established to collect provincial and national data for research, monitoring and evaluation.

Participants stated that many NICUs without ROP screening and treatment developed these services with support from the CRG, with ROP referent teams playing a key local coordinating role. CRG members frequently visited NICUs to identify problems and propose solutions.

Challenges in implementing the program included initial resistance from many hospitals administrators to changing oxygen administration policies and to increasing staff. However, once the national ROP

policies and guidelines were published many successfully adapted to the new protocols. Another barrier to implementation was the lack of coordination and communication regionally.

IV. Evaluation (2012 and onwards)

Quantitative data from 11 of 13 NICUs with data for 2008 and 2011 on the proportion of infants with birth weights less than 1501g treated for ROP declined from 9% to 5.6%, a 38% reduction (**Table VI**). The other two units only had data for 2011 and although the numbers examined were small ($n < 25$), no infant required ROP treatment. The school for the blind in Cordoba was the only school with annual data on the number of children enrolled and their cause of blindness until 2012. The mean proportion of children who were ROP blind declined dramatically from 65% among those enrolled in 1998-2002 to 20% in 2010-2012 (**Table VII**). None of the other schools were able to provide adequate data but all the head teachers commented that ROP was no longer a major cause of blindness. In addition, fewer ROP blind infants attended Hospital Garrahan after 2002 (**Figure 3**).

There was unambiguous agreement that late stage ROP had decreased by 2012,

“ROP has improved a lot. These stages 3 and 4 {ROP}, which before indicated surgery, have diminished. The seriousness has diminished. The number of surgeries too.” (Ophthalmologist and nurse)

Many participants thought that the law had had a major impact on increasing awareness and resources for ROP, particularly in poorer provinces, as Provincial MoH were obliged to comply and provide resources. Participants also described the importance of the law as a catalyst, encouraging implementation of the 2003 National Guidelines for ROP, leading to consistent and equitable programs.

“It’s important because, well, perhaps although the screening spread a lot, the laws also spread. You can arrive at places that became aware of the screening because sometimes when the things are clear, like laws, the people are more conscious of it.” (Neonatologist)

“The impact the law has had is that an agreement was signed where the Province guaranteed the enforcement of the law in the neonatology services. As a consequence they had to facilitate everything that is equipment and give us rooms for the workshops each time we need them. And what was accomplished here was to have an ophthalmologist that does external visits.” (Hospital administrator)

“As head of nursing I can demand from my director to follow the law - to give me everything I need in accordance to the law.” (Nursing Supervisor)

Most also felt that the combination of national leadership and advocacy, the MoH/UNICEF intervention and the law had been very effective in improving neonatal care and ROP screening and treatment in NICUs across Argentina.

“A combination of national leadership, training and advocacy helped decrease ROP in Argentina.” (Neonatologist)

Some commented that a limitation was that the private sector was generally not included in this effort, apart from educational workshops during the UNICEF Week of the Preterm Infant. There are many private NICUs in Argentina in which the rates of ST-ROP are unknown. Nor is there information on adherence to the National ROP Guidelines.

Another issue was that the stipend was only provided to the “ROP Referent Teams” during the four years of the intervention. Despite this, many ROP Referent Teams continued to coordinate programs and report data to the CRG on a voluntary basis.

Finally, the effort to control the epidemic of ROP sparked innovative ideas by ophthalmologists to solve problems locally. For example, one group created a novel computer program called “ROP 21” to monitor and refer patients.

DISCUSSION

A major contribution of this study is the innovative use of combined health policy frameworks in policy analysis in LMICs. The methods and themes identified provide a roadmap for future health policy analysis in LMIC using frameworks to guide data collection and interpretation. Our results document the pitfalls of assuming processes are linear and sequential when applying foundational frameworks such as stages heuristic and Shiffman. Our findings also show that multiple time points, national champions, persistence in advocacy and multiple players had distinct roles in policy creation and implementation which were complex, multi-dimensional and non-linear. Future studies may need to adapt parts of the framework to include more open ended and in-depth questioning from multiple players and time points. These conclusions are echoed in several studies discussed below from authors including Bertran, Walt, Gilson, Shiffman and Smith.

We used the stages heuristic framework in this study because it has “enduring relevance despite simplicity” (Walt and Gilson, 2014). In this study the authors used the stages heuristic framework to synthesize findings from policy analysis research in LMICs, to demonstrate how the framework could be adapted or modified. As suggested by Walt, we expanded the agenda-setting component of the stages heuristic framework using Shiffman’s (2007, 2008) agenda setting framework in order to provide greater insight into this important stage of policy initiation.

Walt and Gilson suggested two modifications to the Shiffman and Smith framework for global agenda setting (Shiffman and Smith, 2007), the first being the addition of contestability or conflict in agenda setting. (Walt and Gilson, 2014). In our study two main actors were involved in agenda setting: the group of professionals and a legislator. While these two actors were not in conflict, the lack of awareness of each other’s actions meant that the legislation was not adequately specific. Despite not being relevant to our study, we agree that the addition of contestability and conflict would be a useful addition to Shiffman and Smith’s agenda setting framework. Walt and Gilson also identify an overlap between guiding institutions and global governance, suggesting that this be replaced by guiding

organizations to help clarify governance levels. For example, in our study the MoH and UNICEF were acting at different levels (national and international), and the distinction of using guiding organizations would have clarified our analysis.

The period between agenda setting and policy implementation is a relatively neglected area in the health policy literature especially in LMICs. However, this “bit in the middle”, as referred to Berlan et al, is key to determining whether a policy will achieve its intended purpose (Berlan et al, 2014). In critiquing the area between agenda setting and policy implementation i.e., policy formulation and adoption, key actors, such as civil society, technical experts or international organizations, can play different roles and at different stages. Berlan et al recognize seven distinct activities inherent in policy formulation and adoption. In our study, several of these activities were relevant including: 1) generation of policy alternatives, 2) deliberation and consultation and 3) drafting and enacting legislation. The generation of policy alternatives was reflected when the MoH Collaborative ROP Group was directly involved in creating evidence based national guidelines and giving technical input to the different components of the ROP program. Deliberation and consultation was demonstrated when coalitions of parents of premature infants were invited to suggest activities to be enacted during the Week of the Premature. International agencies such as UNICEF, PAHO and CBM were also involved in deliberative processes through external consultation. In our study drafting legislation was included in our analysis of agenda setting, according to Shiffman’s framework: enactment of the legislation could be considered as one component of the “bit in the middle”.

There are many advantages in exploring the activities forming “the bit in middle” formulated by Berlan, as they guide specific questions that can assist in analyzing policy formulation and adoption. Future research in ROP could examine questions including: What role do international agencies play in generating policy alternatives? Or what role do medical professionals, civil society and the media play in deliberation and consultation?

Our case study in Argentina also fits the agenda setting component of the Shiffman framework, with a few key distinctions. Translational influences had been promoting ROP programs in the region but in Argentina the trigger for policy change started with the identification of an increasing number of ROP cases by professionals and their national societies. Furthermore, PAHO was instrumental in raising the profile of ROP, as control of ROP was one of their priorities for the region, by facilitating dialog between the MoH, the professional group and leadership in Hospital Garrahan. This highlights the influential role UN agencies can play in priority setting at national level.

Weaknesses of the Shiffman framework however include the difficulty of taking account of externalities and the subjective nature of assessing the weight to give different causal factors. It is also difficult to capture temporality in the policy process, as health policy is complex and rarely linear or static. Limitations of the stages heuristic are well recognized and can result in over simplification of complex processes.

Limitations of the study

Limitations in evaluating the impact of policies include lack of baseline data on ROP in many NICUs and lack of data from schools for the blind. Other limitations include the process of the qualitative research: difficulty meeting with key hospital administrators, legislators and health officials due to time and scheduling restraints; language and cultural barriers may have influenced the interviews, and some data were lost due to overlapping participant responses. Another limitation of the study is that it was not possible to identify which elements of the MoH/UNICEF package of interventions were the most effective, as they were developed and implemented concurrently. Some may have been more effective than others, and the effects may have been multiplicative rather than additive. Still, it seems the combined effect of all the factors led to the reduction of ROP blindness in Argentina.

A further limitation was the potential for bias of SAG members, many of whom had been actively engaged in policy development and implementation processes. This may have introduced selection bias as the Group decided which NICUs to include in the MOH/UNICEF initiative as well as

the stakeholders interviewed in the study. For example, participants with a more a positive outlook may have been preferentially selected for inclusion in the study. However, any bias was likely mitigated as the lead author used snowballing to recruit further participants independently, and SAG members were not present during interviews nor did they play a role in the analysis.

UNICEF played an important role in providing financial and educational resources and this support was universally welcomed. However, there was little other support in terms of logistics, human resources, strategic thinking or integration of initiatives into existing programs for long-term sustainability. This was a missed opportunity for sustained engagement which became manifest when the ROP referent teams were no longer supported when funding ended. Staff turnover and poor communication and documentation within UNICEF also led to lack of institutional learning. In addition, lack of communication between the international players from early on in the policy process meant that key institutional players did not contribute to long-term strategies and plans for sustainability.

CONCLUSIONS

The policy analysis carried out in this study was consistent with the complexity of policy processes identified in the literature. The socio-economic context of a middle-income Latin American country brought additional difficulties in achieving the ROP reduction objectives, but the lessons learned can be useful in other contexts. The performance of health professionals, constituting themselves as a relevant social actor was fundamental to the inclusion of ROP on the governmental agenda, making possible the organization of a policy of national scope. The mobilization of international support was also relevant to the success of the initial policy formulation and implementation processes.

Furthermore, Argentina was one of the first countries in South America to draft and enact legislation, which played a key catalytic role in instigating the MoH resolution and decreasing childhood blindness from ROP. Future studies could compare and contrast the initiation and impact of recent ROP legislation in other LMICs such Mexico, Peru and Chile. The current challenge is ensuring that national

health policies, legislation, strategies and plans have sound monitoring and evaluation systems to ascertain what works well and what does not. Strong national leadership, advocacy, collaboration, persistence and commitment were necessary to strengthen health systems for neonatal care in Argentina and for effective ROP control. Our study demonstrated that a few key national leaders made a significant impact in prioritizing ROP on the Argentinean health agenda. Continued coordination and communication between diverse actors and players are needed to set effective policy agendas for child health and blindness prevention globally.

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FIGURES AND TABLES

Table I: Neonatal intensive care units and blind schools visited in Argentina, by province and region

Region	Provinces	Blind schools visited	NICUs visited
Central	Cordoba	1	3
	Buenos Aires	2	4
North	Tucuman	1	2
West	San Juan	1	1
	Mendoza	1	1
East	Chaco	1	1
	Corrientes	1	1
Total		8	13

Table II: Summary of Interview Events and Participants

Type of event	Participant groups	Interviews/focus groups	Number of participants
Focus group discussions	Neonatologists	13	30
	Ophthalmologists	14	17
	Neonatal nurses	13	26
	Ministry of Health officials	3	13
	Representatives of Clinical Societies (Pediatrics and Ophthalmology)	3	3
	Hospital administrators	6	12
	Mothers of infants with ROP	1	4
In-depth interviews	UNICEF officials	3	5
	Legislators	2	4
	Neonatologists	16	16
	Ophthalmologists	16	12
	Neonatal nurses	13	18

Note: Several participants took part in multiple focus group discussions and in-depth interviews

Table III: 4 Main themes and 17 sub-themes arising from qualitative data

Main themes	Sub-themes
Socio-economic situation	<p>Economic situation</p> <p>Communication between Government, ROP staff, and local NICUs</p> <p>Effect of law</p> <p>New initiatives</p>
UNICEF	<p>Support from UNICEF</p> <p>ROP referent teams in NICU</p> <p>Impact of support from UNICEF</p>
ROP Awareness and treatment	<p>Educational challenges for ROP</p> <p>Knowledge of ROP</p> <p>Ophthalmic expertise in ROP</p> <p>Establishing routine ROP examinations</p> <p>Oxygen treatment in premature babies</p> <p>Treatment of ROP</p>
Equipment and Human resources	<p>Ophthalmic equipment for ROP examination and treatment</p> <p>Equipment for oxygen therapy</p> <p>Equipment challenges in the NICU</p> <p>Human resources and staffing</p>

Table IV: Main sub-themes and key findings mapped to the stages heuristic policy cycle theoretical framework

Stages of the Policy Process	Definition	Main Sub-themes	Summary of Key Findings
1) Agenda Setting	<ul style="list-style-type: none"> Awareness of and priority given to an issue or problem Key and multiple actors may define the agenda 	<ol style="list-style-type: none"> Economic Situation Educational challenges for ROP Knowledge of ROP Oxygen treatment in premature babies 	<ol style="list-style-type: none"> Recognition of ROP epidemic by informal and small group of leaders Advocacy for the improvement of neonatal care and formal declaration of epidemic by MoH Initiation of the idea for ROP legislation by the mother of child blind from ROP
2) Policy Formulation	<ul style="list-style-type: none"> Planning, formulation and creation of policies to address the problem identified Decision making of the analytical and political options and strategies constructed to address the problem 	<ol style="list-style-type: none"> Treatment of ROP Support from UNICEF ROP referent teams in NICU New Initiatives Establishing routine ROP exam 	<ol style="list-style-type: none"> Formation of the Collaborative ROP Working Group <ol style="list-style-type: none"> Situational Analysis Developing National ROP Guidelines Proposal to UNICEF Formation of ROP Legislation Initial spark for ROP National Program
3) Implementation	The activities carried out on the ground in relation to the planned and formulated policies above	<ol style="list-style-type: none"> Human resources and staffing Equipment challenges in the NICU Equipment for oxygen therapy Ophthalmic equipment for ROP examination and treatment Ophthalmic Expertise in ROP Communication between government, ROP staff and local NICUs 	<ol style="list-style-type: none"> Implementation of MoH/UNICEF Initiative Implementation of ROP Legislation Implementation of National ROP Blindness Prevention Program Barriers to Implementation
4) Evaluation	Monitoring and evaluation of Impact of the implementation of the policies	<ol style="list-style-type: none"> Effect of law Impact of support from UNICEF 	Quantitative and Qualitative: <ol style="list-style-type: none"> Reduction of ROP Blindness Decreased children diagnosed with ROP in Schools for Blind Increased coordination and leadership for ROP Control measures

* Framework definitions summarized from Fisher, Miller and Sidney's 2007 Handbook of Public Policy Analysis

Table V: Proportion of children in schools for the blind in seven provinces in Argentina who were blind from retinopathy of prematurity in 1998 and 2002

	1998			2002		
	Enrolled	ROP Blind		Enrolled	ROP Blind	
N		%	N		%	
Province						
Corrientes	69	46	67%	78	46	59%
Cordoba	180	115	64%	180	120	67%
Mendoza	98	39	40%	79	34	43%
San Juan	78	17	22%	ND	ND	ND
Buenos Aires	180	21	12%	160	19	12%
Tucuman	41	3	7%	ND	ND	ND
Chaco	30	0	0%	67	12	18%
TOTAL	676	241	36%	564	231	41%

ND = no data

Table VI: Rates of treatment of retinopathy of prematurity among infants <1500 gms) during UNICEF intervention (2008 data only) and post intervention (2011 data)

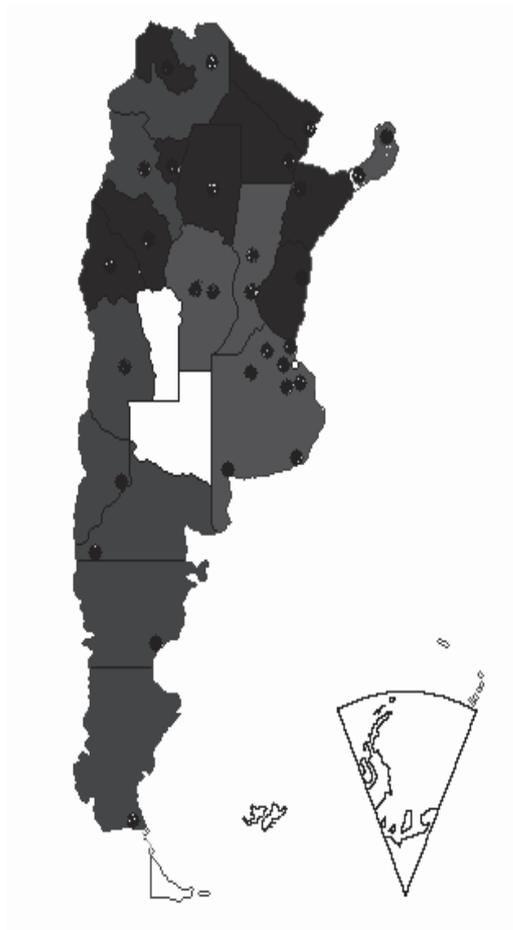
Locality		Last year of UNICEF intervention (2008)					Post-intervention (2011)				
Province	NICU	Examined	Any ROP		Treated with laser		Examined	Any ROP		Treated with laser	
		N	N	%	N	%	N	N	%	N	%
Cordoba	Provincial	91	28	31%	5	5.5%	48	15	31%	7	14.6%
	Neonatal	103	33	32%	8	7.8%	78	37	47%	3	3.8%
Tucuman	N. S de las Mercedes	91	37	41%	10	11.0%	71	23	32%	3	4.2%
Chaco	Perrando	85	6	7%	3	3.5%	82	36	43%	6	7.3%
Corrientes	Vidal	58	28	48%	10	17.2%	46	17	37%	2	4.3%
San Juan	Rawson	13	6	46%	2	15.4%	71	28	39%	10	14.1%
Mendoza	Lagomaggiore	104	29	28%	10	9.6%	96	31	32%	3	3.1%
Buenos Aires	Sarda	85	-	-	6	7.1%	173	-	-	4	2.3%
	Fernandez	34	-	-	6	17.6%	55	-	-	2	3.6%
TOTAL		664	167	25%	60	9.0%	720	187	25%	40	5.6%

Table VII: Proportion of blindness due to retinopathy of prematurity among children in the school for the blind in Cordoba between 1998 and 2012

Year	Total enrolled	Blind from ROP	
		N	%
1998	180	115	64%
2002	180	120	67%
2010	21	2	10%
2011	27	3	11%
2012	39	9	23%

Figure 1. Map of Argentina showing the distribution of NICUs involved in the MoH/UNICEF Initiative from 2004-2008 (Reference obtained from the Ministry of Health Argentina)

Top



14 NICUS in 13 provinces joined between 2004-2005
16 more NICUs in 7 new provinces joined between 2005-2006
12 more NICUs joined between 2006-2007
By 2008 a total of 70 NICUs were part of the MoH/UNICEF ROP Initiative

Figure 2: Overview Timeline of Key Milestones and Events from 1999 to the present

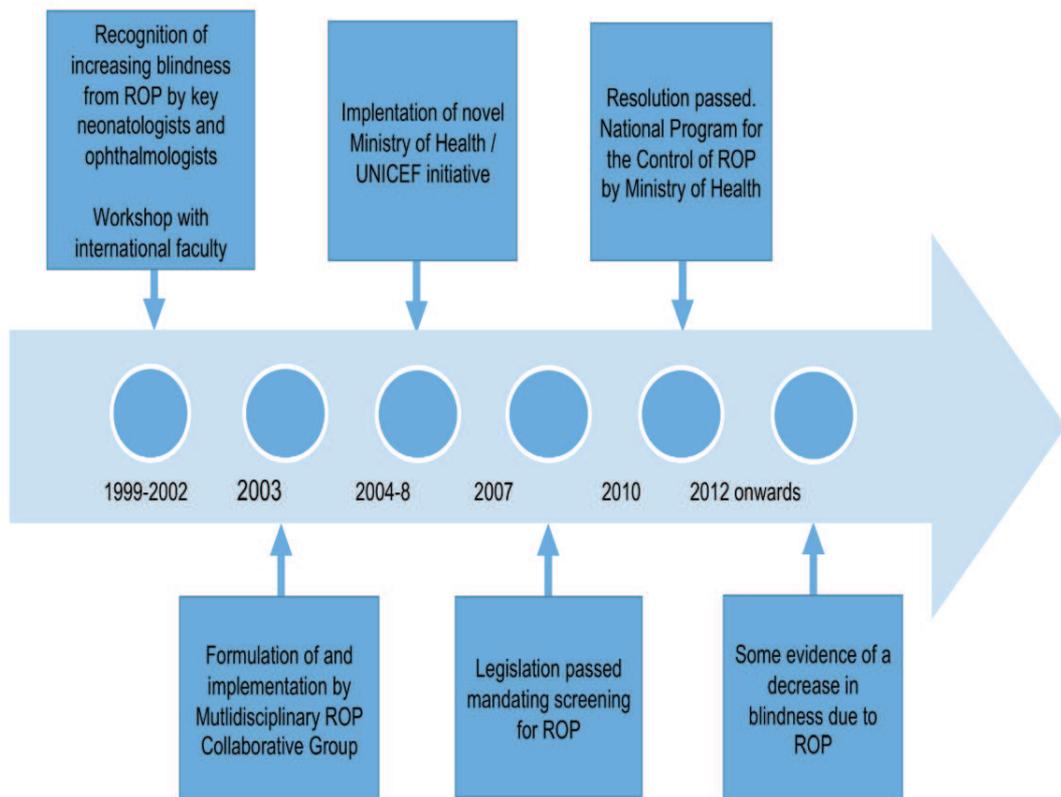
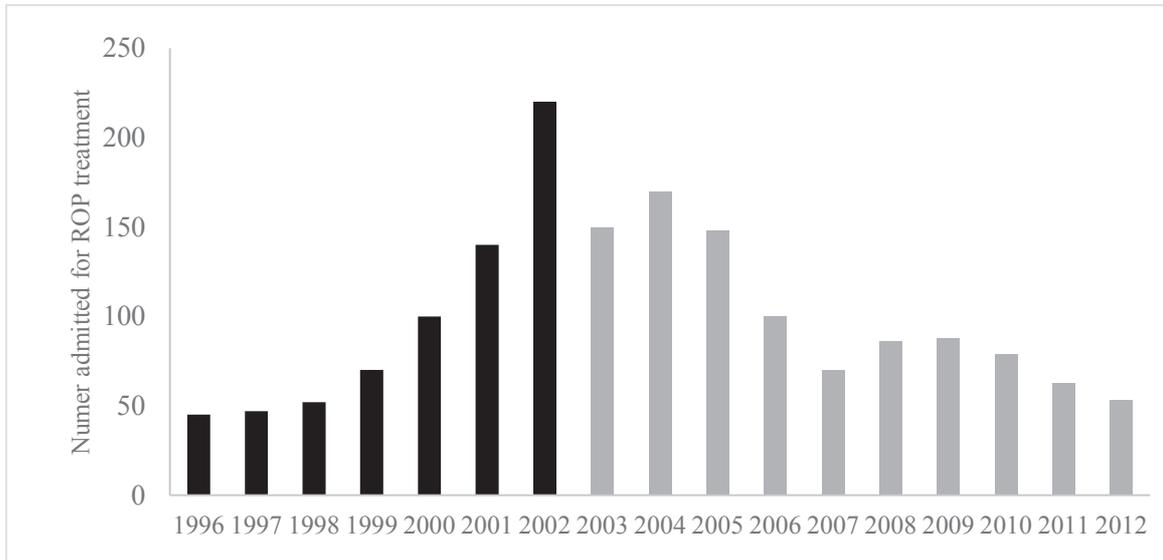


Figure 3: Number of infants admitted to Hospital Garrahan for treatment of severe retinopathy of prematurity between 1996 and 2012



Legend:

Black bars: Prior to MoH/UNICEF Intervention

Grey bars: Post MoH/UNICEF Intervention

Figure 4: Structure of the MoH ROP Blindness Prevention Program: 2010

Structure of the MoH ROP Blindness Prevention Program: 2010
As adapted from the Working Group Proposal to the MoH

