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## Review

# GBS public awareness, advocacy, and prevention—What's working, what's not and why we need a maternal GBS vaccine

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## ABSTRACT

Group B Streptococcus (GBS) is the most common cause of severe early-onset (0–6 days) infection and a significant cause of serious late-onset (7–90 days) infection in infants. While most babies recover from their GBS infection, some are stillborn, more die in the first weeks of life and others suffer lifelong disability. Despite efforts in many developed countries to prevent these infections, the burden of GBS disease remains significant, particularly among the late onset infections, which are not preventable using current risk-based or screening strategies. Vaccination, once available, could prevent more cases of GBS infection than any other strategy, including preventing preterm labor and stillbirths caused by GBS infection, post-delivery GBS infection in the mother and late-onset GBS infection in the baby. Vaccination would also avoid allergic reactions to antibiotics and concern about the emergence of antibiotic resistant bacteria.

We consider the history of the two largest group B Strep parent organizations (Group B Strep Association USA and Group B Strep Support UK) and the history of GBS prevention in their respective countries. We look at what is needed before a vaccine can be introduced and consider how acceptable a GBS vaccine would be from families' perspective. We also summarize what a perfect GBS vaccine would look like and what we should all strive to achieve.

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Group B Streptococcal (GBS) infections have been well recognized since the 1970s in the scientific research communities, the medical professions and the public health agencies. It was not until 1989, when the births and subsequent deaths of three full term babies, created the impetus for public awareness and hence calls for prevention of neonatal GBS infections. By 1989, GBS was listed by CDC (Centers for Disease Control) as the number one infectious killer of newborn babies and the NIH (National Institutes of Health) was funding basic scientific research in support of an eventual GBS maternal vaccine, yet there was still no public voice for this disease. In late fall of 1989, Dr. Carol Baker of Baylor College of Medicine received a phone call from the mother of one of the babies, “was there a parents’ organization?” There was not a consumer-based group who could advocate for prevention. This phone call was the spark that initiated all of the subsequent parent advocacy groups that now exist to support families, push for routine screening and prevention of neonatal GBS and to help lay the public support necessary to for the development of a long overdue GBS vaccine.

Parent advocacy and educational organizations have made an incredible impact on the awareness and prevention of neonatal GBS infections. The first organization, the Group B Strep Association, was formed in 1990 – before the Internet. The early advocacy work was true “grass roots” organizing, with postage stamped mail, newspaper and magazine hardcopy, and television health related stories as well as national parent meetings. The disease was even discussed in community hair salons, as one woman happened to read a magazine article on group B Strep and realized the connection to her own grandson’s infection. Parents ran local fundraisers, ran races, sent memorial donations in honor of their dead infants, bake sales were held, grandparents helped with mailings, and hundreds of volunteers came forth to support the need for education and advocacy.

There is something to be said for the true grassroots organization. In its purest form, it is not owned by anyone but its collective presence. If managed correctly, the energy, passion and commitment of hundreds and thousands of individuals can be heard and can have a huge impact on just about any issue they direct their energies toward. In this case, it was preventing group B Strep disease. It is all too easy to succumb to a variety of for profit interests, who want support for their products in exchange for funding. Yet, as soon as an organization compromises its integrity by accepting funding in exchange for product placement, their message becomes tainted. The true grass roots organization is a labor of love for those who volunteer. And the ultimate goal of the two grass root organizations (GBSA and GBSS) that have committed themselves to fighting group B Strep disease is to put themselves out of business.

### 1. Parent organizations

The two primary parent organizations, GBSA (Group B Strep Association US/International) and GBSS (Group B Strep Support – UK/EU) are separate. Yet they like to think of themselves as sisters. Their focus has been on prevention through education and they are both dedicated advocates for the best standard of care, not only for their own respective countries, but also for all babies and all families globally. Both the Group B Strep Association and Group B Strep Support:

- Were started by families who had lost newborns to GBS.
- Are registered non-profit charitable organizations in their countries.
- Have medical advisory boards.
- Have large bases of volunteers.
- Advocate for routine screening for all pregnant women whose newborns are at low-risk of developing of GBS infection and IV

antibiotics for all women who culture positive or whose babies are otherwise known to be at raised risk.

- Advocate that all pregnant women be offered education on risk factors associated with GBS preterm infections, early onset and late onset infections.
- Recognize that screening-based prevention strategies, while effective, are only meant as an interim solution until a vaccine becomes available.
- Offer wholehearted support for a GBS vaccine that will better prevent pre-term, early onset and late onset GBS infections, and resultant trauma, disability and death.

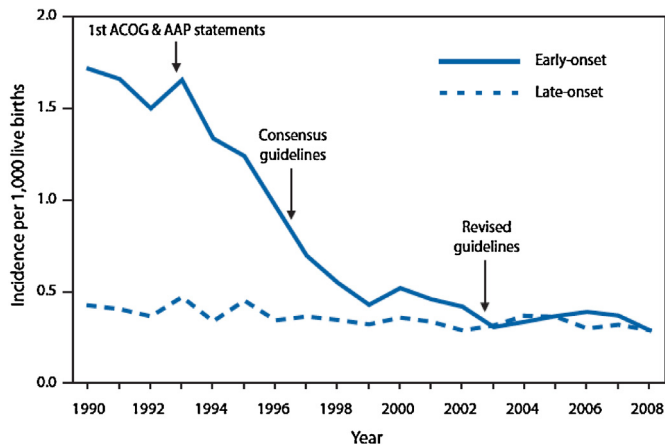
### 2. The Group B Strep Association – USA/International

Formed in June of 1990 by three families who had lost babies to early onset GBS infections, the Group B Strep Association became the voice for this disease in the USA and internationally. Jay Fulker-son and Gina Burns, Robert and Bidy Grant and Bill and Donna Hodous had each lost a newborn within a few months of one another. Dr. Carol Baker had heard from each of these families and put them in touch with one another. After much discussion on whether to form a foundation to support research or to push for public education and a national standard of care for mothers, it was decided to form an educational/advocacy group. In 1990 the GBS vaccine was only a concept that was years from fruition, basic research funding was only beginning and there still was no effective way to prevent babies from dying. The newly formed group struggled with whether to advocate directly for routine screening for pregnant women or to merely provide educational materials to pregnant women. They settled on the following three goals to guide their new organization:

- Educate the public about GBS infections.
- Promote prevention of neonatal GBS infections through routine prenatal screening.
- Promote the development of a GBS vaccine.

### 3. A brief timeline of activities in the U.S.

In 1990 there was no standard of care regarding neonatal GBS infections. In this same year the newly formed Group B Strep Association incorporated as a 501©3 not for profit organization, assembled a national medical advisory board, published its first educational pamphlet and received national media attention (Washington Post and nationally televised HOME Show). By 1991 GBSA parent board members were invited to meet with the NIH Vaccine Grant Officers and subsequently GBS researchers were awarded their first five-year NIH grant for GBS vaccine research. In addition, phone calls from parents across the U.S. to the Centers for Disease Control and Prevention had increased the demand for information on how to prevent GBS infections. By 1992 both the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics had published position papers for their members [1,2]. In addition, in California legislation had been passed calling for a National Consensus Conference of experts to define a path forward. In Florida, legislation was proposed calling for GBS prevention. The Centers for Disease Control and Prevention performed an analysis which showed that screening pregnant women for GBS was cost-effective [3,4]. In 1996 the Centers for Disease Control published a call for comments on GBS Prevention Protocol in the January MMWR. GBSA members sent over 5000 letters to the CDC in support of a prevention strategy of routine screening for all pregnant women. By June of 1996 CDC, ACOG and AAP published the first consensus statement on GBS National Prevention Guidelines [5]. In 1997 AAP published prevention guidelines [6] and the



**Fig. 1.** Incidence of early- and late-onset invasive group B streptococcal (GBS) disease – Active Bacterial Core surveillance areas, 1990–2008, and activities for prevention of GBS disease. Abbreviations: ACOG = American College of Obstetricians and Gynecologists; AAP = American Academy of Pediatrics. Incidence rates for 2008 are preliminary because the live birth denominator had not been finalized at the time of publication.

Adapted from Jordan et al. [8].

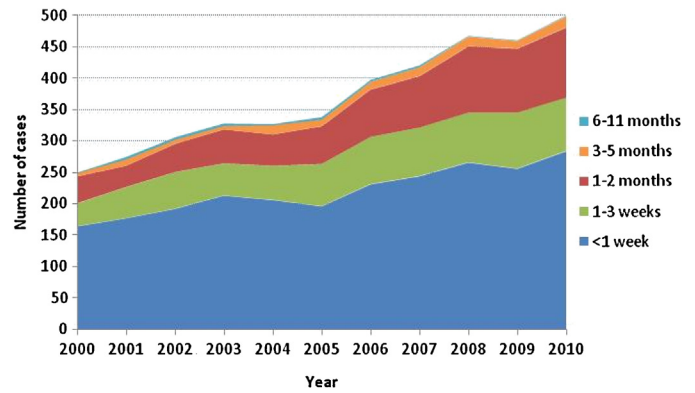
Group B Strep Association launched its first website averaging over 10,000 hits a month. In 2002 the first National Consensus Guidelines recommending routine screening for all pregnant women in the U.S. was published [7]. Fig. 1 shows the effect of guidelines on the incidence of early-onset and late onset group B Strep infection in the US between 1990 and 2008 [8].

In the years following the implementation of the national prevention guidelines the calls and requests for information began to drop off. The GBSA website continued to remain very active and maintained up to 10,000 hits a month, yet the organization was witnessing a huge drop in families whose babies fell victim to this infection. By 2008 CDC Active Bacterial Surveillance Core published data showing that the early onset GBS neonatal morbidity and mortality surrounded had dropped by over 80% [9]. However, while the incidence of early-onset disease had fallen the numbers affected by late-onset GBS remained the same. By 2009 GBSA had launched a face book group for families. In the US, the majority of babies now fall victim to late onset GBS [10]. There is currently no available prevention for these babies.

The GBS national prevention standards have had a tremendous impact on the health and wellbeing of newborns in the US. This would not have come about without collaborative effort between the country's leading researchers, the Centers for Disease Control and Prevention, catalysts of change at the American College of Obstetricians and Gynecologists, leaders at the American Academy of Pediatrics and the American College of Family Physicians and a group of noisy parents committed to prevention. However, it has been clear that this strategy misses late-onset GBS disease [5] and other cases as well, so that an effective vaccine would be a better alternative.

#### 4. Group B Strep Support – UK

Group B Strep Support was formed in 1996 by Robert & Jane Plumb, following their son's death from early-onset GBS infection. With minimal information available in the UK for health professionals and none for families, GBSS was set up to improve awareness and prevention and to support research – a respected medical advisory panel was recruited, and the first members and volunteers joined. The charity has grown significantly since those early days, but retains the same primary goals.



**Fig. 2.** Laboratory reports of GBS bacteremia in infants, England and Wales 2000–2010. The reports exclude a small number of infants with imprecise age data. Source: Health Protection Agency.

From a state of practically no awareness of GBS infection in babies and no guidelines in the UK, the situation has improved. In 1997, the precursor to the Health Protection Agency (HPA) established a GBS Working Group which, in 2001, issued their Interim Good Practice Recommendations for the prevention of early onset GBS infection, the UK's first national recommendations on GBS [11]. In 2003, following a campaign led by the then opposition MP (now Prime Minister) David Cameron, the Royal College of OB/GYN issued risk-based EOGBS prevention guidelines [12]. Research suggested that these could prevent up to 50% of EOGBS infections in babies [13]. An RCOG audit [14] found good adherence to the guidelines in UK hospitals but, even so, since 2003 the incidence of EOGBS infection voluntarily reported in England, Wales & Northern Ireland has risen by 23% to 281 cases in 2011 [15,16]. This suggests that a risk factor based approach may not work for the UK. Fig. 2 shows the incidence of group B Strep bacteremia in England and Wales between 2000 and 2010 [17]. Despite this, the RCOG's 2012 update of their guideline again recommended a risk-based approach, though recommending against IAP for Mums with preterm labor and prolonged rupture of membranes, making the approach even less efficient at preventing EOGBS [18].

In 2006, the HPA first issued their Bacteriology Standard Operating Procedure, Processing swabs for Group B Streptococcal Carriage (B 58) [19], describing the 'gold standard' method of detecting GBS carriage in pregnant women as being the enriched culture method (ECM). Even now, this method is only available in a handful of the NHS Trusts through which most women receive their maternity care. It is available privately, but most women are not told about group B Strep or that sensitive tests for carriage exist. In 2006, a survey of 1000 pregnant women and new mothers [20] found that 9/10 had never heard of GBS and all said "all pregnant women should be automatically told about GBS by their GP or midwife and be offered a free reliable test on the NHS during the last few weeks of pregnancy." A 2011 survey [21] also found that the overwhelming majority of women, when informed about group B Strep, wanted to be given information and offered testing in pregnancy. Within the last 5 years, four publicly funded reports [22–25] have been commissioned to establish how to combat preventable GBS infection in newborn babies. All found screening to be more clinically and/or cost effective than risk-based prevention and recommended that steps to introduce screening should be explored. So far their findings have been ignored.

In December 2012, the UK National Screening Committee decided against recommending routine screening for group B Strep carriage to all pregnant women to reduce infection, disability and death from GBS. The large majority of those who submitted comments during the public consultation – families, health

professionals, medical bodies, charities and Members of the UK Parliament – were in full support of introducing screening. As one senior obstetrician said, “I don’t want to counsel any more parents who lost a baby when £10 worth of antibiotics would have given them a healthy baby to take home.” Despite evidence considered compelling by many countries of the success of screening programmes, the UK National Screening Committee has rejected these calls and is not scheduled to revisit the issue for another 3 years. As mentioned before, sensitive testing for group B Strep carriage is rarely available from UK maternity hospitals, even at the request of pregnant women or their health professionals (although a small number of private laboratories offer it). Without screening and the awareness its introduction would raise, and without knowledge of or access to ‘gold standard’ testing, it seems that UK families will continue to suffer the unnecessary pain, trauma and heartache of preventable group B Strep infections.

## 5. Prevention protocols world wide

Worldwide, prevention strategies for early onset group B Strep infections focus on offering intrapartum antibiotic prophylaxis to women whose babies are identified as being at raised risk of developing these infections. The key differences are how women are selected to be offered the antibiotics – most strategies recommend swab-based screening at 35–37 weeks of pregnancy to select the group of women offered antibiotics in labor. This has proven highly effective, with reported reductions of incidence of more than 80% [8,26–28]. Some countries use a risk-based strategy, offering antibiotics in labor to women with one or more recognized higher risk situations, e.g. maternal fever, prolonged rupture of membranes, etc.; although studies in the US found the screening approach would prevent up to 50% more cases than a risk-based approach [29]. Countries which screen usually also use the risk-factor approach for those women for whom a test result is not available, for example if a baby is delivered preterm, itself an independent risk factor for EOGBS infection [30].

Countries which currently offer antenatal group B Strep screening include: Argentina, Belgium, Canada, Chile, the Czech Republic, France, Germany, Hong Kong, Italy, Japan, Kenya, Lithuania, Oman, Poland, Spain, Slovenia, Switzerland and the USA, plus Australia (where both screening and risk factor strategies are used). In the Netherlands and New Zealand, enriched culture medium screening (the ‘gold standard’ testing method) is available at the request of health professionals; in the UK, few NHS trusts have this capability.

A recent meta-analysis [32] estimated the mean incidence in babies aged 0–89 days worldwide to be 0.53 cases of GBS infection per 1000 live births, with the highest incidence in Africa and the lowest reported incidence in Southeast Asia and noted the need for more high-quality studies, especially in low-income countries. The use of antibiotics in labor clearly made a difference to the incidence of early onset GBS infection (0.23 per 1000 live births in studies with any IAP compared with 0.75 per 1000 live births in studies with none) but even with these lower incidences, the total disease burden from GBS infections in babies and their mothers is significant. But culture proven cases of early onset GBS infection do not present the full picture – there are at least as many probable cases [33,34], which are not measured in most countries.

The DEVANI (DEvelopment of a Vaccine Against Neonatal Infection. <http://www.devaniproject.org>) consortium is working across Europe to understand the distribution of GBS types and to select the most appropriate ones for inclusion in a future vaccine. It is monitoring the level of maternal antibodies of both healthy GBS carriers and GBS-infected babies, and working on ways of inducing a strong, long-lasting protective response in the mothers. They

are also working toward the standardization and improvement of laboratory performance for diagnosing maternal colonization and neonatal infection with GBS in EU countries and on improvements of the methods used for serotyping and molecular typing of European GBS strains [35]. Perhaps this model could be rolled out so that a truly global approach could be taken to preventing these devastating infections.

The failure of prevention strategies to eliminate GBS disease in babies and their mothers highlights the need for a safe and effective vaccine. It has been estimated that a conjugate vaccine incorporating five serotypes (Ia, Ib, II, III and V) could prevent over 85% of global group B Streptococcal disease in infants aged 0–90 days [32].

## 6. What is missing before a vaccine can be introduced?

Even before a safe and reliable vaccine is available, steps can be taken to facilitate its introduction:

- Standardized definition of disease worldwide.
- Standardized monitoring of disease worldwide.
- Routine prenatal care widely available in which a vaccine can be delivered.
- Education of health professionals and parents and expectant parents about group B Strep and the vaccine.

Looking at these issues in two countries where prevention strategies for early onset GBS disease are well established:

- Standardized definition of disease. The US and the UK both define GBS infections in babies as being identified by cultures positive from sterile sites, for example blood and CSF, taken from live born babies.
- Standardized monitoring of disease. In the US, group B Strep is in some states a reportable disease and so there is good information collected. In England, Wales and Northern Ireland, cases of GBS infection are voluntarily reported to the Health Protection Agency so the true burden is uncertain.
- Routine prenatal care widely available in which a vaccine can be delivered – true in both countries.
- Education – of health professionals, parents and expectant parents about group B Strep and the vaccine.

In the US, antenatal GBS screening is a routine part of antenatal care and, as a result, relevant health professionals are knowledgeable about group B Strep and pregnant women are informed about it. In the UK where a risk based prevention strategy is used, knowledge about GBS remains poor, both in the general population and among medical professionals [36]. A survey in 2011 found that just over half of women aged 20–35 had heard of GBS, with only 20% of those knowing what it was [21]. In countries where no GBS prevention strategies exist, it is reasonable to expect the level of knowledge to be even lower.

## 7. Disease burden – a family perspective 2012: who is still slipping through the cracks?

### 7.1. United States – The Group B Strep Association

In 1996 the US initiated a risk-based national standard of care [5]. The Centers for Disease Control recommended one of two strategies. One strategy identified women through prenatal screening cultures at 35–37 weeks of pregnancy and women who developed premature onset of labor or rupture of membranes at less than 37 weeks of pregnancy. The second strategy IV antibiotic prophylaxis was offered to women who developed one or more risk factors at the time of labor or membrane rupture.

Continued surveillance and meticulous data analysis by the Centers for Disease Control prompted a revision to the 1996 guidelines. By 2002, all pregnant women would be screened between 35–37 weeks of pregnancy and if culture was positive, they would be offered IV antibiotics during delivery [7]. The US saw a phenomenal reduction in morbidity and mortality with the advent of routine screening and IV antibiotics for GBS positive mothers. From 2003 onward the Group B Strep Association mail volume and phone calls decreased dramatically. The GBSA website continued to receive approximately 10,000 hits a month in the years following implementation of the new standards. It was clear that women were seeking information about the screening and treatment. It was also clear that the large majority of women and their health professionals were following the prevention protocol.

Prior to either the dual prevention strategy of 1996 or the screening based strategy in 2002, GBSA received hundreds of requests for information on a weekly basis. We had hundreds of families across the country involved with education and advocacy. We had weekly contacts from families who had lost babies either pre-term, at delivery or due to late onset GBS.

## 7.2. United Kingdom – Group B Strep Support

Since 2001, the UK has had a risk-based prevention strategy for early onset GBS infection, first as interim recommendations from the Health Protection Agency and, since 2003, from the Royal College of Obstetricians & Gynaecologists. Despite this, the numbers of both early and late onset GBS infections have increased so that 473 cases (0.63 per 1000 live births) of GBS infections in babies aged 0–90 days in England, Wales and Northern Ireland were reported in 2011, comprising 281 early-onset cases (0.38 per 1000 live births) and 192 late-onset cases (0.26 per 1000 live births) [15]. In Scotland in 2010, there were 46 GBS cases in babies, 27 early and 19 late-onset [37] (0.78, 0.46 and 0.32 per 1000 live births respectively) [38].

Disappointingly, the volume of mail to Group B Strep Support has risen year on year since it was founded in 1996 and, while most of it is now online rather than letters, there is no sign of it slowing, with the website averaging 275,000 hits per month in 2012, up 49% since 2011. Each week, families contact us either to get information that they're unable to obtain from their health professionals about group B Strep or because their baby has suffered serious group B Strep infection. So often, parents of these desperately sick babies ask, "Why wasn't I told about group B Strep?" and "Why wasn't this prevented?"

So the burden continues, not only of the potentially preventable early-onset GBS infections, but also those, which are only potentially preventable with a vaccine – the late onset GBS infections and stillbirths caused by GBS [31] (Figs. 3 and 4).

**Natalie Frost** says, "On the 10th July 2011, we lost our firstborn baby, Ella Alma Frost during labour. No words can ever express the sheer devastation we feel and we will never be the same without her in our lives.

I had an amazing pregnancy with all our scans and measurements spot on. We were so excited about our new arrival and had no idea what we were having. I joyfully updated Facebook daily with my 'peanut' progress, and so all our family and friends felt like they were a part of my pregnancy.

I was in latent labour from the 4th July and we were sent home from the hospital twice assured that everything was progressing as expected. I eventually I went into established labour and was admitted to the maternity ward in Portsmouth, on the Sunday morning. I had a fantastic, text book labour: in the birthing pool and reaching 10 cm dilated – Baby Frost was almost here!



**Fig. 3.** Like and Natalie Frost, at the time when they were waiting for their first child Ella.

Sadly we then lost her heartbeat, after many different midwives and doctors tried to find it. It was too late, Ella passed away just minutes before her birth. The reason for this needless loss was a simple, PREVENTABLE infection, GBS".

**Julie McCulloch** also knows all too well the problems late-onset group B Strep meningitis can cause:

"GBS had devastating effects for my son and us as a family. My son Cameron survived, but with severe brain damage, global developmental delay, microcephaly, epilepsy and he is blind – and that was only the beginning. He is still in nappies at almost 18; he is immobile and non-verbal with horrendous gut and digestion problems which cause him to punch himself when in severe pain. The NHS saved his life but the cost is enormous, including Disability Living Allowance, Carer's Allowance and other help including currently Direct Payments and Residential Care for over 11 years. We have had 128 overnights (which can cost £500 a night), plus Cam is a two person job now for many tasks. Plus a place in SLD school for 18 years, wheelchair provision, nappies/incontinence pads, etc. etc. Prevention is not just better than cure – it's essential!"

## 8. Disease reduction/elimination – a forward perspective 2012 and beyond

We cannot address the global public health issues such as access to prenatal care or funding of preventive care vs. acute care in this short summary of a working group. Each individual government and their public health officials will need to determine if a GBS vaccine is within their scope of care for the pregnant woman and her unborn baby.

Some assumptions are made for the purpose of this perspective:

- There is an effective and safe GBS maternal vaccine available.
- The vaccine is affordable.
- Providers have easy access to the vaccine.



**Fig. 4.** Cameron McCulloch developed late-onset GBS meningitis soon after birth. Cameron, aged 18 days, during hospitalization (left). Cameron at present, aged 17 yr (right).

- The consumer can receive the vaccine within a large enough window to be able to prevent disease in the newborn.

### 9. What are the hurdles?

- We do not have a vaccine.
- Education of provider and education of public.
- Acceptance and approval of a GBS vaccine by government health authorities.
- Identification of a leader, such as the World Health Organization, for implementation globally, as well as the identification of an organization to coordinate collection of data, implementation and its effects.
- Unified epidemiology that allows for data comparison and disease tracking.
- Harmonize sampling methods and screening protocols if used.
- Unified education of providers by their professional societies. Red Papers, White Papers.
- Education in medical schools, nursing schools (future providers).

### 10. Will women take the vaccine?

Based on our collective forty years of experience in working with the public and assuming a safe and effective vaccine is available, our answer is yes, the large majority of women will accept a vaccine to protect their unborn babies. The speed of vaccine uptake will depend in part on how the public is made aware and educated on their options and this will vary among countries and health care delivery options. Group B Streptococcal disease is one vaccine preventable public health problem that has a “face”. People know families affected by group B Strep disease – friends, or friends of friends – and their newborn babies. These families are keen to share if it means that others will not suffer in the same way their children have. Yes, there will be small cohorts of individuals who will choose to not get the vaccine. A maternal vaccine given to protect the unborn baby is very different from a childhood vaccine given to protect a toddler from a disease parents have never seen. In the countries with prenatal screening programs, it might take time to transition from an old prevention strategy to a new one. Some women will want full disclosure of all risks both with a vaccine and without a vaccine. Some women

will opt out of a vaccine and be willing to take their chances with whatever prevention strategy their provider offers. Some women will want the vaccine and screening and treatment with IV antibiotics. Over time, as the vaccine efficacy and safety is proven, the screening strategies will likely fall to the side. There will be new mothers coming for prenatal care who will not know about “old” prevention strategies such as screening. The new standard of care, the vaccine, will likely become the norm.

Over the years, a huge number of expectant parents have sought information from the GBSA and GBSS. Some are looking to increase their knowledge about group B Strep prevention, others are looking for their beliefs to be confirmed and others are looking for reassurance that everything will be fine, whatever the situation. Some want to be tested for GBS; some only want to be tested if it means the result will be negative. Some want intravenous antibiotics in labor regardless of whether they are indicated; some don't want them in any situation. Some want to give birth in hospital, some at home, and some in a midwife led unit. People vary in their beliefs and aspirations but for the vast majority of mothers the most important thing is for their baby to be healthy. Provided the vaccine can almost assure protection against the effects of GBS infection while not incurring other side-effects for them or their baby – and that these facts are clearly communicated – most women will want a GBS vaccination. As always, there will always be some people for whom facts hold no sway; but the large majority of women will want vaccinating against GBS infection, provided:

- The vaccine is safe.
- The vaccine is very effective.
- They understand what devastating infections are being prevented.

### 11. Who might not accept a vaccine and why?

Some women will choose not to receive a new vaccine. With a brand new maternal vaccine being offered, this number is likely to be higher during the first few years. As data flows in on efficacy and safety and shows reductions in morbidity and mortality, then more and more women will begin to accept the vaccine as part of their standard of care. More providers will feel confident offering the vaccine.

It is important to note that while medical organizations and public health officials define a “medical standard of care”, today’s consumer has developed their own “personal standard of care” for their particular health issues, whether it is pregnancy, respiratory disease or cancers. Consumers expect that any medical procedures or interventions offered already have a proven safety record. We expect that any medical intervention will provide a net positive outcome as opposed to no treatment. And we expect that any new treatment is better than a previously offered treatment.

Once having gathered the facts and figures on a procedure or intervention, consumers will add the intangibles into their decision making process. Intangibles can vary from past experience with a particular provider, discussions with family or friends, media information, confidence or lack thereof with their provider, to their own personality and decision making approach and need for control. Consumers will go to the internet for one of two reasons: they will be looking for information to confirm what they already have decided to do (that could be in support of getting a vaccine or not getting a vaccine); or they will be looking for information to further educate themselves on their choices. These individuals will likely pursue scientific information on the particulars of a vaccine and its use during pregnancy. They will look to their trusted “go to” sources such as parenting experts, websites, magazines, and/or blogs. They will Google “group B Streptococcus” and look at parent support organizations. They might send emails to these organizations. They will search for consumers who have used the vaccine and those who have not. They will take time to educate themselves to the extent needed to meet their own comfort level with their choice.

More providers will feel secure in offering a product with a track record [39]. This is true for all new drugs. Obstetric providers have only recently begun offering vaccines to their pregnant patients. By the time a GBS vaccine is available for consumers, providers will be adept at both education and delivery of a maternal vaccine. More of their clients will be aware of having a vaccine during pregnancy (influenza and pertussis). More of their clients will be comfortable with both the idea and reality of maternal vaccination. Maternal vaccination will no longer be uncharted territory for either the consumer or the provider.

Will there ever be 100% uptake of the GBS vaccine? No, there will be women who receive sub-optimal care and will not be offered this option. There will also be women who, for personal reasons, will choose alternative methods. There are women who choose to believe that a clove of garlic along with some yogurt placed in the vagina will prevent their newborns from becoming sick with GBS. There are women who will choose to listen to any advice except scientific advice when accessing their prenatal and delivery care. And lastly we need to ask ourselves, “Has there ever been 100% uptake on any medical intervention?” The lack of our ability to obtain 100% acceptance should not deter us from developing, testing and then using a vaccine.

## 12. Conclusion: what would a perfect GBS vaccine look like?

- The ideal vaccine would prevent pre-term and pre-delivery complications associated with GBS.
- The ideal vaccine would prevent early onset GBS morbidity and mortality in both mother and baby.
- The ideal vaccine would prevent late onset GBS morbidity and mortality in the newborn.
- The ideal vaccine would be administered in early adolescence and would last during childbearing years.
- The ideal vaccine would be safe and have a high level of efficacy.

In a perfect world, we could expect a perfect medical intervention. While this is something that is impossible to achieve, it does

not mean it is something we should not aim for. Both consumers and medical professionals believe that all of the above conditions should be met. If we are all in agreement that this would be the ultimate goal over time then phasing in a vaccine that meets some but not all of the goals is crucial for the advancement of our public’s health. We cannot settle for anything less. As a collective we must continue to improve upon that, striving for the ultimate goal of a world free from GBS disease.

## Conflict of interest statement

The authors are writing as representatives of the following organizations: The Group B Strep Association (GBSA) and Group B Strep Support (GBSS). GBSA is a registered charity in the US and GBSS is a registered charity in the UK. Neither of these organizations has received funds from any pharmaceutical interests. The individual authors have no financial disclosures to make. Both authors were involved in the preparation of the manuscript, reviewed and contributed to the development and final approval for publication.

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