

# Bundle Approach in Clinical Practice: The Concept and Evidences

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## Abstract:

*A bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices-generally three to five-that, when performed collectively and reliably, have been proven to improve patient outcomes. Quality teams should resist the impulse to label any list of good changes a bundle. The power of a bundle comes from the body of science behind it and the method of execution: with complete consistency. It's not that the changes in a bundle are new; these are well established best practices, but are often not performed uniformly, making treatment unreliable, at times idiosyncratic. A bundle ties the changes together into a package of interventions that people know must be followed for every patient, every single time. It resembles a list, but a bundle is more than that. A bundle has specific elements that make it unique. The changes are all necessary and all sufficient. It is a cohesive unit of steps that must all be completed to succeed. The changes are all based on randomized controlled trials, Level 1 evidence. They've been proven in scientific tests and are accepted, well-established. There should be no controversy involved, no debate or discussion of bundle elements. A bundle focuses on how to deliver the best care- not what the care should be. We want providers to get right to work on the how: on completing steps x, y, and z for every patient. The changes in a bundle are clear-cut and straightforward; they involve all-or-nothing measurement. The evidences so far has proven the effectiveness of bundle approach in prevention and treatment of medical conditions.*

**Key Word:** PPH Bundle Approach, PPH Emergency response using Bundle Approach.

## Introduction:

Evidence based interventions are encouraged in the clinical practice. Bundles are usually used in a sequential manner depending on the clinical presentation, cases, and feasibility (in terms of manpower (availability & competence) and many other factors.

## The Concept

We all know about this famous Aesop story on the concept and strength of a bundle. "A certain Father had a family of Sons, who were forever quarreling among themselves. No words he could say did the least good, so he cast about in his mind for some very striking example that should make them see that discord would lead them to misfortune. One day when the quarreling had been much more violent than usual

and each of the Sons was moping in a surly manner, he asked one of them to bring him a bundle of sticks. Then handing the bundle to each of his Sons in turn he told them to try to break it. But although each one tried his best; none was able to do so. The Father then untied the bundle and gave the sticks to his Sons to break one by one. This they did very easily. "My Sons," said the Father, "do you not see how certain it is that if you agree with each other and help each other, it will be impossible for your enemies to injure you? But if you are divided among ourselves, you will be no stronger than a single stick in that bundle. The moral of the story is "unity is strength"<sup>1</sup>.

Evidence-Based Care Bundles in the medical science: A bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward

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set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes. Quality teams should resist the impulse to label any list of good changes a bundle<sup>2</sup>.

What is a bundle? The concept of “bundles” developed by IHI to help health care providers more reliably deliver the best possible care for patients undergoing particular treatments with inherent risks. A bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes<sup>3</sup>.

What makes a bundle so special? The power of a bundle comes from the body of science behind it and the method of execution: with complete consistency. It's not that the changes in a bundle are new; these are well established best practices, but are often not performed uniformly, making treatment unreliable, at times idiosyncratic. A bundle ties the changes together into a package of interventions that people know must be followed for every patient, every single time.

Is the bundle a list of the right things to do for a given patient? It resembles a list, but a bundle is more than that. A bundle has specific elements that make it unique. The changes are all necessary and all sufficient, so if you've got four changes in the bundle and you remove any one of them, you wouldn't get the same results — meaning: the patient won't have as high a chance of getting better. It's a cohesive unit of steps that must all be completed to succeed. The changes are all based on randomized controlled trials, what we call Level 1 evidence. They've been proven in scientific tests and are accepted, well-established. There should be no controversy involved, no debate or discussion of bundle elements. A bundle focuses on how to deliver the best care — not what the care should be. We want providers to get right to work on the how: on completing steps x, y, and z for every patient.

The changes in a bundle are clear-cut and straightforward; they involve all-or-nothing measurement. Successfully completing each step is a simple and straightforward process. It's a “yes” or “no” answer: “Yes, I did this step and that one; no, I did not yet do this last one.” Successfully implementing a bundle is clear-cut: “Yes, I completed the ENTIRE bundle, or no, I did not complete the

ENTIRE bundle.” There is no in between; no partial “credit” for doing some of the steps some of the time.

Bundle changes also occur in the same time and space continuum: at a specific time and in a specific place, no matter what. This might be during morning rounds every day or every six hours at the patient's bedside, for instance.

### Evidences

An example: The 5 Million Lives Campaign has several bundles as “planks” or interventions. This initiative is likely a big factor in the popularity of the bundle — thousands of people in hospitals across the country have learned about bundles by applying them as part of their participation in the Campaign<sup>4</sup>. There are two bundles in the Campaign that have been incredibly effective helping hospitals reduce to nearly zero the incidence of deadly infections that used to be so common they were accepted as unavoidable. A) Central Line Bundle: This is a set of five steps to help prevent “catheter-related blood stream infections,” deadly bacterial infections that can be introduced through an IV in a patient's vein supplying food, medications, blood or fluid. The steps are simple, common sense tasks: using proper hygiene and sterile contact barriers; properly cleaning the patient's skin; finding the best vein possible for the IV; checking every day for infection; and removing or changing the line only when needed. B) Ventilator Bundle: Ventilator-associated pneumonia (VAP) is a serious lung infection that can happen to patients on a ventilator. The Ventilator Bundle has four care steps: raising the head of the patient's bed between 30 and 40 degrees; giving the patient medication to prevent stomach ulcers; preventing blood clots when patients are inactive; and seeing if patients can breathe on their own without a ventilator.

Problem lies with how people use bundles. The concept of a bundle has such traction that people are trying to use them more often and, in more ways, than they really should. There is a tendency to want to call everything a bundle, any checklist involving patient care procedures, for example. But a bundle is not a checklist, and just taking an ineffective checklist and calling it a bundle would not make it any better<sup>2</sup>. The goal is to make a process more reliable, and you do that by improving habits and processes. The magic of the bundle comes from the guidelines laid out; the way the work is organized. People need to ask themselves: why will calling it a bundle make it better?

The differences between a bundle and a checklist are: A checklist can be very helpful and an important vehicle for ensuring safe and reliable care. The elements in a checklist are often a mixture of nice-to-do tasks or processes (useful and important but not evidence-based changes) and have-to-do processes (proven by randomized control trials). A checklist may also have many, many elements.

A bundle is a small but critical set of processes all determined by Level 1 evidence. And it needs to meet all the criteria of a bundle. Because some elements of a checklist are nice to do but not required, when they are not completed, there may be no effect on the patient. When a bundle element is missed, the patient is at much greater risk for serious complications<sup>2</sup>.

There is also a level of accountability tied to a bundle that is not always have with a checklist. An identified person or team owns it. A checklist might be owned by everybody on a floor or on a team, but we know that, in reality, when it is owned by everyone — nobody owns it! Things do not always get done. So maybe the pharmacist does one thing in a checklist, a nurse another, the doctor something else, but really it is no one person's job at the end of the day. A bundle is a person's or a team's responsibility. And it is their job at a certain point and time - during rounds every single day, possibly. So, it is not the kind of thing where people say: "You check that, I'll check this." No. It is very clear who has to do what and when, within a specific time frame. The accountability and focus give a bundle a lot of its power<sup>2</sup>.

An example- Let's take a discharge planning list. It is a reminder list of things people on a team should be doing throughout the patient's stay to help move the treatment process along toward discharge. People look at it often but no one typically "owns" it and there aren't clearly delineated dates and times attached to each element. It's so easy for incredibly busy nurses, aides, therapists, and doctors to assume that the next person will pick up where they left off<sup>3</sup>.

Checklists are important. They can be really helpful; sometimes essential. When you get on a plane, you should be grateful to know that the pilot won't take off until going through every single task in the "pre-flight checklist." It is an incredibly important list; in fact, when you talk to a pilot, they do not call it a "checklist," they call it "pre-flight procedures." It's practically written in stone — revered and followed religiously

with every flight. It is more than a list: it is a codified set of procedures.

Bundles should stay like bundles. We are also seeing a trend where people keep adding changes to an existing bundle, a valid bundle they have adopted. It gets bigger and bigger — ultimately to the point where it is unworkable, impossible to follow and not effective anymore. If add changes to a bundle, the chance of success is much higher if you use the bundle criteria. Inclusion, if any has to be appropriate.

So, the final message about bundles is: A bundle is a specific tool with clear parameters. It has a small number of elements that are all scientifically robust, that when taken together create much improved outcomes. We should not feel compelled to convert helpful checklists into overloaded bundles. If the concept of a bundle becomes so broad and loose in meaning, its power will start to diminish<sup>4</sup>.

A study was conducted at a tertiary care hospital, South India to evaluate the impact of the bundle care approach on reducing device-associated infections (DAIs), from January to September 2016 which was divided into three phases, each comprising 3 months. During the implementation phase, bundle care forms were implemented in all Intensive Care Units (ICUs) and the ICU staff were given a basic education on the importance of bundle care approach. The DAI rates (ventilator-associated pneumonia [VAP] rates, central line-associated bloodstream infection [CLABSI] rate, and catheter-associated urinary tract infection [CAUTI] rate) were calculated throughout the study period. Results show that during preimplementation phase, the VAP rate, CLABSI rate, and CAUTI rate were 14.79, 4.98, and 4.86 per 1000 device days, respectively. Rates were reduced to 13.03, 3.98, and 3.39 per 1000 device days, respectively, during the implementation phase and further reduced into 11.91, 3.49, and 2.36 per 1000 device days during the postimplementation phase. The month-wise decreasing trend of DAI rates was significant for medical ICUs as compared to surgical and pediatric ICUs. The month-wise decreasing trend of VAP rate, CLABSI rate, and CAUTI rate was noted, which signifies that the use of care bundle approach has a great impact on reducing DAIs<sup>5</sup>.

An international technical consultation was conducted in 2017 to develop draft bundles of clinical interventions for PPH taken from the WHO's 2012 and 2017 PPH

recommendations and based on the validated “GRADE Evidence-to-Decision” framework. Objective was to systematically develop evidence-based bundles for care of postpartum hemorrhage (PPH). Twenty three global maternal- health experts participated in the development process, which was informed by a systematic literature search on bundle definitions, designs, and implementation experiences. Over a 6-month period, the expert panel met online and via teleconferences, culminating in a 2- day in person meeting. The consultation led to the definition of two care bundles for facility implementation. The “first response to PPH bundle” comprises uterotonics, isotonic crystalloids, tranexamic acid, and uterine massage. The “response to refractory PPH bundle” comprises compressive measures (aortic or bimanual uterine compression), the non- pneumatic antishock garment, and intrauterine balloon tamponade (IBT). Advocacy, training, teamwork, communication, and use of best clinical practices were defined as PPH bundle supporting elements. In conclusion for the first response bundle, further research should assess its feasibility, acceptability, and effectiveness; and identify optimal implementation strategies. For the response to refractory bundle, further research should address pending controversies, including the operational definition of refractory PPH and effectiveness of IBT devices<sup>6</sup>.

This How-to Guide describes key evidence-based care components of the IHI Central Line Bundle which has been linked to prevention of central line-associated bloodstream infections, describes how to implement these interventions, and recommends measures to gauge improvement. The guide was initially developed as part of IHI’s 5 Million Lives Campaign<sup>7</sup>.

Despite broad implementation of a bundled strategy aimed at preventing ventilator-associated adverse events in many hospitals, the ability of the bundle to prevent VAP has not been definitively established with high-quality studies. A study was conducted to implement VAP bundle as a performance improvement project in adult ICU and follow up the compliance rate over the 12 month study period as well as the effectiveness on surgical and medical subgroups. VAP Bundle Program was implemented in adult ICU, data were collected and analyzed for ventilated-associated pneumonia (VAP), and compared before and after intervention. Their bundle components were head of bed elevation greater than 30°, daily sedation break,

assessment for extubation, peptic ulcer prophylaxis and deep vein thrombosis prophylaxis. The results clearly show the difference between pre and post-intervention period and lower VAP rate after application of VAP bundle. The total VAP bundle compliance rate steadily increased during the period of implementation. We documented a significant reduction of mean ICU LOS (from  $15.4 \pm 5.2$  to  $10.8 \pm 4.9$  days) and duration of mechanical ventilation (from  $12.8 \pm 4.9$  to  $8.5 \pm 4.3$  days) for patients with VAP bundle compliance at the end of the study. There was a significant improvement in the outcome of surgical patients who were studied after VAP bundle initiation reflecting a decreased mortality rate. The study highlights that adherence with the VAP-bundle approach in ICU decreases the incidence of VAP, more rapid ventilator weaning, fewer ICU days, and shorter hospitalizations and it has also a great impact on patient outcomes. Our study looked into surgical sub-population as getting more benefit by initiation of the VAP bundle in reducing the length of stay. Thus, it results in a decrease in the burden of the health care costs and the ICU resources<sup>8</sup>.

The past 20 years have seen increasing Caesarean section (CS) rates in Australia. Increasing antenatal morbidity means that post-CS surgical site infection (SSI) is an issue impacting Australian women, mostly low-socioeconomic and regional communities. Recent trends supporting development of evidence-based bundled approaches to SSI reduction, have not proved efficacy nor supported bundle implementation. This pilot study aimed to develop, implement and assess an evidence-based Caesarean Infection Prevention (“CIP”) bundled intervention to reduce post-CS SSI rates in a high risk population. The study was a pre-post-intervention study, including women undergoing CS at one referral hospital between December 1st 2016 and December 31st 2018. A 12 month retrospective pre-intervention review identified women who developed a post-CS SSI. A comprehensive literature review informed the development of the intervention, which was implemented in December 2017. Data was collected for the subsequent 12 months on women undergoing CS. A total of 710 procedures were monitored with 346 and 364 women in the pre and post-intervention groups respectively. Demographic and comorbidity variables remained consistent over time. Post-CS SSI rates significantly reduced post-intervention (5.5% vs. 1.6%,  $p = 0.007$ ), the greatest benefit in class II and III obese patients (12.2% vs. 2.5%,  $p = 0.019$ ). Higher hypertension rates

(24% vs. 9%,  $p = 0.01$ ) and lower maternal mean age (27 vs. 30,  $p = 0.01$ ) were seen in patients with SSI. The “CIP” bundle effectively reduced post-CS SSIs in a high risk population. Our findings substantiate the need for development and evaluation of multifaceted, evidenced-based interventions to reduce post-CS SSIs<sup>9</sup>.

‘PPH Emergency Response Using Bundle Approach: Engaging National Professional Societies to Combat Postpartum Hemorrhage. A FIGO-SAFOG-OGSB-MGH Project’ has been conducted in Bangladesh from Dec 2019-Sept 2022 with the permission of Govt. of Bangladesh. Major activities included were: formation of FIGO, MGH Core committee, SAFOG Core committee and a Technical Advisory Group (TAG); selection and involvement (issuing letters) of Stakeholders; selection of mater trainers. Clinical trainings were conducted in 3 phase (Phase I: Training of the 16 Master trainers/core trainers; Phase II: ToT of the 64 Service providers; Phase III: Facility based training of the 690 health service providers; also refeshers taining and training of nonclinical staffs). Implementation of PPH EmC was done in 14 selected health facilities including monitoring and evaluation and mentoring; and attention to quality improvement. Occurrence of PPH, mortality due to PPH, data quality, communication and quality of care improved. OGSB is continuing the activities even after completion of project and basically has expanded to new facilities<sup>10</sup>.

The PPH Emergency Response program includes slide presentations, trainer’s manual, how-to toolkits, checklists, post-training technical assistance, monitoring and evaluation support, and lays the groundwork for national policy integration. It is designed to be flexible and adaptable to different contexts and countries based on their specific needs. Strong emphasis is given to utilizing and enhancing local mentorship and quality improvement frameworks for program sustainability<sup>11</sup>.

A single-center retrospective pre-post case-control study was carried out at a tertiary care center and teaching hospital in Varanasi, eastern Uttar Pradesh state, India. From January 2021 to June 2021, pretraining data (PRE) were collected retrospectively on all births from the department of Obstetrics and Gynecology, Sir Sunderlal Hospital, Institute of Medical Sciences, Banaras Hindu University. Subsequently, medical and paramedical personnel of our hospital were trained in Postpartum Hemorrhage Emergency

Care Using a Bundle Approach (PPH EmC) as per the guidelines laid down by the World Health Organization (WHO) for PPH management and implemented in July 2021. Post-training data (POST) were then collected retrospectively on all deliveries at our hospital from August 2021 to January 2022. All the data within two periods were computed and analyzed. The results were then compared for any significant changes in the incidences of maternal mortality and morbidity in terms of the rates of blood transfusion required and the type of management used (medical or medical-surgical), use of tranexamic acid, and additional uterotonics. A total of 1304 women gave birth from January 2021 to January 2022, of whom 107 patients (61 in the PRE and 57 in the POST group) were diagnosed and treated for PPH. There was no significant difference in the incidence of PPH in the PRE and POST groups ( $p=0.581$ ). There was a significant increase in the use of tranexamic acid ( $p=0.041$ ) and a significant reduction in blood transfusion rates ( $p=0.032$ ) after the implementation of bundled care in the POST group. The odds of PPH non-occurrence after pre- and post-test was 1.103 (95% CI=0.747 to 1.635). No significant difference was observed in maternal mortality in the PRE and POST groups ( $p=0.96$ ). The requirement for radical surgical treatment of PPH, which included hysterectomies, was also significantly reduced, from 27.27% in the PRE group to 11.54% in the POST group ( $p=0.032$ ). PPH care bundles might improve the morbidity of PPH with the use of fewer resources and fewer interventions required. While these data are promising, further studies are needed to analyze bundle care’s long-term effects<sup>12</sup>.

### Conclusion

Though relatively new, Bundle approach has already proven to be simple and effective way to prevent and treat different clinical conditions including management of obstetric emergencies.

A combination of evidence based intervention, done together, yields a better result.

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