DESiGN Trial - Implementation of GAP

GAP Team Report October 2020

perinatal institute
for maternal and child health

Background

The Perinatal Institute has welcomed the opportunity of an independent evaluation of the GAP program. There were concerns from the outset about methodology and feasibility, but following extensive discussions and correspondence in 2015/6, assurances were received and a set of 'minimal criteria for implementation' were agreed with the trial's lead investigators. We proceeded to train units randomised to the study arm of the trial, and helped to implement GAP protocols, algorithms and GROW software.

The trial was ended in February 2019, and the GAP team submitted information requested by the DESIGN investigators about the training carried out in each study site, including staff sign-in sheets. We also submitted to the trial organisers details about compliance with the GAP protocol.

The following is a report based on our observations, information from local GAP leads, and analysis of data routinely entered by local users in GROW software.

Priorities and progress

Prior to commencement, nine London Trusts were already in the GAP program or were in the process of joining. The units that were recruited into the trial often showed limited interest or had other more urgent priorities. Three units ended up dropping out altogether, for various reasons. Communication was often poor, with delayed or no responses to the GAP team. There was often a substantial delay from completed training to go-live date, up to 10 or even 12 months, with concern that key aspects of educational content, protocol, algorithm or use of software may have been forgotten. This delay also contributed to the shortened trial period before the data collection was terminated in February 2019.

The GAP lead reported these problems to the investigators at their regular trial meetings but there was no extension provided to allow more time for the trial to embed or for the data collection phase to be extended.

Completeness of implementation

Apart from training and the baseline (pre-trial) audit of detection rates, GAP implementation requires multi-departmental change management which entails local collaboration, motivation and effort. Our minimum requirements for GAP compliance were agreed before commencement of the trial and incorporated into the original DESIGN Trial Protocol (2015) (page 68). These requirements are based on previous experience of the essentials of effective implementation, and include

1. establishment of local multidisciplinary GAP team,
2. training and e-learning for all staff,
3. audit including
    a. baseline detection rate,
    b. recording of birth data after all deliveries to determine SGA detection rates, and
    c. case review of undetected cases using the missed case audit tool;
4. unit protocol to reflect GAP risk assessment and referral pathways.

These markers of compliance were an agreed precondition for the Perinatal Institute's participation in the trial, and were also included (in less detail) in the subsequent, published version of the protocol (BMC 2019), stating the need to collect trial data after *complete* implementation (page 8).

Training – albeit delayed – and baseline audits were mostly completed before access was provided to GROW charts, but compliance with the other elements was incomplete as 1. local teams were often difficult to contact because of staff changes, vacancies or different work priorities; 2. E-learning was in most instances not done, 3. local protocols often deviated from GAP guidelines, with at least one instance known of concurrent use of a different growth chart and 4. routine recording of postnatal centiles and detection rates, and hence also missed case audits, were not undertaken.

Routine recording of birth outcomes

Recording and monitoring SGA detection rates is an essential part of GAP: it facilitates local reporting and feedback about effectiveness of the adopted protocols and referral pathways, and facilitates improvements according to performance. It also identifies missed cases to be reviewed with the GAP review tool, to find blocks and bottlenecks in the care pathway. Without this, clinicians are essentially working blind. This is therefore also the main criterion we use to define 'complete' as opposed to 'partial' implementation. Routine recording of pregnancy outcome (including birthweight centile and SGA detection rate) is defined as at least 75% of all births being recorded; in reality the figure is much higher (90+%) in fully compliant units.

Data analysis

The following table shows a summary of birth data recorded by participating units on the postnatal tab of the GROW App. The information is entered by ward clerks or the midwife conducting the delivery, displayed on the 'reporting page' accessible to the unit that submitted the data for feedback, audit and review, and stored in anonymised form on our servers.

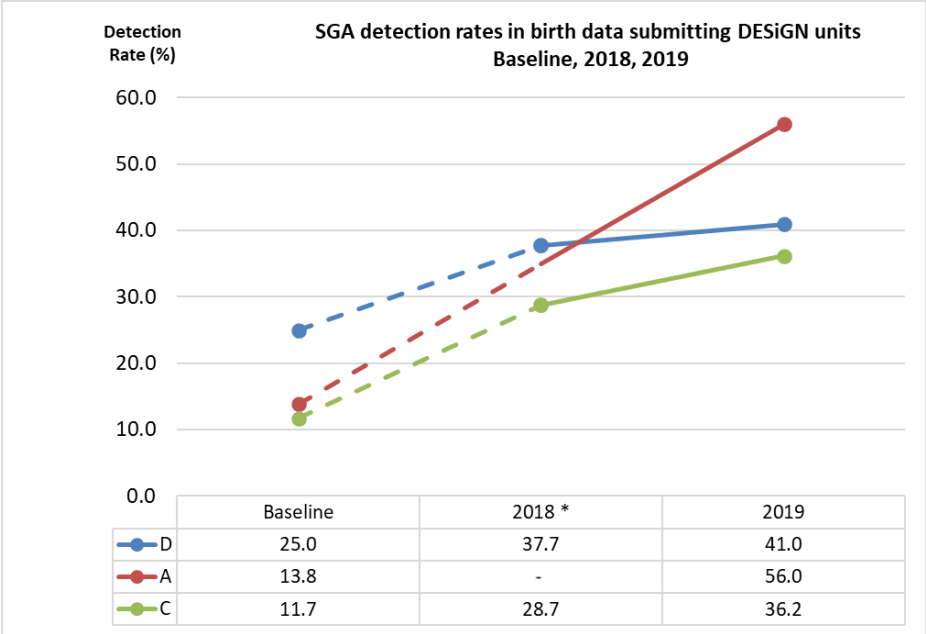
Table 1. Start of chart generation and birth data collection in study arm units, and proportion (%) of deliveries in which data was recorded. Red line indicates end of trial data collection in February 2019

Unit Code	Go-live delay (months)	Start of regular chart generation (at 12 wks)	First deliveries following start of chart generation	Submissions / Births (%) 2018				Submissions / Births (%) 2019			
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
D	**6**	**Nov-17**	**May-18**	1.9	29.5	39.2	57.1	66.0	**74.2**	**75.0**	**83.8**
A	**4**	**May-18**	**Nov-18**	0.0	0.3	0.3	0.2	38.9	**76.3**	**82.2**	**81.8**
F	12	May-18	Nov-18	0.1	0.2	26.8	4.0	6.5	7.5	26.8	43.3
C	**6**	**Jan-18**	**Jul-18**	6.7	16.5	59.0	69.4	**78.7**	**85.7**	**86.6**	**74.9**
G	6	Jan-18	Jul-18	3.5	30.3	61.7	56.6	57.7	59.2	56.2	52.5
E	10	Feb-18	Aug-18	0.9	6.6	30.3	51.7	31.6	22.2	26.6	13.0

The Table shows that Trusts coded D, A and C reached the minimum requirement (≥75% submission rate) for 'complete' GAP implementation, but only in 2019 – meaning trial data up to the Feb 19 cut-off were collected almost exclusively from units with incomplete implementation of the GAP program. Only Trust C had fulfilled implementation criteria, for 2 months before the end of the trial data collection period.

Figure 1 shows the SGA detection rates of these units, from the baseline audit onwards.

Fig 1: SGA detection rates recorded in 3 units reaching routine (>75%) recording of birth data.

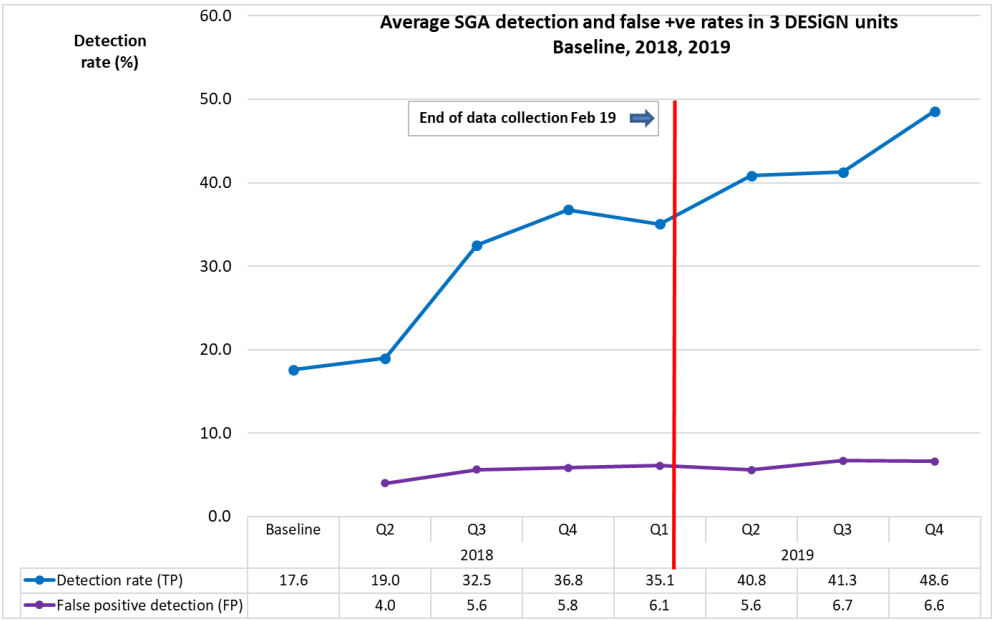


	Baseline	2018 *	2019
D	25.0	37.7	41.0
A	13.8	-	56.0
C	11.7	28.7	36.2

* 2018 points based on incomplete (<75%) recordings of birth data (D, C) or imputed (A)

The graphs start with the pre-trial **Baseline** SGA detection rate recorded by the three units (average 17.6%; similar to the average for the three non-compliant units F,G,E): 16.0%. For **2018**, the plotted data are low quality due to low submission rates; while the **2019** figures are based on high ascertainment birth data recording. The increased detection rates over time reflect observations in many GAP units and emphasise the need to allow sufficient time for the program to embed itself, with local audit, benchmarking and missed case review.

Fig 2: Averaged SGA detection rates (TP) and false +ve rates (FP) in units D, A and C from pre-trial baseline to 2019. Values for 2018 imputed from incomplete submissions.



	Baseline	Q2	Q3	Q4	Q1	Q2	Q3	Q4
		2018			2019			
Detection rate (TP)	17.6	19.0	32.5	36.8	35.1	40.8	41.3	48.6
False positive detection (FP)		4.0	5.6	5.8	6.1	5.6	6.7	6.6

Fig 2 shows data averaged for three units that reached routine birth date submission by 2019. There was a 65% increase in false positive detection rates from 4.0% (Q1, 2018) to 6.6% (Q4, 2019) and a near three-fold increase in SGA detection from 17.6% (baseline) to 49.6%. which is above the national GAP user average (42%). Unit A's detection rate in 2019, 56% (Fig 1) is in the 'Top Ten' of the current national average.

NB: Data are based on submissions at unit level using GROW software and are anonymised and stored on secure servers. The data are available on request for checks and further analyses.

Control group concerns

Concurrent to the training and implementation of GAP in the study arm, units in the control group were implementing the Saving Babies Lives Care Bundle in 2017/18 as part of the national roll-out by NHS England. This was despite pre-trial assurances that, through the London maternity networks, implementation of the Fetal Growth element of the Care Bundle will be delayed until after completion of the study.

This is significant as the GAP care pathway was in fact the template used for the 2016 (v1) SBL Care Bundle Element 2 (Fetal Growth) algorithm, without growth chart specified. This can be confirmed by comparing the original GAP algorithm, reproduced in the original (2015) Trial Protocol, page 30, and the algorithm of the SBL v1 Care Bundle (2016), page 19. Therefore important elements of the GAP 'package' were also implemented and changed practice in the control group of the Design Trial.

Summary

GAP implementation was hampered by a number of factors, including delays and slow progress within Trusts, possibly because of competing priorities. There were long delays between training and go-live, which resulted in a shortened trial period, and little time for the new practice to embed. Based on routinely submitted GAP data, implementation was incomplete in all units, and benefits in terms of SGA detection became apparent in each of the data submitting units only after completion of the trial.

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